Communicating with Patients – Who and How?

I am very fortunate in my role as a strategic medical writer – clients who recognise that I've been doing this for longer than it would be polite to admit often ask for my opinion, rather than just give me a set of instructions and tell me to churn out a document. However, what never ceases to amaze me is that whilst discussions of regulatory strategy can certainly become heated, this is nothing compared with the extremes of reaction seen in discussions about patient information, and particularly about who should produce it, and when and how to involve patients in these documents.

Despite the fact that patient-friendly versions of many regulatory documents are now mandated by the regulations, the most frequently encountered reaction to communicating patient information is apathy, and there are many possible reasons for this. The most usual is that patient information is seen as 'nothing special', and something that 'anyone can write'. Therefore, anyone who has the time or vague inclination is given the task of writing the information for patients. Therefore, when a medical writer is finally approached for help with the situation, explaining to clients why their leaflet has failed its readability test or their summary of clinical trial results documents are not getting the desired results is met with a mixture of irritation and bemusement.

This is all understandable, of course, and one of the skills required of a medical writer is to manage such reactions and minimise any conflict until a happy client, and hopefully a beautiful and effective document, result. However, it is worth examining the reasons why a lot of patient information is so poorly communicated, as this has far deeper implications.

The quality of patient information is particularly important in the clinical trial setting, when new drugs or procedures are being investigated, and patient understanding of the potential benefits and risks of their involvement is paramount. Poor patient information can lead to both reluctance to join a trial and poor compliance during it. Once patients have been involved in a trial, they really want to know what the outcome was, and to understand how this has impacted clinical development and the next steps. Therefore, the communication with patients should not stop when the trial ends.

Additionally, the increasing influence of patient groups should not be underestimated. The European Patients' Forum has called for patient group involvement in healthcare policy decisions, and Patient View was formed in 2000 to gather together worldwide health non-governmental organisations (including disability groups, carers' groups, gender-based groups), work with, and study, these organisations, and is growing continually in numbers and scale of influence. Recently, Patient View conducted a survey that ranked the top 30 pharma companies on nine indicators, all related to the perspective of patient groups[1], and so this issue is under scrutiny by patients themselves.

Failure to take medicines properly is a growing problem, and is very common – 50% of people don't take their medications as prescribed, and this is responsible for 10% of all hospitalisations and over 125,000 deaths annually in the cardiovascular area alone[2,3]. Shockingly, approximately 10% of adverse drug reactions can be attributed to a communication failure between provider and patient [4].

Low health literacy is associated with poorer health outcomes and poorer use of healthcare services. It is significantly associated with higher all-cause mortality[5], and in the US it is estimated to cost $300 billion per year in avoidable healthcare costs[3]. Health literacy can be defined as the ability to obtain, process, and understand the basic health information and services needed to make appropriate health decisions and follow instructions for treatment[6]. There is certainly no doubt that health literacy and numeracy have huge impacts on patient engagement, compliance and health outcomes. But this is not affected only by an individual's general ability to read, write, and understand text and numbers, and certainly not just by their overall 'intelligence'. An individual's experience of the healthcare system, the complexity of the information being presented, how the material is being presented or explained, and cultural factors (that may influence how decisions are made) all affect the level of 'health literacy' or 'numeracy' of any individual at any given time.

So how severe is the problem of poor health literacy? In a recent study of adults presenting to an average city emergency department in the US, 15.5% had limited health literacy, which was associated with increasing age, male sex, non-English first language, non-white ethnicity, limited education, and unstable housing[7]. There is limited information on levels of health literacy in England, however the Skills for Life Survey showed that 1.1 million people in England were functionally illiterate, and approximately 16% of adults have lower literacy skills than those of an average 11-year-old[8]. The figures are even worse for numeracy, with almost 50% of the population (aged 16–65 years) having lower numeracy skills than an average 11-year-old[8], and it is known that people with a lower numeracy level make larger errors in interpreting medicines' side-effect risk information. It is therefore very likely that for many people, low health literacy acts as a significant barrier to achieving and maintaining good health.

The regulatory agencies have recognised the increased need for better and more effective patient information. The European Medicines Agency have responded with the introduction of a requirement for a patient-friendly part of the Risk Management Plan[9], which was followed by Regulation (EU) 536/2014, which mandates the production of a Lay Summary of Clinical Trial

Results[10], not currently mandated by the FDA, but patient-friendly summaries of clinical trial results are recommended). Both of these documents aim to explain complex clinical concepts and results to the general public, to help patients and their carers to make more informed decisions about their healthcare, to increase transparency in the clinical development process, and to put patients at the centre of drug development. In this way, patients are put at the heart of the clinical development process. These aims are vital in the evolving healthcare setting, but all rely on the information produced being clear, understandable, and fit for purpose.

The need for effective communication is especially important in vulnerable groups such as the elderly or paediatric populations. The elderly population is increasing (there will be around 72 million individuals aged at least 65 in the US in 2030[11], compared with 38.6 million in 2010[12]) and there are increasing numbers of individuals with dementia. Poor reading skills are particularly problematic in the elderly because of the high prevalence of chronic disease and poor eyesight or cognitive decline – often their diseases have complex treatment regimens, and require multiple consultations with different clinicians. Adherence to medicines by children and young people is even worse than that of adults, despite the oversight of parents[13,14].

Tackling the problem of poor patient information has its own challenges. We live in an increasingly information-rich environment, and patients are one of the most information-hungry sub-sections. In a survey of adult internet users, over 50% of internet users looked for health information online[15] and 60% said that it had an impact on their decisions or actions[16]. This trend has increased over the last 10 years in Europe[15]. Unfortunately, patients do not always understand the information they receive. Studies have consistently shown that patient education leaflets are written at an excessively high reading level. One survey showed that almost a third of patients did not understand their medicine label instructions[17] and in a UK outpatients study of COPD patients, 15% were not able to use the written information they had been given[18].

It is well known that patients recall less than 50% of what they are told during their consultations[19,20], and so it is perhaps understandable that patients would turn to the internet for further information or explanation. Unfortunately, not only are there myriad uncontrolled and unreviewed sites available, but the internet does not necessarily offer more easily understandable healthcare information – even on reputable sites. As examples, information on breast cancer prevention obtained from the National Cancer Institute's website has been assessed as being written at far too high a level[21], and there is marked variation in the quality of available patient information on websites about the treatment options for Crohn's disease and ulcerative colitis; few of which provide high-quality information[22].

So what can be done to improve patient information? The documents need to be written for the right audience. This means taking into account what the reader wants to know, what they need to know, and what they might know already. Patients prioritise four key points of information when they are reading about medicines: the side-effects they might get from the medicine; what to do and what not to do; what the medicine does; and how they should take it.

The medical writer's job therefore is to provide this information in a format the patient can understand and access as easily as possible. Whilst this might sound very straightforward, it is often far from simple, particularly considering that English might not be the first language of the reader, or that they might be affected by mental or visual impairment, or 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 counter them, but there are some general guidelines that can help along the way.

To be effective, patient information should focus on eliciting key behaviours from the patient, e.g. taking a tablet at the right time, in the right way — not lengthy and unnecessary detail about biochemistry and pathology. Yet many patient leaflets begin with a lengthy discussion of the disease area or physiology, instead of explaining to the patient what they need to do and why they need to do it.

There are a number of tools and techniques which can be employed to make documents more 'patient-friendly' such as style and formatting changes, sentence structure, and grammar and vocabulary considerations. The average reading ability of the general public means that text should be written at or below the level of a 12-year-old, and short paragraphs and the active voice should be used. Humans have a cognitive preference for picture-based information, and research has shown that using pictures, including cartoons or pictographs with verbal explanations and use of models, can greatly increase patient understanding and retention of information. Readers will very rarely put effort into trying to decipher what a sentence or paragraph means – they just skim-read it and move on. If the message can't be gleaned from a quick skim of the text, they will miss the point and the information leaflet is wasted.

Using tools like these can lead to more effective communication with patients and thus higher rates of recruitment, retention and compliance in clinical trials, and lower incidence of side-effects, and more effective use of medicines. However, there is also a certain amount of knowledge and expertise needed to refine the documents even further, and therefore to maximise the effectiveness of the document for its intended audience. It is extremely useful to have patient materials reviewed by people as close to the target audience as possible — ideally patients themselves — to ensure that the information, in the format in which it has been written, can be understood and interpreted correctly. This concept is not new; in 2005, the European Commission introduced a requirement for pharmaceutical companies to undertake 'consultations with target patient groups' to ensure that patient information leaflets were usable and understandable for patients[23], and the guidance accompanying Regulation (EU) 536/2014 also recommends user testing[24].

An extraordinary amount of time, effort, and money is put into creating and marketing medicines – doesn't it make sense to have the patient information written by specialists who can maximise the chance of the medicine being used in the way it was meant to – or even used at all? If we are truly wishing to increase transparency and put patients at the heart of clinical development, surely we should also be involving them in the production of the documents aimed at helping them to understand the process and the results of the studies they may have taken part in?

Most people believe that writing for patients is 'common sense' and that, just like driving well, anyone can write well for patients. Far be it from me to criticise anyone else's driving, but the road traffic statistics indicate that not everyone is able to drive as well as they might believe … is it really unreasonable to suggest that not everyone can write as well for patients as they might wish?

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