

Plain language summaries of publications: What has COVID-19 taught us?

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Abstract

The COVID-19 pandemic has significantly impacted the whole world, and the public has had to struggle with understanding scientific data on a daily basis. The impact of scientific misunderstanding became painfully apparent with the decline in vaccine uptake, so the need for clear, understandable scientific information has never been more vital. Plain language summaries of publications (PLSPs) could be an elegant and much-needed solution to this problem. This article will explore what these documents are, the approaches taken to date, and the challenges that remain. Moreover, the authors will aim to answer the question – what has COVID-19 taught us?

The development, approval, and dissemination of COVID-19 vaccines has been in the forefront of our lives for a long time now. The discussions around potential side effects and efficacy of the vaccines have been many and varied and have sometimes been delivered with a startling lack of scientific evidence or even basic understanding. The resulting public mistrust and ensuing reluctance to have one or any of the vaccines was swift and devastating and undoubtedly cost lives. This has highlighted the need and demand for scientific research to be delivered accurately and plainly.

The public's demand for more and better scientific information is not new, and the regulatory agencies have already responded with an increase in transparency and patient engagement. The most recent and largest changes from a documentary point of view have been the

inclusion of a new patient-friendly part of the Risk Management Plan (mandated by the EMA in 2013),¹ which was closely followed by the introduction of Regulation (EU) 536/2014, which mandates the production of a lay summary of clinical trial results.² This is not currently mandated by the FDA, but patient-friendly summaries of clinical trial results are recommended.

With this in mind, it is unsurprising that there is a growing demand for plain language summaries of publications (PLSPs).

What are PLSPs?

PLSPs are short summaries of research papers written in plain language, a language that is understandable to a non-specialist audience. A PLSP aims to improve access to the results of an original research article so that non-specialist healthcare professionals, patients, and consumers of healthcare without a medical background can readily understand the findings and recommendations. It is not specifically aimed at patients or the general public, but it is likely that these audiences will take a keen interest in PLSPs.

Although there is a growing demand for PLSPs, there is no requirement to produce or publish one alongside a manuscript in peer-reviewed journals. There is also no standard guidance available on how to prepare a PLSP. Cochrane Methods in 2013³ and the Canadian Frailty Network in 2017⁴ issued helpful guidance, but even PLSPs following the Cochrane guidance remained highly heterogeneous with very low adherence to these standards.⁵ However, other guidance and best practice documents have been (or are currently being) developed, for example, by Patient Focused Medicines Development and Open Pharma. The update to the Good Publication Practice Guidelines is also expected to include a new section on information for the patient. With increasing guidance being made available, it is hoped that the awareness and quality of these documents will increase.

Why should we care about PLSPs?

PLSPs not only benefit the general public and patients, they also benefit researchers, study sponsors, healthcare providers, and healthcare professionals. For the general public and patients, these patient-centric documents can help the lay audience understand complicated issues so that they are empowered to actively participate with their healthcare provider about their treatment: “No decision about me without me” has been a mantra in the UK since 2010, supported by government and the NHS.⁶

For time-poor and overstretched healthcare professionals, it can be difficult and time-consuming to extract key messages from scientific papers. Therefore, PLSPs are a good way to increase scientific learning by assimilating complex information quickly and easily, in turn promoting good evidence-based medicine. Both patient empowerment and evidence-based medicine are also likely to promote patient engagement, meaning that patients are more likely to comply with their treatment, which ultimately improves clinical outcomes.

In 2019, participants in a US survey rated the pharmaceutical industry lowest in a list of 25 industries, ranking lower than the oil and gas industry, the federal government, and the US healthcare system.⁷ For researchers and study sponsors, PLSPs are a key way of communicating research results to a wider audience, increasing accessibility to their work, and aiding transparency, which in turn may help ease negative

opinions of the pharmaceutical industry.

A survey among physicians, patients and caregivers showed that scientific journals were the third most common source of health-related information online (47%).⁸ It also identified the value of PLSPs in facilitating a patient-physician dialogue. In the US, a survey identified that 73% of Americans obtain health-related information from the internet,⁹ and in the EU, another survey showed that within 3 months, 52% of EU citizens aged 16 to 74 reported they sought online health

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information.¹⁰ As the demand for information about health-related topics continues to rise, it is important to optimise its dissemination and reach.

However, despite the benefits related to the availability of health-related information, one survey showed that respondents had concerns about the credibility of the information: fears that it was false or misleading (52%), that it was trying to sell products or services (47%), confusion over research studies that seem to contradict each other (43%), difficulty understanding the information (31%), and that companies were tracking the information being searched for (29%).⁹ Despite roughly two-thirds of respondents reporting that they see health information on social media, the majority (83%) were concerned that this information was incorrect or misleading. These surveys highlight that the quality of health information available to patients is a major concern and increasingly important. When the public searches for information, it is vital that it is accurate, reliable, and presented so that they understand and can engage with it. This will aid clarity and help to avoid misinterpretation. This

growing demand for clear and unbiased information is pushing the drive for PLSPs.

What is out there and what approaches are being taken?

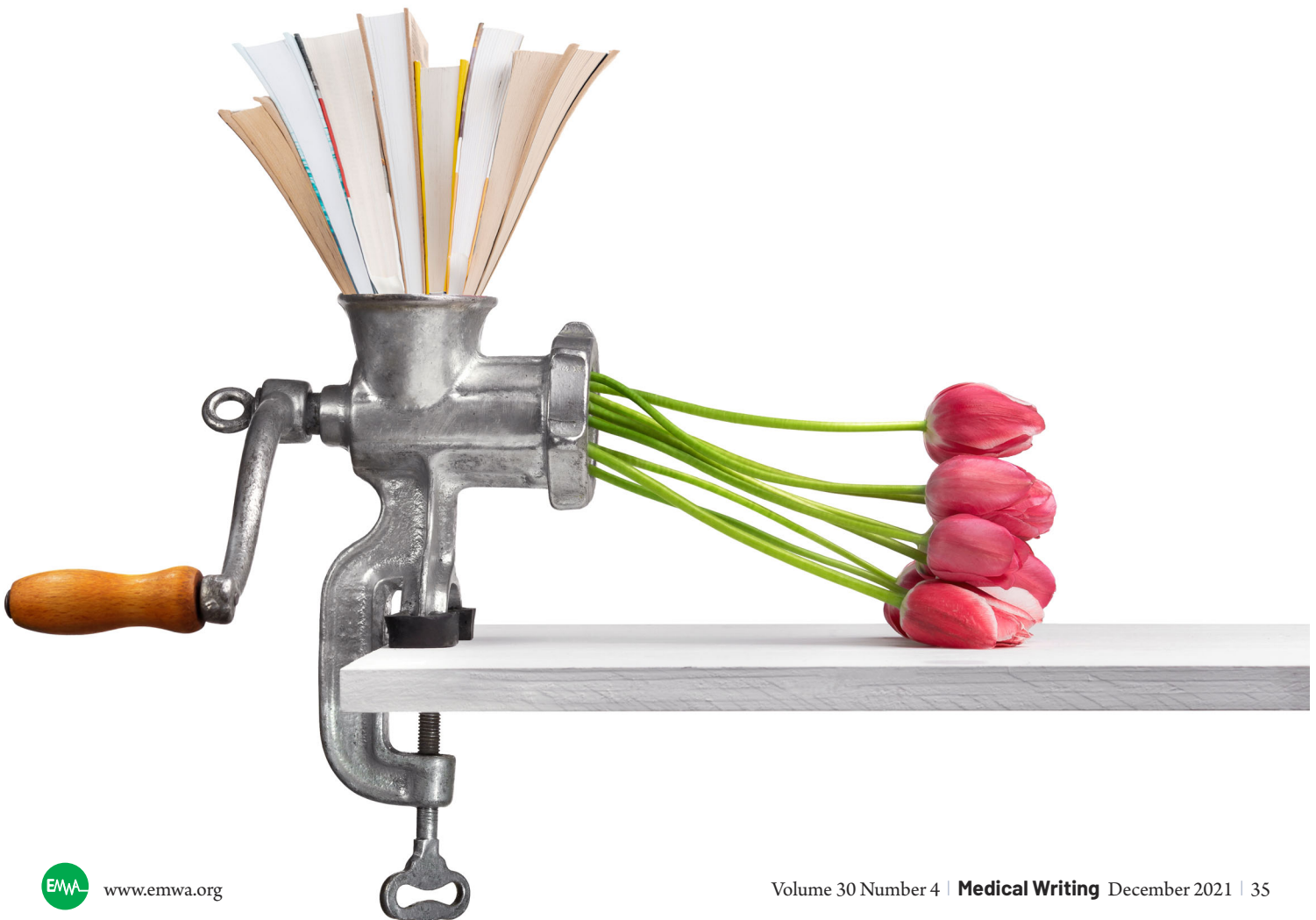
PLSPs are increasingly being considered as part of the publication plan.^{11–13} In recent years, there has been an increase in the number of PLSPs produced, an increase in journals including PLSPs in their requirements, and a more visible inclusion in their guidelines for authors. Although journals such as *Autism* have been producing PLSPs since 2011, and *PLOS Medicine* since 2004, prior to 2016, there were only approximately 100 PLSPs available on PubMed. This number slowly began to grow year on year to over 400 available in 2018 and then doubled to approximately 800 by 2020.¹⁴

Various approaches are being taken to communicate these clinical data to a wider audience. These include text-only PLSPs, a combination of text and visuals, infographics, videos, and podcasts. Gardner et al.¹⁵ investigated patient format preferences of PLSPs and identified that infographic style summaries were the first choice

followed by medium complexity PLSPs (reading age of 14–17 years) in all patient groups investigated.

Bredbenner and Simon¹¹ found that original abstracts and graphical abstracts are not as successful as video abstracts and plain language summaries at being understood, giving a feeling of understanding, or enjoyment. However, visual PLSPs are more expensive and difficult to produce. There are also problems with visual PLSPs being “found” by search engines since these engines search by text. The importance and effectiveness of infographics has been demonstrated most recently during the COVID-19 pandemic, when they were the medium of choice to convey important messaging quickly to the public, whether related to COVID symptoms, handwashing, or results of clinical trials and vaccinations. However, even when it was of the most importance – in a pandemic – governments struggle to use data visualisation well.¹⁶

Publishers and individual journals vary dramatically in how they approach PLSPs. Some journals include a PLSP as part of the manuscript submission process or on acceptance of the main



article; for others, it is optional or not required at all. Some companies have developed their own guidelines,¹⁷ and some publishers have produced short articles on how to write PLSPs (e.g., Elsevier's "In a nutshell: how to write a lay summary"¹⁸ and Wiley's "How to write a lay summary for your research"¹⁹). However, the majority still provide little to no guidance for authors.

In general, journals most frequently specify the length of the PLSP and target audience only, and the guidance itself varies widely. The target length of the PLSP can vary from 60 to 80 words²⁰ up to 250 words.²¹ The target audience for the PLSPs varies among journals, with some aiming to be "understandable by media and educated patients", "someone in high school", or "an interested person without a scientific background".²² Others advise to "pretend you're trying to explain your article to a distant family member who works in retail/fashion/hospitality".¹⁸ Generally, most journals target a higher reading age or ability than is expected in the general population.

Very few journals give guidance on language, and when it is offered, the guidance varies dramatically from journal to journal. One journal recommended using a readability analyser²⁰ to get an indication of the reading age level of the given text, but in general, the content and structure of the PLSPs is based on the abstract of the manuscript, and the advice is to simply summarise the impact/importance/relevance/key findings of the study.

Challenges

Non-specialists have access to a vast amount of medical content online, but how discoverable and easy is it for them to find peer-reviewed content of published research? Despite publishers increasingly publishing PLSPs, their availability, accessibility, visibility, and discoverability are still challenging.

Most journals have tried to make PLSPs easily accessible and open access; however, there are some that do not make them available at all or place them behind a paywall. For the general public, who may not be aware of publishers' websites, PLSPs are generally not publicly available or easy to find.²³ Journals and databases rarely have a dedicated PLSP category, and Fitzgibbon et al. in 2020 identified that only 2 out of 11 PLSPs were visible on PubMed.²⁴ Another factor that may contribute to the difficulty in

discovering PLSPs is the lack of standardisation of terminology, making searching difficult. PLSPs are referred to by a number of different terms, including lay summary, plain language summary, plain English summary, patient summary, author summary, general scientific summary, non-technical abstract, significance statement, highlights, or blog. Some journals have also been found to use more than one term for a PLSP,²⁴ and these terms also have different meanings for different people.

This lack of visibility and discoverability is a huge challenge and is frustrating for the general public. Patients feel that there is not enough open access material online to be useful and that it is difficult to find.²⁵

The challenges for medical writers and the value they bring

Many medical writers have been trained in the scientific writing of complex documents that convey information to specialist audiences who are experts within their fields. However, writing for a non-specialist audience requires far more than a translation of difficult vocabulary into simpler terms. It requires a completely different skill set, necessitating training and practice. Once the documents have been produced, the teams reviewing them must also be aware of, and skilled in providing for, the needs of a non-specialist audience so that their review is meaningful and helpful, and most review teams are far more used to reviewing highly complex documents aimed at regulatory agencies. It would help both writers and review teams to have the PLSP available as part of the manuscript and peer-reviewed alongside it.

The lack of guidance on the content of PLSPs drives the huge variation in the quality and length of the current offerings. Medical writers are trained to provide documents complying with a variety of requirements, but best practices are needed to help provide standardisation of PLSPs across the industry. In particular, guidelines are needed on the best format to use, text length, structure of infographics, reading age, and where the information should be made available.

Beyond this, even stand-alone PLSPs should not contain more information than that presented in the main manuscript but should include some context to allow non-specialist readers to fully understand the messages. Therefore, it is important that the main manuscript is also written well!

Conclusion

It is clear that there is a growing demand and need for information for non-specialist audiences, and it is equally clear that we face many challenges to be able to provide fit for purpose information in the form of a PLSP. However, this effort is vital, for without it, the PLSP will not be read or understood, and the monumental effort will be wasted.

Although many publishers have responded and are making great strides towards this goal, more can be done to help industry, authors, and ultimately the non-specialist audience. If journals require PLSPs and insist on high quality, fit for purpose documents, this will drive uptake and PLSP quality. The journals' demand for PLSPs may also ease company compliance issues and the danger of companies being accused of cherry-picking journals with no requirement for PLSPs. Whatever the decisions made by publishers on this issue, it is clear that PLSPs should be made available free of charge and should be a routine part of publication planning.

Medical writers are uniquely placed to bring data to life and help non-specialists to visualise them and put them into context. Writing for non-specialists is part of the evolution of the medical writing profession, and as communication experts, medical writers should be involved in the production of PLSPs right at the start of publication planning. The lack of PLSP availability and visibility could in part be due to the lack of standardised guidance on terminology, language and content of PLSPs, all of which have been called for by the medical writing profession.

Perhaps this is a simplistic view, but many of the challenges could be solved by simply producing the abstract in plain language. In this way, non-specialist audiences would have an easily accessible summary of the paper in a language they can understand, which would also be appreciated by time-poor healthcare practitioners. This would have the added advantage of having more in-depth detail available (directly attached to the abstract) with no risk of decoupling detailed scientific information from the summary and a much lower chance of misunderstanding and confusion.

This should be the ultimate aim. If we are to learn any lesson from COVID-19, surely it is this.

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