European Commission - Public consultation on "Summary of Clinical Trial Results for Laypersons"
http://ec.europa.eu/health/human-use/clinical-trials/developments/index_en.htm

Comment from Shaun Treweek, Health Services Research Unit, University of Aberdeen, UK

Many thanks for giving me the opportunity to comment on the proposed summary of clinical trial results for laypersons. A clear, non-technical summary of a trial is a great idea, and not just for lay-people but for other types of user too, for example, health professionals and policymakers.

My comments below are mainly influenced by my experience of coordinating the 5-year FP7 project DECIDE (http://www.decide-collaboration.eu and especially http://www.decide-collaboration.eu/patients-and-public), which looked at improving the way research information is presented in guidelines to different types of user, including the public. I've also worked in trial design many years.

General comments

Preparing summaries for the public is difficult and it would be reassuring to know that the information being proposed for the lay summary is known to be the sort of information that a lay user wants from such a summary. From my experience of working with the public in DECIDE I am not sure that this is the case with the current draft. A summary of what we (and others) have found for presenting research information from guidelines is given at http://www.g-i-n.net/working-groups/gin-public/toolkit (Chapter 7).

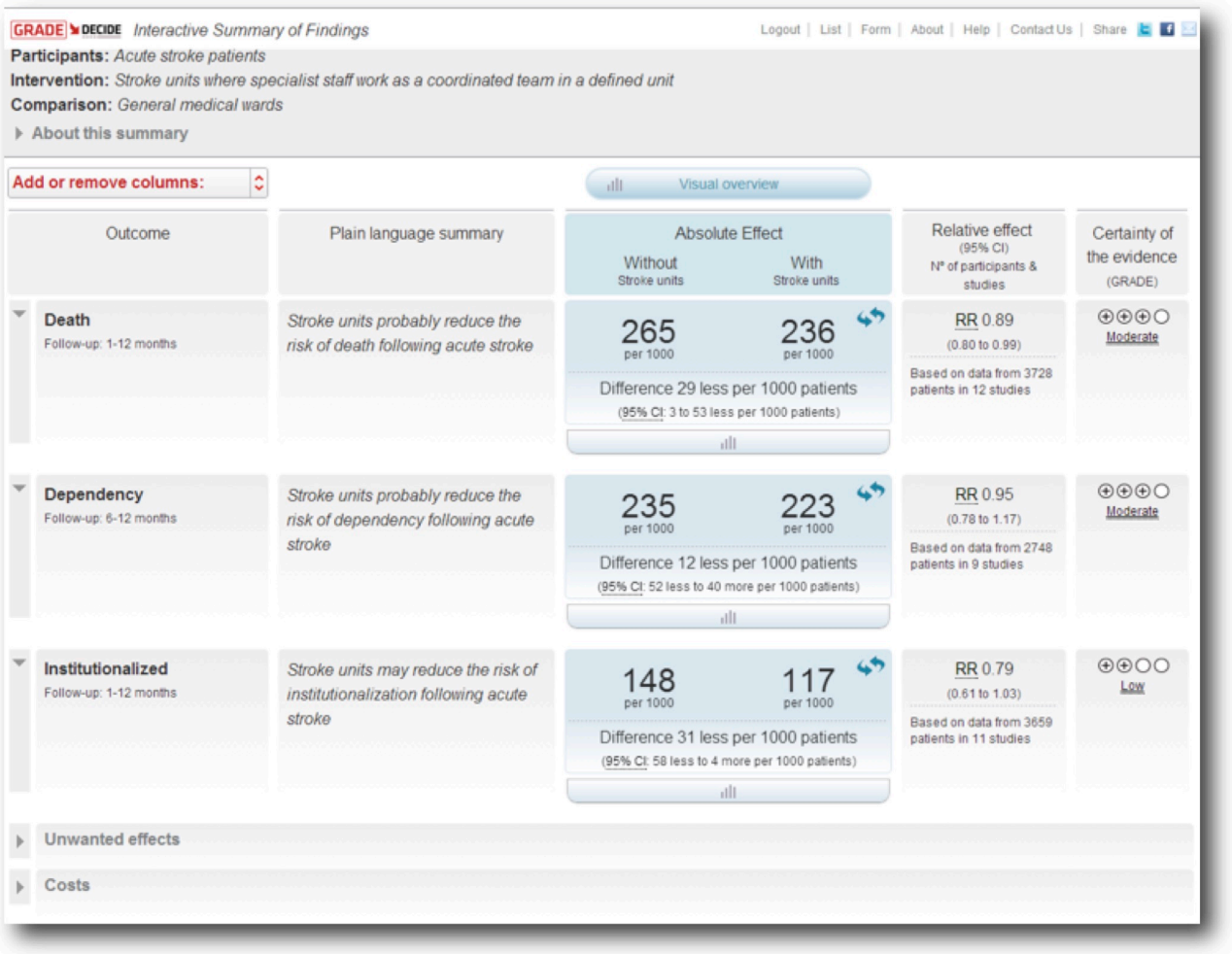
We were not trying to summarise trials, though we were often trying to summarise trial results. There will be differences between what you aim to do and what we were doing with guidelines but some things came through so strongly that I think they will apply here too:

- I think the current lay summary leans too heavily on the idea that a lay summary is just a summary of the trial written in simpler language. Our work with guidelines in DECIDE strongly suggests that there is much more to it than this. A fairly big problem with the current summary is that I don't think it pays enough attention to exactly what sort of

people you are targeting and what sort of information they want to get, and how. Our review of patient versions of guidelines (http://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-14-321) and focus group work with patients and public (http://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-016-1319-4) was pretty clear in saying that the public does not know guidelines exist, which means there are some conceptual things (randomisation, say) that might be new. The public and other types of stakeholder are often far less interested in methods than we think they are, meaning we should hit them with methods before we present what they are most interested in (Conclusions) first. The summary ought to bear this in mind; it is about more than using simpler language.

- People want information in layers, most important first. You can do this several ways but one way is simply the order of presentation. I'm pretty sure that people who might look at this summary will be most interested in the conclusions and results, having probably come to the site via Google or another search engine. The results are currently item 7 in a ten-item list, which seems very late to me. There are some thoughts on that in Chapter 7 of http://www.g-i-n.net/working-groups/gin-public/toolkit as well as http://www.ncbi.nlm.nih.gov/pubmed/25317597.
- Cochrane has some good guidance on writing Plain Language Summaries at http://www.cochrane.no/sites/cochrane.no/files/uploads/How%20to%20write%20a%20Cochrane%20PLS%209th%20June%202016.pdf, which is worth looking at.
- Plain language summaries of trial results should use structured formats where the words used are directly (and consistently) linked to the size of the effect, the confidence intervals and an assessment of trial quality (risk of bias). I've attached a summary page ('CC expressing benefits standard text.pdf') taken from Cochrane (http://www.cochrane.org) (I can't find the exact page right now but could if needed). The key point here is that phrases like 'probably increases' are interpreted differently and it would be good to be consistent across all summaries in the words used so that at least the use of the words, if not their interpretation, is consistent and linked to the trial results and quality.
- People like words and tend to shy away from numerical information but providing both increases understanding. How the numbers are presented is important though. I think the lay summary should absolutely insist on results being presented as absolute numbers (e.g. 28 fewer deaths per 1000 patients taking [name of treatment] over five years]) rather than relative risks, odds ratios or anything similar. DECIDE has developed something called an interactive Summary of Findings (iSoF) tool, which you

might be interested in. You can read about the tool at http://www.decide-collaboration.eu/interactive-summary-findings-isof-table. I've pasted in an image of the iSoF below.



An example of an interactive Summary of Findings (iSoF) table. See http://www.decide-collaboration.eu/interactive-summary-findings-isof-table for more information.

- It would be great if Section 8 included an attempt to put the trial results into the context of other similar trials. In other words, what does the totality of trial data tell us now that we have results from this new trial? It would also help to emphasise the point you already make about this being a single trial: what we want to do is reach a conclusion in light of all trials, not just this one, if we can.
- It might be worth using a glossary to help the public read the summaries. DECIDE developed one called GET IT (http://getitglossary.org), which others can use free of charge, including using APIs to support mouse 'hover-over' presentation of the definitions. The definition set can be tailored to a particular use (the glossary was

mainly developed to help people assess claims about treatment effect) although modifications would likely attract a modest charge from the glossary developer because it does involve some technical work.

To end, it is a great idea to provide a standardised summary of trial results for lay people and it would be fantastic to make it as good as it can be. If you'd like clarification of any of the above, feel free to get in touch.

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Results - general comments

	Important benefit/harm	Less important benefit/ harm	No important benefit/harm or null effect
High quality evidence	Will improve/ decrease/ prevent/ lead to fewer (more) [outcome]	will improve slightly/ decrease slightly/ lead to slightly fewer (more) [outcome]	will not improve/ will lead to little or no difference in [outcome]
Moderate quality evidence	probably improves/ decreases/ prevents/ leads to fewer (more) [outcome]	probably improves slightly/ probably decreases slightly/ probably leads to slightly fewer (more) [outcome]	probably will not improve/ probably leads to little or no difference in [outcome]
Low quality evidence	may improve/ decrease/ prevent/ lead to fewer (more) [outcome]	may improve slightly/ may decrease slightly/ may lead to slightly fewer (more) [outcome]	may not improve/ may not lead to any difference in [outcome]
Very low quality evidence	We are very uncertain whether [intervention] improves [outcome]		
No events or rare events	Use comments in SoF in a plainer language or summarise results		
No studies found or reported	No studies found/reported [outcome]		