Patient education in clinical trials and throughout the product lifecycle

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Abstract

Good patient education supports improved outcomes and an efficient, cost-effective healthcare system. In the highly regulated, fast-paced pharmaceutical industry, the challenges that medical writers face in writing for patients are multi-fold. Patient education can be confusing given the wealth of new technologies in healthcare communications, combined with patients being more involved in decisions about their health, and different national and international guidelines and legislations to be adhered to. Furthermore, writers face complexities of trying to meet the needs of diverse populations of patients and specific individuals. In this article, we discuss the importance of effective patient education activities for specific phases of the product lifecycle (from clinical trial participation through to prescribed medicines) and of the patient journey (from disease awareness and diagnosis through to living with long-term chronic illness). The considerations and constraints of developing educational content for patients, and practical guidance for writing such materials are discussed.

Introduction

In this era of patient-centred care, a broad aim of patient education is to encourage individuals to actively participate in their own healthcare through:[1,2]

- Improved ability to make appropriate health decisions
- Ability to recognise symptoms and take actions to visit a healthcare professional
- Increased self-care
- Better management of symptoms and ability to cope
- Adherence to treatment
- Participation in a health programme

Whilst specific objectives of a given patient education initiative will vary by project, the overarching goal is generally to improve health outcomes and/or achieve a more efficient, cost-effective healthcare system.[3]

Patient education has evolved, particularly with the rise of digital media as a tool in healthcare and pharmaceuticals.[4] Patients are now more informed and more likely to actively seek education. Not only has use of the internet for accessing health information dramatically risen,[5] but greater possibilities now exist for delivering healthcare solutions digitally via technologies such as e-learning and apps. These technologies are becoming more commonly accepted and utilised in the industry,[6] and are valuable additions to the patient educators' toolkit.

Multiple challenges and nuances exist for the medical writer in navigating content development for the purposes of patient education. This is not least because of multiple legislation, industry codes of practice, and guidelines that govern various stages of the pharmaceutical product lifecycle and that also vary by country. The need for personalisation in patient education is broadly recognised.[7] To this end, knowing the target audience well (based on robust insights), and ensuring that the content, technology/ delivery method and creative aspects all work together, contribute to an end product that is engaging and understandable. Health literacy is becoming a buzz-phrase within this discipline and is defined later in this article. A specific skillset is required to take complex medical and scientific information and translate it into language that is understandable to a lay audience, as recently described by Salita.[8]

Education for clinical trial participants

Clinical trials are hugely expensive, often lengthy processes, so it is important to be as efficient as possible to avoid cost and time creep.[9] Key factors in completion and ultimate success of clinical trials are timely recruitment of participants, and compliance (to study procedures, study drug and scheduled visits) and retention of sufficient participants throughout the study to meet the sample size and power requirements.[9,10] It follows that effective education of potential and enrolled trial participants can positively influence these factors. In a study of 125 people with cancer, greater knowledge and understanding of the clinical trial were found to be associated with consent to participate, even after accounting for other demographic factors.[11] Indeed, in a global survey of 5,701 people, 35% of those who dropped out found the informed consent form difficult to understand.[12] For pre-approval trials, poor recruitment and retention can also mean a substantial delay to authorisation and availability of new treatments.

Development of content for initiatives aimed at clinical trial participants is subject to stringent ethical considerations. According to Good Clinical Practice (GCP) guidelines, all written information that is to be provided to clinical trial participants (and potential participants) must not be coercive and requires review and approval by an Independent Ethics Committee (IEC) or Institutional Review Board (IRB).[13] In practical terms, this means additional rounds of review and amends over those of the Sponsor. It is also not uncommon for a trial protocol to be updated even after start up. Updates impacting participant materials must be made and need to be re-routed through the IEC/IRB. Hence the cycle of amends, review and re-review (as well as re-printing or re-programming) can be prolonged. Tracking version number and date of document as a footnote is advantageous.

Recruitment

At the point of recruitment, the main educational goals for potential participants include fully informing them about the study and ensuring that they understand the information. This is achieved through the process of informed consent. This process involves provision of written information, which should also be explained to the patient, and the signing of a consent form. When a clinical trial includes participants who require a legally acceptable representative to give consent (e.g., children or patients with cognitive impairment), the participants nevertheless should be informed about the trial to an extent compatible with their understanding. If capable, the participant should assent, sign and personally date an assent form.[13] The Declaration of Helsinki (the origin of the ethical principles of current international guidelines) requires that all participants have knowledge and perceived understanding of all relevant aspects of the trial.[13-16] All communications must also be factual and not persuasive in terms of either agreeing to participate or, later, to remain participating.[13]

Despite the guidance, many studies show insufficient knowledge and understanding among participants. This is both an ethical and legal concern and, as noted already, can also impair successful participant recruitment. Interventions to help people overcome barriers to participation in clinical trials (for participants and/or their carers where appropriate) most commonly involve tools to support the informed consent conversation or printed educational materials. It is worth also considering more personalised and interactive interventions to address specific barriers to participation and to check understanding. For example, supplementing the informed consent process by employment of non-clinical lay staff to provide participant education and logistic and emotional support, or personalising the informed consent conversation to allow individuals to receive the information that they want or need.[17,18] Utilisation of electronic informed consent (defined as use of electronic media [such as text, graphics, audio, video, podcasts, interactive websites, biological recognition devices, and card readers] to convey information related to the study and to obtain and document informed consent), is also becoming more commonplace, with the aim of increasing retention and comprehension of information.[19] For example, videos and animation could be considered to aid understanding in populations who have reduced understanding, such as young children. Sometimes, short tests may be used to check participants' understanding.

In proposing and drafting educational content for clinical trial participants, it can be useful to consider the reasons why people may not participate in clinical trials, and address these specific barriers in other educational efforts that

Table 1. Commonly cited reasons for participation or non-participation in clinical trials[10,11,35]

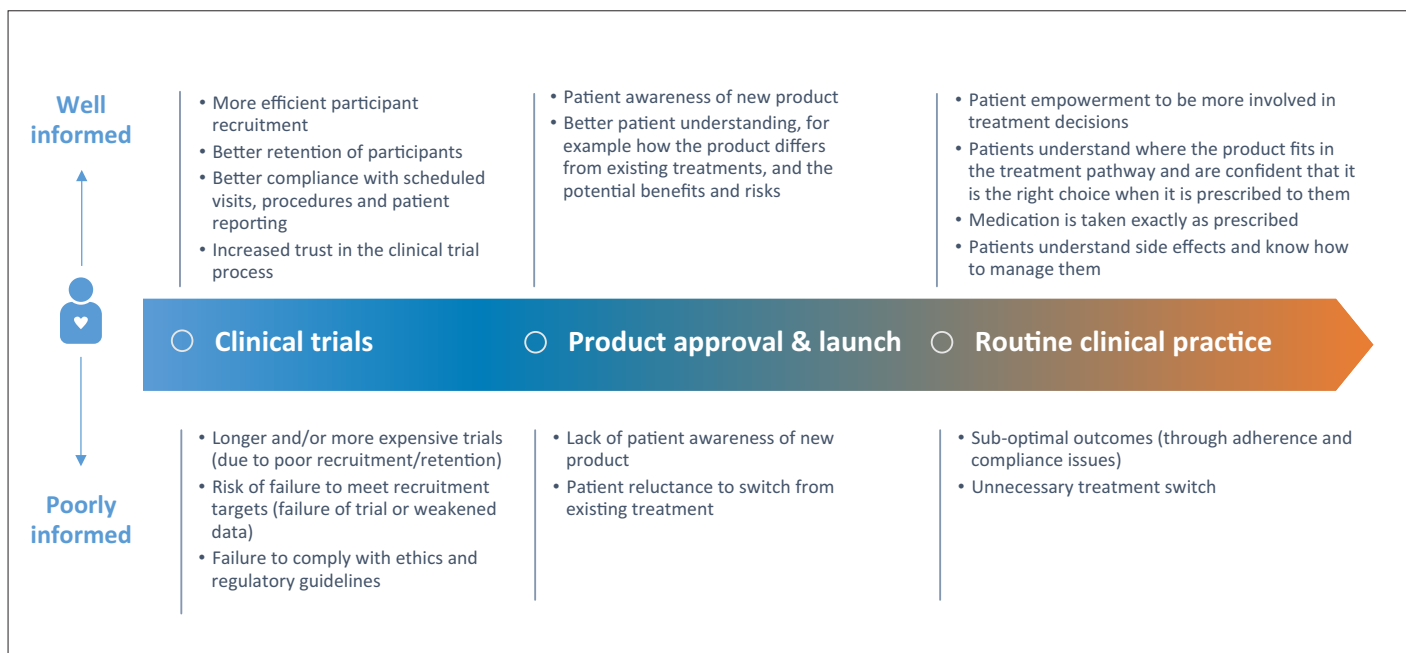| Common reasons for participation	Common reasons for non-participation
Perception of personal gain (of receiving better care and extra attention) through participation	Perception of personal risk and fear (experimental nature, adverse events, study procedures etc.)
Possible eventual benefits to others, altruism, (especially for future generations of family or when cure for own condition is unlikely)	Concern about potentially receiving a placebo
Gaining access to healthcare (for example US individuals with no health insurance)	Financial cost (for example, travel, unpaid time off work, childcare cost)
Access to new treatments	Time commitment (quantity or duration of study centre visits, study duration, requirement for diary or questionnaires)
Feeling of control in own care	Perceived or real impact on carer (financial or time costs, emotional burden)
	Inadequate communication (lack of understanding, misconceptions, unanswered questions and uncertainty)

Figure 1. The consequences of informed versus misinformed patients in the product lifecycle

support the formal informed consent process. These barriers may be specific to the patient population or protocol, a reason why it is important to gather insights and personalise the approach.[11] Some frequently cited reasons for taking part or not taking part in clinical trials are shown in Table 1.

Retention
Particularly for studies of long duration, educational and engagement efforts should ideally be continued throughout the study, to support retention of participants. Depending on the needs of the participant population and the study specifics, this may take the form of a comprehensive, multi-channel participant support and communications programme, or may be a simple automated text messaging service that sends motivational, informational or reminder messages at set points in time. Regardless, the same constraints and ethical considerations apply to all content for participants throughout the study duration, as for recruitment. For studies over a prolonged period, it is useful to measure the effectiveness of the activities and make adjustments to the programme as necessary.

Clinical trial results
Recent regulations and public demand have driven a need for participant access to clinical

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trial results on completion of the trial. For studies with sites in EU member states, there will soon be a requirement for a layperson's summary of results to be published to the European database within 12 months of the last patient's last visit.[20] An overview of the regulatory guidance and resources for layperson summaries was recently published.[21] However, lay summaries do not need to be limited to the EU database. This is where communications experts can get creative and tailor the format, content and visual style of a results summary to a specific audience. Consideration should be given to the purpose of the communication – whether to satisfy the regulatory requirement, to thank participants personally for their involvement, or to inform interested patient communities about potential new medicines for their condition. Potential benefits include increased public awareness and trust in the clinical trial process, a more positive participant experience, and a greater desire to participate.

Patient education through the product lifecycle

From clinical trials to product approval, launch and use in routine clinical practice, there are always good reasons to inform and engage the relevant patients (Figure 1). Patients now are more in control of their own health and

treatment decisions than ever before. With the development of a vast array of health information websites and healthcare apps, patients are able to access more, relevant, health information. This practice is less widespread with elderly patients, who often prefer verbal communications from their regular doctor for receiving information, and studies have shown that they also appreciate brief written information in a clear language.[1,22] Another useful method is the use of decision aid tools that provide evidence-based information about options and outcomes, to help patients make informed choices.[23] It is essential that healthcare professionals are receptive to shared decision making. Generally speaking, involvement of patients in the decision making process is becoming increasingly widespread and more accepted. Patients are becoming more empowered, by their own initiative and the increasing resources available to them, and by changes in practice driven by the industry and campaigns such as the European Patients' Forum Patient Empowerment Campaign.[24]

Patient education plays an important role in influencing patients to take their medication exactly as prescribed. Lack of adherence to treatment costs healthcare systems millions (approximately 1.25 billion Euros annually in the EU) and is responsible for 194,500 deaths per year in the EU.[25] Adherence to treatment is influenced by health literacy, suggesting that addressing health literacy issues can positively influence adherence.[26]

In Europe, patient communications relating to pharmaceutical products must be completely non-promotional, balanced and factual. Whilst content needs will vary, it is worth noting that patients frequently rate highly the importance of receiving information about side effects related to the products they are taking.[1]

Health education and patient support

For any given patient education initiative, it is prudent to consider where the patient is on their personal journey with respect to their disease. The information that a patient needs changes from diagnosis through the course of treatment, and depends on a number of factors such as age and education.[27] Furthermore, patients may change behaviour over time, according to the stages of change model (transtheoretical model of behaviour change), which can be a useful tool to help understand, predict and influence patients' behaviour.[28,29]

Prior to diagnosis, disease awareness campaigns (DACs) play an important role, with the overall aim of earlier diagnosis enabling earlier treatment and potentially better outcomes. The primary purpose of a DAC must be to increase awareness of a disease or diseases and to provide health educational information on that disease and its management. Regulations, such as those in the UK, stipulate that it should not promote the use of a particular medicinal product, with emphasis on the condition and its recognition.[30]

The point of diagnosis is important in terms of patient education because it sets the foundation for motivation and empowerment. To this end, it is vital that patients receive sufficient information to fully understand the condition (including prognosis), the treatment pathway and potential risks and benefits of the different therapy options. At treatment initiation (whether at the point of diagnosis, or later), patients should be informed about the available choices so that they may actively participate in that decision.

For chronic conditions, patient education initiatives can help patients in their own long-term management; for example, managing medications and self-care. An example of this is patient support programmes (PSPs) which can be used to bridge the gap between scheduled appointments and daily management of a chronic condition. Personalisation of PSPs is important because every patient has different needs in terms of the level of support required, and their preferred method and frequency of receiving information and support. Where complete personalisation is not possible (perhaps due to complexity or scale), it can be advantageous to offer patients a variety of options so that they can choose the tools that they prefer. Useful delivery channels include nurse-led support (via helplines or face-to-face online offering personalisation, credibility and accessibility), and increasingly, the use of multimedia technologies such as apps, emails that link to videos, and text messages, for example. Safety is a priority in PSPs, and the pharmaceutical company must be able to meet pharmacovigilance requirements, as well as other ethical, legal and regulatory obligations. Patients must sign informed consent to enrol in a PSP where they will be directly contacted.[31]

Practical aspects of writing for patients

Defining objectives

The art of educating patients is a delicate balance between addressing what patients (or their carers) want, and meeting the objectives of the particular initiative to achieve the desired outcome from the perspective of the healthcare provider, and/or pharmaceutical sponsor. A mismatch can render the initiative of limited value. It is imperative that appropriate objectives are defined and agreed with invested parties at the start and it is often down to the medical writer to represent and defend the patients' perspective, based on insights.

Health literacy and insights

In 2007, the Center for Disease Control and Prevention published evidence-based, guiding principles for health literacy and clear patient communication.[32] Health literacy is defined as the ability to find, understand, and use basic health information and services needed to make appropriate health decisions. The core pillars of these principles are to write and design for easy reading, involve the reader, provide relatable content that solves problems, use common language and use visuals to enhance learning.

Patient education programmes are often driven by the perceptions of healthcare providers who have not walked in a patient's shoes. To truly engage patients, programme planners and writers must understand the motivators, barriers, attitudes, beliefs, misperceptions and educational needs that patients and family caregivers bring to the table. It is critical that patients and family care-givers understand the benefits and risks of these programs. Some core patient barriers to health literacy and learning include cognitive challenges, stress related to disease burden, low motivation, poor adherence, lack of a supportive environment, complex healthcare systems and treatment regimens, lack of support and denial regarding the need and benefits of treatment.

It is also critical to understand the cultural beliefs and "language" that patients are most comfortable with. One approach to understanding these elements is immersing in the advocacy space. Advocacy organisations live and work with patients every day and best represent the tone and language of their target patients. Other channels to better understand patient insights include social listening, end-user interviews, channel analytics and peer-reviewed literature review. The most core patient insights are those that rise to the top across all of these channels and prove to be timely, relevant, actionable and accurate. These core insights should serve as the foundation of patient education offerings.

Format and channels

When educating patients about their disease and treatment options, health literacy can play a significant role in helping patients to understand and weigh the benefits and risks of treatment. Patient materials should also enhance the dialogue between patients and their healthcare providers.

In addition to clear writing and communication, the format and channel of education can greatly impact processing and retention of critical health information.[33] Patients bring a variety of learning styles to the patient education space, so multi-model educational strategies drive optimal learning

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Table 2. Regulation, guidelines and codes of practice governing patient communications

Stage	Regulation/guidelines[a]
Clinical trials	
	ICH GCP guidelines[b]
	EU clinical trial legislation (Directive 2001/20/EC)
	FDA Code of Federal Regulations Title 21, part 50: Protection of Human Subjects in Clinical Trials (US)
	CIOMS ethical guidelines
	IRBs/IECs guidelines[c]
Public disclosure of results:	EU Clinical Trials Regulation 536/2014
	EMA transparency policies (Access to Documents [Policy 0043]),
	Publication and Access to Clinical Trial Data [Policy 0070]
	EFPIA Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases
	PhRMA Principles on Conduct of Clinical Trials (US)
	Food and Drug Administration Amendments Act 801 (US)
General patient communications involving pharmaceutical products	
Legislation:	The Human Medicines Regulations, and Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC
	FDA Code of Federal Regulations Title 21, part 202: Drug Advertising (US)
Industry codes of practice:	IFPMA
	EFPIA
	Each country also has its own code of practice[d]
Guidelines:	PhRMA Principles on Interactions with Patient Organizations (US)
	MHRA Advertising and Promotion of Medicines in the UK: The Blue Guide (UK)
OTC products	
Ethical criteria:	WHO Regulatory Assessment of Medicinal Products for use in Self-Medication
Codes:	PAGB consumer code (UK)[e]
Patient communications not involving specific pharmaceutical products	
	MHRA Disease Awareness Campaign Guidelines (UK)

Abbreviations:

CIOMS, The Council for International Organizations of Medical Sciences; EFPIA, European Federation of Pharmaceutical Industries and Associations; FDA, US Food and Drug Administration; GCP, Good Clinical Practice guidelines; IEC, independent ethics committee; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; IFPMA, International Federation of Pharmaceutical Manufacturers; IRB, institutional review board; MHRA, Medicines and Healthcare products Regulatory Agency; OTC, over-the-counter; PAGB, Proprietary Association of Great Britain; PhRMA, Pharmaceutical Research and Manufacturers of America; WHO, World Health Organization.

a   Note this is not an exhaustive list, and national level guidelines may exist.
b   Grounded in ethics principles from the Declaration of Helsinki.
c   Each IRB/EC has its own set of guidelines. All are in the spirit of regulatory guidance, but if the IRB of record is known, it is worth checking their guidance documents prior to developing materials. The FDA has also published guidance for IRBs.[36]
d   Most European country-specific codes of practice reflect the requirements of European and national laws, and in many cases go beyond those requirements.
e   In Great Britain, PAGB pre-approves advertisements and other information for the public to ensure it adheres to regulations. Some other countries including Germany, Croatia, Mexico, Argentina and the US are governed by a post-publication control system.[37]

and outcomes. Most patient education offerings provide only the opportunity to see, read and hear health information. True learning and retention occurs when patients have an opportunity to interact with the material. Some examples of this are simulation, demonstrations, discussion and offering space for patients to write in their print materials. It goes without saying that the most engaging space for multi-modal learning is through digital communication. However, programme planners need to remember that many patients, particularly older adults, may not have access or comfort with digital communications, so we need to ensure that offline learning opportunities are always present.

Table 3. General guidance for writing patient educational content

Stage	Guidance notes[a]	References
Phase I-IV clinical trials		
Pre-enrollment of participant	• Do not use coercive language	ICH GCP
	• Avoid use of drug or device name (generic or trade names) as it can be viewed as promotional, unless prior use is part of a key eligibility criterion[b]	General IRB guidance
All stages (pre- and post-enrollment, and informed consent)	• Do not talk about 'free medical care' or emphasise 'free'[c]	ICH GCP,
	• Do not state that the drug is 'new' without also explaining that it is investigational	FDA & IRB guidance
	• Avoid implying therapeutic benefit (for example do not state 'medicine' without 'investigational')	
	• Avoid explicit claims of safety or efficacy of the investigational product	
	• Use language that is as non-technical as is practical so that it is understandable to the participant or their legally acceptable representative	
Marketed products		
	• Avoid use of 'safe' which should not be used without proper qualification	ABPI code,
	• Avoid claiming that a product has no side effects	EFPIA code
	• Include a statement about reporting of side effects	
	• Avoid use of 'new' for a marketed product of more than one year[d]	
	• Ensure that artwork does not mislead (for example implying use in a different patient population)	
	• Product comparisons must be fair and balanced and not misleading	
	• Health education materials referring to specific medicinal products must contain balanced, non-promotional information about alternative treatments	
	• Websites containing health education information must always advise persons to consult a healthcare professional for further information	

Abbreviations:

[a] This list contains key regulatory and ethical guidance for developing content for patients. However, it is not an exhaustive list. The relevant national and international guidelines should always be adhered to.

[b] Note that this does not apply to the informed consent process, which requires full transparency and an explanation of the investigational product.

[c] It is acceptable to mention payment (in countries where payment is permissible) for participating and free study-related medical care.

[d] Whilst it is acceptable to use 'new' for a product of less than one year, this does limit the shelf life of materials.

Writing styles

Written communications that are aimed at educating patients require a descriptive style that is factual and balanced, aiming to explain rather than persuade. Even with the constraints of writing in a factual style, carefully chosen language can be extremely powerful in connecting with the audience. For example, it can be more effective in terms of engagement to avoid language that defines people by their condition (e.g., use 'people with diabetes' rather than 'diabetes patients'). As already discussed, tailoring materials to the health literacy level and preferred learning style also improves understanding and therefore engagement.[34]

There are some occasions under the umbrella of patient education where more persuasive writing is appropriate, for example when there is a clear call to action such as finding out more about a clinical trial or signing up to a PSP. Effective persuasive writing typically uses three main techniques, as originally coined by Aristotle in his essay on rhetoric:

• Ethos (Ethical appeal via credibility, use of appropriate language, fair and unbiased content)
• Pathos (Emotional appeal)
• Logos (Logical appeal and use of reason)

Not all of these need to be addressed using words alone. Graphics can be made to effectively with the content to address these approaches. Note that persuasive writing in this context is different to coercion to participate in a clinical study or to take a particular medication, both of which are forbidden.

Navigating regulations

The multiple ethics guidelines, industry codes of practice and regulations that differ by country and region, and are periodically updated, can be challenging for the medical writer to navigate. Table 2 shows a summary of those that are most

pertinent to content for patients. Some general do's and don'ts are provided in Table 3.

Being the expert

Managing client feedback and expectations is one of the most challenging aspects of writing for patients. Most pharmaceutical clients, clinical trial study teams, and other invested parties are not experts in patient communication. It is common for materials to come back from review with proposed changes to the language that are overly complex, scientific or contain complex medical terms without explanation of their meaning. In these circumstances, it is always best to respectfully explain that the proposed language is not likely to be understood by patients, and to suggest an alternative, patient-friendly wording that conveys the same message. It is always worth remembering that medical writers and communications experts are employed for their expertise so should have confidence to advise in these matters.

Conclusion

Patient education is important for different reasons at different stages of the product lifecycle and patient journey, but broadly speaking, the main purpose throughout is to improve health outcomes and to empower individuals to take control of their own health. Effective patient education requires well-defined objectives; compliance from ethical and regulatory stand-points; personalisation; appropriate language and design that are based on health literacy principles; and the right channels for delivery, at the right time. For long-term programmes, it is advisable to build in ways to measure outcomes along the way and be flexible to adjust the approach accordingly.

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Conflicts of Interest and Disclaimers

The opinions and conclusions in this paper are those of the authors and do not necessarily represent the views of QuintilesIMS.

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