Learning to listen: A complementary approach to informed consent for patients with visual impairments

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This forum describes an exploratory approach for assisting individuals with visual impairment during the informed consent (IC) process to participate in a cutting-edge trial. Our approach has been developed to focus on potential participants’ preparedness to give IC, along with the creation of supporting audio material.

An important premise in clinical research ethics is respect for participant autonomy. This must be protected by a robust IC process to aid potential participants’ decision-making (World Medical Association, 2013). However, obtaining IC can pose an inherent challenge when unfamiliar information, such as scientific knowledge, is delivered to them. This challenge may become acute when potential participants with visual impairment are considering whether to participate in cutting-edge clinical trials. This forum describes an exploratory approach for assisting the potential participants who are visually impaired during the IC process, focusing on their preparedness to give IC along with the creation of supporting audio material. We employed this approach in our recently completed first-in-human trial for corneal diseases using induced pluripotent stem cells (iPSCs), which was based on a relevant pre-clinical study (Hayashi et al., 2016).

In ophthalmology—one of the leading fields for clinical trials involving iPSCs—the diversity and severity of a patient’s disabilities should be carefully considered when obtaining their IC to participate in such a trial (McCaughey et al., 2016). In our clinical trial, potential participants needed to understand ordinary clinical trial information, such as the trial’s main purpose of developing medical knowledge for future patients rather than providing clinical care for the trial participants. In addition, they also had to comprehend more specific information regarding the trial’s potential risks and benefits, the characteristics of the iPSC products used for transplantation, and the trial’s invasive procedures.

A key characteristic of the process of obtaining IC in ophthalmology is that the decision-making of potential participants with visual impairment often depends on information gained through aural processing. In other words, visual supports (e.g., figures) offer little to no value in aiding their comprehension. In this regard, recent technologies, including voice-enabled browsers and text-to-speech technology, may help individuals (especially those who have not studied Braille) obtain information easily. However, use of these technologies cannot always ensure that information is conveyed clearly. Therefore, even when such technologies are used, an effective communication approach is also needed. In our clinical trial, we hypothesized that enriching the preliminary stage before formally obtaining IC may facilitate the understanding of potential participants with visual impairment. Such an approach aligns with the concept of a “concise summary” of key information (Menikoff et al., 2017), which is required by the United States Common Rule.

To enhance the potential participants’ understanding, we created audio support material for the IC process in our first-in-human trial. A key characteristic of our attempt was not simply to incorporate the opinions of interested parties (i.e., individuals with visual impairment) but also to actualize their recommendations by drawing on the knowledge and experiences of various experts. One of the most important findings produced in that way on how to obtain robust IC was the need to avoid disturbing the potential participant’s concentration during the listening period. This initiative was supported by the four essential elements outlined below.

The first element was to engage in a co-creative initiative with relevant actors to enhance the accessibility of the information in the audio materials. Our initiative involved two specific processes. First, we invited around 10 people from communities of visual impairment and relevant fields to conceive and develop the material we would later use. Second, during the process of establishing the research protocol, material drafted together with video creators was refined through group discussions with the individuals with visual impairments and other experts as well as through advice from the ethics committee. Notably, regarding the technical aspects of the device, the video creators used their expertise to ensure that a high quality of the audio is maintained, even if...
listeners change the playback speed to align with their preference. The need for this adjustment arose from the support professionals’ and barrier-free creators’ observation that individuals with visual impairment tend to prefer listening to audio information at increased speeds.

The second element was consideration of how to inform potential participants of the structure of the information in the recorded audio material. As such individuals depend on aural cues, there was a possibility that they would lose their current position in the structure of the overall audio presentation, become confused about the topic, or struggle to recognize transitions to new topics. To avoid these issues, we adopted a well-known method of describing the structure of the information, beginning with large categories and then listing the finer details within each category—similar to how restaurant menus are explained to someone who is visually impaired. A meaningful approach to doing so, endorsed by individuals with visual impairments engaged in the material-creation process, was to provide auditory hints, that is, different sound effects (beep/ping) based on broader or finer categories, inserted at the end of each topic. This can allow potential participants with visual impairment to easily identify topic transitions and distinguish categories following a hierarchical structure while the information flows continuously.

The third element was to avoid the potential participants’ inadvertent loss of context due to instantaneous language-based misinterpretation. For example, an individual with visual impairment engaged in the material-creation process described obtaining information aurally as similar to listening to a song without having the written lyrics, potentially leading to misinterpretation. A case of such misinterpretation occurred when the term taka (他家, allogeneic) transplantation was mentioned to an individual with visual impairment engaged in the material-creation process, who initially misinterpreted it as transplantation conducted by itaka (他科, other departments). Unfamiliar terms and verbose explanations can unhelpfully disrupt the listener’s understanding, causing them to miss subsequent information. To avoid that happening, the information should be presented in a cogent and accessible way, which requires that it is carefully checked for possible points of misinterpretation, to ensure that the listener can understand without impediment.

Finally, consideration of diverse types of visual impairment was essential, as the degree of visual impairment and means of dealing with it vary from person to person. Alongside the audio information, we created audiovisual materials in a movie format with PowerPoint autoplay to aid potential participants who have some remaining vision. These materials were intended to mitigate language-based misinterpretations, such as the example of taka above. For this support, as commonly recommended in the vision care field, individuals with visual impairment engaged in the material-creation process advocated the use of high-contrast colors, such as white gothic font (block-type letters) on a black background, and the avoidance of graphs and figures due to the difficulty of seeing the entire frame. Such tools, as described above, can be valuable for assisting potential participants with low vision in confirming the words in audio explanations.

The United Nations (2006) has highlighted the importance of the concept of “reasonable accommodations,” which refers to appropriate modifications that avoid overburdening individuals with disabilities and facilitate equal human rights and autonomy. Although obtaining IC using recorded audio in ophthalmology has been proposed in prior research (McCaughey et al., 2016; Saleh, 2004), such an approach has yet to be sufficiently implemented in emerging clinical trials. Our approach contributes to clarifying and furthering the concept of reasonable accommodations to support IC in a state-of-the-art clinical trial.

One cannot gain insight into the thoughts and experiences of people with visual impairments simply by closing one’s eyes. The phrase “learning to listen” used in the title has a dual meaning: it relates to how individuals with visual impairments can comfortably receive the aural information they need to give IC and, at the same time, how we can apply these individuals’ contributions to better engage them in research.

AUTHOR CONTRIBUTIONS

Writing – original draft, K.T. and J.M.; writing – revision & review, K.T., T.S., K.M., K.N., and J.M.; funding acquisition, K.T., T.S., K.N., and J.M.

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CONFLICT OF INTERESTS

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