English Summary of the report on development of comprehensible research information for minors

De ontwikkeling van begrijpelijke onderzoeksinformatie voor minderjarigen;

Templates voor proefpersoneninformatie 12-16 jaar en een bespreekblad <12 jaar.

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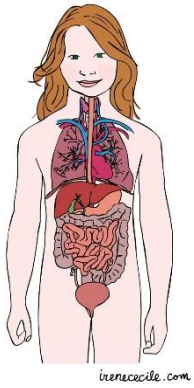

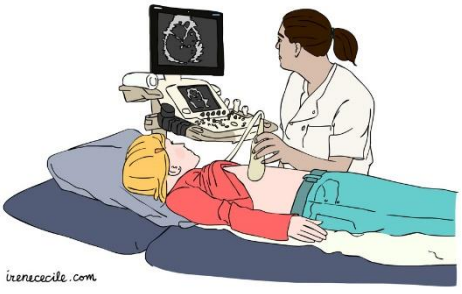

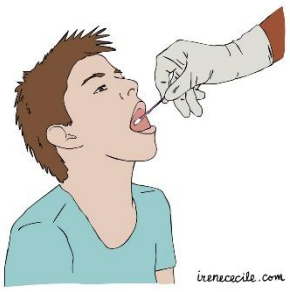

English Summary

The development of comprehensible research information for minors;

Templates for patient information sheets aimed at 12-16 year and a conversation sheet for <12 year.

Background

In the Netherlands, children between the age of 12 and 16 year have an official role in the decision about participation in medical-scientific resarch: they have to provide a *shared consent* together with their parents. It is instructed by law that they should receive research information targeted towards their capacity. However, Patient Information Sheets (PIS) for minors are often written at an adult-level and fail to create the required understanding for making an informed decision [1]. In addition, children younger than 12 years old often do not get any written information to help them understand what research participation entails. In order to address this issue, we have developed a PIS-template for minors and a conversation-sheet for children younger than 12 years old.

This project relied heavily upon end-user involvement: Research information has to be understandable, scientifically correct, and legally correct, while at the same time usable in reseach practice and easy to draft by researchers. In order to ensure that the templates would fulfill all these requirements, all end-users were involved in multiple ways during the project.

Scope

The aim of this report is threefold:

(1) A description of the developmental process of the templates and the role and input of the involved end-users.
(2) To serve as an example and inspiration for those who are looking for how to involve end-users in order to succesfully implement a new product.
(3) Agenda-setting: during this project a number of issues were identified concerning informing and involving participants in clinical trials that need addressing in further projects and research.

Products

The final products of the project are: an instruction manual, a PIS template, and conversation sheet template, and a database with illustrations. The manual contains instructions on how to fill in the templates, how to use illustrations in an effective way, how to write comprehensible texts, and for each section of the information explanations and example texts are provided. The templates are Word-based documents with clear formatting, in which the example texts and illustations can be copy-pasted. The database contains anatomical illustrations and drawings of the most common procedures and treatments in paediatric research.

Participatory approach

All end-users of the research information templates were involved: children, adolescents, parents, researchers, research nurses, pharma, CRO, lawyers, Institutional Review Boards (IRBs) and the Central Committee on Research with humans (CCMO).

The project was led by the principal investigator who had previously developed other types of research information for minors. The project was performed in collaboration with the Dutch Clinical Research Foundation (DCRF) in order to warrant final implementation.

An advisory group was set up, with each member representing an end-user group, and also researchers with expertise in participatory methods. The group guided the project organization, progress and decisions. Also, end-users were involved in iterative stages in the development. An initial pre-consultation was performed in order to identify the prerequisites for the end products in terms of format, content, and legal, regulatory and practical demands. Based on the results, concepts for the templates were developed, and all end-users provided feedback in multiple rounds, after each round the concepts were adapted and re-evaluated. The illustrations were also evaluated with the various end-users, and researchers and legal and regulatory actors were consulted for feedback on the instruction manual.

Lessons Learned on end-user involvement

- The intensive collaborations and participation of end-users was key to the success of this project. Identification of all stakeholders of a product or problem, and involvement of each of these parties is an important step in solving complex problems effectively.
- The collaboration with the DCRF was essential for the implementaton of the products. Collaborating with existing platforms and networks can help to find and connect to relevant stakeholders
- Involvement of the advisory group proved to be a very useful method to be able to include end-users also in project set up, planning and execution. This led to valuable participation even before extensive end-user sessions were held.
- Children's Advisory Groups were contacted for input from children and adolescents, as in past projects already many healthy children had been involved, and the perspective of diseased minors was not represented sufficiently. Even though these groups had regular meetings, it was still challenging to include them in the project planning, as they had many agenda requests and also meetings were sometimes rescheduled last minute. This challenge was mostly solved by being flexible in planning and in participation methods.
- This project was performed in a timespan of two years: one year of preparations and one year of execution. The advantage of this relatively short timespan is that usable products were delivered quickly, impacting practice and demonstrating to participants that their efforts have led to an actual product. The downside is that a tight planning made inclusion challenging, which was mostly overcome by flexible planning and methods (e.g. when the PI was unable to attend, she made vlogs to explain the purpose and the session, pre-discussed it with the chair of the advisory group, who then led the session).

Agenda-setting

A number of issues concerning informed consent were identified by the end-users involved in this project. Not all these issues could be addressed in the current project, therefore a list is provided to set the agenda for research, policy and practice:

(1) **Insufficient guarantees for comprehensible research information;** in spite of the Dutcch Medical Research Involving Human Subjects Act (WMO) it turns out that in practice research information is often hard to understand, complex and lengthy. This applies not only to information for minors, but also for adults [2]. More efforts are needed to guarantee an *informed* consent.

(2) **Different aims for research information;** a Patient Information Sheet serves to imform research participants, but also needs to be scientifically and legally correct. These different aims may contradict each other, and often the legal requirements prevail over research participants' interests.

(3) **Disproportional emphasis on printed information;** IRBs evaluate the written forms, but few standards and directions exists for providing research informatin orally, which is also an important part of the informed consent process.

(4) **The template for the adult PIS has not been developed in a participatory manner;** as a result, this template may still lead to complex information sheets and also does the format not always fit optimally in current practices of professionals writing the PIS.

(5) **Differences in IRB evaluation of the PIS;** different IRBs sometimes appear to evaluate the same PIS in a different way. Unclarity over exact approval assessments can lead to unnecessary delays of trial approvals.

(6) **PIS in international trials vs. Dutch trials;** Patient Information Sheets for international trials often require an English 'motherPIS', and are then translated in e.g. the Dutch language. If adaptations are required, these are then translated again into English and from English to Dutch. These steps not seldom result into incorrect or suboptimal language, and thereby lead to needless delays in trial approval and trial initiation.

(7) **Insufficient acknowledgement of the importance of communication and empowerment;** research information is often written by scientists with little education in communication. Informed consent conversations are not rarely performed in between other tasks. In addition, knowledge on the most effective ways and formats for informing research participants is lacking [2]. These issues need addresising in order to safaguard research ethics, and improve understanding, adherence and well being of study participants.

The templates and manual (in Dutch) can be downloaded from the CCMO website:

https://www.ccmo.nl/publicaties/formulieren/2019/10/14/e1-e2.-model-proefpersoneninformatie-voor-proefpersonen-jonger-dan-16-jaar-kinderen