Meeting report: summary of the 54th EMWA Conference mini-symposium on plain language summaries

The 54th European Medical Writers Association (EMWA) Conference mini-symposium on plain language summaries, entitled "Plain language summaries (PLS) for scientific publications: exploring multistakeholder perspectives" took place on 4 November. The half-day mini-symposium explored the topic of PLS and provided insights from medical writers, industry, publishers, and patients through presentations and panel discussions.

A summary of the mini-symposium is provided below to benefit those who were unable to attend, and as a timely reminder of the key topics for those who did.

Introduction and welcome

KEY TAKEAWAYS

- PLS should be accessible, discoverable, and inclusive.

Slavka Baronikova (EMWA Conference Director; Galapagos) and Adeline Rosenberg (Oxford PharmaGenesis) welcomed attendees to the event and began proceedings by introducing the topic of PLS. Rosenberg explained that PLS should be accessible and understandable. They are intended for a non-expert audience, so should be jargon-free and are not to be confused with regulatory lay summaries, which refer to EU-mandated summaries of clinical trials provided by a trial sponsor for the general public. In addition, plain language summaries of publications (PLSP) are a specific type of PLS featured in publications such as the Future Science Group journals, which summarise whole publications as standalone articles.

Rosenberg recognised that the value of PLS for healthcare professionals (HCPs) is fairly well-established, as evidenced by one study reporting that 71% of HCPs rated PLS to be "very/extremely useful" (compared with 65% and 64% for infographics and videos, respectively). In another study, 46% of neurologists surveyed rated PLS as valuable and 60% would use them when communicating with patients. In a third study, 57% of HCPs would use plain language guides with patients and 65% would share them with colleagues. Rosenberg then discussed the value of PLS for patients, referring to a study in which 41% of patients surveyed used journal articles to find health-related information online, making journal articles the third most important source (after general internet searches and patient-specific websites). Journal articles are especially important for patients with rare diseases, for which information is often not readily available.

Baronikova then went on to highlight the Open Pharma recommendations for PLS, which were published in September 2021. These recommendations advise that PLS are accessible, discoverable, and inclusive. As a minimum, they should comprise a short (about 250 words) text-based summary, written in understandable language. The PLS should be developed and peer reviewed alongside the main manuscript content. Baronikova highlighted some of the many resources available to help with the development of PLS, including Patient Focused Medicines Development (PFMD), Good Publication Practice (GPP) guidelines, ISMPP resource, and Clinical Data Interchange Standards Consortium (CDISC), a glossary of terms to use in PLS.

Medical writer perspective

KEY TAKEAWAYS

- PLS should be peer reviewed, citable, and discoverable.
- PLS save the reader time, are easily shared on social media, are inclusive for people less proficient in English, result in a higher number of downloads, and increase the chance of journalist coverage.
- Health literacy is generally low, so it is important to ensure that PLS are readable.

Jill Shuman (Sci-Comm-Network and Writers Group) discussed the value and uses of PLS from the perspective of a medical writer. Shuman began by noting that a PLS should contain the same information as the scientific abstract, but use different language and tone, avoid jargon and acronyms, and preferably be written in the active voice.

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PLS should be peer reviewed, citable, and discoverable on indexing databases. Ideally, a non-expert should be involved in PLS development, by either co-authoring or reviewing the PLS. Shuman also clarified the distinction between PLS and lay summaries (also known as clinical trial summaries). The latter are EU-mandated summaries of completed clinical trials, which focus on the primary endpoint. They are aimed at the general public and trial participants and have a reading level of around 10–12 years. On the other hand, a PLS is a clear, non-technical overview of a scientific study, which is not mandated. It is aimed at patients and non-specialist professionals with no defined reading level, but is typically written at undergraduate college level (around 18 years of age).

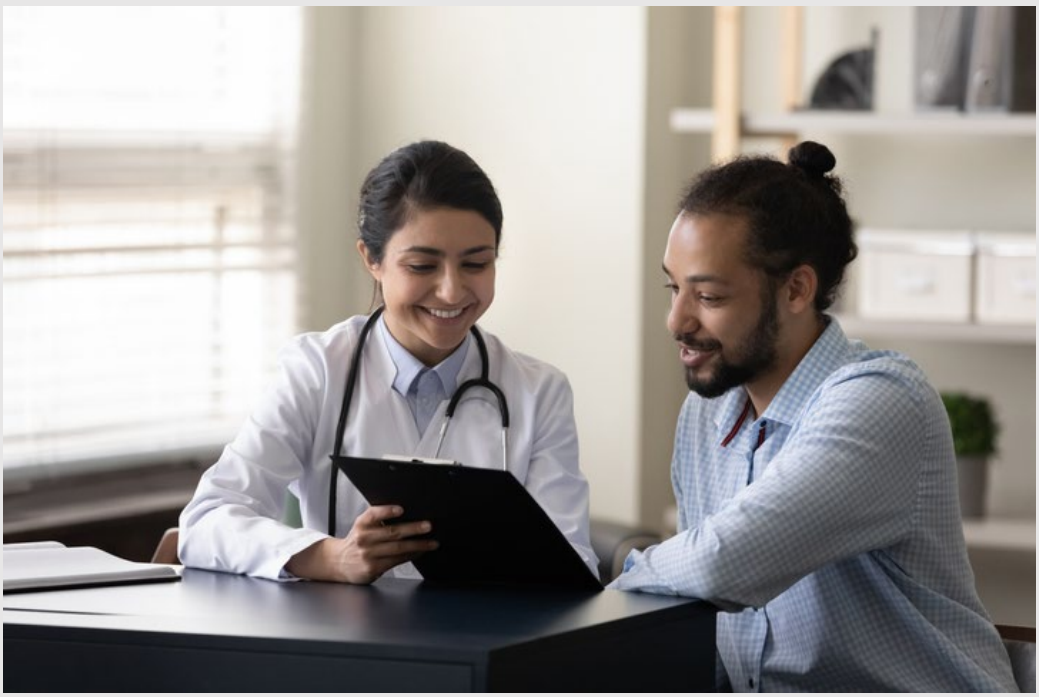
Shuman discussed the possible audience of a PLS in more detail, noting that it may include scientists, HCPs, policy makers, patient advocacy groups, journalists, educators, and non-native speakers. Compared with scientific abstracts, PLS save the reader time, they are easily shared on social media and are more inclusive for people less proficient in English. In addition, Shuman noted that the inclusion of a PLS results in a higher number of downloads, citations and Altmetric scores, and increases the chance of journalist coverage. Furthermore, PLS may attract collaborators from different areas, encouraging interdisciplinary research.

Next up, Sarah Griffiths (Oxford PharmaGenesis) provided her top tips for writing PLS. Griffiths flagged that preparation is key. Important considerations are the format of the PLS (eg text-based, infographic, video, or audio) and whether the client has any guidance or policies on PLS. Griffiths recommended informing authors at the outset that a PLS will be developed and sharing timelines and processes with them to manage their expectations. She also advised contacting journals to ask about possible PLS options if such information is not readily available. Griffiths noted that the recently published GPP 2022 guidelines recommend that PLS should be:

- considered for all clinical publications
- consistent with the original publication, and be non-promotional
- reviewed and approved by the authors; in addition review by a patient or member of the public should be considered to ensure that the PLS is understandable

- freely available, indexed, and discoverable
- published and peer reviewed alongside the original publication.

Griffiths went on to explain the importance of ensuring that PLS are readable, noting that health literacy is generally low, with over 60% of adults in the UK struggling to understand basic health information. Poor health literacy is associated with poor health, but if a PLS is well written, it can make complex health information accessible and understandable to a broad audience and facilitate shared decision-making between patients and physicians.



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Griffiths highlighted that as medical writers, we are used to communicating at complex levels. Glossaries could be used to provide suitable words or phrases for PLS, and use of comment boxes within a document allows the content or rationale to be explained to authors or reviewers. To check that a PLS is written appropriately, it might be worth reading it aloud to ensure that sentences are not

too long or complex, use online readability tools, or have the PLS reviewed by a patient or PLS expert. Griffiths concluded by summarising that PLS should be:

- **understandable** by target audiences
- an **accurate** reflection of the original publication
- **non-promotional** and **jargon-free**
- **discoverable** and **accessible**.

Industry perspective

KEY TAKEAWAYS

- Future goals at Ipsen are to improve accessibility and discoverability of PLS and to establish metrics to assess their impact.
- GSK also plan to enhance discoverability, in addition to broadening the development of PLS in the company, using more inclusive formats such as visual or audio and consolidating collaboration with patient representatives.

Sarah Thomas (Ipsen) began this session by highlighting Ipsen's 2019 commitment to publish all research open access. She noted, however, that while patients are regularly turning to journal articles as a source of information, due to the technical language used, the readability of articles is decreasing.

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In January this year, Ipsen committed to publishing (as a minimum) a 250-word PLS for all journal articles reporting company-sponsored data from human studies. Thomas explained that the Open Pharma recommendations were used as a framework for internal guidelines and a lexicon was developed to ensure use of consistent terminology across publications. At Ipsen, PLS are developed alongside manuscripts so that they can be peer reviewed in parallel. Each PLS is reviewed internally by at least two individuals who are not familiar with the therapy area, to check that it is understandable to non-experts. Looking to the future, Thomas described plans to establish a patient expert review panel and incorporate the process into a formal standard operating procedure (SOP), along with updates to the lexicon. Ipsen also plan on working on ways to improve accessibility and discoverability of their PLS (to avoid them being published only in a supplement) and to investigate metrics to assess their impact.

Laurence Rouxhet (GSK) gave the second talk in the session on industry perspectives, by providing an overview of PLS use at GSK. Rouxhet noted that the audience for a PLS includes not only (informed) patients but also HCPs, caregivers,

and health authorities. Data reported in a PLS may be clinical, but PLS could also report epidemiological, health outcomes data, or accompany review and technical articles. In addition to manuscripts, PLS are also used for posters or oral presentations at congresses, to reach non-expert attendees. In 2018, GSK began a pilot for one brand where PLS were written mainly for clinical manuscripts, using a template containing three sections:

- what is the context?
- what is new?
- what is the impact?

In 2019, following positive feedback from authors and editors, the pilot was expanded to all vaccine projects and all relevant manuscripts and, in 2020, the format of the PLS was diversified (ie made more graphical), to help facilitate understanding. PLS were also developed for medicine projects when requested by journals. In terms of congress materials, detailed, multipage PLS started to be developed for clinical posters or presentations for medicine projects, while simple, concise PLS started to be included in posters for the vaccine projects. Guidance is now being developed to align the principles and approaches for PLS development across GSK.

Rouxhet highlighted that, initially, PLS were mainly published in the supplementary materials, but they are now included in the main body of the manuscript, ideally just below the scientific abstract, increasing visibility. In the future, GSK plans to systematically include PLS, use inclusive formats such as visual or audio, consolidate collaboration with patient representatives, enhance discoverability, develop PLSPs, and further simplify posters so that separate PLS are not needed.

Publisher perspective

KEY TAKEAWAYS

- PLS can allow important, complex science to be understood by a broad audience.

- A consistent rationale should be used when deciding which articles should include a PLS.

In this session, representatives from the publishing industry shared their views and insights on PLS. Caroline Halford (Springer Healthcare) began by describing some of the motivations for publishing a PLS:

- increase **comprehension**
- reduce **misunderstandings**
- enable **sharing** and increased **reach** of information
- translate complex science into an **understandable** format for a **global** audience
- facilitate **HCP–patient** discussions.

Halford highlighted that some stakeholders might not be convinced of the value of PLS. However, there is much evidence to support their use. For example, one study showed that articles containing a PLS were more likely to be downloaded than those with no PLS; another study evaluating enhanced features found that that video abstracts and PLS resulted in the highest level of understanding, were more enjoyable, and left the reader interested in updates.

Halford then handed over to fellow publisher, Kelly Soldavin (Taylor & Francis), who shared her thoughts on best practices when developing PLS. In line with previous speakers, Soldavin recommended reading relevant guidelines, checking that PLS are supported by the target journal or publisher, and discussing PLS options with the editor, especially when details are not apparent on the journal website. Soldavin also advised using jargon-free, non-promotional content in a format suitable for the audience. She suggested including patient or non-expert review during PLS development, and noted the need to obtain permission from the authors and original publisher if a standalone PLS is developed. Soldavin advised applying consistent criteria when selecting which articles should include a PLS, to avoid accusations of cherry picking, and listed ways to increase discoverability, including:

- selecting a journal that indexes PLS on **PubMed**
- choosing a publisher with a **microsite** that features PLS

- publishing **open access**
- providing **keywords** and **metadata**
- discussing with the publisher whether the PLS can be shared on **social media**
- involving **patient advocacy groups** who may be able to distribute the PLS to the target audience.

Soldavin stressed the need for multi-stakeholder buy-in, the importance of tailoring PLS content to the target audience, and the benefit of asking the target audience to give their input and feedback on the PLS.

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Soldavin concluded the session by noting that further improvements are needed to provide metrics regarding reach and impact of PLS, and to enable enhanced search functions.

Patient perspective

KEY TAKEAWAYS

- PLS have an important role to play in meeting the unmet information needs of patients.
- Key requirements of PLS are that they come from a trusted source and are easily accessible, including being published open access.

The patient perspective was the focus of the next session and was opened by Mitchell Silva, patient advocate, co-founder of Esperity and Patient Centrics, and chair of the Belgium National Platform of the European Patients' Academy on Therapeutic Innovation (EUPATI). Silva considered the evolving space for patient engagement with PLS, with many pharmaceutical companies now building patient involvement into their routine processes. Alongside this welcome development, it is important to consider how to get all of the information in front of patients.

Why is it important to translate the results of, for example, clinical trials into something that is relevant and understandable for patients? There has been growing attention on the information needs of patients, including how unmet needs change during the journey of their disease – from understanding the signs and symptoms of disease, through the process of diagnosis, then on to the choice of treatment and either long-term treatment or cure. At the same time, medicine is evolving, with new and innovative treatments reaching the market.

Patient experts and advocates are now actively looking for PLS and related materials, as they need the information for their work with the patient communities and populations they represent. They may also need the knowledge to engage effectively with other stakeholders, including the regulatory authorities and

pharmaceutical industry representatives, for example, when working to optimise study design from a patient perspective.

Silva considered the risk that important detail or context may be lost when translating information for a patient audience, and noted that while not easy, it is possible to overcome this risk with the right mindset. He highlighted that it is important to involve the patient from an early stage and as an equal partner as part of a consistently applied approach.

With the growing contribution of patient experts, there is also a need for training for these experts. Silva highlighted that courses are now becoming available, such as the Belgian Patient Expert Center, including training on how to review materials such as PLS. EUPATI also offers a toolbox of resources for patient experts and a series of learning modules that can help pharmaceutical organisations really understand how to go about capturing the patient perspective.

Silva concluded his presentation by noting that trying to put yourself in the patient's shoes is not the same as actually asking the patient, and he would strongly recommend talking with patients and listening to what they have to say when preparing PLS.

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Richard Stephens, patient advocate and editor of the *Journal of Research Involvement and Engagement*, started by discussing that for him, as a patient, important requirements of a PLS include trust and accessibility. Trusted sources of information might include doctors and HCPs, charities, and patient advocates, as well as other patients. In terms of accessibility, Stephens highlighted that there is no point in producing PLS if patients don't know where to find them or can't access them due to their being hidden behind a paywall. With patients increasingly engaged in shared-decision making in terms of their treatment, it is essential that they are well-informed and understand the implications of information. Patients need to be able to check the evidence in order to make informed decisions and understand the recommendations of their doctors.

The *Journal of Research Involvement and Engagement* is an interdisciplinary, health and social care journal that publishes articles focused on involving and engaging patients and other members of the public in research. A PLS is included as the introduction to every paper and is required for every submission. The journal is open access and accredited by *Patients Included*. Approximately 40% of recent articles have included patient authors. Stephens considered that, with the increasing involvement of patient authors, there will be a growing need and opportunity for medical writers to support them in developing PLS and publications.

Panel discussion

The presentations were followed by a lively panel discussion bringing together all of the presenters from the symposium plus Stuart Spencer (Lancet). Key discussion points included:

- **The importance of including PLS by journal impact factor:** panellists concluded that with many publishers moving away from using impact factors, and publications in low impact factor journals still reaching patients, inclusion of a PLS remains an important consideration regardless of journal impact factor.

- **Strategies for working with journals to encourage inclusion of PLS:** while many journals are currently unclear regarding inclusion of PLS in their instructions to authors, this does not mean they won't be open to including a PLS. The starting point should be a conversation with the publisher and editor. When making the case for PLS, it is important to stress the impact and evidence.
- **Dissemination of patient-oriented materials:** while more and more patient-orientated materials are being developed, too often they end up sitting on a shelf in the doctor's office and are not distributed to patients. HCPs need to be aware of the right moment to provide information to patients, and nurses and pharmacists have an important role to play.
- **Development of materials for patients with accessibility needs:** this can pose particular challenges, but the panel considered that use of plain language was the essential starting point. After plain language content has been developed, the steps and formats needed to optimise the materials for the audience's accessibility needs, such as alt text and closed captioning, can be addressed.
- **Social media:** the panel considered younger patients, noting that many now rely on social media to meet their information needs, eg some use TikTok, with consequent issues with the quality of information they receive. Alongside PLS in medical journals, other routes for dissemination of trusted and reliable medical information need to be developed, such as 'plain language tweets'. The challenges for pharmaceutical companies in engaging with patients through social media were discussed, with the panel noting that companies vary in their approaches to social media.
- **Patient engagement:** variation between companies was also highlighted in terms of possible approaches to patient engagement, eg based on therapeutic area – in some therapeutic areas patient engagement is best addressed through patient organisations, in others it is not feasible and therefore they have to depend on clinicians treating these patients. The panel considered the need for industry members to work together to address and define how patient engagement can be achieved in the most appropriate way.

Written as part of a Media Partnership between EMWA and The Publication Plan.