

iCAN Youth Council's Response to Questions for Young People about Summaries of Clinical Trial Results for Laypersons

The iCAN Youth Council was delighted to take part in analyzing the documents concerning clinical trials and the use of summaries for the paediatric population. After reading the gl_1 and gl_3 consult documents, we created a survey that was distributed to the entirety of the iCAN network and had 27 responses from youth in different countries. Using these results, as well as feedback from the youth council, we summarized these opinions into the summary paragraphs seen below in accordance to the questions provided.

Background

In Europe a new law about clinical trials will start working next year. The law requires the people who run a clinical trial to publish a summary of that clinical trial. The rules about summaries have not been decided yet. We have a chance to influence the rules.

The draft rules may not suit young people and so we would like to know your views.

Question 1A

Are you happy with a “Summary for a general public audience”, that is for adults. Do you think that children and young people should have their own summary if the trial has involved children and young people?

iCAN believes that children and young people should certainly have their own summary for trials involving their patient demographic. All patients should have access to information about potential benefits or costs of studies so that regardless of age, they can be active participants in their own healthcare. Multiple summaries pertaining to the different age groups in a particular trial should be developed and children of those specific age groups should be consulted in the development of these summaries. Some particular concerns raised for the lack of summaries for children and youth people was that research trials are often presented in a way that is understandable for healthcare professionals but the technical language is not easily understood by young patients and their families. Providing children and young people with their own summaries would also alleviate stress associated with the treatment process for the young patient. Especially when assent is offered, it is necessary to provide young patients with information that is easily understandable so that they can make an accurate decision on whether they would like to participate in the trial. Some patients of the group mention that the fear of dishonesty and unethical procedures due to lack of transparency between clinicians and patients to be reasons why a summary catered specifically for young patients is critical to their time spent in research trials. As their lives continue to be influenced by the trial, it is important that its results are also available to them in a way they can understand and have full knowledge of opportunities for withdrawal.

Question 1B

If children and young people should have their own summaries what are the reasons for this and what should go into summaries for children and young people?

The primary reason for these summaries is to ensure that children and youth have a good understanding of the objective of the research, the findings, and impact of that research on affected youth. It should include a summary of how the treatment will affect their lives, including possible side effects. If the research

only provides intermediate steps and not the final treatments as an outcome, then the summary should include an outline and schedule of future steps until completion. The summaries should also include how the participants are impacted socially, emotionally, and physically. Personal stories may be included so young people can understand and envision themselves in the same situation to understand more clearly. The summaries should be translated into simple, straightforward language that is easy for everyone, including young people, to understand. Depending on the nature of the trial, a separate summary for children may not be necessary if the summaries for laypersons are already written in simple language. If it is written in a basic level of literacy, it should already be accessible for young people aged 10 and above to read and understand. However, some extra information from the adult summaries could be cut out and adapted into a separate children's summary. Analogies, Illustrations, graphics, pictures should be included to draw more interest and aid in the explanation of complicated terms.

Question 2A

The “health literacy and numeracy principles” talk about how complicated the sentences should be. Is that enough?

In general, the health literacy and numeracy principles were thought to be useful. However, they are not specific to youth literacy levels so are not sufficient in ensuring that summaries are comprehensible for children. However, constructing guidelines applicable to children of all ages would be very difficult. Therefore, while guidelines on how to ensure language is suitable for children would be useful, it is most important that summaries are read by children of all the age groups involved in the trial and who may be affected by the results of the trial, to ensure that the summaries can be easily understood. If in doubt of what complexity of language can be understood, it is better to make language too simple, rather than too complex. However, while it is important to keep sentences short and language simple, several people also said that too many short, ‘choppy’ sentences make it easy to lose focus and miss information. Some people thought the guidelines were repetitive and could be shortened, with ‘simple everyday language’ being somewhat synonymous with ‘avoid long and complex sentences’ and ‘avoid jargon’. It was suggested that similar parameters for language and writing style should be used to those regarding informed consent and paediatric assent. Many people suggested colour, pictures and videos could be used in summaries to aid comprehension and engage readers.

Question 2B

How do you think summaries for children and young people should be written?

With regard to alterations that should be made to make the document accessible for children and young people the most common aspect highlighted was the need to remove or explain medical jargon as this makes it impossible for children to understand it hence the making the document worthless. Also the language should not be overbearing or patronising or too formal as this would again scare children and make them unlikely to read and understand the document. There should be no assumption of any prior knowledge as these documents are aimed at such a large age group with varying levels of experience and understanding. Guidelines that would be helpful to follow when writing these documents include the IRB guidelines for assent and consent written by the FDA, help of organisations such as the department of health in England and the health literacy and numeracy principles. To help ensure that the documents as appropriate to the audience they could be written by medical writer who have experience in writing documents for children and young people. In some cases it may be better that several documents are written, each aimed at a different age group. Hence this would also mean using different formats of communication such as pictures, videos or even comic strips making the information easy to understand and

also making it seem less daunting. Finally we would also recommend having the document published in several languages to reach the maximum number of children and young people possible.

Question 3

**Should it be compulsory to check the summaries with children and young people?
What are the reasons for your answer?**

Yes, iCAN believes that only children and young people can respond in a genuine way and thus determine how others in their age demographic will react to these summaries. Youth can check summaries for language, readability, visual content, and how easily concepts can be understood by potential patients and participants. Some members said that having children and young people check these summaries is analogous to having peer reviewers look over research articles before they are accepted for publication. Publication of paediatric research should contain a checkpoint where a youth advisory group would have to approve the material before it is released. Focus groups and youth patient advisory groups (YPAG) would be an asset to assist researchers in determining whether language is appropriate in the summaries. Summaries that are too complicated for a child can be demoralising and frightening while summaries that are appropriate for the child's developmental levels will be empowering and can help the child be an active participant in their own healthcare. Consulting a YPAG would ensure that all areas that are relevant are covered in sufficient detail and anything that young patients may want to know about the trial is included.

Question 4

**When the trials have involved children and young people should the people who write the summaries (medical writers) have experience writing for children and young people?
What are the reasons for your answer?**

It was agreed, almost unanimously, that it would be very helpful to have summaries for children written by medical writers with experience writing for children and young people. It would save time and effort, as fewer corrections would need to be made when the summaries are reviewed, in order to make them easily understood by children. Writers who have written for children before will know what language, writing style and sentence complexity is appropriate. There would be less need for health literacy guidelines specific to writing for children if writers experienced in writing for children were used. However, on the whole it was felt that it was not essential for writers to have experience in writing for children, providing summaries were reviewed by children of the age group involved in or affected by the study, including participants in the study and possibly members of iCAN chapters. It would also be helpful to provide resources on writing for children and young people in the health literacy section of the summary guidelines. Some people felt that, if writers have not previously written for children, it would be useful for them to educate themselves prior to writing the summary, by speaking to children of the appropriate age group, including participants of the study. Some people felt that it would be useful to have some or all of the summary written from a child participant's point of view. Others suggested that it would be useful for members of iCAN chapters to review the previous work of medical writers who write for children, to ensure their work is of the write literacy level for the children who will be reading the summary.