Writing for patients:
When and how?

Lisa Chamberlain James[1], **Deborah Collyar**[2]
Allen Todd[3], **Catina O'Leary**[3]
[1] Trilogy Writing & Consulting, Cambridge, UK
[2] Patient Advocates in Research, San Francisco, CA, USA
[3] Health Literacy Media, St. Louis, MO, USA

Correspondence to:

Dr Lisa Chamberlain James
Trilogy Writing & Consulting Ltd.
Merlin Place
Milton Road
Cambridge, UK
CB4 0DP
+44 1223 603 564
Lisa@trilogywriting.com

Abstract

The move towards patient engagement and patient involvement in healthcare decisions ("shared care") has triggered a raft of new guidances from regulatory authorities, accompanied by new regulations mandating that pharmaceutical companies engage with patients and the general public in a way that has been improbable up to now. While this has generally been supported and welcomed by both industry and patients, the initiative has brought with it considerable challenges. Producing complex scientific and medical information in health-literate language that is appropriate and helpful for the general public ("plain language") requires skills beyond those usually required for communicating with healthcare professionals and regulatory authorities. Medical writers are highly trained in a specific technical writing style and tone that is aimed at readers with a very high level of literacy, and often considerable scientific and medical knowledge. Translating this information into plain language for readers who may have low health literacy, and perhaps little or no scientific or medical knowledge, is a significant challenge – as reflected in the level of information currently available.

What do patients want and what are they getting?

The clamour for more and better information for patients has been growing over the last 5 years. In a survey of adult internet users, 83% looked online for health information and 60% admitted that it affected their actions.[1] This indicates that the quality of information for patients and the general public is of vital importance. This is echoed in the latest survey from the Patient Information Forum, which showed that two-thirds of those working within the UK National Health Service believe that patient information is rising in importance. Access to patient information is now firmly embedded in health policy across the UK, including in the National Health Service Constitution and England's Health and Social Care Act 2012, the Patient Rights (Scotland) Act 2011, Together for Health (Wales), and Quality 2020 (Northern Ireland), as well as in professional codes of conduct, and it is at the forefront of consideration in the EU.[2] In this way, the EU leads the US, which operates with a more diffused regulatory framework. Global interests are following suit, making it imperative for all drug and device sponsors to develop understandable and usable information for patients.

However, the quality and amount of appropriate information available to patients is far from ideal. Twenty percent of patients say they were not given enough information about their condition or treatment while in hospital, and while doctors are the preferred source of health information for most people, 17% do not feel that their general practitioner is good at explaining tests and treatments.[2] Even when recommended by regulatory guidelines, information for patients is often lacking. The latest regulation involving plain-language information (EU Clinical Trial Results Regulation EU CTR 536/2014) mandates that a plain language summary of the clinical trial results should be made available to all trial participants no more than 1 year after the last patient's, last visit. Although the portal for uploading these summaries is not yet open, companies are expected to prepare this information and make it available, following a list of 10 required items. However, less than 2% of all clinical trials completed or terminated within the past 3 years have returned results to study volunteers in plain language.[3] More worryingly, the information that is available to patients is of variable quality and is often not fit for purpose.[4]

Why is good quality information important to patients?

When people are diagnosed with a medical condition, disease, or life-threatening illness, they often feel that they have been thrown onto a foreign planet without a roadmap or dictionary, and without any type of survival training. Useful information is critical to help make some of the most important decisions in their lives, yet most current medical information is designed to "talk down to", rather than assist, patients.

The medical system typically focuses on the medical treatment a patient may take. A person who has just become a patient, however, has a much broader spectrum to consider and has to figure out how each medical option may impact all of the facets of their life. Context is most often missing for patients. If the pharma industry can help healthcare providers accurately show how a treatment option fits into a bigger plan, patients can understand what to expect and choose those that fit their lifestyles, personal needs, and beliefs. It is important to communicate these effectively to patients, yet this is often not included in medical training or is only considered within the realm of advertising in life sciences. Companies that learn how to produce accurate, objective information for patients without it being promotional (deliberate or otherwise) will find receptive audiences with patients, those who support them, and with health authorities.

What should be available for patients and when?

In response to the previously mentioned EU regulations, much of the focus on health materials for patients is currently on clinical trials, specifically, the return of clinical trial results in plain language to patients were were enrolled in a specific trial. Providing clinical trial results to those who were enrolled is certainly an important ethical, and now regulatory, obligation. However, it is only a small step toward fully meeting patients' needs.

To more fully meet patients' needs in clinical

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trials, materials understandable to all patients must be made available throughout the process, from the early stages of drug development, through recruitment and the informed consent process, to participation, maintenance, and completion of clinical trials. The same holds true in clinical care. Patients and caregivers require clear and understandable information through every step of the process, from diagnosis to selecting appropriate treatments and adopting those treatments into a workable, practical plan that works for their lives. Transitions in care settings, specifically, are particularly problematic as the risk of complications to patients is increased due to the shifting of responsibility between professionals or caregivers and the resulting potential for miscommunication.[5]

In all contexts, health materials must be understandable, contextual, and accessible. Accessibility considerations must focus on all aspects of health information, including the text, audio, images, video, and delivery formats.[6] While there are active conversations about the use of alternate, supporting formats, such as video and illustrated versions of summary reports, particularly for paediatric trials, the templates most commonly used for plain language clinical trial summaries are text-based with charts and figures to support the quantitative information. Delivery of plain language, accessible materials to clinical trial populations diverse in age, literacy, language access, and vision requires materials in formats other than text alone.

The challenges in writing for patients

If patient information is to be fit for purpose, it should be understandable and relevant for the patients it is aimed at. It should explain not only the scientific or medical details, but also make clear what all of this means for the patient. Plain language is not just a translation of difficult or long scientific words – it should include sufficient explanation of the context and concepts to allow the reader to understand the importance of the information.

To write appropriately and for the right audience means understanding what the reader (either patients or the general public) wants to know, what they need to know, and what they might know already. Patients prioritise four key points of information when they read about medicines: what the medicine does, what to do and what not to do when taking the medicine, the side effects they might experience, and what the medicine means for them in their day-to-day lives.

The medical writer's job is to provide this information in a format the patient can understand as easily as possible. This is often far from simple, particularly considering that the reader's first language might not be English, they might be affected by cognitive or visual impairment, or they might not be able to read at all (necessitating the careful use of visuals). It takes experience and skill to identify potential hurdles to understanding, let alone to overcome them. Different types of context (scientific, medical, and social) may be needed to allow the reader to fully understand the messages being given.

Tips to create health-literate information

To be effective, information should be given with short words and short sentences in the active voice, and only essential information should be included. Long or unfamiliar words are often

difficult to understand, and they slow down reading speed. Content should be limited to one or two key objectives and should be appropriate for the age and culture of the target audience. If medical terms will be used with the patients on a regular basis, they should be clearly defined so that patients can comprehend their meaning and context.

Humans have a cognitive preference for picture-based information, and research has shown that using pictures, including appropriate infographics or pictographs with verbal explanations and use of models, can greatly increase patient understanding and retention of information. In one study, mean correct recall of information was 85% with pictographs and 14% without.[7] Another study found that patients receiving wound care instructions with pictures were able to answer questions correctly 46% of the time 3 days later, compared to only 6% of patients who received only written instructions.[8] However, graphics should be used carefully, and all images should be age- and culture-appropriate.

Using graphical information can lead to more effective communication with patients and thus higher rates of recruitment and retention in clinical trials, as well as more effective use of medicines. Producing effective material requires additional knowledge, skills, and expertise in health literacy to refine the document for its intended audience.

Medical writers mindful of best evidence practices will often check their work for "readability". Although automated readability scores are available, they have their drawbacks. The score is based primarily on word and sentence length without considering content or vocabulary. Therefore, it is useful to take an additional step and have patient materials reviewed by people as close to the target audience as possible to ensure that the materials can be understood and interpreted correctly. Several approaches ensure that medical information serves its purpose. One method of testing patient-facing materials is engaging with patient advocacy groups or individuals who represent the intended audience to determine whether they can find and understand key pieces of information.[9] Individual interviews can be especially appropriate when materials are focused on sensitive health topics or involve patients who may have challenges participating in a group as a result of their health condition, geographic location, or other personal factors. There are obvious ethical, logistical, and budget implications that must be factored in to developing an audience testing plan and process that is feasible and appropriate for a particular material or therapeutic area.

What is the future?

Plain language materials are finally being recognised and understood as essential tools to provide patients with effective treatment options. How to produce them so that they are fit for purpose and not part of a regulatory "box ticking" exercise is both an opportunity and a challenge faced by the whole pharma industry. Initiatives to discuss and standardise the content will undoubtedly help improve the quality of the information and will also help address some of the challenges, but given the variety of studies undertaken in clinical development, this is more of a mountain than a molehill.

Once the materials are produced, they must also be easily accessible to their target audience – an audience that the pharma industry has not previously been able to engage with in this way. Partnering with patients and patient advocacy groups can certainly help industry address some of the current and future challenges. As always, it will also be crucial to provide tips and tools for healthcare providers to ensure smooth communication directly with patients and their caregivers, so that they receive clear information that they can use to improve their health.

The demand for better information for patients and the general public is increasing, and this is being reflected and responded to by regulatory authorities. The expected tightening of the clinical trial results regulation and its enforcement in the EU and North America could result in global adoption, which has the potential to increase patient engagement and trust in clinical development.[3] Despite the challenges this brings, it will be a positive move for everyone involved. The pharma industry now has the opportunity to engage directly with the general public in a way forbidden up to now; and if used correctly, patients and the general public will have access to unbiased, trustworthy information that is evidence-based and easily digestible. To do this well, we must listen to and understand patients, either through user testing or engagement with patient advocacy groups.

Medical writers are uniquely placed to carry these initiatives through and to make sure that the information produced is really what patients want and need.

Conflicts of interest

The authors declare no conflicts of interest.

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Author information

Lisa Chamberlain James is a Senior Partner and CEO of Trilogy Writing & Consulting Ltd. Aside from management, she leads client projects, with extensive experience in a variety of documents. Lisa has a special interest in writing for the general public and in patient information. Following a post doc in Pathology at Cambridge, Lisa began medical writing in 2000. Since then she has been involved in EMWA as a member of the Educational Committee, mentor, leader, and assessor of workshops, and teaches and reviews workshops for the American Medical Writers Association. Lisa holds an EMWA PDC, is a member of TOPRA, DIA, and PIPA, initiated the EMWA PV Special Interest Group, is chair of the Geoff Hall Scholarship Committee, and is a Fellow of the Royal Society of Medicine.

Deborah Collyar has been a leader in patient engagement and advocacy since her first cancer diagnosis. She founded the Patient Advocates in Research (PAIR) international network in 1996, has infused hundreds of patient advocates into research programmes while creating many trainings and her work encompasses many diseases, programmes, and policies at grassroots, national and international levels, and emphasises patient issues throughout early development and protocols, recruitment, retention, and results reporting. Deborah serves as a consultant to Health Literacy Media, has been a key member in many pivotal projects, e.g, with the NIH, DIA, MRCT, and academic institutions. She and her husband have survived 3+ cancers, and they work with multiple communities and patients.

Allen Todd is the Director of Partnership and Initiatives for Health Literacy Media. He has nearly two decades of experience in relationship development and clear communication through his work at various non-profit, governmental, and political organisations. His policy career is diverse and includes work on issues such as healthcare, education, poverty, homeland security, and national defence. Allen holds a bachelor's degree in communication from University of Missouri-Columbia. He is a member of numerous boards and committees, including serving on the Webster Groves School District Board of Education, where his children attend school. Allen is also the Secretary / Treasurer of the Board for Nonprofit Missouri, which promotes the common interests of the state's more than 30,000 non-profit organisations.

As President and CEO, **Catina O'Leary**, PhD, LMSW oversees Health Literacy Media's core activities and the strategic vision for the organisation. Catina has steered HLM onto becoming a true partner to a broad spectrum of health care organisations globally. A primary goal is to empower people with health information they can use. Catina believes in changing health behaviours to improve quality of life. For more than a decade, she led research at Washington University School of Medicine on connecting people at-risk for health conditions with medical and social resources aimed at improving health behaviours, preventing illness, and improving health and well-being. Catina is an active member of many boards and committees, including the International Health Literacy Association's Standing Committee on Strategic Planning and Implementation and the National Academies of Sciences, Engineering, and Medicine's Roundtable on Health Literacy.