



Lay summaries and writing for patients

Lisa Chamberlain James of Trilogy Writing & Consulting and **Trishna Bharadia**, patient engagement consultant, examine the trend for increasing and more transparent patient information, and ask how close we have come in the past few years to producing useful and meaningful information for patients.

The most recent changes to regulatory legislation in terms of information for patients – the introduction of the lay summary of the risk management plan (RMP) and the lay summary of clinical trial results (CTRs) – have caused great discussion and concern in an industry very willing to provide information to patients, but more used to producing complex scientific information for regulatory authorities (RAs). These documents can

be challenging to write, and however much they are needed, all of this effort is wasted if they do not reach or connect with their intended audience. Medical writers usually produce documentation for RAs; they are highly trained in a specific writing style and tone, and aim their documents at readers who have a very high level of health literacy, and often a considerable knowledge of the specific disease or therapy area.

Writing instead for an audience who may have a low level of health literacy, and perhaps little or no disease and therapy area knowledge, is a significant challenge. This article looks at the challenges in writing the RMP and CTR lay summaries from the medical writing side and offers a viewpoint from the patient's perspective.

Legislation and its challenges: RMP (Rev 2) Section VI

Revision 2 to the RMP was introduced in March 2017, and significantly revised the sections on the lay summary, which is given in part VI of the RMP.

The Revision 2 guidance states that the lay summary should contain information including safety concerns, risk minimisation measures, and pharmacovigilance activities. These sections would not pose any difficulty for medical writers producing documentation for an RA, but in the UK for example, 16% of adults (7.1 million people), are functionally illiterate. This means that they can understand short, straightforward texts on familiar topics, but have problems reading information from unfamiliar sources, or on unfamiliar topics. Considering that the average reading age in the UK is 11 years, the challenge of explaining the risks and harms becomes apparent.

These discussions are also often supported by statistical information. Simply providing these numbers is not sufficient for the lay audience – an understanding of what the numbers mean must also be conveyed, so that the risks, benefits, and incidence/prevalence can be put into context. Additionally, the removal of the efficacy and epidemiology sections, although simplifying the lay summary for the medical writer to produce, makes it very difficult for the reader to understand the benefits of the drug and the impact of the disease in general.

Clinical Trial Regulation EU 536/2014

In 2014, the EMA mandated that clinical trial sponsors should produce a summary of the results of every clinical trial in plain language (language that is understandable to the lay audience) no later than one year after the end of the trial in the EU. These CTR lay summaries will be made available in a new EU database once it becomes available. A global survey in 2017 showed that 91% of the general public want to receive a summary of a study after they had taken part, and so the information would appear to be wanted and needed by the general public.

The EU provided further guidance in January 2017 that suggested more lay-friendly headings, and a question-and-answer format. It allows the

medical writer to add subheadings and change the order of the headings, both of which can help the reader understand and navigate the document more easily. However, translating clinical study information for the lay audience is very challenging because of the complexities of both study design and the resulting end points.

What do patients really want and need?

What industry and clinicians think a patient wants can be different from the reality, especially when it comes to patient input into their own healthcare. If lay summaries are to be fit for purpose, they need to be understandable, relevant and accessible.

With an ever-increasing importance being placed on shared decision-making, patients are increasingly looking towards lay summaries to help inform their healthcare journey. We need to find a middle ground between a lay summary being simplified so much that it loses its educational value and it not being simple enough for a patient to digest the information without the help of a qualified medical professional.

An important aspect is for the lay summary to use words that are familiar to a lay audience. One such example is the explanation of medical terminology. Listing 'high blood pressure' with 'hypertension' in parenthesis would be a better way to describe this adverse event than simply listing hypertension on its own. It means that the document is still understandable but can also help to educate and improve health literacy.

“There needs to be a middle ground between a lay summary being simplified so much that it loses its educational value and it not being simple enough for a patient to digest the information without the help of a qualified medical professional.”

The use of graphics can enhance a lay summary, but it is important to ascertain what are suitable data for translation into an infographic, chart or table, and what formats are most likely to be understood by readers. In a user-testing study on CTR lay summaries, one participant asked why a certain bar chart was “upside down”, indicating that this particular format could be confusing.

As a decision-making and educational tool, the lay summary needs to be relevant. The content should be useful for the intended audience, not just what the sponsor wants to



Lisa Chamberlain James

Lisa Chamberlain James is a senior partner of Trilog Writing & Consulting, and has a special interest in drug safety and patient information. She has experience of both communications and regulatory medical writing, and also runs and assesses workshops for EMWA. She is a member of EMWA's Educational Committee, PV Special Interest Group, Med Comm Special Interest Group, a Fellow of the Royal Society of Medicine, and editor of the Medical Communications and Writing for Patients section of Medical Writing.

16%

Adults in the UK (7.1 million people in total) are functionally illiterate.

Trilogy Writing & Consulting

convey. For a patient who is considering a new intervention, the risk-benefit profile is likely to be a top concern. However, there are other factors that patients consider to be important and that the lay summary can and should include so that an overall assessment can be made. These include who took part in the study (to assess applicability to the reader); the mode of intervention (for example, was the treatment administered orally, via IV infusion, via injection and so on); the frequency of intervention, and any monitoring requirements.

“Lay summary development cannot progress without the involvement of the patient. As standard operating procedures for processing lay summaries are developed and templates for producing content are created, patients should be constantly considered.”

These can all have an impact on a patient’s decision to pursue a certain intervention, whether that is within further clinical study settings or once the drug is licensed and available.

Including an explanation of the stage in the development process the lay summary relates to will help the reader to understand whether the intervention will be available imminently or not. The general public, and many patients, are unaware of the complexities and timelines of the drug development process. Presenting them with a document that, for example, talks about a positive phase-II trial, could result in misguided belief that they will be able to go to their doctor and ask to be prescribed the drug.

Once published, lay summaries need to be accessible; for example, they need to be easy to find and available to all. Some sponsors already use an open-access model, and mandate that all affiliated research must be published in open access sources.

Not all patients are the same

Any type of engagement with patients necessitates the reminder that not all patients are the same. ‘Patients by experience’ and ‘expert patients’ are terms that are now widely used within healthcare settings. However, there is also the emergence of the so-called ‘pro-patient’. These are patients who look at the overarching issues and systemic issues that cross over patient communities. They are often well connected with various stakeholders and have a high level of health literacy, even outside of their own disease area. When involving patients in the development of lay summaries, we should bear in

mind that each group of patients will be able to bring different value and expertise to the process and, therefore, may only be suitable for involvement at certain points.

Having the end user assess the readability of a lay summary can be highly successful, as evidenced by the production of lay summaries for the ‘Newcastle Cognitive Function after Stroke’ cohort study.

Lay summary development cannot progress without the involvement of the patient. As standard operating procedures for processing lay summaries are developed and templates for producing content are created, patients should be constantly considered. Ultimately, patients will be the primary end user of this document and establishing them into the process will be key to it becoming less of a ‘box ticking’ exercise and more of an exercise in producing good quality, relevant health information that can help people to make better decisions about their healthcare.

Conclusion

The latest regulations, and the drive for transparency and patient engagement require us to present data and messages in a way that the lay audience can both understand and use. It is a huge challenge and requires a different medical writing skill set from that used to present data to RAs. Writing in lay language is far more than just translating clinical words into simpler ones, and it is crucial that we reach out to our audience, either through user testing or through engagement with patient advocacy groups, to allow us to understand what they really want and need.

What is clear is that this drive for clearer and better information for the lay audience is not decreasing but is most certainly gaining in momentum, and this is being acknowledged in the latest regulations and guidance. In a survey of adult internet users, 83% looked online for health information, and 60% said that it had an impact on their decisions or actions. This means that the quality of health information available to patients is a major concern and increasingly important. Medical writers are the gatekeepers for this information, and we should certainly welcome the ‘trend’ for increased information to patients – as long as it is in a form that is helpful and fit for purpose. ●

References available on request. The authors acknowledge the help and advice of Dr Barry Drees, Trilogy Writing & Consulting, in the preparation of this article.



Trishna Bharadia

Trishna Bharadia is a multi-award winning international health advocate and patient engagement champion. She lives with several chronic illnesses, including multiple sclerosis. She writes for various publications and is an adviser to industry, academic institutions, and the third sector on health-related and patient engagement issues. She regularly speaks at events, conferences and in the media, and is also involved in the co-production of information and services, including plain language summaries.