

Publications

SECTION EDITOR



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Editorial

In this instalment of Publications, Phil Leventhal, Danielle Drachmann, and Soren Skovlund discuss patient authorship, where people with lived experience in a specific disease or

condition are listed as byline authors of peer-reviewed publications. Phil, Danielle, and Soren explain why patient authorship is important, how patient authors can meet the International

Committee of Medical Journal Editors authorship criteria, and the potential barriers to patient authorship.

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Can patients and caregivers be authors of peer-reviewed publications?

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Increasingly, patients' and caregivers' experiences, needs, and desires are being considered in medical research and in the development and selection of treatments.¹ Patient engagement in research is a movement that promotes "the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, guided by patients' contributions as partners, recognising their specific experiences, values, and expertise."² In some cases, for example when the patient is a child, the caregiver may be better positioned to play this role, so, in this context, "patient" can also mean a caregiver, family member, or representative of a patient association.

Patient engagement can take many forms, including in the conception, planning, conduct, interpretation, or dissemination of research.³⁻⁵ It can range from patients or caregivers serving as consultants to themselves driving research or its dissemination.^{6,7} Underlying this is the understanding that people who have "lived experience" of a disease or condition can provide

unique insight and perspective.^{5,8,9} For example, patients and caregivers often have different priorities for treatment and different preferences for benefits and risks than clinicians, which can help in developing and selecting treatments.³ Partnering with people who have lived experience, and especially patient organisations, can be particularly helpful when little information about an illness or disease is available, such as in rare diseases.^{10,11}

Patient engagement is increasingly being recognised as essential and valuable,^{8,12-14} and patient advocacy groups are actively seeking opportunities to partner in advancing research, developing new treatments, and driving policy.^{11,15,16} Patient engagement has become a priority for the US FDA and other regulators, and the patient perspective is being increasingly considered in reimbursement decisions.^{8,17,18}

Patient authorship

Patient authorship is a relatively new concept where people with lived experience of a specific disease or condition are listed as byline authors and sometimes even lead the development of peer-reviewed publications.¹⁹ The concept of patient authorship has arisen because of the substantial contributions that patient partners are starting to make to medical research and its dissemination. The term "lived experience author" may actually be more precise than "patient author" because, in this context, "patient" can also include caregivers, family members, and representatives of patient or associations.

Partnering with patient authors is being increasingly encouraged.^{19,20} Patient authors can add value as authors by validating the need, relevance, and value of the research and by increasing the credibility of and trust in the results.¹⁷

The number of peer-reviewed publications with patient authors is low but rapidly increasing.^{19,21,22} Despite this trend and calls to include people with lived experience as authors, there are some barriers to overcome. Practices for including patient authors remain heterogeneous, and clear standards are lacking. Further, the medical research community has expressed doubt that people with lived experience can or should be byline authors of peer-reviewed publications. A survey of 112 editors-in-chief published in 2021 found that nearly one-third considered patient authorship inappropriate, and about one in six thought that patients should have an academic affiliation.³ Further, about one-third felt that the International Committee of Medical Journal

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Editors (ICMJE) authorship criteria should be revised to accommodate patient authors, although some of these editors stated that this was in the interest of protecting privacy or more clearly defining responsibilities.

What do guidelines say about patient authorship?

According to the ICMJE recommendations, which is the main ethical guideline for peer-reviewed medical publications, authorship should be based on the following four criteria:²³

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

All four of these criteria can be met by people with lived experience, and, in contradiction to what some journal editors feel, academic credentials are not required.²⁴ As for the first ICMJE criterion, any author can make substantial contributions to a publication without being involved in all aspects of the research. For patients or caregivers, this could be by providing their unique perspective to interpret and communicate the results. Partnering with patients or caregivers is also encouraged for plain language summaries within publications as well as in stand-alone plain-language summaries of publications.²⁵ For the second ICMJE criterion, like other coauthors, patient partners do not need to write the manuscript but rather can contribute as critical reviewers of the content and writing, bringing their unique perspective. Finally, the last two of the four ICMJE authorship criteria can be met by any author and, for patient partners, only requires educating them about what the criteria imply and ensuring their agreement and compliance.

Beyond the ICMJE Recommendations, the 2022 update to the Good Publication Practice guidelines specifically validates the concept of patient authorship, stating:²⁶

“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.”

The Guidance for Reporting Involvement of Patients and the Public, version 2 (GRIPP2) is currently the main guideline for patient engagement in research. It provides a detailed list of



items to include in publications including patient or public involvement. However, it does not currently provide any guidance on authorship.

In sum, based on existing guidelines, people with lived experience can, and in many cases should, be included as authors of peer-reviewed publications.

Current issues to address

A main issue limiting patient authorship is a lack of clarity around how their role in preparing the publication should be indicated. Currently, there is no systematic way of doing this, making identifying publications with patients or caregivers authors time-consuming and inexact.^{19,20,22,27} Using “patient author” or “patient/public author” as the affiliation has been proposed as a solution,^{20,28} but patients and caregivers may not want personal information about themselves or their family members to be made public. Our own research has shown that, in articles on the experiences of people with rare diseases, 95% of patient authors list a patient advocacy group or association as the affiliation.²² This may help keep their illness or condition confidential, while providing them with a respected affiliation. Similarly, authors who have both lived experience and an

academic or professional affiliation may choose to make public only their affiliation. An alternative to tagging individual authors as having lived experience could be to simply indicate in a searchable field that people with lived experience participated as authors.

Based on existing guidelines, people with lived experience can, and in many cases should, be included as authors of peer-reviewed publications.

Education about patient authorship is another barrier limiting its adoption.^{3,17,24,29} Patient and caregiver partners in research need to be made aware of and understand their responsibilities as byline authors of peer-reviewed publications. This will allow them to make decisions about whether they accept to participate as an author and how they want their contribution to be stated. Also, clinicians and other stakeholders need to be made aware that patients and caregivers can be authors and that they can provide added value to a publication. This can help them feel accepted as part of the authoring team and better navigate the team’s dynamics. Fortunately, detailed guidance on how all of this can be accomplished is available in two recent publications.^{17,24}

Conclusion

Patient authorship of peer-reviewed publications is a relatively new phenomenon that is part of the patient engagement movement. Partnering with patients, caregivers, and patient advocacy groups can provide added value to medical publications by enhancing their relevance and reach. As long as they meet authorship requirements, patients and caregivers should be able to be byline authors of publications. Continued work is needed to encourage this within the medical research community and find consensus on how to identify authors with lived experience in a way that respects their privacy.

Disclaimers

The opinions expressed in this article are the authors’ own and not necessarily shared by their employers or EMWA.

Disclosures and conflicts of interest

All authors are employees of Evidera Ltd. or PPD, parts of Thermo Fisher Scientific.

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