

Crucial role of patient authors in content co-creation of patient-relevant scientific data

Learnings from a plain language summary publication (PLSP) of prostate-specific antigen (PSA) response during treatment of advanced prostate cancer

Ken Mastris¹, Thomas Flannery², Fred Saad³

¹Patient advocate, Tackle Prostate Cancer, UK; ²Patient advocate, National Advanced Prostate Support Group, Prostate Cancer Foundation, Canada;

³Department of Surgery/Urology, Centre Hospitalier de l'Université de Montréal, University of Montreal, Montreal, QC, Canada

Introduction

Clinical study results are of value to patients

- Prostate-specific antigen (PSA) changes during treatment help patients and healthcare professionals assess whether the treatment is working or whether the disease is progressing and requires different management^{1,2}
- PSA levels and their association with other important outcomes, such as survival, have therefore been measured in phase 3 studies of treatments for advanced prostate cancer
- However, complex analysis methods and technical language can mean that the findings from these studies are difficult for patients to read and interpret, limiting their ability to participate in their treatment decision making

Helping patients understand clinical data can improve outcomes

- When patients and caregivers are able to take an active role in treatment decision making, they feel ownership of the decisions, understand the benefits of adhering to treatment, are able to recognize and manage side effects or seek support to ensure that they gain optimal benefit from treatment³
- To participate effectively in treatment decisions, patients and caregivers need to be able to understand the evidence for the available treatments and to apply this information to their own situation
- The European Clinical Trial Regulation requires study sponsors to provide lay summaries of their completed clinical trials.⁴ However, these summaries are required to be very factual and do not always provide enough context to help readers understand what the study results might mean for them

Plain language summaries of publications (PLSPs)

Communicating the context

- In recent years, PLSPs have been developed as one approach to communicate detailed clinical study results and their relevance for patients in less technical language for non-specialist or lay readers
- By making clinical study results accessible and easy to understand, PLSPs can enhance trust, transparency, and partnership between study sponsors, study participants, healthcare professionals, and patients

Involving patient representatives in PLSP development benefits readers

Objective

- Here, we show the value of involving patient authors in the development of a PLSP of PSA response data from a phase 3 clinical study

Recognizing the need

- The development of this PLSP was driven by feedback from patient advocacy groups, who flagged a high interest in understanding PSA data and addressing an unmet need for patient perspectives on what these data mean to the patient community

Working together

- The PLSP development followed a structured process facilitated by the study sponsor



1. Defining and agreeing author responsibilities

The study sponsor ensured that all authors understood their responsibilities up front

Why it matters

Authors have to be accountable for the content of their article and be willing and able to address any queries about the work. Therefore any potential authors have to be willing to meet strict authorship criteria.⁵ These responsibilities and **expectations need to be clarified with patient authors** who have limited publication experience



2. Patient author review

The patient authors critically reviewed the content to ensure appropriateness of language, style, and format

Why it matters

Regardless of education level achieved, most people have **difficultly understanding medical terminology**, and patients may be **overwhelmed by their recent diagnosis** and unable to focus on large amounts of information.⁶⁻⁸ **Patient authors are well placed to understand the difficulties** that lay audiences have understanding crucial information and can provide guidance on appropriate language and presentation of data⁹

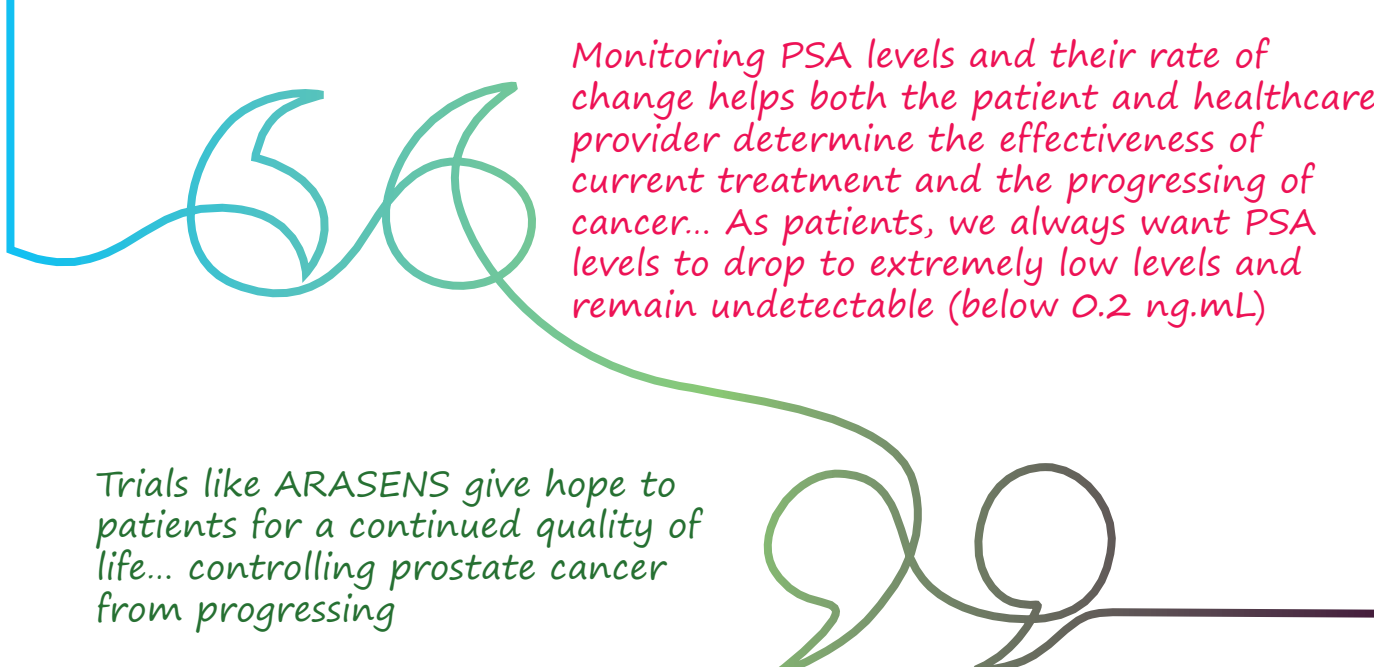


3. Patient author perspectives

To put the study findings into context for a lay audience, the patient authors explained what the study meant for them, including the benefit of PSA measurement for treatment decision making and the value of the study treatment for patients' long-term well-being

Why it matters

Including the patient voice in a PLSP helps to **humanize the study findings** for readers and demonstrates to other patients that their voice is important.^{10,11} Patient perspectives are also **valuable for healthcare professionals**, helping them to understand patients' priorities and preferences¹⁰



Monitoring PSA levels and their rate of change helps both the patient and healthcare provider determine the effectiveness of current treatment and the progressing of cancer.. As patients, we always want PSA levels to drop to extremely low levels and remain undetectable (below 0.2 ng/mL)

Trials like ARASENS give hope to patients for a continued quality of life... controlling prostate cancer from progressing

4. Healthcare professional review

Healthcare professionals who took part in the study as investigators reviewed the content for scientific accuracy

Why it matters

In the attempt to redraft scientific information for lay audiences, there is a **risk of oversimplification**, resulting in important information being missed or misrepresented. It is therefore **crucial to ensure that the study results are accurately represented** in a fair and balanced way⁹



5. Collaborative agreement on content

All authors discussed and agreed on content decisions that balanced accurate and transparent scientific data with patient information needs and health literacy levels

Why it matters

Because all authors are accountable for the content of their article, it is **crucial that they are all in agreement** on the content. Agreement can be **achieved through good communication** either by email or in face-to-face calls where the needs of all stakeholders are acknowledged and addressed



6. Publication and dissemination of the article

The full article is freely available online. The journal publisher and prostate cancer patient organizations are raising awareness of the article on social media and in newsletters

Why it matters

Patients and lay audiences need to be **able to easily find and access** the article and its supporting materials (infographic and video), so that they can use the information presented to **help them in their treatment decisions**^{9,12}



Conclusion

- PLSPs are intended to communicate scientific data in a patient-friendly format to the broader general audience
- However, not all PLSPs involve patients as authors or include patient perspectives, running the risk that the data and the implications for patients remains difficult for non-specialist or lay audiences to understand
- The PLSP described here demonstrates the benefits of close partnership between study sponsors and patient advocacy groups to identify patient information needs
- Involvement of patient authors ensures that patient insights are prioritized to help patients understand data of interest and relevance to them with their perspectives
- Patients who understand the data are better able to participate in their treatment decisions with their healthcare providers

Glossary

Article: a written report summarizing the results of a study, published in a journal; also referred to as publications or papers; before an article has been accepted for publication, it is often referred to as a manuscript.

Authorship criteria: four requirements that individuals must agree to before they can be considered as authors of a publication. These requirements, set by the International Committee of Medical Journal Editors are: (1) to make a substantial contribution to the article, for example by collecting data or interpreting results; (2) to draft the article or critically review a draft that someone else has written; (3) approval of the version being submitted to a journal; and (4) agreement to be accountable for the article, ensuring that any questions about the accuracy or integrity of the content are appropriately addressed.⁵

Health literacy: a person's ability to find and understand information about health, illness, and treatment and apply this information to decisions about their own illness and treatment.

Journal: a format for reviewing and publishing scientific articles to make new research available to other healthcare professionals and lay audiences; journals may publish articles at regular intervals, collated into issues, or may publish individual articles online as soon as each article is finalized. Some journals publish articles on specific topics (e.g., cancer), whereas others have a broader scope.

Manuscript: a draft article before it has been accepted for publication.

Open Access: a way of publishing an article in which the authors or study sponsors pay for the publication process, so that readers can access the content without having to pay for it.

Publication: 1. the process of making an article publicly available in a journal; this process usually involves reviewing the content for scientific accuracy, balance, and relevance, laying the content out in a consistent style and format within a journal issue, and providing the article online and/or in print. 2. an individual article.

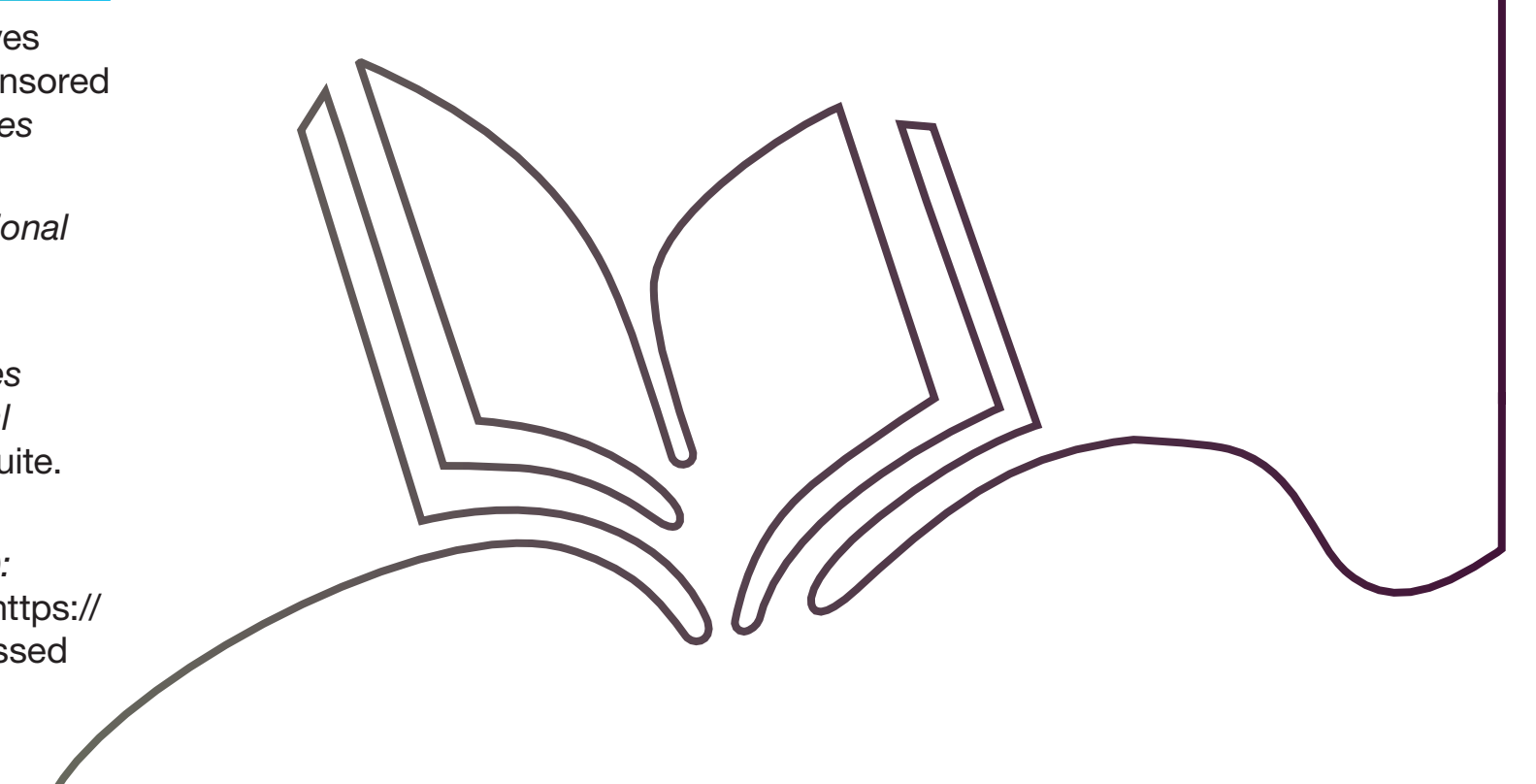
Further reading

Lobban D, Gardner J, Matheison R, on behalf of the ISMPP PLS Perspectives Working Group. Plain language summaries of publications of company-sponsored medical research: what key questions do we need to address? *Curr Med Res Opin* 2022;38:2. DOI: doi:10.1080/03007995.2021.1997221.

OPEN Health. *Embracing the patient voice within publications: Cross-functional perspectives toward better patient partnerships*. Available at: <https://tinyurl.com/3fza7j6x?OPENHealthWhitePaper> (accessed January 21, 2025).

Patient Focused Medicines Development (PFMD). *Plain language summaries (PLS) of peer-reviewed publications and conference presentations; practical 'How-To' Guide for multi-stakeholder co-creation*. Available at: <https://pemsuite.org/How-to-Guides/WG5.pdf> (accessed January 21, 2025).

Taylor & Francis Group. *Plain Language Summaries of Publications (PLSPs): author guidelines for development, submission & publication*. Available at: <https://files.taylorandfrancis.com/plsp%20guidelines%20for%20authors.pdf> (accessed January 21, 2025).



Acknowledgments

Writing and editorial support in the development of this poster was provided by Sara Black, ISMPP CMPP™, of Luna, OPEN Health Scientific Communications, London, UK, with funding from Bayer HealthCare Pharmaceuticals, Inc., Whippany, NJ, USA

Disclosures

Ken Mastris is a previous chair of Tackle Prostate Cancer, previous President of the European Cancer Patient Coalition, and previous Chair of Europa Uomo and has been involved in other European organizations including European Medicine Agency (EMA), European Association of Urology (EAU), and European Cancer Organisation (ECO). Thomas Flannery has received honoraria from Janssen and Johnson & Johnson for steering committee membership and is an Advanced Prostate Cancer Support Group leader for the Prostate Cancer Foundation Canada. Fred Saad has held consulting or advisory roles with, and has received honoraria or institutional research funding from AbbVie, Advanced Accelerator Applications, Astellas Pharma, AstraZeneca/MedImmune, Bayer, Bristol-Myers Squibb, Janssen Oncology, Knight Therapeutics, Merck, Myovant Sciences, Novartis, Pfizer, and Sanofi.

References

- Hofmann MR, et al. *Urology* 2021;155:165-171.
- Saad F, et al. *Eur Urol* 2020;78:847-853.
- Coulter A, Collins A. Available at: <https://www.kingsfund.org.uk/insight-and-analysis/reports/making-shared-decision-making-reality> (accessed Jan 21, 2025).
- European Commission. Available at: https://health.ec.europa.eu/system/files/2020-02/2017_01_26_summaries_of_ct_results_for_laypersons_0.pdf (accessed Jan 21, 2025).
- International Committee of Medical Journal Editors. Available at: <https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> (accessed Jan 21, 2025).
- von Itzstein MS et al. *Cancer* 2020;126:1605-1618.
- Sullivan HW et al. *Oncologist* 2020;25:1090-1096.
- Holden CE, et al. *PLoS One* 19:e0203104.
- Patient Focused Medicines Development. Available at: <https://pemsuite.org/How-to-Guides/WG5.pdf> (accessed Jan 21, 2025).
- Johnson DS, et al. *Res Involvement Engagem* 2016;2:6.
- Sjövall K, et al. *Support Care Cancer* 2024;32:442.
- OPEN Health. Available at: <https://tinyurl.com/3fza7j6x?OPENHealthWhitePaper> (accessed Jan 21, 2025).

Scan QR code to download the poster. Copies of this e-poster are for personal use only and may not be reproduced without written permission from the authors.

