SANTE-B4-GL-results-laypersons@ec.europa.eu

Consultation document:

Summary of Clinical Trial Results for Laypersons

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This is my response as a professor at the University of Leeds, and can be directly published with my personal and organisation information.

- I consent to publication of all information in my contribution in whole or in part including my name and the name of my organisation
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Declaration of interest:

I am co-founder and academic advisor to Luto Research (www.luto.co.uk) which develops refines and tests health information materials.

Parallel user testing of a clinical trial lay summary

This response should be read in conjunction with the report of user testing of a sample clinical trial lay summary. This was recently conducted by MSD together with Luto Research, and a summary of the results of this testing is being submitted separately to the consultation. In particular, I will not in this personal response, cover issues related to:

- the acceptability of a plain language summary to those with high educational qualifications
- the need for charts and graphs to be clear and simple
- the need for a pdf version for readers to print out

These points are covered in the report of the user testing.

Overview

There are many examples of good practice in the draft guidance – for example using '*simple, everyday language*'and not using '*jargon'*. However, this advice is not always followed through in the template in the Annex of the guidance – I have given examples of this.

As well as examples of good practice in information writing and design for lay people, there are other aspects which are absent, or inappropriately described – and I have suggested appropriate amendments to the guidance and template.

General points

1. Strict templating can stifle innovation

The introduction to the consultation describes that the draft document includes: '*recommendations and templates to help authors'* when writing the lay summary.

However, it is important that the subsequently approved document is not treated as a 'straight-jacket' and that it is, indeed, treated as guidance and not strict rules. It is right that consistency '*will help to improve familiarity*' but not that it will necessarily improve '*comprehension'*.

If all summaries are exactly the same, there will never be innovation. Strict application of the QRD template for package leaflets is an example of this. In particular, if changes to the template are shown to work well with lay people – through user testing – then they should be accepted.

2. Readability tests do not tell you if documents are 'easy to read'

Of the 6 pages of text in the main document, more than 2 pages are devoted to '*language specific reading tests'*. It is stated that sponsors should use such tests '*to assess the literacy level of each lay summary that they produce*'. It then goes on to describe in detail the use of readability formulae in various languages.

Specifically under 'English' it notes that the Flesch formula is '*based on counting syllables and sentence length*'. However, later on it says '*Readability scores are useful but not in themselves enough to ensure that a text is easy to understand*'. In that case, I would recommend that more of the guidance is devoted to guidance on how to produce summaries using plain language and good layout and design. This is much more important than '*reading tests'* which only measure word and sentence length – there are so many more aspects of writing that affect readability.

It is stated in the text '*anything that scores 70 and above is easy to read*' – this is simply not true. Such readability tests only measure word and sentence length – this means that information written backwards will have the same readability score as when written forwards (as the words and sentence lengths are the same). The severe limitations of readability tests need to be more clearly described in the guidance.

If the details of the readability tests for each language **have** to be included, I suggest this is as an Annex – it will then not 'crowd-out' the much more important information on good writing practice.

See also the comment below on 'Involving patients in the development of summaries'.

Individual points

3. 'Who is this document for?' is critical information

The consultation document itself makes it clear who the lay summaries are for: '*research participants and the general public …. also ….. healthcare professionals and academics.* However, the draft guidance does not emphasise that enough - 'Who is this document for?' is critical information for the lay summary itself. User testing of EPAR and RMP summaries has shown how important it is to explain to the reader who the document is for, and why it has been written. This is the text developed after user testing for EPAR summaries:

> ***Who this report is for***
> *This 'summary European Public Assessment Report' contains information for the general public.*
> - *The purpose of the report is to explain how it was decided to make X available to patients in Europe.*

4. Short not necessarily good and longer bad

The information in the summaries should reflect the amount of information that lay people need to understand the results of the clinical trial. It is true that producers should '*keep the document as short as possible*' - but a short document is not necessarily good, and a longer document bad.

Longer documents can work well if well designed, and easy to navigate. Documents made artificially short are likely to be difficult to read and digest.

I suggest that the advice should be changed to '*Keep documents as short as is compatible with giving the necessary information in an understandable form. Longer summaries are acceptable if the layout and design allow readers to easily navigate around, and follow, the summary*'.

5. Involving patients in development of summaries

I have noted the major drawbacks of '*readability tests'* above. A much more effective method of testing information for lay people is 'user testing' - which is routinely used to test the leaflets supplied with medicines and other lay materials. Such performance-based testing assesses whether real people can find and understand key pieces of information. This is reflected in the statement in the guidance 'Consider *involving patients, patient representatives, or advocates in the development and review of the summary information to ensure that it truly meets their needs. This won't be feasible for some studies but where it is a possibility, it may enhance the final version'*

However, user testing only works properly if the participants are real people – the man and woman in the street. I recommend removal of the words '*patient representatives or advocates*' as such 'expert patients' are too educated and informed about medicines to give the information a real test. Such 'expert patients' have a definite role in providing more general input, but when testing if information works for the man and woman in the street, then participants have to be such '*real people*'.

The guidance later notes that 'w*here feasible, sponsors should consider testing the readability of an initial version of the study results summary with a small number of people who represent the target population.* User testing could fulfil this role, as such testing routinely uses small cohorts of 10 people.

6. Who should write lay summaries?

Writing for lay people is a particular skill which requires training and experience. The guidance suggests that '*medical writers with experience of writing in plain language for the public may also be helpful*'. Although, some medical writers do have the skills for writing for lay people, many only write for professionals - and they may be the wrong people. It is very hard to 'undo' many years of scientific writing for professionals.

7. Simple everyday language

The first rule of writing for lay people is to use '*simple everyday language',* as the guidance recommends. However, the template in the Annex does not always follow that rule.

Experience shows that people using such official guidance are very likely to follow template wording exactly (rather to apply the guidance that precedes it). Therefore it is very important that the summary template follows its own good practice guidance.

Here are some examples of wording used in the template and plain language alternatives:

- *participants* -> people (taking part)
- *sponsor* -> company responsible for the study
- *placebo* -> dummy medicine
- *enrolled* -> signed up or took part
- *bone fracture* -> broken bone
- *require* -> need
- *individual* -> person
- *conducted* -> done
- *assigned* -> put into
- *seek* -> get
- *received* -> had

There is also a figure which is headed '*Figure1. Baseline demographics by sex*'. This wording will mean nothing to most lay people. Instead it should be the more conversational, such as '*At the start, how many were men and women*'. The term '*Figure 1*' should be removed – most lay people have no concept of 'figures' in documents – they will not know what it means.

Another piece of terminology 'e.g.' will mean nothing to some people, especially people with low reading skills. This should be replaced by 'such as'.

The guidance correctly says that if a medical term has to be used, to put it in brackets after the lay term. However, you do not **have** to use the medical term – only use it if it will be helpful to a lay person. In the following examples from the template, 'vertebrae' and 'intra-ocular pressure' are not needed:

- *back bone* (vertebrae)
- *lowered pressure in the eye* (called intra-ocular pressure)

8. Short sentences and dashes are the friends of lay readers

The guidance correctly says that '*long and complex sentences …… are difficult to understand'*. However, the template itself does include examples of long sentences – for example these two sentences:
Women who had a bone fracture after they stopped having their monthly periods (menopause) were put into 2 groups by chance (randomised) to reduce differences between groups. The study was carried out using two different groups because no one knew if one treatment was better than another.

Sentences with one key message work best for lay readers, particularly less skilled readers. As well as separating into two sentences, introducing bullets or dashes can also separate a long sentence into it's constituent parts. So the above could become:

Women who had a bone fracture after they stopped having their monthly periods (menopause) were put into 2 groups.

- *They were put into the 2 groups by chance (randomised) - to reduce differences between groups.*
- *The study was carried out using two different groups – this was because no one knew if one treatment was better than another.*

9. Bullet points are under-used in the template

The guidance recommends use of bullets instead of paragraphs of text – which the template does in places. However, bullets are under-used in template – for example:

56 in 100 patients (56%) in Group A (ABC treatment) had tumours that stayed the same, while 12 in 100 patients (12%) had tumours that grew, and 32 in 100 patients (32%) had tumours that shrunk.

This would be much more easily digested and understood as:

The results in Group A (ABC treatment) were:

- *56 in 100 patients (56%) had tumours that stayed the same,*
- *12 in 100 patients (12%) had tumours that grew,*
- *32 in 100 patients (32%) had tumours that shrunk.*

10. Wording of headings or 'elements' must be improved

The guidance states that '*the wording of the ten elements cannot be changed'*. My view is that these wordings are so far from being lay-friendly, that **not** changing them would render the whole process fruitless. These headings are at the heart of whether the summaries can be understood and navigated by lay people – especially less skilled readers. As well as being difficult to understand, they put readers off the material

For example

- Clinical trial identification -> Name of the clinical trial
- Name and contact of sponsor -> Who was responsible for the study
- Population of subjects -> Who took part in the study?
- Investigational medicinal products used -> What medicine was used in the study?
- Indication if follow up trials are foreseen –> Are more studies planned in the future?

Finally, the numbering of main headings has been shown to work well in other lay summaries. However, the use of 1.1, 1.2 and so on for sub-sections will not work with lay people. They are simply not used to reading information with such detailed numbered headings. Sub-sections should be indicated by a lay friendly heading in bold.

DKTR 26th August 2016

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