

Development of children's assent documents using a child-centred approach

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Abstract

The call for researchers to obtain children's informed assent, prior to their participation in medical procedures and research, has increased over recent years and parallels moves to implement child-centred approaches to health care. This article describes the processes used to include children in developing a research information sheet and assent form for use in future research into children's understandings of their surgery and hospital experiences. The process involved primary school children aged between six and 12 years. Children worked in small groups to consider information to include in these documents. Their words were collated to construct the research information sheet and assent form. Working with children resulted in documents that were more understandable for their intended audience. The article includes discussion of 'language', 'understandability' and 'readability'; concepts that researchers seeking to work with children need to come to terms with if they are to obtain 'informed assent'.

Key words: children's assent, child centred research, ethics.

Introduction

Researchers who seek to include children as participants in research need to give careful consideration to the importance of gaining children's informed assent. Assent is the term used to convey a sense of agreement obtained from those who are not able to enter into a legal contract. The researcher's commitment to obtaining informed assent recognises the rights and responsibilities of children (Broome and Stieglitz, 1992) and informed assent can be given by children and young people prior to them reaching the age of legal consent. The exact age when informed assent should be obtained is largely at the discretion of individual researchers and local ethics committees (Green, et al, 2003). However, with developmentally appropriate language and information, children as young as 5 years can understand what research studies are about and are capable of giving voluntary assent (Meaux and Bell, 2001).

The processes described within this paper were used in the development of a Research Information Sheet and an Assent Form associated with our proposed research into children's understandings of surgery and their hospital experiences. While legal consent is obtained from parents or guardians, we believed that obtaining informed assent from the children is also important, and congruent with the fact that our study views children's viewpoints as central. Local Human Research Ethics Committees provide a good deal of information concerning the production of information sheets and consent forms.

Guidelines for developing similar documents for obtaining assent from school-aged children are, however, not normally provided.

We found that examples of assent documents within the literature were in a language primary school-aged children would find difficult to understand. In addition, we found our first attempts to develop information sheets and assent forms specific for this research were not appropriate for young children in their language and content. We had to resolve the contradictions that exist between using a child centred approach to research and the traditional consenting processes that virtually exclude children's voices. In meetings we discussed this issue and ways we could address this. We decided to invite children to participate in designing assent documents that are in a language children can understand.

Aim

There is little research on the most effective means of how to obtain children's assent, yet the subject is central to research involving children. There is little in the literature to inform the process of generating children's assent documents, therefore we wanted to develop and test such a process. Our aim was to develop a process of generating a Research Information Sheet and Assent Form for children, by children, that provide the information children are most likely to need in a form that is readily understood by them. In the process of developing these documents, the children decided what information was important to them. When completed, the documents were tested for their appropriateness for primary school-aged children by assessing their readability using validated readability tools.

The importance of obtaining informed assent from children

When children are enabled to ‘speak in their own right’ and communicate their views and experiences through participation in research they are no longer excluded and silenced (Alderson, 2000). The direct involvement of children in research activities gives children a voice and in demonstrating respect for their voluntary and informed assent, children are given some protection against research that may be covert, harmful or exploitative (Alderson, 2000). Children’s participation in the development of assent documents is consistent with the intent of the United Nations Convention on the Rights of the Child (1989) to give children a voice and is an example of a research approach that is child centred.

There is a call for children’s participation in all stages of the research process, yet in the literature there are limited references to activities where assent documents have been developed with children. Cree et al (2002) conducted a study of children and young people with a parent or carer with HIV. In that study, a group of six children helped design information and assent documents and a logo for the project. In addition, Prout (2002) referred to an unpublished study by Christensen and James where groups of children designed the information sheet about their project exploring aspects of contemporary childhood in the UK. In both studies, the processes the researchers utilised to develop these documents with children were not described. It has been difficult to locate work in the nursing literature describing this kind of activity.

Reasons for obtaining assent from even very young children are presented by Diekema (2003). The first reason for obtaining assent is that it is a reminder that children should be

treated with dignity and respect: 'It would be disrespectful to attempt to involve children without first discussing the procedure and requesting their permission' (Diekema 2003). Second, providing children a shared role in decision-making benefits their development as autonomous individuals and their practice of self-governance. Third, parents and researchers are reminded that children are individuals with interests. Failure to approach children to obtain their assent diminishes the moral status of the children. On the other hand, including children in a meaningful way 'recognises their status as partners in the research enterprise, empowers them to make a choice, ...and encourages a more respectful relationship between the child and investigator' (Diekema 2003). Finally, a requirement for assent provides school-aged children with an opportunity to learn about respect for others.

In the process of developing Research information Sheet and Assent Form for this study, inadequacies and inconsistencies in the guidelines and in the literature became apparent. For example, the terms *assent* and *consent* are used interchangeably, and there is no consistency about when children are considered capable of giving assent (Ondrusek and Abramovitch et al. 1998; Olechnowicz and Eder, et al. 2002; Green and Duncan, et al. 2003; Paasche-Orlow and Taylor, et al. 2003). Exemplars provided in the literature and by ethics committees were not consistent with the requirements that information be provided at a comprehension level and in a medium that is age appropriate, especially when research participants are children less than 12 years of age.

Ondrusek and Abramovitch, et al (1998) conducted a study that considered the age children were able to give assent and found that children under 9 years of age had 'poor

to non-existent' abilities to understand the information they provided in the assent document. When sections of text from this document were assessed for readability, using the Flesch-Kincaid scale (described in more detail below), results showed the text was suited for children aged 9 through to 14 years. It is therefore understandable that the authors found children less than 9 years of age had difficulty understanding this document. The Plain Language Statement (PLS) is presented by these researchers as an exemplar of a suitable PLS for children but it is long and includes sophisticated language such as 'calories,' 'blood sample' and 'transportation' (Ondrusek and Eder, et al. 1998). Indeed, some of the terms used in this PLS, for example 'electrocardiogram' might be confusing to adults.

The assent documents we wished to develop needed to be appropriate for children between 6 and 12 years of age. Bruner (1960, p243) called for the teacher to be 'courteous enough to translate material into (a child's) logical form' when educating young people. Bruner also emphasised the importance of 'starting where children are' in terms of the information, the language and the images researchers offer to children (Bruner 1960). We made the decision to 'start where children are' and develop assent documents for the research with children themselves.

Method for developing the Research Information Sheet and Assent Form

The process to develop the Research Information Sheet and Assent Form with children included initial planning by the researchers; collaboration with teachers; providing

information to parents and gaining their consent; and informing the children and obtaining their agreement to participate in the activity.

The children who participated in this activity were from an independent primary school within the first researcher's (KF) own community. Twelve children aged between 6 and 12 years were involved in the development of assent documents and there was an even distribution of boys and girls.

A preliminary meeting was held with the teachers of the school to plan for the activity and to determine appropriate ways to inform parents and to include the children. Parents were informed of the activity through a notice in the school newsletter and were provided with information about the wider research to explore children's experiences of surgery. Parents were also given information about this specific activity that aimed to work with children from the school to develop children's assent documents. The newsletter also explained that teachers would be with children to assist in the activity. Parents were asked to contact the principal if they were unhappy with any aspect of the proposed activity. If parents did not want their child to participate they could opt out by contacting the school. The researchers considered the possible risk that parents who would not have wanted their child to participate may not have read the information. However the nature of the school and the integrated character of parents' participation in school activities meant that the teachers and researchers were confident that all parents would be aware of the proposed activity.

The children were asked if they would like to help develop the documents after an introduction and discussion about what the process would involve. The introduction was critical in order to gain the children's trust and ensure their assent to participate in this activity was given freely. The incongruence of not gaining formal assent from the children in an activity aimed at developing forms for children's assent for the primary study was not lost on the researchers. The researchers believed that this activity with the school children was an ethical activity that had the interests of the children as a central concern. Ethical considerations in the process included: 1) Parents were informed of the proposed activity and given the opportunity to ask questions prior to approaching the children. 2) Children were given information about the process before being asked if they would like to participate. 3) The contribution of the children was respected and they had control over the development of the documents.

Development session

The children were very enthusiastic about the idea of helping to develop the documents. Before commencing this work however they wanted to talk about their own experiences of illness and injury. It was important that the children had the opportunity to talk about their experiences; that the researcher respected this form of participation and the children's participation in all its forms.

The children were divided into 3 groups of 4 and the groups included children of varying ages, with similar numbers of boys and girls in each. A teacher or teacher's aide worked with each group by presenting the children with small segments of an earlier draft of the

plain language statement developed by the researcher. The teaching staff asked the children how they would articulate the ideas contained within these segments in language of their choice. The teachers then assisted the children with documenting their work. The groups then undertook the same process in development of the assent form.

During the development session, the primary researcher went between each group of children clarifying points or posing questions. The role of the researcher in this instance was not that of leader or controller, but of facilitator. Such a stance is appropriate for a project aimed to foreground the voices and the words of the children.

As stated, the children were very keen to participate as a group, although some children were noted to be more active contributors than others. Because the individual groups were quite small however, teaching staff were able to ensure each child had an opportunity to contribute throughout the activity.

The entire activity with the children was about one hour. This included approximately 15 minutes of introductory discussions with the larger group, then approximately 40 minutes of small group work and collation of the works to form the 'finished' pieces. An hour was quite long enough for the children to remain focused and interested in the activity. However, the duration of the activity was relatively short when we consider the significance of the outcomes for the research.

Outcomes of the process of working with children

The session with the children resulted in the development of two documents: the Research Information Sheet and the Assent Form. The children decided on the content and the language of the documents. The children named the Research Information Sheet *The Information Letter* (Figure 1) and the Assent Form was called *The Letter That Gives Your Permission* (Figure 2). These new, alternative names were suggested in one of the groups after it was recognised by the facilitator that the more conventional titles held little meaning for the children. The children were asked: *'what could you call these papers?'* Agreement to use of the new names was obtained from the larger group. The names the children chose for the documents clearly indicate their purpose in language that is familiar to children.

Readability

Readability refers to the ease with which a written piece of work can be understood and readability formulae are based on objective measures such as length of words and sentences, and familiarity of vocabulary. Recommendations for material prepared for the general population include firstly, use of written language with a readability level of 12 years of age, and secondly, that plain language, known as the 'standard register of language,' is used (Green and Duncan, et al. 2003). However, in the study exploring the understandings of primary school-aged children who undergo surgery, written material suitable for children 12 years of age will only be appropriate for the oldest of the study participants. For the assent documents to be suitable for all participant children, they need to be suitable for children aged between 6 and 12 years.

The assent documents the children wrote were assessed for readability using the Flesch-Kincaid Grade Level Scale and the Flesch Reading Ease Scale. The Flesch-Kincaid Grade Level scale assigns a score on the basis of the minimal grade level required to read and understand text (to grade 12) (Paasche-Orlow and Taylor, et al. 2003). The Flesch Reading Ease scale rates text on a 100-point scale: the higher the score, the easier it is to understand the text. These scales have been demonstrated to be valid and reliable; they have been used widely in studies of readability and have good correlation with other readability scales (Paasche-Orlow and Taylor, et al. 2003). The Flesch Reading Ease and Flesch-Kincaid Grade scales are fairly readily accessible and convenient to use as they are embedded in the computer word processing program, Microsoft Word ©. The assent documents prepared by the children have a readability score of grade 3.9 according to the Flesch Kincaid Grade Level rating, and the Flesch Reading Ease is 86.3 (out of 100). See Figure 3.

The language in these documents is quite different to that of first drafts and to examples within the literature. For example, instead of ‘an adult has read this Information Sheet with me’ as was in an earlier draft, the children chose to say instead ‘*I have read the information letter with Karen*’. ‘The talk will be tape recorded,’ became ‘*Karen will record my voice on a tape when I talk to her*’. These statements are in the active voice, and the entire documents are in fact in active, rather than passive voice. The use of active voice is recommended for clarity and ease of understanding. The children also chose to name the researcher, instead of retaining the previous references to an anonymous ‘adult’.

The decisions relating to language also reflected the experiences of the children. For example, the children came from various kinds of family units. When children in one group were asked whom children should talk to if they were worried about any thing, one child had offered that the child should ‘ask their mum and dad.’ Another child, who lived with one parent, offered that the child should ‘ask their parent.’ All the children in the group agreed on the latter choice: ‘If there is something you don’t understand or are scared about you can talk to your parents.’

The inclusion of children in the early stages of development of reading skills meant that a distinction needed to be made between a child’s capacity to read the document for themselves versus the ability to understand the content if someone else read the material to them. When the finalised draft was presented to the children, the youngest child in the group who was six years old said, ‘I can’t read that by myself.’ The critical thing is that this child was able to understand the information within the document. In working with children of primary school-age, the differences in terms of understanding and reading abilities of children of different ages must be recognised and taken into account. Where children are unable to read the assent documents independently, the documents can be read out loud with children or be used as verbal scripts.

The Plain Language Statement and consent forms for parents of children undergoing surgery contain more information than contained in The information Letter and Letter That Gives Your Permission. For example, the children are directed to ‘talk to their parents’ should they be worried about anything. Adults, on the other hand, are provided

with contact names and numbers of the researchers and the appropriate ethics committee. According to Foreman (1999), the amount of detail included in assent forms will vary according to the level of competence of the children. This difference is also consistent with the position of Diekema (2003) that children should not be considered capable of making decisions as fully informed and autonomous as adults. But the assent documents reflect our belief that children are able to decide for themselves whether they would like to participate.

Conclusion

This paper presents one way that children can participate in research that has not been described in nursing literature to date. By using the materials developed with the children, we can be confident that children approached to participate in our research will fully understand what they were being asked to do. These assent documents are written for children by children with the result that they present essential information in language that primary school-aged children can read and understand. When children who are asked to participate in research are able to fully understand what is being asked of them they are empowered in their decision-making processes.

The authors would like to thank the children for their participation and their enthusiasm in helping to develop the documents.

Figure 1: 'The Information Letter'

The Information Letter

My name is Karen Ford. I am finding out what it is like for primary school children who have an operation.

This letter tells you what will happen if you want to help.

I will interview you. That means I will ask you questions. I will ask you questions like what is it like to have an operation, and what are the good things and what are the bad things.

I will record your voice on a tape. I will also ask you to draw pictures about hospital.

This information will help me write a report that can help other children.

You don't have to do this if you don't want to. If you don't understand anything you can just ask me what I am doing.

I won't use your real name when I write my report. If there is something you don't understand or are scared about you can talk to your parents.

You get to keep a copy of this information letter and the letter that gives your permission.

Thank you for your help.

Karen Ford

Figure 2: 'The Letter That Gives Your Permission'

The Letter that Gives Your Permission

I have read the information letter with Karen.

I understand what Karen is asking me to do.

I will talk to Karen about what it is like to have an operation.

Karen will record my voice on a tape when I talk to her.

I will draw pictures about hospital.

Karen has answered all my questions.

Karen won't use my real name when she writes the report.

If I don't want to do this I don't have to.

I can stop doing this if I want to.

I get to keep a copy of the Information Letter and the Letter That Gives Permission.

Signature:

Date:

Witness:

Figure 3: Readability Statistics (from the software program Microsoft Word ©)

Readability Statistics

Counts_____

Words	303
Characters	1270
Paragraphs	25
Sentences	25

Averages_____

Sentences per Paragraph	1.3
Words per Sentence	11.2
Characters per Word	3.9

Readability_____

Passive Sentences	0%
Flesch Reading Ease	86.3%
Flesch-Kincaid Grade Level	3.9

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