

CONSULTATION - Summary of Clinical Trial Results for Laypersons

Comments from [REDACTED]
[REDACTED]

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Page 3 line 72 – they may also not have any prior knowledge of what a trial is and may not be familiar with the intervention type and may be new to having the condition so their level of knowledge of the condition may also not be comprehensive.

Page 3 line 81 – It would be good to see this sentence started with ‘Wherever possible’ rather than ‘consider’ to emphasise the potential value of involving patients in this process.

Page 3 final bullet commencing line 81 – Whilst it is good to see reference made to the importance of involving patients in developing and reviewing such information, as a patient reviewer myself I am aware of how researchers often do not know how to involve patients in such processes. For example, a researcher may think that patients know what to comment on when they send an information sheet out for feedback. Patients need direction, they need to know what is expected of them when undertaking the role of planning or reviewing patient information. Researchers also need to be really clear about how to request such feedback – researchers often use ‘Track Changes’ for example, but patients might not be familiar with this. In a recent paper that we have had published we provide examples of resources for involving patients in participant information review (<https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-016-0029-8>). Also this bulleted section should ensure that it talks about the importance of good quality Patient and Public Involvement in general. Researchers could be directed to INVOLVE resources as an example.

Page 4 line 89 – I am not certain of the literature in this area but I imagine average literacy levels may differ by country(?) If this is the case it would be important to emphasise this.

Page 4 line 96 – It would be good to highlight at this point the various free resources that are available to help with writing in simple language – I know that some are listed in the appendices but it would be useful to flag this at this point

Page 4 line 100 – the example given could be misinterpreted – being able to fill in a form – some research teams with less experience of writing for the public might have different types of ‘forms’ in mind than other teams.

Page 4 line 97 – this whole bullet seems quite complex and difficult to understand – is there any way this could be written in a simpler way to avoid misunderstanding (I think it’s the proficiency levels that take away from the key message of ‘keeping things simple in lay summaries’). So perhaps this section would be clearer in its message by saying something simpler like: “Text should be suitable for people with a low to average level of literacy, so for example, the text should be designed for people who might be able to read and complete a simple form to a level of a high school leaver” (this working isn’t quite right but basically a simpler bullet that keeps the message more succinct.

Page 4 line 104 – It might be better to start with a more positive and clear introduction to the sentence so maybe “Use short sentences (maximum of 15-20 words) and avoid” (This maximum word for sentences came from Plain English Campaign Advice). The sentence could also do with an example of what to avoid to make this point more clearly.

Page 4 line 106 – this bullet might benefit from a reference to things like the free Jargon Buster provided by the Plain English Campaign.

Page 4 line 115 – could do with a bullet about using the term ‘we’ rather than ‘the research team’ when presenting results.

Page 4 line 115 – could also do with a bullet about avoiding nominalisations, eg. Complete / completion, Provide / provision, Investigate / investigation Eg rather than “The completion of a consent form was a requirement for all participants” use something simpler like “All participants had to complete a consent form”

Page 4 line 125 – will all readers know what the inverted pyramid is and how to write in this style – is there a reference or further information that could further explain this bullet.

Page 5 line 127 – I didn’t understand this bullet. I think it could be written in a simpler way. It is also important to point out that as well as differences in literacy levels there are also differences in numeracy levels and that this needs to be taken into account also when producing lay summaries (I think that this is a particularly important point given the potential emphasis on ‘results data’). Presentation of this information needs to be very clear.

Page 5 Line 138 – Should say something about making sure that the images used are appropriate so always checking these with patients too.

Page 5 Line 139 – Maybe just say “Be concise”.

Page 5 Line 140 – other things that are important to say are - Imagine you are talking to your reader. Write sincerely, personally, in a style that is suitable and with the right tone of voice. And always check that your writing is clear, helpful, human and polite. (Information from Plain English Campaign and I think really important to grasp when you are writing for a public audience).

Page 5 line 148 – I found the level of information in this bullet took away from the key message intended (see my earlier points). There is also repetition from earlier.

Page 5 line 156 – In the UK the Plain English Campaign always give words of warning on the use of readability scores – an extract from this is:

“We always warn people not to rely totally on readability indices. They make a good starting point in making sure your writing is clear, but they are by no means everything. Their main weakness is that they take no account of context, design or meaning. For example, ‘The cat sat on the mat’ has exactly the same readability index as ‘The mat sat cat the on.’ Readability is also dependent on design - a document in 6-point type will not be as legible as one in 12-point type.”

The formulae take account of the average number of syllables in each word. While this is useful, there can be many technical and uncommon words which, while having only a few syllables, will still be unfamiliar to many readers, and these will not adversely affect the readability score.

These formulae also assume that everyone finds every long word to be difficult to read - this simply isn't the case either".

Bearing this in mind I think that it is important to introduce the use of readability indices in a more balanced way, eg. introducing the content that is written in lines 233-241 at the beginning of the discussion about readability indices.

Page 5 line 159 - I would prefer to see the readability indices used in different countries as appendices as I think that this detracts from the main message which I think should essentially relate to the fact that readability scores can help give an indication of readability but that they should not be used alone – readability scores are not a substitute for feedback on how understandable your information is.

Page 6 line 175 – The Plain English Campaign say “We prefer to use the passive percentage test and the average sentence length to analyse documents, as virtually all documents are made clearer by using active sentences and a relatively short sentence length”

Page 7 line 245 – should say something like I mentioned previously about the need to emphasise that there are differing levels of numeracy (as there are different levels of literacy) so this needs to be given as much consideration as literacy levels.

Page 8 line 160 – you need to be careful when recommending cartoons as these need to be appropriate and suitable and tactful.

Page 8 line 265 – there are many really important considerations for when information is to be translated into other languages (eg the fact that you are translating meaning not just words) and I don't feel this paragraph provides this important information or reference to it.

Page 8 line 271 – Sometimes trial results are not what is expected and / or providing information to trial participants may require highly sensitive approaches (including the method of delivering the information – eg. this may need to be face to face in particular studies and should have been costed in at the start). I feel that the sensitivity of results and the needs of trials participants in receiving this information is not emphasised enough in this paragraph.

Page 8 line 277 – There is no information about the further accessibility issues involved in producing lay summaries for the public, eg. writing Easy Read document for people with additional needs (learning disabilities) or about producing information for people with blindness / colour blindness and the fact that there are specific considerations for these populations.

Page 11, Under “For more Information” - There is also the following information available from the European Commission: How to write clearly (this guide is available in 23 languages)

<http://bookshop.europa.eu/en/how-to-write-clearly-pbHC3212148/?CatalogCategoryID=SIKABst.SEAAAEjGJEY4e5L>

Also it would be nice to have a brief one sentence explanation of what each resource is that is listed.

Have the wording examples in the following section been checked with patients for their understanding. If not, then I think it is important to do so.

Page 13 – section 1 I would suggest the following rewording under Example Language: “Researchers look at the results of many studies to decide which drugs work best and are safest for patients. This summary only shows the results from this one study. Other studies may find different results. It takes participants in many studies all around the world to advance medical science.”

Page 15 – suggested wording – it is worth noting that the word ‘drug’ can have negative connotations in some countries and therefore other words like medicines are used. Also is a Phase 1 trial medicine commonly referred to as something different – given its not fully tested- I’m not sure what the plain English word is for this though.

Example of phase 3 study – I’d be careful with the description as you have previously talked about avoiding jargon and then used the word ‘placebo’ with no plain language explanation.

Example of phase 4 study – “after the new treatment had been approved for use” – many patients won’t be aware of this approval process so I think you need to be careful with this sentence.

Page 15 – section 4 – patients may not understand the terminology ‘healthy volunteer’.

Page 16 – Inclusion / exclusion criteria – patients might not know what is meant by this anyhow.

Page 19 –Patients might not understand such terms as patient reported outcome measures and endpoints / outcomes and make this clear as researchers can assume that patients understand such terms. Similarly researchers should not assume an understanding of the differences between primary / secondary outcomes.

Page 20 Composite endpoint description – the word ‘event’ is a medical term in such a sentence and may not be understood.

Page 21 – Morbidity – “put into 2 groups by chance” reads rather awkwardly (I think that it was referred to in this way somewhere earlier and later in the document also).

Page 21 – morbidity – “All people were followed to test the health of their heart and blood system, including stroke, high blood pressure and heart disease”. It feels like there should be a couple of words before stroke as the sentence didn’t seem to make sense. Also under EFFECT – I would avoid using the term outcome as patients often don’t understand this term.

Page 22 – prevention / incidence – “to reduce differences between groups”. This may not make sense to a patient

Page 24 – Result analysis – patients may well not understand this so be aware of this in any explanation. Also “Findings from this study...” patients may think only one study of a drug needs to be conducted to find out if it is safe and works so it’s important to have this in mind when writing this.

Page 25 section 9 – should also explain what a follow up trial is and why it might be needed

