The Experiences of Children Enrolled in Pediatric Oncology Research: Implications for Assent

WHAT’S KNOWN ON THIS SUBJECT: Despite broad-based support for empirical studies examining children’s understanding of what it means when they assent to research and their preference for research involvement, existing studies have focused primarily on healthy children using hypothetical cases and on decision-making preferences of adolescents with cancer.

WHAT THIS STUDY ADDS: This report represents the first study to examine both younger and older children’s understanding of the oncology research in which they are involved and their preferences for decision-making related to their illness.

abstract

BACKGROUND: Most children with cancer enroll in clinical research trials. Whenever possible, children must provide their assent before enrolling in research studies. We studied what children aged 7 to 18 with cancer understand about research, their research-related treatment, and their preferences for inclusion in decision-making.

PROCEDURE: Thirty-seven face-to-face, audiorecorded interviews using a novel, semi-structured tool, the quality-of-assent instrument, were conducted. Exploratory univariate and bivariate analyses of the quantitative data elucidated patterns and trends of understanding and preferences.

RESULTS: Nineteen of the 37 children (51%) did not know or recall that their treatment was considered research, and 19 of 22 (86%) did not understand their doctor when he or she discussed the trial. More children enrolled in trials to help future children with cancer (27 of 37 [73%]), than to get better personally (22 of 37 [60%]). Irrespective of age, children with Hodgkin’s disease, germ-cell tumors, and leukemia had significantly greater research awareness and appreciation than children with other cancers (P = .019 and P < .001, respectively). Although all children wanted to be involved in decision-making, 18 of 37 (49%) did not have or recall having a role in deciding to enroll in their trial, and 14 of 37 (38%) did not feel free to dissent to trial enrollment. Only 4 of 37 children (11%) discussed increased decision-making roles with parents, and only 7 of 37 (19%) discussed them with their doctors.

CONCLUSIONS: Most children have limited understanding of research despite physicians’ explanations. Many children reported that they feel minimally involved in the decision to enroll in clinical trials. Tools to assist investigators ascertain that children understand what they are agreeing to when they assent to research and to determine their preferences for inclusion in research may help make assent more meaningful. Pediatrics 2010;125:e876–e883

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KEY WORDS clinical trials, assent, decision-making, research ethics, understanding, preferences

ABBREVIATIONS
AAP—American Academy of Pediatrics
QuAs—quality of assent
CI—confidence interval
HD—Hodgkin’s disease
GCT—germ-cell tumor

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Significant improvements in childhood cancer survival rates largely derive from greater understanding of disease and improved therapies directly linked to widespread participation by children in oncology clinical trials. Federal regulations require that, whenever possible, children affirmatively agree to participate in research, termed “assent,” before enrolling in research. Often overlooked in this process is ensuring that children understand the research protocol and the assent process itself. Although the Belmont report and the American Academy of Pediatrics (AAP) Committee on Bioethics have stipulated that investigators ascertain that adult and child research subjects comprehend the information about their research participation, federal regulations have not made this a requirement.

Despite broad-based support for empirical studies examining children’s understanding of what it means to assent to research and their preference for involvement in research, existing studies have focused primarily on healthy children using hypothetical cases on decision-making preferences of adolescents with cancer. Few studies have examined children’s understanding of their disease and its treatment and the extent of their desire to be included in research-related decisions. To begin to fill this gap, we developed a quality-of-assent (QuAs) instrument modeled after the quality-of-consent tool by Joffe et al to assess what children with cancer enrolled in therapeutic pediatric oncology research protocols understand about research, their research-related treatment, and their preferences for inclusion in decision-making about their care.

METHODS

Instrument Design

The QuAs instrument was developed after an extensive literature review that examined usage of existing questionnaires regarding the concerns of children, parents, and providers. Questions adapted from existing tools were selected because they were relevant to foundational aspects of assent described in the study’s 2 primary aims: children’s understanding of, and preference for, involvement in research. In addition, novel questions relating to each of these 2 domains were constructed. The result was a 69-item QuAs instrument. To ensure content validity and clinical relevance, a preliminary version was reviewed by 30 pediatric hematology/oncology professionals familiar with research trial methodology and child development. The consultants’ feedback was incorporated into a revised instrument. For clarity, comprehension, and acceptance, this instrument was then evaluated by a social scientist with expertise in both bioethics and survey development. To determine whether children were easily able to understand the instrument and the intent of its questions, and to enable the interviewer (Dr Unguru) to practice asking questions in a nonexpressive fashion, the instrument was pretested in a convenience sample of 4 patients with cancer and 4 healthy peers aged 7 to 16 years. Generally, subjects responded that questions were clear and interpreted items as intended. Where necessary, wording of specific items was simplified.

The 69-item questionnaire consisted of open- and closed-ended questions. Open-ended questions were included to facilitate a more nuanced understanding of children’s views. Interviews were private, face-to-face, and audiorecorded, and they lasted <30 minutes. Children were provided with a questionnaire identical to that used by the interviewer and followed along as each question was read aloud to them. Oral and written presentation is an established effective method for improving understanding and comprehension. Children responded to questions orally. On the basis of responses (ie, initial understanding), prompts were included to ensure that children comprehended each question’s intent. By allowing children to answer orally, children who were unable to read, those who were poor readers, and those whose writing skills were poor still were able to participate effectively.

Five dimensions of comprehension were assessed: familiarity, knowledge, awareness, understanding, and appreciation (Table 1). Children were “familiar with research” if they recalled hearing a given research term from a list of 9 items (“study,” “research,” “protocol,” etc). Research knowledge was defined as a combination of children’s responses to the 9 familiarity items and recognition that trial participation was one way to treat their disease as reflected by the question, “Before starting treatment, did your doctor meet with you to talk about the ways to treat your illness?” Research awareness reflected the children’s recognition of objectives of research (eg, to benefit future children with cancer or to determine the effectiveness of a treatment) and of their own role in trial participation.

TABLE 1 Themes Related to Children’s Understanding and Preferences for Involvement in Research

<table>
<thead>
<tr>
<th>Research</th>
<th>Familiarity</th>
<th>Knowledge</th>
<th>Awareness</th>
<th>Understanding</th>
<th>Appreciation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision-making</td>
<td>Decisional priority</td>
<td>Types of decisions</td>
<td>Role in decision to enroll in the protocol</td>
<td>Preferences/perceptions</td>
<td>Suggestions</td>
</tr>
</tbody>
</table>

Definition of concepts (ie, understanding, knowledge, etc) is provided in the text.
Children’s understanding of the nature of research was based on their responses to 6 questions relating to the components of research (comparing known to unknown interventions, randomization, risk/benefit, efficacy of treatment, generalizable knowledge, and voluntariness). Responses were then coded as correct or incorrect to reflect understanding (ie, correct response = understanding). Children then responded to 5 additional questions relating to the purpose of research: (1) know/aware of purpose; (2) define purpose; (3) correctness of definition; (4) know/aware of research goal; and (5) correctness of goal. General understanding of research was operationally defined as the sum of correct responses to these 11 questions. Appreciation of research goals was determined by the children’s reason or reasons for participating in a research trial as reflected by their responses to the multiple-choice question, “Why did you decide to participate in a clinical research study?”

Children’s preference for involvement in research was based on their responses to 5 domains of research-related decision-making listed in Table 1. Developmental scholars have established 14 years as the age of abstract reasoning and the ability to comprehend a research agenda. Consistent with this practice, age 14 was selected as the assessment point for the preference-related component of the instrument.

Sample
The study was conducted at Children’s National Medical Center and approved by its institutional review board. Children were eligible if they were between the ages of 7 and 18 years at the time of cancer diagnosis and had consented to a Children’s Oncology Group/Pediatric Brain Tumor Consortium research protocol between January 2005 and September 2007, as evidenced by their signature.

Study Procedures
Consent and developmentally appropriate assent forms were signed after study purpose and procedures were explained and reviewed with the children’s parents or guardians present, and again when the child was alone. Interviews were conducted in a private lounge before or after a routine clinic visit, on a separate day altogether, or in a child’s inpatient room. Children followed along as each question was read aloud by Dr Unguru, and they responded orally. Interviews were transcribed verbatim, and transcripts were verified against the audiotape.

Data Analysis
Descriptive exploratory analyses of distributions, means, medians, and proportions were calculated before subjecting data to parametric statistics (t tests, χ² test, and analysis of variance). Significant departures from distributional normality were considered for data transformation and non-parametric analyses (Wilcoxon rank test, Fisher’s exact test). Research knowledge and awareness were measured by summing the children’s responses to a set of 10 and a set of 7 questions (possible range of scores was 0–10 and 0–7, respectively). General understanding of research was calculated by summing correct responses to 11 questions (score range was 0–11) related to the nature and purpose of research. Higher scores indicate greater knowledge, awareness, and understanding. Children were assigned a research-appreciation score of 1 to 3, with 1 indicating less appreciation and 3 indicating greater appreciation, only if they selected from 3 of 6 possible options: “to get better,” “to help other children,” or “to help my doctor to learn about my illness.” Distributions of summation scores (familiarity, knowledge, awareness, understanding, and appreciation) were found to be normally distributed; thus, parametric analyses were used when examining these scores. Bivariate relationships were examined by using linear regression analyses while controlling for variables thought to confound relationships. Internal consistency within the summed scores was determined by calculating Cronbach’s α value to assess the intraitem correlations for each “scale” included in the summed score. Gender, age, cancer diagnosis, protocol type/phase, months since diagnosis, and ongoing versus completed treatment were selected a priori to determine whether these variables had a potential confounding effect on the associations with the 5 dimensions of research comprehension. All quantitative analyses were performed in SPSS 13.0 (SPSS Inc, Chicago, IL). Responses to open-ended questions were analyzed qualitatively by identifying and developing codes for common themes in the interview transcripts. Dr Unguru coded all transcripts.

RESULTS
Respondent Characteristics
Of 62 eligible subjects, 37 children aged 7 to 19 (mean: 13.6 years) whose malignancies represented those seen in the general population participated (60% response rate). Nonrespondents did not differ from respondents with respect to clinical characteristics. Thirty-two participants completed the study as outpatients, and 5 completed it as inpatients. Table 2 provides respondent characteristics.

Internal Consistency
Postpiori scale content-validity studies revealed poor intercorrelation between items included in the summed scores: familiarity, knowledge, awareness, understanding, and apprecia-
TABLE 2  Respondent Characteristics (N = 37)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
<td>43</td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>57</td>
</tr>
<tr>
<td>Age, y*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys, &lt;14</td>
<td>8</td>
<td>22</td>
</tr>
<tr>
<td>Boys, &gt;14</td>
<td>8</td>
<td>22</td>
</tr>
<tr>
<td>Girls, &lt;14</td>
<td>9</td>
<td>24</td>
</tr>
<tr>
<td>Girls, &gt;14</td>
<td>12</td>
<td>32</td>
</tr>
<tr>
<td>Cancer diagnosis</td>
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<td></td>
</tr>
<tr>
<td>ALL</td>
<td>11</td>
<td>30</td>
</tr>
<tr>
<td>AML</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>CNS</td>
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<tr>
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<td>6</td>
<td>16</td>
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<tr>
<td>NHL</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>GCT</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Osteosarcoma</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Ewing</td>
<td>1</td>
<td>3</td>
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<tr>
<td>Research protocol</td>
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<tr>
<td>Pilot</td>
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<td>5</td>
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<tr>
<td>Phase I</td>
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<td>3</td>
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<tr>
<td>Phase I/II</td>
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<td>3</td>
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<tr>
<td>Phase II</td>
<td>6</td>
<td>16</td>
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<tr>
<td>Phase III</td>
<td>26</td>
<td>70</td>
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<tr>
<td>Biology (tissue sample)</td>
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<td>3</td>
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<tr>
<td>Months since protocol enrollment</td>
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<tr>
<td>&lt;4</td>
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<td>30</td>
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<td>4–12</td>
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<td>19</td>
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<td>12–24</td>
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<td>38</td>
</tr>
<tr>
<td>&gt;24</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
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<tr>
<td>Ongoing</td>
<td>23</td>
<td>62</td>
</tr>
<tr>
<td>Completed</td>
<td>14</td>
<td>38</td>
</tr>
</tbody>
</table>

*Respondents were aged 7 to 18 years at the time of cancer diagnosis. Some interviews took place months after diagnosis; therefore, 3 respondents, 2 aged 17 years and 1 aged 18 years at diagnosis, were 19 years old at the time interviews occurred. ALL indicates acute lymphoblastic leukemia; AML, acute myelogenous leukemia; CNS, central nervous system; NHL, non-Hodgkin’s lymphoma.

Research Familiarity

Although most children reported hearing the words “research” (87% [n = 32]) or “study” (95% [n = 35]) from their parents/doctor, 51% (n = 19) said they were not told/did not recall being told that their treatment was considered research. Table 3 lists the respondents’ familiarity with research terms; 65% (n = 24) could not indicate which research term best described the type of research in which they were involved. Of the 13 children who selected a term, 54% correctly defined it.

Children’s Knowledge and Awareness of Research

Table 3 lists the frequencies of children’s knowledge and awareness of research. Knowledge scores ranged from 1 to 10 (mean: 5.7 [95% confidence interval (CI): 4.9–6.5]). Awareness scores ranged from 2 to 7 (mean: 4.8 [95% CI: 4.2–5.4]).

Fifteen of 37 children said that they could differentiate clinical from non-clinical research-related treatments, but of those, 80% (n = 12) did so incorrectly. Forty-one percent of the children (n = 15) said that they did not know the specific purpose of their trial. Of those who did, only 22% (5 of 23) correctly defined the purpose of their specific trial.

Children’s Understanding and Appreciation of Research

Asked to indicate their understanding of trial-related information at the time they assented by choosing 1 of 3 options, 70% of the children (n = 26) responded that it was either a “little hard” or “very hard” to understand, with only a minority selecting “easy to understand.” Asked what made the information hard to understand, 86% (19 of 22) responded that they did not understand the language their doctor had used.

Although the majority of the children (89% [n = 33]) correctly answered that research seeks to further generalizable knowledge, most (73% [n = 27]) incorrectly responded that research interventions were not more risky than other interventions. Similarly, 73% (n = 27) incorrectly responded that medicines given as part of the research component of their trial were proven to be the best treatment for their illness. Mean understanding was 6.9 (95% CI: 6.1–7.8). Assessing children’s appreciation of the goals of research, the 3 most common reasons children gave for deciding to participate in a trial were to (1) help other children (73% [n = 27]), (2) get better (60% [n = 22]), and (3) help their doctor to learn (43% [n = 16]). Mean appreciation was 1.7 (95% CI: 1.4–2.1; range: 0–3).

Knowledge, awareness, understanding, and appreciation were not significantly associated with gender,
protocol type/phase, months since diagnosis, or ongoing versus completed treatment. Children with Hodgkin’s disease (HD) and germ-cell tumors (GCTs) had greater knowledge (mean = 7.6) than children with other diagnoses (mean = 5.0; P = .003). Children with HD, central nervous system tumors, and leukemia had higher mean understanding (mean = 7.8, 7.5, and 6.8, respectively) than children with other cancers (mean = 6.0). However, when controlling for age, neither of these associations was significant (P = .38 and .22, respectively).

Children with HD, GCT, and leukemia had significantly greater awareness (mean: 5.5) and appreciation (mean: 2.2) than children with other cancers (mean: 3.6 and 1.0, respectively). These relationships remained significant when controlling for age (P = .019 and P < .001, respectively).

Asked if they felt free to dissent to study participation, 14 children (38%) said they did not. The most common reason given for still enrolling (8 of 14) was pressure from parents (3 of 8), the message was one of expression of involvement in the enrollment decision more often than physicians (4 of 8). However, nearly half (49% [n = 18]) of the children reported that they had “very little,” “little,” or “no role” in actually deciding to enroll in their study. The older the child, the more likely they were to be included in the enrollment decision (P = .039). Children who stated that they had a greater role in the decision to enroll in their trial were more likely to have been spoken to by their parents and/or physician (P = .005).

**Children’s Preferences for Research-Related Information**

Most children, 87% (n = 32), answered that it would have been helpful if someone had explained to them why research is done before they were asked to enroll in a study. Children appreciated that delaying treatment was not inconsequential, yet 53% (n = 17) still would have wanted the explanation. Three-quarters (n = 28) would have liked to speak to other children enrolled in research to help them understand what it means to be part of a study.

**Children’s Preferences and Perceptions**

As children preferred to be involved “totally,” “a little bit,” or “not at all” in decisions about their clinical and research-related care, 60% (n = 22) said they wanted total involvement in decisions (mean age: 14.5 years; range: 9–19 years); 40% (n = 15) wanted a “little involvement” (mean age: 12 years; range: 7–16 years). Children were not interested, however, in making decisions on their own. Their desire for joint decision-making was nearly universal: 97% (n = 36) wanted to include their parents in decisions, and 94% (n = 35) wanted physicians involved. Despite their desire to be included in decision-making, only 11% (n = 4) and 19% (n = 7) of the children discussed increased decision-making roles with their parents and doctors, respectively. Some were reluctant to engage their parents/physicians, because they did not think it would make a difference.

**Children’s Suggestions for Improving Their Role in Decision-Making**

Asked what their doctor could do to improve their role in decision-making, 49% (n = 18) of the children responded, and most had several suggestions. Children’s most frequent suggestion (39% [7 of 18]) was that doctors talk directly to children, not solely to parents; 33% (6 of 18) said that doctors should solicit children’s concerns; 22% (4 of 18) emphasized that what doctors say should be “understandable;” and 16% (3 of 18) expected doctors not to treat them like children based solely on their age.

**DISCUSSION**

Enrollment in clinical research trials has been the norm for pediatric patients with cancer.40,41 Calls for ensuring research subjects’ understanding have been widely enumerated. To our knowledge, this report represents the first study to examine both younger and older children’s understanding of the oncology research in which they are involved and their preferences for decision-making related to their illness. Our findings show that children’s understanding and knowledge of research, types of decisions made, roles in the actual decision to enroll in research studies, and physicians’ willingness to broach decision-making all were age-dependent. Awareness and appreciation of research, however, were not age-dependent.

More than half of the children in our study did not know/recall that their...
treatment was considered clinical research, which differs only slightly from results from adult research subjects.42 Generally, children had limited understanding of research despite what they recalled of physicians’ explanations. Most children recalled not understanding their doctor when he or she spoke to them about their study, and only half of the older adolescents found the information easy to understand. This finding underscores the well-acknowledged need for enhanced communication33,43 between pediatric oncologists and families to improve the assent/consent process.44

Many children stated that ultimate decisional priority resided with parents/doctors and their own voices had little influence on the important decision of whether to enroll in a clinical trial. This might explain why so few children actually spoke to parents/doctors about increasing their decision-making role. Although children preferred joint decision-making, they did not believe that the decisions of parents or physicians should be absolute. Others have reported similar findings.29,31,45 Moreover, our data support previous findings that children often enroll/remain in studies because of parent/physician pressure.46,47 Our findings suggest that parents/physicians could do more to involve children in decision-making to avoid forcing them to enroll in trials. Because there seem to be morally relevant differences for children’s reasons to enroll in oncology trials (the desire to help future children with cancer and to help physicians acquire knowledge, fear of being treated differently by doctors for refusing trial participation, avoidance of physician/parental pressure to participate in trials, and fear of disappointing parents by not participating), a greater focus on children who enroll in research because their parents/doctors tell them to is needed. Perhaps these children have a better appreciation of research based on their perception of decision-making control and the limited role they have in it. If indeed this phenomenon is more pervasive, this is ethically problematic and contrary to AAP recommendations that children be included in decision-making.7

When we controlled for age, the children in our study with HD, GCT, and leukemia showed greater research awareness and appreciation than children with other cancers. One possible explanation for this may be related to outcome. As a group, overall survival rates for children with HD, GCT, and leukemia are considerably better than those for children with other cancers.1 As discussed by others,48–50 we speculate that parents/physicians are more willing to talk to these children, because they are more likely to survive than are children with other cancers. Parents/physicians may also tell these children different things about the studies of which they are a part, which might explain their greater awareness and appreciation. Although research awareness and appreciation were not associated with protocol type/phase, it is possible that the HD and GCT protocols, for example, were less complex (e.g., fewer treatment modalities) and shorter in duration (lasting 2–6 months) compared with more complex protocols (some lasting as long as 31 months), which might account for these children’s greater research awareness and appreciation.

There are several limitations to this study. First, our sample, although subject to the therapeutic misconception. More generally, pediatric investigators often fail to solicit children’s assent before they consent to research enrollment. We envision that after the assent/consent conference, and before soliciting children’s assent, providers would use an appropriate tool for this purpose. Instead of physician-
investigators relying on their own assumptions about what children understand, such an instrument is intended as a generalizable tool for physician-investigators to clarify topics children themselves describe as poorly understood, thus equipping physician-investigators to include children as active research participants rather than as mere subjects. Such a tool would also satisfy the Belmont report and AAP’s requirement that investigators ascertain comprehension, establishing that children’s assent and research participation are more valid and meaningful. On the basis of our experience described herein, our next area of research will be to develop such a tool. Physicians must establish that children and parents understand their own and each other’s role and responsibilities. Effective communication is a prerequisite for shared decision-making and provides a strong foundation on which to base assent.

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