Fortrea

Incorporating the voice of the patient in pediatric assent forms

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The right to be heard is one of the four basic principles from the United Nations Convention on the Rights of the Child,[1] as highlighted in our blog recognizing International Children's Day. With this basic tenet in mind, Fortrea recently worked to re-design their assent templates to better incorporate the voices of children. They aimed to make the template more engaging, understandable and appropriate for young children, including those who can read and those who are too young to read, to help potential pediatric clinical trial participants comprehend, to the best of their ability, what their involvement in the clinical trial process entails.

This white paper provides an overview of the assent process and shares survey findings that explored the use of cartoons and photographic images to supplement text in assent forms.

The importance of pediatric research and assent

Children represent a unique population, one that is often prescribed "off-label" medication due to a lack of data pertaining to the dosing, efficacy and safety.[2] Pediatric clinical research helps address this gap but participation in a trial requires a huge commitment from both the child and their family.

Before a child can join a clinical trial, the pre-enrollment process usually includes asking for the child's assent along with consent from the child's parent(s) or guardian(s). Similar to the informed consent process, the assent process is intended to provide the child with a clear understanding of a clinical trial by explaining the treatment, the possible side effects, risks and benefits associated with participation.

With the assent process, children can actively engage in the decision-making process. In one research study, 52 children aged 10-17 showed a substantial level of understanding regarding the information provided to them and 96.6% of their parents considered the implementation of assent fundamental to their child's acceptance of healthcare in a research study setting.[3]

Fortrea's unique collaboration with iCAN: Enhancing pediatric assent forms

To improve their pediatric assent form, Fortrea first assembled a cross-functional group of stakeholders with team members from Rare Disease & Pediatrics, Patient Recruitment and Engagement, Study Start-Up and Product Development, and Market Access Consulting. With an in-house design team, they reviewed and reimagined Fortrea's pediatric assent form template for younger children by:

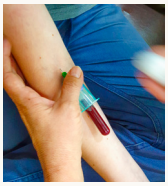
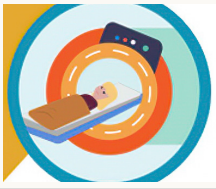
- Incorporating custom cartoon illustrations to complement the text
- Aligning the material to the intended audience

The team then worked to gather feedback and incorporate the voice of the child and the voice of the parent. They collaborated with the International Children's Advisory Network (iCAN), a non-profit patient advocacy group that works to foster a greater global understanding of the importance of the pediatric patient and caregiver voice in healthcare, clinical trials and research.

Key findings from the iCAN survey

To better understand how their assent form was perceived by children and adults/caregivers, Fortrea worked with iCAN to develop a survey. The survey included Fortrea's redesigned assent form with cartoons alongside their previous version with photographs for comparison. Table 1 shows a sample of some of the imagery used in child assent forms.

Table 1: Comparison of photographs vs. cartoons for child assent forms

Assent form text "At some visits we will..."	Photograph	Cartoon
Collect some of your blood.		
Look at how your heart is beating using a special machine called an ECG. Having an ECG won't hurt.		
Take pictures of the inside of your body using an MRI/CT machine to help see how your body is working.		

The team received feedback from 33 respondents. The majority of the respondents (67%) were 8 or 9 years of age; 21% were 12-18 years of age and 12% were 21-38 years of age. Most of the respondents (89%) were from a U.S.-based iCAN chapter; the remainder included respondents from iCAN chapters in the UK, Cameroon and Albania.

The key findings were gathered from a series of questions and comments.

Themes	Findings
Use imagery to supplement text	**Imagery aids understanding:** The majority of respondents (93%) agreed that adding photographs to the adolescent form made it easier to understand the words in the form. **Imagery should correspond to the text:** Pictures can aid understanding and make assent forms more engaging, but only if they serve a purpose and correspond to the text. For example, the respondents mentioned they liked pictures that "shows what is going on" and "what's going to happen" with a procedure.
Find a balance between "realistic" and "scary" images	**Cartoons are appreciated but they need to be realistic:** 75% of the respondents commented that the cartoons helped them understand, liked that they were colorful and explained the procedure but 25% commented that the cartoons needed to be "more realistic" to aid understanding. **Realistic photos can be uncomfortable for children:** When shown a photograph of a blood draw procedure, five of the respondents mentioned that they didn't like seeing blood, commenting the image "makes me scared," "creeps me out," "gives me goose bumps," and "makes me feel weird." This stresses the need for a thoughtful balance between realistic photos and ones that don't scare the potential trial participant.
Consider integrated educational tools	**Artificial intelligence (AI) could play a role in patient education:** Three respondents suggested using technology, such as an AI tool that could read the form to younger children or provide definitions of unknown words. **Consider supplemental/alternate media forms:** Three respondents suggested other media formats, such as animation, a video, or a demonstration, to help explain a procedure.
Use age-appropriate language	**Remove technical jargon:** Five respondents mentioned using "simple language" or "easier words" for younger children to understand.

Championing children's voices in pediatric research

Through this collaborative process, the Fortrea team received unexpected insights from the survey respondents, highlighting the importance of consulting children and guardians/caregivers when designing educational materials.

As a result of this feedback, the team made changes to the form's design and revisited the need for an older child, pre-adolescent assent template. This aligns with the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) guidelines on assent, which recommends a separate assent for children ages 2-5, 6-9, and 10-18.[4]

Fortrea will continue to champion children's voices in pediatric clinical trials and design engaging and appropriate materials as part of their comprehensive support to advance pediatric clinical trials.

Learn more about how our patient-centric practices address the needs of pediatric patients and their families across your development journey.

Fortrea pediatrics

References

1. Office of the High Commissioner for Human Rights, United Nations. Convention on the Rights of the Child. 1989. https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child. Accessed September 9, 2024.
2. Allen HC, Garbe MC, Lees J, Aziz N, Chaaban H, Miller JL, Johnson P, DeLeon S. Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature. *J Okla State Med Assoc*. 2018 Oct;111(8):776-783.
3. Cotrim H, Granja C, Carvalho AS, Cotrim C, Martins R. Children's Understanding of Informed Assents in Research Studies. *Healthcare (Basel)*. 2021 Jul 10;9(7):871.
4. The European Network of Paediatric Research at the European Medicines Agency. Assent/Informed Consent Guidance for Paediatric Clinical Trials with Medicinal Products in Europe. https://www.ejprarediseases.org/wp-content/uploads/2021/10/EnprEMA_informed-consent-guidance-for-paediatric-clinical-trials_2021.pdf. Accessed September 10, 2024.

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