

Lay summaries and writing for patients: Where are we now and where are we going?

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Abstract

We examine the trend for increasing and more transparent patient information and ask how close we have come in the last few years to producing useful and meaningful information for patients. We also outline the challenges faced by medical writers and the pharmaceutical industry as a whole in trying to comply with recent European requirements for the creation of lay summaries of key regulatory submission documents. The risk management plan and the results section describe outcomes of clinical trials – and what this means for patients – who are the target audience that this monumental effort is intended to help.

“Patient-centricity” and “transparency” have been hot topics in the pharmaceutical industry for the past few years. They are not new, but they are increasingly important in the context of regulatory documentation. Their implementation has been supported by various official guidance documents and mandated by legislation, much to the delight of patient

advocacy groups and the public in general. Some information has always been available to patients, of course. Information about a medicine’s side effects and how to reduce any associated risks is given in the package leaflet that is supplied with the medicine, and so most patients are aware of this – even if its usefulness has been questioned regularly.^{1–3} Other patient-specific information is also available via the EMA website. The European Public Assessment Report summary explains how the EMA has assessed the benefits and risks of a medicine before allowing it to be used. However, the availability of this information is perhaps less well known to the general public, who are likely to be unfamiliar with the EMA website and may not instinctively know how to navigate it.

The most recent changes to the legislation in terms of information for patients and the lay audience (the introduction of the lay summary of the Risk Management Plan [RMP] and the lay summary of Clinical Trial Results [CTR]) have caused great discussion and concern in an industry very willing to provide information to patients but more experienced with producing complex scientific information for regulatory authorities. RMP summaries describe how the important risks of a medicine are being managed or will be managed, and the CTR lay summary explains the results of a clinical trial and what the sponsor believes they mean. However, these documents can be challenging to write, and however much they are needed, this effort is wasted if they do not reach or connect with their intended audience. Medical writers, who usually produce documentation for regulatory authorities, are highly trained in a specific writing style and tone, and the usual audience for their work consists of 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 of readers 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

In March 2014, the EMA began publishing lay summaries of RMPs for centrally authorised medicines to explain and make more transparent to the general public how the European regulatory authorities make decisions about the safety of medicines (the details of which have been discussed previously).^{4,5} This was intended to be a further step towards increased transparency and improved public access to information on medicines and was mandated by the European pharmacovigilance legislation (Regulation (EU) No 1235/2010 and Directive 2010/84/EU).

In March 2017, the guidance on drafting risk management plans was revised to make significant changes to how lay summaries should be written, which is given in part VI of the RMP.

The guidance states that the audience for RMP summaries is very broad, and that the summary should be “written and presented clearly, using a plain-language approach”.⁶ The 2017 changes also removed the description of the efficacy of the drug and the epidemiology description.

The revised (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 a regulatory authority. The problem, however, is conveying that information to a lay audience and particularly to those with difficulty reading. 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.⁷ Considering that the average reading age in the UK is 11 years,⁸ 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 (CTR) EU 536/2014

In 2014, as part of its clinical trial transparency initiative, in the EU CTR 536/2014 (Article 37

EU CT Regulation), the EMA mandated that clinical trial sponsors produce a summary of the results of every clinical trial in plain language (language that is understandable to the lay audience) no later than 1 year after the end of the trial in the EU.⁹⁻¹² These CTR lay summaries will be made available in a new EU database once it becomes available.

This requirement had originally been planned to take effect in 2018, but the creation of the database and upload portal was delayed, and so it is likely that it will not be implemented before 2020. In the meantime, many pharmaceutical companies are making the documents available to the general public via their own company website (e.g., UCB¹³ and Boehringer Ingelheim).¹⁴

Despite the challenges involved in writing for a lay audience, the introduction of CTR EU No 536/2014 has been seen as a welcome opportunity for the pharmaceutical industry to deliver clinical study results to the general public – and especially to patients. A global survey in 2017 showed that 91% of the general public wants to receive a summary of a study after they had taken part,¹⁵ and so the information would appear to be wanted and needed by the general public. However, there is a danger that this opportunity will be wasted because writing for the lay audience is very challenging.

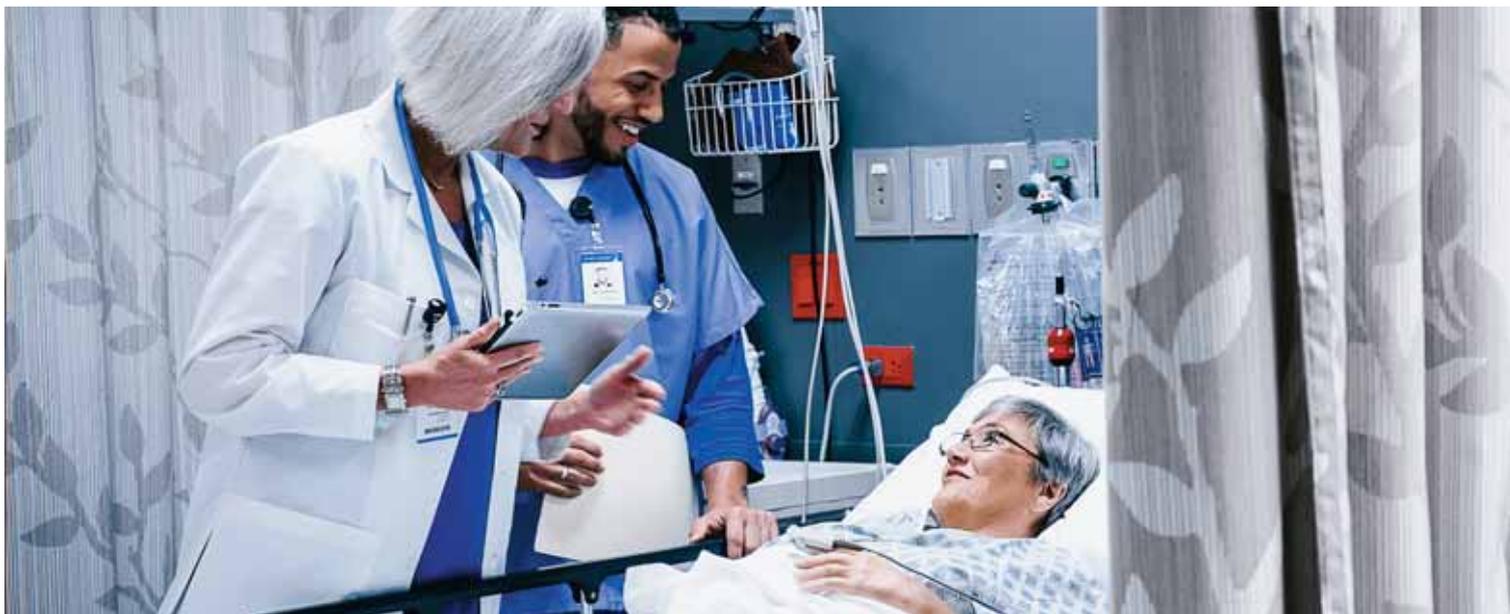
To address this, the EU provided further

guidance on the European Commission website in January 2017.¹⁶ This guidance gives example text and formatting, which, although not perfect, are certainly helpful. The updated guidance also suggests 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 readers more easily understand and navigate the document. Visuals and infographics are also mentioned in the guidance, but care should be taken with any graphics, since they do not always increase comprehension.¹⁷ However, they may make the CTR lay summary more user-friendly, and if used appropriately can be a powerful tool to help understanding.

Variable quality of existing patient information

Given the relative newness of CTR and RMP lay summaries and the lack of a general standard against which quality can be assessed, it is not surprising that the quality of current offerings varies considerably.

We conducted an online search for CTR lay summaries, which returned several pharmaceutical company web pages that contain lay summaries of trials that they have sponsored. Whilst some use graphics and tables to an extent, most still contain too much text; tools such as



bullet points and lists, which would make the document easier to read, are underused. One company's lay summaries contained only text and whilst the summaries were only about a page long, they were incredibly difficult to read and understand. In addition, even where companies used graphics, charts, and tables, sometimes they would have been better employed for different content within the document.

Generally, the content found in the summaries appeared to be relevant for a lay audience. However, it was difficult to assess whether all useful information from the original document was included. The best summaries answered the following questions for any potential patient reading the document:

- "Is this trial relevant to me?"
- "How would this intervention be administered and monitored?"
- "Can I fully assess the risks and benefits of this intervention?"
- "Will this intervention be available to me in the future and what will it mean for me?"
- "Where do I go for further information?"

Good examples of lay summaries also provide background information and explanation of the disease in question and the type of trial taking place. However, currently only some do this, possibly assuming that patients would already have basic knowledge in these areas.

What is clear is that that a systematic and comprehensive review of the current offerings is needed to fully gauge what is being done well and where improvements are required.

What do patients really want and need?

Putting aside legislative requirements, the quality of a lay summary can be benchmarked against whether it meets what a patient wants and needs. 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.¹⁸ If lay summaries are to be fit for purpose, they need to be understandable, relevant, and accessible.

Understandability

It is important to avoid over-simplifying information to the point of losing the opportunity to educate patients or a lay audience about a particular disease area or intervention. These documents have the potential to be key decision-making tools – an informed patient often makes different choices about their healthcare.¹⁹ With an ever-increasing importance being placed on shared-decision making,²⁰ patients are increasingly looking towards lay summaries to help inform their healthcare journey. A lay summary that directs the reader towards a discussion with their clinician can support this. We need to find the 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.

Another important aspect is for the lay summary to use words that are familiar to a lay audience. One such example is the use of brand names for medications. Some guidelines suggest

listing both generic and brand names where possible.²¹ If the brand name is not or cannot be used, providing signposts to where the reader can find that information is necessary. The same applies to explanations 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.

As already discussed, the use of graphics can enhance a lay summary to a certain extent. It is also 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", demonstrating that some figure formats may be confusing to someone not used to them.²² Formatting of the lay summary is also important, with accessibility standards such as font size, colour, use of bullet points, and layout requiring some consideration to improve comprehension.

Relevance

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 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 which the lay summary can and should include so that an



overall assessment can be made. These include who took part in the trial (to assess applicability to the reader); the mode of intervention (e.g., was the treatment administered orally, via IV infusion, via injection, etc.); the frequency of intervention, and any monitoring requirements. These can all have an impact on a patient's decision to pursue a certain intervention, whether that is within further clinical trial settings or once the drug is licensed and available.

Following on from this is the benefit of including an explanation of the stage in the development process the lay summary relates to. This could be a marker on a timeline or a "What does this mean for me?" section. It 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 drugs development process. Presenting them with a document that, for example, talks about a positive Phase 2 trial, could result in misguided belief that they will be able to go to their doctor and ask to be prescribed the drug.

Accessibility

Once published, lay summaries need to be accessible, i.e., they need to be easy to find and available to all. Open access sources are critical for this so that the lay reader is not blocked by a paywall. It is incredibly frustrating when a patient finds information, only to discover they are unable to access it. Some sponsors already use an open-access model and mandate that all affiliated research must be published in open access sources.^{23,24}

Finally, whilst there are already plans for a single upload portal for lay summaries, it is of the utmost importance that this is widely advertised to lay audiences generally and to patients specifically. This should be done via as many different channels as possible – via healthcare professionals, national healthcare systems (e.g., the NHS website), charities and patient associations, and the sponsors' own website. Participants in particular trials should also be informed of the availability of a lay summary of results. In addition, a single portal should not necessarily be the only place where lay summaries are published. If they are published in multiple locations, such as through the sponsor's website, via academic-sponsored sites, or through relevant research events, they are more likely to be seen. A discussion of the relative advantages and disadvantages of dissemination via different sources can be found in lay summary implementation guidelines published by TransCelerate Biopharma.²⁵

Involving patients in the production of lay summaries

There are many guidance documents for lay summaries that suggest the involvement of patients in their production. How this involvement would work, however, is not outlined as clearly, indicating that there is a need for best practice to be shared and a standard to be set. The Roadmap Initiative to Good Lay Summary Practices²⁶ could be a step towards this.

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.

Patients could potentially become involved by reviewing the lay summary for relevance of

content, and readability. A patient by experience could review a lay summary for readability and how well it might be understood by a lay audience, whereas expert and pro-patients would be more suitable to assess relevance of content. This is because those tasks would require a much higher level of health literacy and, potentially, the ability to understand the original clinical trial documentation from which the lay summary has been produced. It can also be beneficial to involve patients in developing lay summaries that do not cover their particular disease area. This is because patients may be in danger of becoming "too expert" or "too comfortable" in their own disease area to consider the document from a lay perspective.

User-testing for readability

There has been much discussion about whether readability tools are suitable for assessing health information. The Patient Information Forum points out that these tools only assess language and do not consider design, layout, structure, or the tone of information. In addition, different readability tools can often produce different reading levels and scores when applied to the same text.²⁷ Having end users assess the readability of a lay summary is not only an obvious choice but is also both feasible and can be highly successful, as evidenced by the Production of Lay Summaries for the Newcastle Cognitive Function after Stroke Cohort Study.²⁸

Initially, organisations may be put off from involving patients, due to cost and the possibility of having to train external collaborators. Training can be made easier with the use of available toolkits, such as the one co-produced by Envision Pharma, and multiple stakeholders.²⁹ It offers a template to provide patient reviewers with key information so that the lay summary can be put into context and the review process made easier. The cost of involving patients in the process should be offset against the added value that they will bring to producing a high quality, fit-for-purpose document. In the future, this cost needs to be considered as integral and necessary to the budget as the cost of involving a medical writer.

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 need to be constantly considered. Ultimately, patients will be the primary end user of this document

and involving them in 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 medical writing skill set different from that used to present data to regulatory authorities. 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.^{30,31} 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.

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Conflicts of interest

The authors declare no conflicts of interest.

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