

Establishing a patient publication steering committee: A case study with insights for medical writers

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Abstract

Development of a patient publication steering committee (PPSC) is an innovation in industry publication practices. In this brief article, we summarise how UCB Pharma, a global biopharmaceutical company, plans to partner with patients to establish a PPSC and share insights on how medical writers could support PPSCs. The purpose of a PPSC is to plan and oversee the timely and ethical development of high-quality publications on disease burden and the patient journey, as identified by patients. In this case study, we collaborated with key internal and external stakeholders, including medical writers, to identify the key roles, governance, and documentation required for a PPSC. We have demonstrated that it is feasible to develop a PPSC framework that will guide the ethical and effective development of a patient-led publication plan. Medical writers would work within this framework to help develop and implement the plan.

About the word *patient*

In this article, we use the word *patient* in a broad sense to encompass people living with or affected by disease (this includes caregivers and family members).

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Patient involvement in the publication life cycle is an innovation in industry publication practices. The most recent version of the Good Publication Practice guidelines (GPP3)¹ did not cover patient involvement in publications, but this gap should be addressed in the next version. This evolution reflects the increasing interest from patient leaders, industry sponsors, medical writers, publishers, journal editors, researchers, and other stakeholders in HOW to involve patients ethically, compliantly, and effectively in publications. Medical writers will need evidence-based guidance and practical insights to provide professional support in this

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new patient-partnered publication era.

We have proposed that patients can be involved, as partners, at multiple points during the publication life cycle (Figure 1).

We have conducted and published research on how to involve patients as co-creators of plain language summaries of publications and as authors of publications.²⁻⁵ However, to the best of our knowledge, there have been no published studies on how to involve patients as members of a patient publication steering committee (PPSC), nor any guidance offered to medical writers about how to support PPSCs. The

purpose of a PPSC would be to plan and oversee the timely and ethical development of high-quality publications on disease burden and the patient journey, as identified by patients. Our objectives for this real-world feasibility study were to identify the key roles, governance, and documentation required to establish a PPSC for a global biopharmaceutical company.

Through this article, we hope to share our early insights about establishing a PPSC and how medical writers could provide valuable support to PPSCs.





Figure 1. Patient involvement in the publication life cycle

Method

To establish a framework for UCB Pharma’s first PPSC, we followed a stepwise process from October 2019 through to May 2020 (Figure 2). After conducting a literature search to confirm that the PPSC would be an innovation in industry publication practices, we consulted with stakeholders who would be required to support, approve, and implement a PPSC. These stakeholders included key internal (patient engagement and advocacy, publications, compliance, medical) and external (expert patients, patient advocates, medical writers) partners. These early and critical discussions confirmed the need for a PPSC, a compliant process to implement the PPSC, and plain language documents to guide PPSC governance

and operations. We subsequently collaborated with internal and external stakeholders, including medical writers to develop a PPSC framework that would be needed for the ethical, compliant, and effective initiation of UCB Pharma’s first PPSC.

Results

Our PPSC initiative is ongoing, with a pilot planned for 2021. However, the critical stages to prepare for the first PPSC meeting have been completed successfully (Figure 3).^{6,7}

Our PPSC framework is based on UCB Pharma’s existing publications standard operating procedure, which aligns with GPP3, and addresses important compliance considerations including:

Methods

- **October 2019**
Review literature to confirm PPSC would be an innovation in industry publication practices
- **November 2019-February 2020**
Collaborate with internal (patient engagement and advocacy, publications, compliance, medical) and external (expert patient partners, publication professionals) stakeholders
- **November 2019-April 2020**
Co-create PPSC governance documents and measure document metrics (readability, reading speed, speaking speed)
- **May 2020**
Endorsed by key internal stakeholders



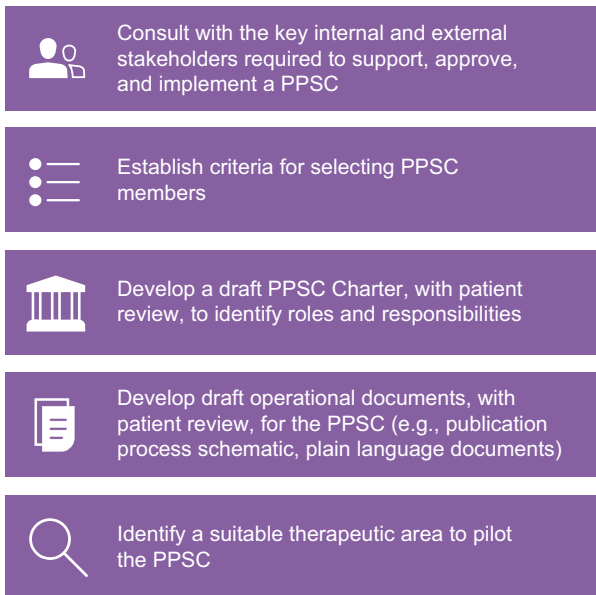
Figure 2. Timeline and key steps for developing the patient publication steering committee framework

- Pre-specified, fair, and robust selection criteria for patient representatives to join the PPSC
- A written PPSC charter that clearly defines roles and responsibilities for PPSC members
- Transparent and justifiable inclusion of clearly identified, non-product specific, publications in a strategic publication plan.

Draft PPSC documents (N=7) for the first meeting were co-created by patient experts and medical writers who had expertise in plain language and patient involvement in publications. For legal reasons, we did not alter UCB Pharma’s Confidentiality Agreement and Author Agreement forms but did co-create a plain language guide to each. These guides were more suitable for patients (Figure 4). The other documents (PPSC Charter; PPSC Invitation; Publication Process Overview; Patient Author Candidate Matrix; Plain Language Summary of GPP3 guideline) followed plain language principles, met readability targets, and were deemed suitable for patients.

In terms of next steps, we plan to pilot the PPSC in one therapeutic area and follow UCB Pharma’s existing patient engagement principles.

COMPLETED STEPS



NEXT STEPS

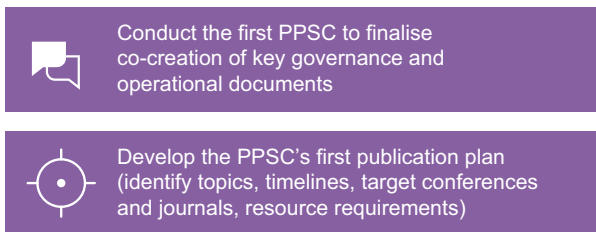


Figure 3. Completed and planned steps for the patient publication steering committee pilot

We will invite qualifying members of one of UCB Pharma’s existing patient councils to become PPSC members. The council members will select PPSC members based on pre-specified PPSC

selection criteria (e.g., recognised patient expertise in the disease area knowledge of the relevant patient community, fluent in oral and written English, interest, availability, and willingness to participate). The first PPSC meeting will focus on PPSC roles and responsibilities and will include a formal review of the draft PPSC documents. The PPSC documents will be finalised based on the input from the PPSC members.

Discussion

To the best of our knowledge, we have conducted the first feasibility study to establish a PPSC for a global biopharmaceutical company.^{6,7} Our results indicate that it is feasible for industry sponsors to partner with patients to establish PPSCs.^{6,7} This has the potential to change industry publication practices to enable early, compliant, and important partnerships with patients in the publication life cycle. Medical writers could play a key role in supporting PPSC members to plan, develop, and share patient-led publications.

Within the broad field of medical communications, patient engagement in publications is novel. Patient engagement in publications of industry-sponsored research is certainly a recent innovation, even in comparison with patient engagement in other relatively new areas (e.g., patient engagement in protocol development, clinical trial conduct, and involvement in regulatory and reimbursement reviews). In order to remain at the forefront of innovations in medical communications, medical writers should have training in patient engagement. The training could include The Patient Focused Medicines Development (PFMD) Patient Engagement



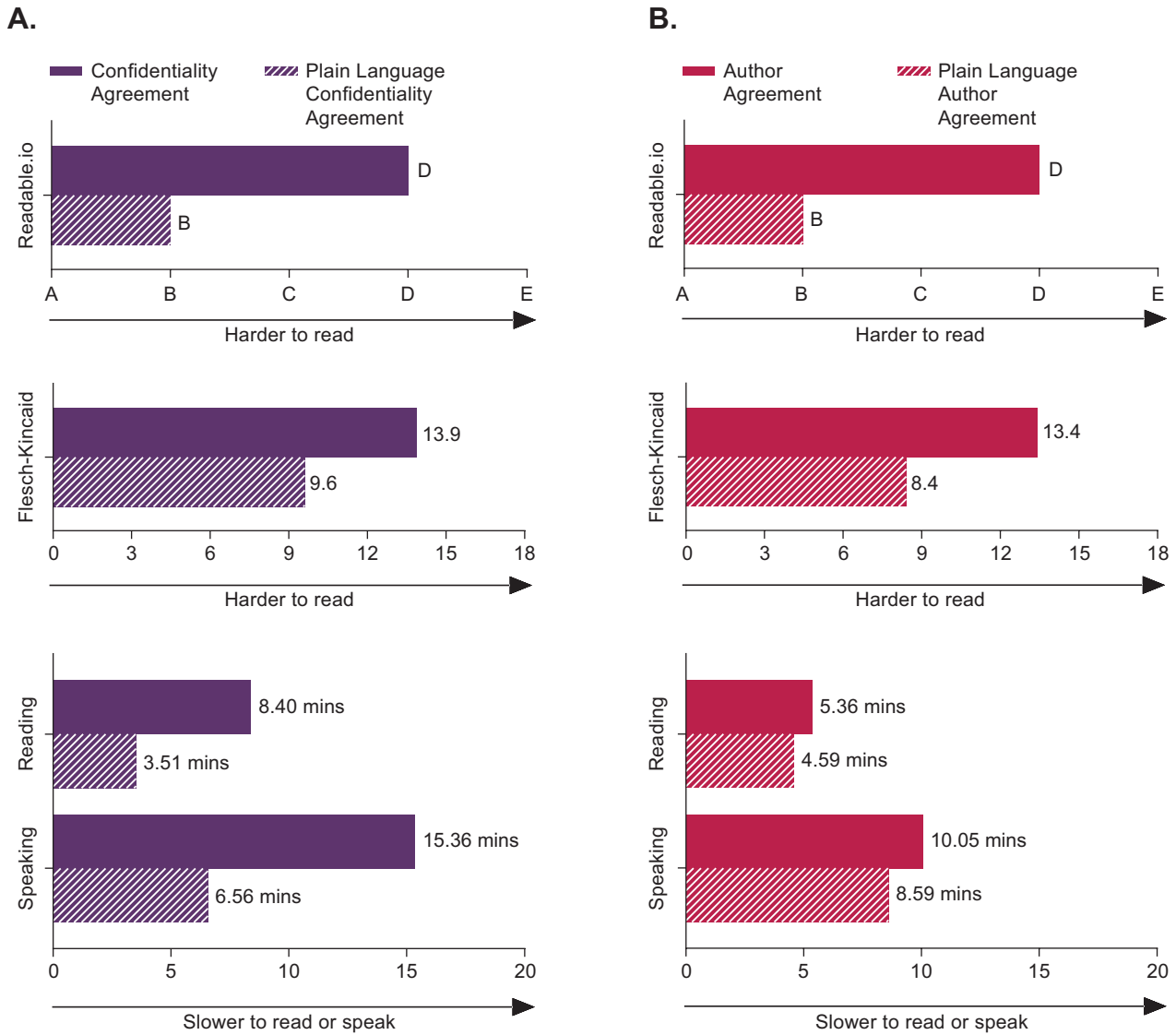


Figure 4. Readability metrics for the original document and the accompanying plain language guide for the (A) confidentiality agreement and (B) author agreement

Metrics were generated by the Readable.io software program.



Quality Guidance,⁸ which was co-created with patients and provides a useful framework for planning, developing, and assessing the quality of patient engagement activities throughout the development and lifecycle of medicines. The guidance contains seven quality criteria based on an agreed set of principles to improve consistency in patient engagement practices that could be applied by medical writers or other stakeholders to plan and assess a PPSC (Figure 5).

Although pharmaceutical companies have recognised the value of plain language summaries of publications,⁹ and have started to involve patient experts later in the publication life cycle

(e.g., as co-creators of plain language summaries of publications and as authors of publications), we are unaware of published reports of patient involvement early in the publication life cycle (e.g., in publication steering committees). Our interest in establishing a PPSC was driven by several factors, including:

- Belief in the unique and important value that the patient perspective can provide to presentations and publications^{6,7}
- Recognition that publication steering committees are recommended in GPP3 for industry-sponsored research¹
- Increasing advocacy by patient experts and



Figure 5. Seven patient engagement quality criteria⁸

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patient advocates for involvement in publication planning

- Evidence from our recent systematic review on patient authorship that reinforced the importance of involving patients before publication writing begins³
- Recognition of the benefits of early and non-tokenistic involvement of patients in other advisory groups (e.g., trial steering committees)¹⁰⁻¹²

As experts in GPP3 and publication planning, medical writers can play an important role in supporting the PPSC and patient authors throughout the publication life cycle, providing guidance and practical assistance as needed. As part of the current initiative, medical writers were involved in generating the documents needed for industry compliance purposes, as well as preparing plain language guides and documents for use in the first PPSC meeting. Although we are still in the early stages of this PPSC initiative, we anticipate that medical writers will continue

to play a key role in the development and execution of the strategic publication plan. We have identified a number of ways in which medical writers could contribute to success of a PPSC. These insights reflect the diversity of perspectives from our PPSC initiation team (Table 1).

As medical writers may appreciate, “upstream” involvement of patients at the publication steering committee stage of the publication life cycle should differentiate patient-led publication plans from traditional publication plans. Both plans should complement each other, but a patient-led publication plan may differ in terms of:

- **Publication topics.** Patients are in the best position to identify topics that are important to their care in the real world. As topic prioritisation may differ between patients and healthcare

professionals, a PPSC would ensure that the publication plan addresses patient priorities. Ultimately, these publications should help inform shared decision-making and, thus, help both patients and clinicians.

- **Publication author candidates.** Patient leaders have access to networks that could include people with the most relevant skills and expertise to author or contribute to publications. Training courses for patient authors are being developed,¹³ and a PPSC could help ensure that the pool of potential authors expands to include patients. Healthcare professionals do not have to be the surrogate voice for patients in the peer-reviewed literature.
- **Publication dissemination plans.** Patients have started to present at conferences and author publications in peer-reviewed medical journals.³⁻⁵ These experiences could help patients nominate target conferences and journals that may be most interested in patient-led publications. Patients may also be less tied to traditional considerations regarding dissemination (e.g., a strong focus on journal impact factors). This “freedom” from historical and academic constraints could help drive innovation. For example, patients and the public have advocated for plain language summaries of publications and have been shown to drive awareness of publications and accompanying plain language summaries within their patient advocacy communities and via social media.¹⁴

We recognise that our study has limitations. We are only able to share one industry sponsor’s experience and we are conducting a pilot PPSC

study in only one therapeutic area. However, we believe that this highly focused approach is prudent for a feasibility study. We intend to update and share our PPSC insights as we continue this PPSC initiative. We welcome the uptake of PPSCs by other sponsors and encourage them to share their findings with the broader publication community, including patients.

To conclude, this novel, real-world, “how to” case study indicates it is feasible for a global

This novel, real-world, “how to” case study indicates it is feasible for a global biopharmaceutical company to partner with patients to establish a patient publication steering committee.

biopharmaceutical company to partner with patients to establish a PPSC.^{6,7} By working collaboratively with internal and external stake-

Table 1. Perspectives from different stakeholders on how medical writers could support a patient publication steering committee

Stakeholder	How medical writers could support a PPSC
Industry sponsor	<ul style="list-style-type: none"> ● Help prepare documents for internal colleagues (e.g., compliance) to gain their support and approval for a PPSC ● Contribute to the PPSC framework document that will guide the development of the PPSCs and ensure consistency across the company ● Contribute to the first PPSC meeting (e.g., to provide an overview of GPP3 and outline the stepwise approach used for publication planning and development) ● Assist with the development and execution of the strategic publication plan
Patient advocate	<ul style="list-style-type: none"> ● Work with patient leaders to gather and summarise feedback from patient communities that could help inform the development and implementation of a PPSC ● Identify PPSC documents that should have a plain language version ● Help co-create PPSC documentation ● Work with patient leaders to identify suitable candidates for the PPSC based on the skills and knowledge that could optimise effective involvement ● Identify novel and suitable dissemination methods for publications to wider and targeted audiences ● Identify and address training requirements and knowledge gaps for PPSC members to fully engage successfully with the publications process
Medical writer	<ul style="list-style-type: none"> ● In general, be the “go to” person for PPSC members and patient authors for questions about GPP3 (consider setting up recurring check-in meetings) ● Work in an ethical, compliant, and effective manner with PPSC members to help them develop and execute the publication plan ● Provide a summary of scientific publishing practices ● Provide a practical overview of the key steps and timelines involved in preparing a publication plan, as well as presentations and publications ● Explain common terminology and abbreviations used in scientific publishing (e.g., abstract, encore, congress, manuscript, journal, disclosure of COI, GPP3, ICMJE, IF, open access, peer review) ● Explain key considerations in selecting a target journal or congress ● Provide guidance to the PPSC on how to nominate and select patient authors in a compliant manner ● Help explain authorship roles and responsibilities to the patient author candidates identified by PPSC members (e.g., share the Plain Language Guide to GPP3¹⁵) including issues that might affect their decision to accept authorship (e.g., inclusion of their name on the publication, potential time required) ● Explain who co-authors are and their roles in the research (if necessary) ● Establish patient author’s preferred publication feedback method (in writing, via phone/email) and be aware they may need more time or flexibility to provide feedback ● Provide medical writing support to translate author feedback into publications ● Suggest metrics for evaluating the success of the PPSC ● Volunteer to help adapt tools and processes that will contribute to the success of future PPSCs

Abbreviations: COI, conflict of interest; GPP3, Good Publication Practice 3 guideline; ICMJE, International Committee of Medical Journal Editors; IF, impact factor; PPSC, Patient Publication Steering Committee

holders, we developed a compliant PPSC process and plain language documents.^{6,7} By sharing our insights, we hope other industry sponsors will consider how to partner with patients to establish PPSCs and that medical writers will recognise how they could play an important role in supporting PPSCs.

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Conflicts of interest

Non-financial: All authors support patient involvement in medicines development. Financial: LF and AM are employees of UCB Pharma and hold stock and/or stock options in UCB Pharma. TB is a patient engagement consultant to Envision Pharma Group, receiving fees for plain language document review. NM, HC, and KW are employees of Envision Pharma Group.

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