Lay writing: Strategies for improving assent forms for children and adolescent participation in health research

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Abstract

Writing for lay audiences is recognised as a difficult task for medical writers, whose specialised knowledge can often hinder effective lay communication. This task is even more challenging when preparing clinical trial information for a paediatric population. Involving advisory groups in the development of clinical trial materials improves their quality and ensures that they are fit for purpose. This article describes how medical writers can build successful partnerships with advisory groups in developing assent forms for children being approached to participate in clinical trials.

Research involving children has more complex considerations than research with adults. Although children are dependent on their parent(s)/legal guardian to provide written informed consent for their participation in clinical trials, they should be involved in the decision-making process if they have the capacity to assent.[1–4] Assent is, therefore, given by children with capacity, in addition to consent by the legal representative(s), and indicates their understanding of the trial procedures and willingness to participate.[2] In the European Union, while there is consensus regarding the need for assent forms to be adapted in accordance with the age and level of understanding of the children targeted for inclusion, there is discordance regarding the appropriate age of assent and the requirement of a child's signature to confirm their agreement to participate.[5] A medical writer tasked with developing assent form templates for use across multiple countries and multiple trials is, therefore, presented with challenges in negotiating national laws and local practices, as well as trying to ensure the use of appropriate language to aid a child's understanding of a clinical trial.

We advocate partnering with children's advisory groups to overcome some of the challenges of writing for paediatric populations; such partnering is a concept that is newly emerging in the pharmaceutical industry and often daunting for medical writers to undertake. This article describes the process of assessing the suitability of assent forms and how the support of advisory groups can aid medical writers in preparing clinical trial materials that are fit for purpose.

Where to start

As medical writers, how do we write assent forms to adequately inform children of differing levels of maturity about participation in clinical trials? How do we know that what we produce provides adequate information to enable a child to make a choice? The internet is an abundant source of information, and there are several examples of ethically approved informed assent forms, which medical writers could use to develop their own company-specific templates. Most of these examples, however, are outdated and do not describe the involvement of children and young people in their development.

> An important element of involving lay groups in clinical research is acknowledging the value of the reviewers' input.

We aimed to develop two new assent form templates for use in our paediatric clinical trials that provide sufficient information for children and young people to make informed decisions about participation.

Our original assent form templates (categorised as being suitable for younger children and older children) had been developed in 2013 when we conducted our first clinical trial in paediatric patients. On review in 2016, we determined that there was scope to improve the design and overall comprehensibility of the templates. Having prior experience with lay writing and the involvement of patient and public groups

in research placed our working group in a good position for carrying out this task.

Readability

The first step in the redevelopment of the templates was to assess the current readability of the assent forms. Readability tests are designed to measure how difficult a passage of text is to understand, using a formula based on the number of syllables per word and the number of words per sentence. Flesch-Kincaid readability tests are one of the most widely used measures of readability.[6] Using the Flesch-Kincaid grade level (Table 1), our assent form for younger children had a reading grade level score of 6 and our assent form for older children had a reading grade level score of 6.7. Although these readability outputs suggested that our assent forms were *easy* or *fairly easy* to read (i.e. accessible to an *average* 11- to 12-year-old), the difference in grading between younger children and older children was thought to be inadequate, suggesting younger children, in particular, would find our assent forms challenging. Furthermore, as many of our clinical trials involve children and young people with diminished capacity, we felt a score of 6.7 was too high, even for older children.

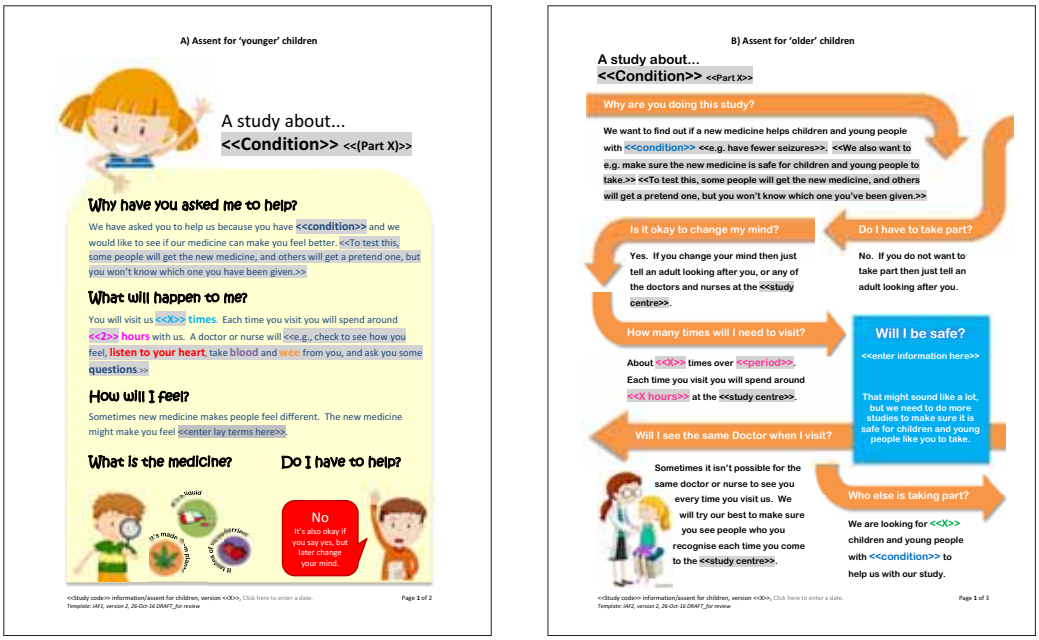

Figure 1. Assent form templates pre-YPAG review

The importance of design

Readability tests can only provide a mathematical assumption of understanding and do not take into account other important factors that contribute to a person's ability to comprehend written text. Such factors include the motivation of the reader, the style of the writer, and the design and layout of the written material.[7] When designing materials for children, we recommend using smaller pieces of information, illustrations or pictures that have meaning, and lots of colour.[8] Although this seems like common sense, few examples of assent forms available for download on the internet use these basic elements of design.

A key skill in lay writing is the ability of the writer to understand the audience and how the audience interprets information. This is particularly challenging for medical writers when preparing material for children and young people, as they are required to disregard their scientific knowledge as well as best practice in writing for adults, optimising their work for a different generation. This task has added complexities for medical writers with limited personal interaction with children and young people. To overcome these challenges, the involvement of children's advisory groups is recommended.

From theory to practice

We revised the language and overall design of our assent forms using the guidance produced by the National Institute for Health Research (NIHR) Medicines for Children Research Network on designing patient information leaflets[8] and the top tips for researchers published by INVOLVE,[9] a national advisory group supporting public involvement in research.

The revised templates had a Flesch-Kincaid reading level grade score of 4.4 for younger children and 6.1 for older children, an improvement on the previous scores. Regarding design, for younger children we opted for simplicity, using illustrations to make the content appealing. For older children, we used a series of arrows and illustrations to guide users around and down the page to different elements of information regarding the clinical trial (Figure 1).

Involving lay groups

Recognising that, as adults, we are not experts in understanding how children and young people think and process complex information, we then contacted the NIHR GenerationR Young Person's Advisory Group (YPAG) to ask for their support in reviewing the revised assent forms. Set up in 2006, GenerationR YPAGs support the design and development of clinical research and have several groups across the UK including Liverpool, Birmingham, London, Bristol, and Nottingham. Each group consists of approximately 10 to 15 members aged 8 to 19 years. The groups meet every 6 weeks during weekends, evenings, or school holidays; research professionals are encouraged to attend the meetings to discuss their findings.

We attended the YPAG at the NIHR Alder Hey Clinical Research Facility, Liverpool, UK, on December 3, 2016. Thirteen children and young people aged 13 to 19 reviewed the assent forms,

Table 1. Flesch-Kincaid grade level scoring

Flesch-Kincaid grade level score	Age	Reading difficulty
5th	10–11	Very easy
6th	11–12	Easy
7th	12–13	Fairly easy
8–9th	13–15	Standard
10–12th	15–18	Fairly difficult
College	18–22	Difficult
College graduate	>22	Very difficult

Figure 2. Completed YPAG review form based on assessment of assent for younger children

during which the overall comprehension of the templates was assessed, including design, format, clarity, and readability. Although all reviewers felt that the information presented in both assent forms was sufficiently *lay* for children and young people to understand, drastic improvements to the designs were suggested by the reviewers to aid overall comprehension and make them more user-friendly. We had detailed discussions with the children and young people on how to achieve this.

Acting on advice

For younger children, the YPAG suggested "cute animals instead of people" to make the information more reader-friendly (Figure 2). As adults with several years of experience in clinical research, we initially felt that this would be suggestive of animal testing. However, on discussing these concerns with the group, they explained how younger children would not necessarily be aware of animal testing. For older children, the YPAG thought that the "layout [was] confusing with arrows" and suggested a design based on colourful sticky notes and stickers pinned to a notice board.

During our meeting, the group raised an issue regarding the need for a child's signature on the assent form, as per the International Conference on Harmonisation E11 guidelines (clinical investigation of medicinal products in the paediatric population).[2] On both assent forms, our initial design used a traditional consent form template with the ethical elements for signature tailored for assent (e.g., "I understand I can stop the study at any time"). For older children, the YPAG altered some of the wording on the signature page to ensure it was understandable. For younger children, however, the YPAG was concerned that they would be unable to understand the elements of assent and provide a signature. To overcome this issue, the group suggested the use of a happy face with a corresponding tick box to acknowledge assent, and a sad face to acknowledge dissent.

Acknowledging advice

An important element of involving lay groups in clinical research is acknowledging the value of a reviewer's input.[9,10] Once we had completed the redesign of both assent form templates, we sent a copy of these to the YPAG to show the young people who took part in the review process how we had incorporated their ideas and suggestions (Figure 3).

Conclusion

The input of children and young people highlighted the value of involving YPAGs or similar groups in clinical trial design and

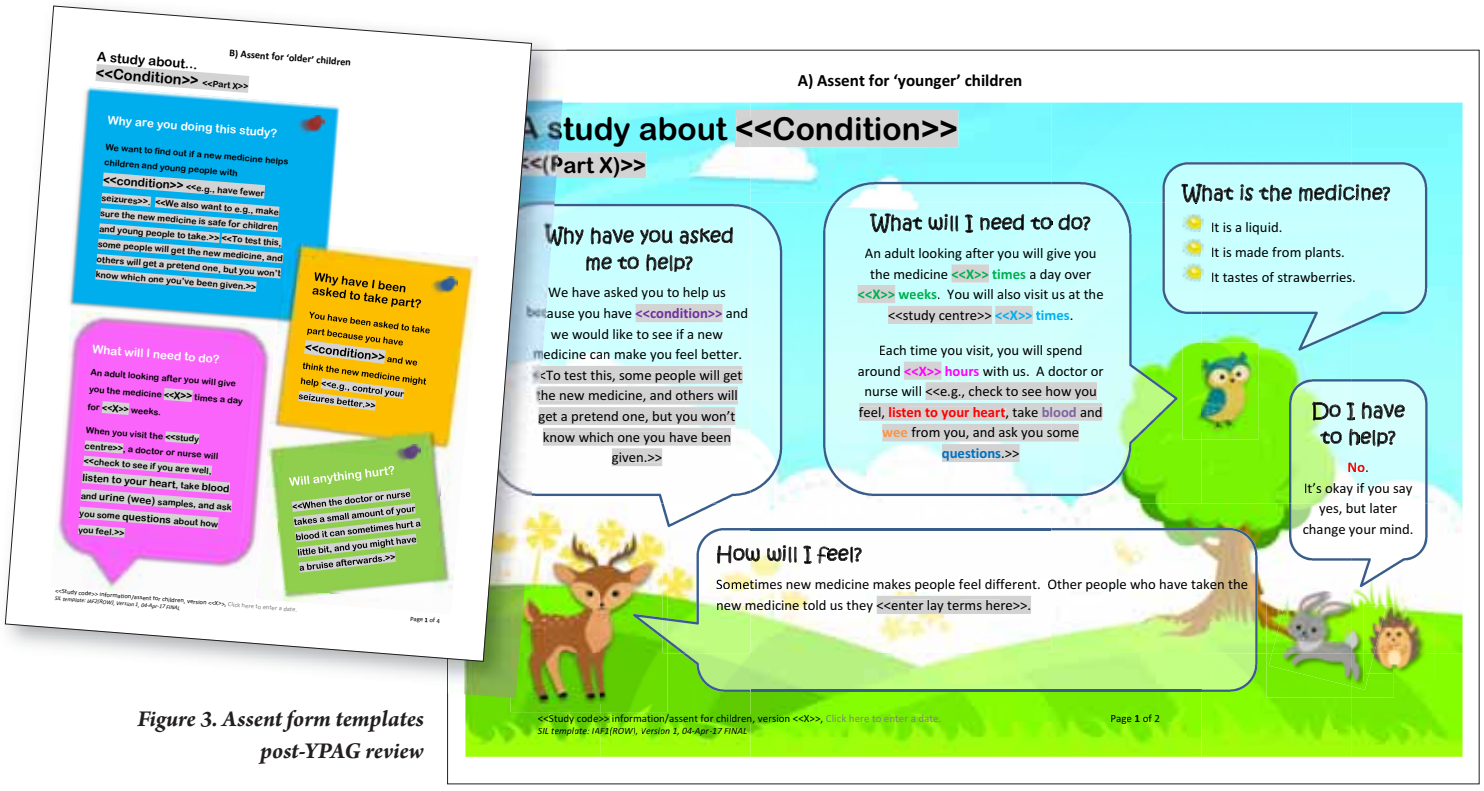

Figure 3. Assent form templates post-YPAG review

development. Although the initial feedback gave testament to our ability to write for lay audiences, and indeed the Flesch-Kincaid scores of our revised templates were aligned with this finding, the overall design of the draft templates affected their suitability. As such, had we not involved the YPAG, although it could be assumed that younger and older children would be able to understand our clinical trials, it is plausible that they would not have engaged with the material, resulting in dissent or potentially subsequent withdrawal post-enrolment.

It should be recognised that there is not necessarily a one-size-fits-all model of assent, as a child's level of understanding will differ on an individual basis. While it is possible to create templates to aid the development of trial-specific assent forms, the decision regarding the suitability of clinical trial materials is ultimately in the hands of the ethics committees from whom approval is being sought. As such, adaptations should be made to templates based on feedback from ethics committees and evidence-based learning and research.

Although writing for children and young people can be difficult, and involving advisory groups can be daunting, medical writers should not be discouraged from pursuing this important area of work. The involvement of advisory groups benefits the paediatric clinical trial process through an improved understanding of clinical trial materials by potential participants and can, in turn, improve medical writers' lay writing skills.

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Conflicts of interest

The authors declare no conflicts of interest.

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