

# Under the Sheets

Peter Knapp and DK Theo Raynor at the University of Leeds discuss how employing user testing to improve readability can ensure clinical trial participants have a full understanding and improve levels of adherence to trial procedures

When we ask people to take part in a clinical trial, what information do they need in order to make up their minds? And after they have consented, what information would we like them to know as participants to ensure the trial runs smoothly and efficiently? Suppose the trial involves the testing of a new unlicensed medicine – would that change what we tell potential participants? Can we be sure that they will understand the days and times of their planned blood test visits? We provide the participant with written information – the ‘participant information sheet’ – so that they know about all these things. The information sheet plays an essential role in the process of obtaining consent from a participant.

The Declaration of Helsinki – first adopted in 1964 and revised several times since – lays out the requirements for recruiting participants to clinical research (1). Participants should be given written information to allow them to make an informed decision about whether or not to participate. They should also have access to a clinician when giving consent – someone who will answer their questions and provide clarification, if required.

## THE PURPOSE OF THE INFORMATION SHEET

In the period before giving consent, the information sheet helps the participant to make an informed decision about whether or not to take part. If they give consent, the sheet performs a slightly different function, acting as a reminder both in a practical sense (for example about the timing of blood tests or pre-drug fasting) and also in terms of their rights as a participant (such as the right to withdraw and any remuneration).

The sheet’s function after consent means that it should be written clearly enough for a participant to use it in the absence of a clinician. They might want to find the answer to a question about potential side effects of the medicine, or to know more about the impact of their trial participation on their private medical cover. As such, the document must be written and laid out in such a way that people can find and understand important information about the trial.

## INFORMATION SHEETS: MEETING PARTICIPANTS’ AND TRIAL ORGANISERS’ NEEDS

Currently, the judgement about participants’ understanding of the sheets has rested with both the organisation running the trial – frequently a contract research organisation (CRO) – and the research ethics committee (REC) that approves it. The REC will need to assess the information for participants before giving any approval. Often, the REC’s emphasis is on ensuring that all information it regards as important is included. There appears to have been relatively little concern about how the information sheet might function; about whether or not (potential) participants would be able to use the sheet to understand what consent might

mean. This emphasis on comprehensiveness can mean that trial participants are faced with many, many pages of information, as the CRO includes in the sheet everything that the participant might feasibly want or need to know about the study. The result can be an unmanageable amount of information.

But it would be wrong to suggest that RECs pay no attention to participant understanding. In order to make their judgements a little more objective, many US committees (the Institutional Review Boards (IRBs)) insist that the information sheet is tested by using a readability formula, and that it achieves a readability score below a stated reading age (2). Only then will the study be approved and the trial allowed to proceed.

## BACKWARDS THINKING?

Such readability formulae or scales have been developed over the past 50 years or more (3). They have been used most often in the field of education to monitor the reading development of children, and also to guide teachers and parents in choosing books for children and young people. They continue to be used, and more recent formulae or scales have been developed in order to demonstrate the difficulties that many people would face in reading public documents. Recent examples are the Simple Measure of Gobbledygook (SMOG) index and the Gunning-Fox index (4,5). Readability formulae mostly draw on word length (the number of syllables in a word) and sentence length, in order to calculate a score. As such they can give some idea of the ‘difficulty’ of a document.

The main weaknesses of readability formulae are that they can indicate only part of the picture – they cannot show how a document will perform when it is read. Therefore they do not indicate whether someone could use a bus timetable to work out their route; nor can they indicate if a restaurant menu is usable; nor whether an *EPC* article can convey its story to the reader. They cannot tell the CRO or REC whether a trial participant could find important information in the sheets provided to them. In addition, formulae cannot indicate the meaning or sense of a document, an aspect that is crucially linked to its performance.

The way that readability formulae – which offer a content-based assessment of documents – fail to indicate meaning can be illustrated by calculating the scores for a sentence written both conventionally and backwards. The Gunning-Fox index score for ‘The medicine will be given to you intravenously’ is the same as that obtained for the meaningless phrase ‘Intravenously you to given be will medicine the’. The exclusive use of words and sentences to calculate a readability score means that such a content-based assessment tool can only ever give a partial view of the quality of a document (6). It also means that difficult documents, such as trial participant information sheets, can

achieve lower (that is, better) readability scores by making some superficial adjustments to sentence length.

## IMPROVING PERFORMANCE

An alternative approach that carries considerable promise is to use a performance-based method to assess the readability of the participant information sheets. 'User testing', which is a form of performance-based testing, does just that – it tests what will happen when the 'user' tries to extract information from it (7). The user might be the bus traveller, or the restaurant customer or, in the case of trial information sheets, the potential trial participant. For participants in your trial, does the sheet tell them about randomisation, or allocation to groups, or the right to withdraw, in ways that they can understand? Only a form of performance-based testing will indicate this. At the University of Leeds, we have conducted studies of three trial participant information sheets, the results of which suggest that user testing might provide a very good indicator of the strengths and weaknesses of information for trial participants, and allow any necessary improvements to be identified and undertaken.

## WHAT DOES USER TESTING INVOLVE?

User testing can be applied to any type of written document, but is most closely associated with the patient information leaflets (PILs) provided to patients with licensed medicines. Testing has gained impetus since 2005, when European law first required medicine manufacturers to test their PILs (8). Without a successful and documented test, a new medicine will not be granted market authorisation. As a result, several thousand PILs across Europe have had their readability tested by using a performance-based method (9). Almost always, user testing has been the preferred method, as described in EU guidance documents.

User testing of PILs involves potential medicine users reading the leaflet, and then being asked to find and explain 12 to 15 items of information. (The term 'user testing' can mislead – it is the users who are testing the information, rather than the users being tested.) Participants are usually potential users of the information, rather than current medicine users, whose prior knowledge might provide misleading results. Most importantly, user testing is intended to be developmental, with the PIL being revised after rounds of 10 participants to remedy any problems that the testing identifies. Crucially, such revisions need to be informed by the research evidence and good practice in writing and information design. The EU standard is that the final version of the PIL performs well enough in testing for each item of information to be found by at least 90 per cent participants and, of those found items, 90 per cent being understood. User testing has been applied to medicine information leaflets in Australia since the 1990s (10).

## APPLYING USER TESTING TO TRIAL INFORMATION SHEETS

The University of Leeds research on the sheets provided to trial participants has examined the information sheets for a Phase I (healthy volunteers) trial, and two sheets written for Phase III (NHS patients) trials. Before testing, our initial impression of the documents was that they varied considerably, and that each was less than perfect in terms of document design and/or wording.

The Phase I trial participant information sheet was 11 pages long and contained more than 5,500 words. User testing indicated that participants (all from the target group for the trial concerned) took a great deal of time to find the answers to the 21 factual questions we put to them after they had read the sheets. The 21 questions dealt with four aspects of the trial:

- Its nature and purpose
- The meaning and process of consent
- The role of the participant in the trial
- The safety and efficacy of the tested medicine

In particular, participants in the user test struggled with six questions, including aspects as important as the presence of a placebo group, telling their GP about trial participation, and the emergency telephone number they should ring after leaving the hospital in the event of illness (11).

The sheets for the two Phase III trials were in the settings of cardiology and fertility. Not unexpectedly, the original sheets were shorter than the Phase I sheet we tested. More care appeared to have been taken over the wording and design of the Phase III information sheets, but both contained difficult or complex information that was explained less clearly than we hoped. User testing with members of the public suggested that both sheets would benefit from re-writing and re-design in order to improve people's ability to understand them.

User testing the sheet for the Phase III cardiology trial showed that it provided most participants with answers to the questions we asked of them, but the information was not clearly organised and people took a long time to find answers (12). A different picture emerged in the testing of the Phase III fertility trial sheets; most people could find answers to most of the questions, but the

### About the authors



Dr Peter Knapp is an experienced health services researcher who has worked on aspects of medicines information for patients since 1998. He is a Senior Lecturer in the School of Healthcare at the University of Leeds, UK. His clinical background in nursing and academic degrees in Psychology underpin his research, and he has published and presented his work widely. He is a Director of a university spin-out company, Luto Research Ltd, which provides consumer information testing services to the pharmaceutical industry. Email: [p.r.knapp@leeds.ac.uk](mailto:p.r.knapp@leeds.ac.uk)



After 20 years in hospital pharmacy practice, Professor DK Theo Raynor completed his PhD on medicines information for patients in 1991. He became inaugural Professor of Pharmacy Practice at the University of Leeds, UK, in 2001. His research focuses on the effective delivery of medicines information for patients. He is Chair of the World Pharmacy Federation working group on Medication Literacy and is Chairman of Luto Research Ltd. Email: [dk@luto.ac.uk](mailto:dk@luto.ac.uk)

information was not well understood. In particular, the user testing participants found the technical information about various medicines and their dosing schedules confusing (13).

The participant information sheets for the three trials were re-written and re-designed (using the services of a specialist graphic designer), taking account of best practice in writing and information design (14). The revisions also took into account the user testing data derived from participants, included in the testing of the original versions of the sheets. These data make a unique contribution to the revision of documents. Whatever expertise is held by those writing and designing trial participant sheets, the data obtained from people trying to use a document say a great deal about its strengths and weaknesses.

Revisions included the use of shortened sentences and lay-friendly language, and important design considerations such as clear headings and sub-headings, a contents page, and more obvious page numbers. The layout and structure of a document help the reader to understand how a document is organised. Testing of the revised versions of all three trial sheets showed noticeable improvements: people found it easier to find and understand information about the trial and their (hypothetical) participation in it. When asked to compare the original and revised versions of the participant information sheets, in all three instances most people preferred the revised version.

The user testing data for the revised information sheets would give reassurance that participants in the trial could give consent that was valid, and that they would have known what would happen to them during the trial and the details of their own responsibilities.

## MAKING SURE THAT INFORMATION SHEETS WORK

User testing – a powerful performance-based approach to assessing the readability of a document – could become the standard method of developing information materials for trial participants. Because it can indicate whether a document ‘works’ or not, it can lead to significant improvements in the information provided to trial participants. It might also give the REC and those running the trial comfort that research participants were able to understand the nature of the trial they were signing up to, and improve their adherence to trial procedures during their participation. Both could lead to fewer drop-outs and more usable and complete data.

### References

1. World Medical Association Declaration of Helsinki, Ethical principles for medical research involving human subjects, 2008, <http://www.wma.net/e/policy/pdf/17c.pdf>
2. Burman W, Breese P, Weis S *et al*, The effects of local review on informed consent documents from a multicenter clinical trials consortium, *Controlled Clinical Trials* 24: pp245-255, 2003
3. Flesch R, A new readability yardstick, *Journal of Applied Psychology* 32: pp221-233, 1948
4. Laughlin MC and Harry G, SMOG grading – a new readability formula, *Journal of Reading* 12 (8): pp639-646, 1969
5. Gunning R, *The Technique of Clear Writing*, 1952
6. Ancker J, Assessing patient comprehension of informed consent forms, *Controlled Clinical Trials* 25 (1): pp72-74, 2004

7. Blenkinsopp J, Linking POM to P to PIL – the UK agenda for the EU self-care revolution, *Regulatory Rapporteur* 2 (3): pp2-5, 2005
8. European Commission, Draft Guideline on the readability of the label and package leaflet of medicinal products for human use, Revision, September 2006, [http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2006/09\\_2006/readability\\_consultation\\_2006\\_09\\_25.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2006/09_2006/readability_consultation_2006_09_25.pdf)
9. Medicines and Healthcare Products Regulatory Agency, *Always read the leaflet: Getting the best information with every medicine*, 2005
10. Sless D and Wiseman R, *Writing about medicines for people*, 1997
11. Knapp P, Raynor DK, Silcock J and Parkinson B, Performance-based readability testing of participant materials for a Phase I trial: TGN1412, *Journal of Medical Ethics*, (in press)
12. Knapp P, Raynor DK, Silcock J and Parkinson B, Performance-based readability testing of the information for participants in a Phase 3 cardiology trial, (under review)
13. Knapp P, Raynor DK, Silcock J and Parkinson B, Performance-based readability testing of the participant information for a Phase 3 IVF trial, (under review)
14. Raynor DK, Blenkinsopp A, Knapp P, Grime J, Nicolson DJ, Pollock K, Dorer G, Gilbody SM, Dickinson D, Maule AJ and Spoor PA, A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines, *Health Technology Assessment* 11(5), 2007