AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N2 / 2022

THEME ARTICLE

Generating Plain Language Summaries of Scientific Publications with Ethical Foundations: A Practical "How-To" Guide Cocreated with Patients

Thomas M. Schindler, PhD / Boehringer Ingelheim Pharma GmbH & Co KG and Lay & Regulatory Writing, Biberach a. d. Riss, Germany

ABSTRACT

Peer-reviewed scientific publications are written by scientists with peers in mind. However, there is a growing demand of patients and other nonspecialists to understand the potential implications of clinical and medical research. Research summaries of scientific articles in easy-to-read language—called plain language summaries (PLS)—are currently being developed to broaden the reach of scientific articles beyond expert audiences. While PLS can help nonexperts to understand and be informed about scientific articles, there is a risk that PLS contribute to publication bias and hence misinformation of patients and the public and thus achieve the opposite of their intention. Potential issues are an unbalanced selection of the scientific source articles for which a PLS is initiated, lack of alignment of the data presented in the PLS and in the source article, unbalanced reporting of efficacy and safety data, absence of reporting the primary endpoint, or over- or underreporting of secondary endpoint results. To objectively inform patients and to become a trustworthy source of information, the writing of PLS needs to be firmly embedded in a set of ethical principles. To safeguard balanced and fair PLS writing, the cocreated "How-To" Guide on PLS writing developed by the Patient Focused Medicines Development initiative comprises a set of 15 ethical considerations. These include the necessity for objective reporting, the need for balanced presentation, the importance of audience focus, the need to apply health literacy principles, and the importance of using inclusive and respectful language. The "How-To" Guide was developed in a stepwise process with several rounds of cocreation, public consultation (two rounds), internal review, and a final external review. The iterative development process ensured input from a wide variety of stakeholders (patient representatives, industry members, publishers, researchers, medical communications agencies, and public officials involved in research bodies). The final "How-To" Guide is a standalone, practical, ready-to-use tool to support multistakeholder cocreation of PLS.

Peer-reviewed scientific publications are the established channels through which researchers share results and data with their peers. These communications are typically written by scientists with peers and fellow experts in mind and are characterized by extensive use of technical language and complex graphical representations. Scientific articles are therefore often impenetrable for nonspecialist audiences. On the other hand, patients, patient organizations, and other nonexperts want to be informed about scientific research results that may impact on them or to whose generation they have contributed, eg, as participants in clinical trials or by anonymously being a included in health resource use study. Patients and their caregivers want to know what the research activity may mean for them and the conditions they are living with.[1-3]

Plain language summaries (PLS) are summaries of scientific articles written in easy-to-read, nontechnical language. They have the potential to increase the understanding of scientific data by making complex information more accessible to wider audiences. This includes patient organizations, patients, caregivers, healthcare professionals from different fields, and the public.[4-6] By improving knowledge and understanding of clinical research, PLS may facilitate patient–physician communication that could contribute to shared decision-making. Importantly, PLS are only of value when facts, numbers, and conclusions are conveyed truthfully and objectively, without promotional intent or spin. PLS can only fulfil their objectives if readers can fully trust that all relevant data—including information on the uncertainty of research conclusions—have been made available to them. Thus, the writing of PLS needs to be based on ethical considerations and requires a documented institutional framework.

The number of PLS associated with peer-reviewed publications is still relatively low, and there is currently wide variation in content, format, quality, and location (i.e., where people can access them) of PLS.[7] Efforts are

ISSN 2163-5315

ongoing to provide guidance, and minimum standards for PLS have recently been proposed.[8-10] However, previous guidelines do not address the need of ethical considerations for the generation of PLS nor do they provide guidance on cocreation with the target audience.

In line with key ethical principles formulated in the Declaration of Helsinki[11] that have become the basis for all clinical research in humans, members of the science communication continuum, ie, researchers, authors, sponsors, editors, and publishers, share the obligation to appropriately and ethically share the results of research (principle 36).

An ethical key consideration for PLS writing that expresses respect for potential and enrolled subjects of clinical research is the aspect of cocreation. PLS should be prepared in collaboration with members of the target audience to achieve an optimal outcome in respect to adequacy of content and presentation.[12] However, in current practice, patient involvement is often restricted to the late stages of PLS development, for example the review process.

The need for a practical "how-to" guidance that will ensure both ethical considerations and early involvement of patients was recognized by Patient Focused Medicines Development (PFMD).[13]

PFMD is a collaboration of health stakeholders, including publishers, patient organizations, and pharmaceutical companies, whose aim is to facilitate patient engagement (PE) across the medicine development lifecycle.

COCREATION OF THE "HOW-TO" GUIDE

For the development of the "How-To" Guide on PLS, an international working group was established, and members were required to have PE experience and/or expertise in generating PLS. The "How-To" Guide was developed in a stepwise approach using established cocreation methodology.[14-16] This included several rounds of cocreation, public consultation, internal review, and an external review. Feedback from each step in the review process was used to refine the draft "How-To" Guide, which was then validated through additional consultation. The first round of public consultation focused on the content, while the second public consultation gathered feedback on the usability and the associated user experience; a detailed description of the process is provided by Dormer et al.[17]

Ethical Considerations for PLS Writing

According to the Declaration of Helsinki,[11] a universally accepted ethical standard for medical research in humans, researchers, editors, and publishers have ethical obligations regarding the publication and dissemination of the results of research (principle 36). These actors in the biomedical communication continuum are accountable for completeness and accuracy of their reports and that negative and inconclusive as well as positive results are published or otherwise made publicly available (principle 36). Compliance with ethical principles is particularly relevant for PLS because they are intended for patients and nonexperts who are likely lacking the expertise to detect potential methodological flaws in scientific publications. In this regard, patients, caregivers, and other nonexperts constitute a vulnerable group that needs to be protected from harm inflicted by misinformation. While scientists are trained in presenting research in a structured way, the common format is alien to most patients and nonexperts. Hence, authors, editors, and publishers have the obligation to minimize the potential for misunderstanding of scientific results that are presented in PLS. This is supported by the 15 ethical considerations included in the "How-To" Guide.

The considerations cover the necessity for objective reporting, the need to apply health literacy principles, the importance of audience focus and the absence of any promotional intent, the need for balanced presentation, and the importance of using inclusive and respectful language. It is also essential for both sponsors and journals to have a consistent policy for the development and publishing of PLS. This means there should be transparent, prospective, and objective selection criteria for choosing publications from which to develop PLS and for deciding how and when they will be published to prevent publication bias. For example, one criterion from a sponsor could be a commitment to producing PLS for all phase 3 trials, regardless of outcomes. PLS on single trials need to include a disclaimer on the limitations and generalizability of the results. Details on the ethical principles are provided in Table 1.

Table 1. Ethical Considerations for PLS Writing

Any statement in the PLS should be objective and aligned with the data provided in the scientific publication.
Health literacy and numeracy principles should be applied in the writing and design of the PLS.
The choice of words should be neutral and factual. Superlative and emotional words, phrases, and metaphors should be avoided.
The PLS should be free of any commercial bias and must be strictly nonpromotional.
For PLS linked to primary scientific publications of clinical trials, there should be a balanced presentation of efficacy and safety data.
The overall objective (ie, the primary objective) of the research that is reported needs to be described in the respective PLS.
All data provided in the PLS should also be given in the scientific article. The data presented in a PLS should not go beyond the data provided in the scientific article.

Table continued on next page

Table 1. Ethical Considerations for PLS Writing (continued)

The results of the primary endpoint need to be described and explained in the PLS when reported in the scientific publication. Results of key secondary endpoints could be included if they have been prespecified in the study protocol or analysis plan, are statistically powered and analyzed, and are of particular relevance to patients.
The PLS needs to mention the important limitations of the research or study that is reported in the scientific article.
To make PLS accessible for patients whose native language is not English, appropriate translations should be done that faithfully reflect the content of the PLS. Translations need to be mindful of the cultural diversities between audiences and ideally reviewed by members of the target audience for each language.
The PLS should be inclusive of all genders, nationalities, and ethnicities.
The PLS should be reviewed by members of the public and/or by patients or patient representatives ideally with the condition that was studied in the scientific article.
The PLS should be approved by the lead author (the author who is named first in the author list) of the scientific article, as a minimum. All authors of the scientific article on which the PLS is based should be given the opportunity to review and comment on the PLS.
The authors of the PLS as well as the funding source of the research work and the funding of the PLS should be disclosed in the PLS.
Links to the scientific publication should be included in the PLS.

Cocreation of content expresses respect for the target audience and hence is an important aspect in generating PLS of peer-reviewed scientific publications. The methodology proposed in the "How-To" ensures adequate representation of the target population.

Seven Steps for Generating a PLS: Proposed Algorithm

The generation of PLS was broken down into seven steps that serve the overall aims of maximum audience focus and full cocreation with members of the target audience. A summary is provided in Table 2 below; a more detailed description is available in Dormer et al.[17]

DISCUSSION AND CONCLUSION

The field of PLS writing is evolving as more and more journals provide the opportunity for PLS.[5-7] Some guidelines for the content of PLS have been published by collaborative networks such as Cochrane[8,9] and Open Pharma.[10] Although these guidelines are applicable to all PLS, they do not explicitly provide ethical considerations, and they provide no methodology for cocreation of PLS with members of the target audience. It is very important to realize that PLS

Table 2. Seven Steps of Creating a PLS

Step	Action	Content
1	Have a rationale and scope for developing the PLS	The selecting criteria for the source scientific publication for a PLS must be clear before the writing is initiated. It is important to have a transparent process, such as a standard operating procedure, across an organization, to avoid publication bias by selectively providing PLS. Reasons for a PLS could be the impact of the data, the uniqueness of the scientific approach, or the needs of a certain audience.
2	Identify the target audience	The target audience should be defined before the start of the writing process. This choice will impact the resource needs in the cocreation process and will determine the administrative and operational complexity of the PLS writing.
3	Consider the dissemination channels	It is essential to consider the dissemination of the PLS based on the identified target audience. Free access is important to optimize distribution. The method of dissemination will influence the amount of aggregation and summarization of data from the source article. For example, if a manuscript and its PLS appear in the same issue of a journal, certain details may be omitted from the PLS and provided solely as reference to the source. Some journals may allow the inclusion of supplementary material, eg, for additional infographics.
4	Identify key stakeholders for cocreation	It is important to identify the key stakeholders for their engagement in cocreation before a PLS is written. It is desirable to have a broad range of stakeholders, including patients, caregivers, and others. The PLS cocreators should determine whether they have the appropriate reach into the target audience or whether new cocreation relationships need to be established. Resourcing (eg, contracting, payment, technical infrastructure) and any applicable legal requirements need to be considered to ensure that relationships can be maintained throughout the process.
5	Write PLS	PLS cocreators should establish an appropriate infrastructure and should agree on roles and interaction in the writing process. Based on the target audience, the PLS cocreators need to decide on the literacy level and the structure of the PLS and the use of visuals or infographics. It is highly recommended to have a member of the target audience review the draft PLS. The PLS must reference the source scientific article or contain a link to it.
6	Disseminate PLS	Once the PLS is published, it may be shared in print, in online repositories, or on relevant websites; the channels should be chosen based on target audience preference. The use of social media for dissemination depends on the legal restrictions in some countries and the corresponding compliance rules in large organizations.
7	Track dissemination and measure success	Ways to monitor the impact of the PLS should be developed to gauge future efforts. Various metrics may be available depending on where a PLS is located/hosted. The journal site/website/repository that hosts the PLS might provide metrics such as the number of views or downloads. Another measure is the attention the PLS or the source article has received on social media or in other commentaries. Posts on social media that link to the PLS may be liked or shared, and monitoring this activity can provide an indication of the reach of the PLS. It should also be measured whether the PLS is shared by patient organizations and healthcare providers in the respective disease area.

written without strict consideration of ethical principles bear the risk of contributing to misinformation rather than providing insight and understanding to nonexperts. To make this new format a trustworthy source for patients, caregivers, and others, a firm commitment to ethical conduct in PLS writing is mandatory. However, while not being explicit about their ethical considerations, the existing guidelines[8,9] stipulate a number of requirements that are in line with the recommendations of the PFMD guidance. For example, the Cochrane collaboration mentions consistency between the source and the PLS and the need to report the primary outcome as well as balanced reporting of efficacy and safety data as mandatory requirements.[8] Interestingly, in the latest version of the Cochrane guidance published in January 2022, the ethical considerations in regard to content of PLS, are substantially less explicit than in the previous version.[9] The Open Pharma collaboration mentions that PLS need to be nonpromotional and unbiased and that PLS need to include a link to the source publication.[10] In a recently published modified Delphi approach of stakeholders' perceptions of issues in generating PLS,[18] a number of items emerged as "important" that are in line with the ethical considerations put forward in the PFMD guidance. Stakeholders considered it "important" that the primary endpoint results are included in the PLS as well as mentioning the limitations of the study. Other obligations related to ethical conduct, such as having the authors of the source article approve the PLS, are only to be "considered" in PLS generation, according to this stakeholder group.

In summary, the "How-To" Guide developed by PFMD is the first one to more explicitly require compliance with a set of ethical considerations. The value of these stipulations was corroborated by the fact that the "How-To" Guide had been developed using an iterative and robust co-creation methodology with substantial public consultation.[14-16]

To ease implementation, selected resources for PLS development, complementary tools, and good-practice examples are available directly in the "How-To" Guide. The "How-To" Guide[19] has been uploaded onto the PFMD PE Management Suite, a central repository that allows open access to all PFMD tools.

Acknowledgment

I take full responsibility for the content and the presentation. However, I thankfully acknowledge the discussions within the PFMD PLS working group on the topic. The members of the PLS guidance core team were Laura Dormer, Lauri Arnstein Williams, Dawn Lobban, Sheila Khawaja, Amanda Hunn, Daniela Luzuriaga Ubilla, and Anne-Marie Hamoir.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

Author contact: *lay_and_regulatory_writing@gmx.de*

References

1. Pushparajah DS, Manning E, Michels E, Arnaudeau-Bégard C. Value of developing plain language summaries of scientific and clinical articles: a survey of patients and physicians. *Ther Innov Regul Sci*. 2018;52(4):474-481. https://doi.org/10.1177/2168479017738723
2. Geissler J, Ryll B, Leto di Priolo S, Uhlenhopp M. Improving patient involvement in medicines research and development: a practical roadmap. *Ther Innov Regul Sci*. 2017;51(5):612-619. https://doi.org/10.1177/2168479017706405
3. Dietrich, J, Alivojvodic J, Seliverstov I, Metcalf M, Jakee K. Improving information exchange with clinical trial participants: a proposal for industry. *Ther Innov Regul Sci*. 2017;51(5):542-550. https://doi.org/10.1177/2168479017725109
4. Kerwer M, Chasiotis A, Stricker J, Günther A, Rosman T. Straight from the scientist's mouth—plain language summaries promote laypeople's comprehension and knowledge acquisition when reading about individual research findings in psychology. *Collabra Psychol*. 2021;7(1):18898. https://doi.org/10.1525/collabra.18898
5. Nunn E, Pinfield S. Lay summaries of open access journal articles: engaging with the general public on medical research. *Learn Publ*. 2014;27(3):173-184. https://doi.org/10.1087/20140303
6. Anstey A. Plain language summaries in the *British Journal of Dermatology*: connecting with patients (editorial). *Br J Dermatol*. 2014;170(1):1-3. https://doi.org/10.1111/bjd.12760
7. FitzGibbon H, King K, Piano C, Wilk C, Gaskarth M. Where are biomedical research plain-language summaries? *Health Sci Rep*. 2020;3(3):e175. https://doi.org/10.1002/hsr2.175
8. McIlwain C, Santesso N, Simi S, et al. Standards for the reporting of Plain language summaries in new Cochrane intervention reviews Version 1. Cochrane: London. 2013. Available from: training.cochrane.org/resource/cochrane-standards-preparing-plain-languagesummaries
9. Pitcher N, Mitchell D, Hughes C. Template and guidance for writing a Cochrane plain language summary. Version 1 January 2022. Accessed April 25, 2022. https://training.cochrane.org/guidance-writing-cochrane-plain-language-summary
10. Rosenberg A, Baróniková S, Feighery L, et al. Open Pharma recommendations for plain language summaries of peer-reviewed medical journal publications. *Curr Med Res Opin*. 2021;37(11):2015-2016. https://doi.org/10.1080/03007995.2021.1971185
11. WMA Declaration of Helsinki – ethical principles for medical research involving human subjects. World Medical Association. Published 2018. Accessed March 10, 2022. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
12. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA* 2000;283(20):2701-2711. https://doi.org/10.1001/jama.283.20.2701

13. Patient Focused Medicines Development. Workshop 3: the role of patients in co-designing plain language summaries. Published 2019. Accessed March 10, 2022. https://patientengagementopenforum.org/docs/Workshop-3-PE-in-PLS-development.pdf
14. Deane K, Delbecque L, Gorbenko O, et al. Co-creation of patient engagement quality guidance for medicines development: an international multistakeholder initiative. *BMJ Innov*. 2019;5(1):43-55. https://doi.org/10.1136/bmjinnov-2018-000317
15. Feldman D, Kruger P, Delbecque L, et al. Co-creation of practical "how-to guides" for patient engagement in key phases of medicines development—from theory to implementation. *Res Involv Engagem*. 2021;7(1):57. https://doi.org/10.1186/s40900-021-00294-x
16. Patient Focused Medicines Development. Practical how-to guides for patient engagement. Accessed March 10, 2022. https://pemsuite.org/how-to-guides/
17. Dormer L, Schinder T, Arnstein-Williams L, et al. A practical 'how-to' guide to plain language summaries (PLS) of peer-reviewed scientific publications: results of a multi-stakeholder initiative utilizing co-creation methodology. *Res Involv Engagem*, 2022;8(1):23. https://doi.org/10.1186/s40900-022-00358-6
18. Lobban D, Gardner J, Matheis R. 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): 189-200. https://doi.org/10.1080/03007995.2021.1997221
19. Patient Focused Medicines Development. How-to guides for patient engagement: plain language summaries (PLS) of peer-reviewed publications and conference presentations: practical 'how-to' guide for multi-stakeholder co-creation. Accessed March 10, 2022. https://pemsuite.org/How-to-Guides/WG5.pdf