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Patient Involvement in Informed Consent for Pediatric Phase I Cancer Research

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Abstract

Objective—To examine children's and adolescents' involvement in the informed consent conference for phase I cancer trials and test associations with patient age, ease of understanding, and pressure to participate.

Procedure—Participants included 61 patients ages 7 through 21 years who were offered participation in a phase I trial. Consent conferences were audiotaped, transcribed, and coded for communication between patients and physicians and between patients and parents.

Results—Based on word counts, the mean proportion of the consent conference in which the physician was talking to the patient was 36%; the vast majority (73%) of this communication consisted of giving information. Physician-patient communication increased with age, but overall levels of patient-to-physician communication were low (3%). After controlling for patient age, greater physician-to-patient communication was associated with greater ease of understanding.

Conclusions—The focus on providing information in the context of informed consent may come at the expense of other communication exchanges that are important to patients, especially in the context of end of life decisions. Children and adolescents may benefit from the assent process when physicians direct more of their communication to them. Future research should identify the reasons for low patient communication during the consent conference and strategies to enhance their participation in decision making about phase I trial enrollment.

Keywords

informed consent; assent; decision making; phase I; ethics; communication

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Child and adolescent involvement in research decision making has been of increasing interest to the pediatrics community ¹, especially in the context of chronic or life-threatening illness ²⁻⁵. For example, a vast majority of children with cancer participate in a clinical trial at some point ⁶. Many children with cancer who enroll in trials at diagnosis do not recall or were not told that their treatment was considered research ⁵ or were not present for the research discussion ^{7, 8}. Almost half reported having little to no role in the decision ⁵. In terms of preference, 60% reported that they preferred “total” involvement, and 40% wanted “a little” involvement in such decisions ⁵.

Phase I studies, designed to test the safety profile of novel agents, raise particular challenges compared with other trials, because they are offered to patients who have no remaining curative options. The decision to enroll in a phase I trial can be difficult for patients and families and creates a tension between continuing cancer-directed therapies, with their concomitant side effects and low probability of benefit ⁹, and opting for palliative care ¹⁰. The way in which children and adolescents with cancer and their families navigate this decision is a complex process that is not well understood ¹⁰. In one prior study ¹¹ four of the seven patients involved in a decision about a phase I study reported that a chance of cure was a factor in the final decision about enrollment, and two reported being uncomfortable with enrolling in the trial. These patients reported that they agreed because loved ones wanted them to, even though they did not desire additional disease-directed interventions. Another study included interviews with three children who were offered participation in a phase I trial ¹². The hope for cure was a consistent theme from the child participants.

This study reflects a step forward in our understanding of how children, adolescents, and emerging adults with cancer are involved in discussions about phase I trial enrollment. It was based on observations of actual informed consent conferences (ICCs) about phase I research participation, during which physicians provided detailed information about the trial and discussed the patient’s and family’s willingness to participate. The goals of this study were to describe children’s and adolescents’ involvement by measuring physician-patient and parent-patient communication during the ICC; test whether involvement in ICC discussions increased with patient age; and examine whether involvement was associated with patients’ perceptions of difficulty understanding the information, pressure to participate in the phase I trial, and difficulty making the decision.

Methods

Recruitment and Procedures

This study was based on a larger study to assess physician-parent communication, parent understanding, and parent and patient perspectives regarding phase I cancer research ¹³. Participants included parents and their children who were offered a pediatric phase I trial at six children’s hospitals in the United States. Data collection occurred between June 2008 and June 2011. The study was approved by the institutional review board at each site.

Parents and patients ages 18–21 years provided written informed consent. Verbal or written assent, depending on the institution, was obtained for children and adolescents ages 7–17

years. The ICCs for the phase I trial were observed and audiotaped. Patients ages 14–21 years were then interviewed to assess additional variables related to the decision. Audiotapes of the ICCs were transcribed, anonymized, verified, and uploaded into NVivo 8 for coding and analysis.

Measures

Coding System to Measure Communication—The coding system was adapted from the Roter Interaction Analysis System (RIAS) ¹⁴. While the original RIAS codes for all communication during a medical encounter, we focused only on communication that involved the patient: patient-to-parent, patient-to-physician, physician-to-patient, and parent-to-patient. Each utterance was coded for the relevant exchange pair, followed by the specific category of communication (Table I). Codes were collapsed into five domains: Socio-emotional, Giving Information, Asking and Checking, Partnership, and Social/Personal (i.e., chit-chat).

NVivo tools were used to generate word counts for each exchange pair and each communication domain. Final variables for the exchange pairs were computed to determine the proportion of the ICC in which each pair was talking. For example, the total word count for physician-to-patient communication was divided by the total word count for the ICC and multiplied by 100 to determine the proportion of the ICC in which the physician was talking to the patient. Final variables for the five communication domains were then computed to determine the proportion of each exchange pair's communication that was from each domain. For example, the total word count for physician-to-patient Socioemotional communication was divided by the total word count for physician-to-patient communication and multiplied by 100 to determine the proportion of physician-to-patient communication that was Socioemotional. Thirteen (21%) transcripts were double-coded for interrater reliability. The mean intraclass correlation was .88 ($SD = .09$, range: .71-.99), indicating acceptable reliability.

Patient Interview—A subset of patients (14–21 years-old) was available and consented to participate in the Patient Interview. We were interested in three items that assessed difficulty understanding the information, perceived pressure to participate in the phase I study, and difficulty of the decision. The understanding and pressure items were answered on a visual analogue scale; higher scores indicated more difficulty understanding and more pressure. The decision difficulty item had three response options (easy, somewhat difficult, or very difficult), with higher scores indicating greater difficulty. Eighteen participants had data available for these items.

Data Analysis

We utilized means, standard deviations, and frequencies to describe communication during the ICC that involved the patient. To reduce the number of statistical comparisons, we focused on the broad domains of physician-to-patient and patient-to-physician communication as indicators of patient involvement for the remaining analyses, which included Spearman's rho correlations and independent samples *t*-tests.

Results

Participants

Eighty-five ICCs were observed for the larger study on which this analysis is based¹³. Sixty-six of these involved cases in which the patient was 7 years or older. The patient was present for all or part of the ICC in 97% ($n = 64$) of these 66 cases. One case was excluded because the patient was a legal adult without parental involvement, one because only a portion of the ICC was audiotaped, and one because the audiotape was not transcribed verbatim, resulting in 61 cases. Demographic, illness, and ICC descriptive information is in Table II. Descriptive data for patient interviews are in Table III.

Description of Patient Involvement during the ICC Discussion

Based on word counts, the mean proportion of the ICC in which the physician was talking to the patient was 36.43% ($SD = 31.23$, range: 0–87.44). In two ICCs, there was no communication from physician to patient. The mean proportion of the ICC in which the parent was talking to the patient was 1.76% ($SD = 1.96$, range: 0–10.69). In three ICCs, there was no communication from parent to patient. The mean proportion of the ICC in which the patient was talking to the physician was 3.21% ($SD = 3.60$, range: 0–16.81). There were three ICCs in which there was no communication from patient to physician. The mean proportion of the ICC in which the patient was talking to the parent was 0.57% ($SD = 1.02$, range: 0–5.26). There were 10 ICCs in which there was no communication from patient to parent.

The most frequent type of communication across all exchange pairs was Gives Information (Table IV). For example, 73.28% of physician communication to patients consisted of giving information, while 8.73% was asking and checking, 7.34% was socio-emotional, 5.74% was partnership-building, and 4.80% was social/personal.

Overall Patient Involvement—The mean proportion of the ICC in which the patient was involved, by speaking or being spoken to, was 43% ($SD = 33$, range: 0–96). Either the physician or parent asked for the patient's decision or opinion about the trial or treatment in 66% ($n = 40$) of ICCs. The patient gave a decision or opinion about the trial or treatment in 67% ($n = 41$) of ICCs. The patient was asked to sign the consent form by the physician or parent in 49% ($n = 30$) of ICCs. In 10% ($n = 6$) of ICCs, the patient was asked to sign the consent form without having been asked for a decision or opinion about the trial or treatment during the ICC.

Associations between Involvement and Age

Patient age was positively associated with the proportions of physician-to-patient communication ($r = 0.65$, $p < .0001$) and patient-to-physician communication ($r = 0.36$, $p = .004$). The proportion of physician-to-patient communication was greater for patients who were 18–21 years old than for the younger group ($t(59) = -5.35$, $p < .0001$; 70.44% versus 27.22%). The proportion of patient-to-physician communication was similar in the two age groups.

Associations between Involvement and Difficulty Understanding, Pressure to Participate, and Difficulty of Decision

In the subsample of patients ages 14–21 years ($n = 18$), the proportion of physician-to-patient communication was negatively associated with difficulty understanding ($r = -.53$, $p = .03$) and perceived pressure ($r = -.55$, $p = .021$). However, after controlling for patient age, only difficulty understanding remained associated with physician-to-patient communication ($r = -.62$, $p = .01$). In other words, when there was more physician-to-patient communication, patients perceived that the information was easier to understand. Physician-to-patient communication was not associated with perceived difficulty of the decision. Patient-to-physician communication was not associated with difficulty understanding, perceived pressure, or perceived difficulty.

Discussion

To our knowledge, this was the first study to observe and measure pediatric patients' involvement in ICCs for phase I trial enrollment. Phase I trials are unique because they typically are offered when no other curative options remain, a time when patients and families are struggling with maintaining hope while also preparing for loss¹⁵. Parents view end-of-life decisions, including phase I trial enrollment, as the most difficult to make during the cancer experience¹⁶, and both parents and children frequently hold on to the possibility of cure even when told otherwise¹⁷. Understanding the extent to which children and adolescents are involved in such decisions is important for enhancing the assent, communication, and decision making for phase I studies.

The majority of physician-to-patient communication during these phase I consent conferences consisted of providing information. This finding is not surprising, given the focus on disclosure for informed consent. However, such focus may come at the expense of other communication, such as partnership building and socio-emotional exchange, which contribute to a trusting relationship and increase satisfaction with decision making¹⁸. These forms of communication may be critical for end of life decisions¹⁹, when uncertainty and distress are potentially high¹⁵.

Difficulty understanding and perceived pressure to participate were generally low in the subsample of patients ages 14 to 21 years. Nonetheless, when physicians directed more of their communication to patients, patients perceived that the information was easier to understand, even after controlling for patient age. Until now, claims about the benefits of child involvement in decisions about research participation have been hypothetical. When physicians communicate directly to children and adolescents, it shows respect for them as developing persons²⁰. Direct communication also may help them to listen to and absorb the information about trial and treatment options. It is also possible that direct communication to patients, as measured by word counts in this study, is an indicator of other aspects of physician communication, such as a patient-oriented style, that may be related to patient outcomes²¹.

The mean proportion of patient-to-physician communication during these phase I ICCs was low (3%), similar to pediatric primary care²² and ER visits²³. There is little data to shed

light on whether low levels of patient engagement during medical encounters, including ICCs, are related to important outcomes in children and adolescents. Low levels of patient communication during the ICC could be due to a variety of factors, including relying on parents as managers of information²⁴, feeling marginalized in the medical setting²⁴, and lacking communication skills. In addition, physicians and parents may fail to engage children and adolescents in the discussion or actively interfere with their involvement (e.g., interrupting or answering a question that was directed to the child)²⁴. The physician's expectation that the parent will make the final decision is likely to limit attempts to engage the patient in trial or treatment discussions^{25, 26}. Family patterns of coping and decision making may also shape patient involvement. For example, when standard treatments have failed, a frequent goal of parents is to leave no stone unturned²⁷. The extent to which children and adolescents feel free to communicate their concerns, questions, and preferences in this context is likely to be constrained. Prior research, while limited, does suggest that some patients may not want further disease-directed intervention but agree to phase I participation because parents want them to¹¹.

In 10% of ICCs, the patient was asked for a signature on the consent form without being asked for an opinion about the trial or treatment. Children and adolescents may experience signing the consent form as empowering. On the other hand, there may be discomfort or confusion when signing for something that the child does not fully understand or has given no input otherwise. While there may be regulatory reasons to obtain a signature, too much focus on the consent form may give the impression that the patient has a voice in the process while other, more meaningful ways of participating are overlooked (i.e., tokenism)²⁸. Additional research is needed to understand how children and adolescents perceive different forms of involvement, including signing the consent form.

The findings should be interpreted in light of several limitations. First, the coding scheme was applied to transcripts, so at times it was difficult to determine to whom the physician was talking. We could not assess non-verbal communication, which may facilitate or hinder patient participation, and the coding system focused on quantity and content of communication rather than communication quality. Furthermore, the use of word counts does not allow for a nuanced understanding of communication between physicians and patients. Second, there were probably episodes of communication about the trial and treatment options that occurred outside of the formal ICC, either with parents and patients together or with patients alone, and were not measured as part of this study. For example, some families came to the institution specifically to enroll in the phase I study, making it likely that much communication and decision making occurred beforehand. Third, the sample was skewed toward male sex and older age. It also consisted of participants who agreed to participate in a study about informed consent. As such, the participants in our sample might have been less distressed or struggled less with the decision than other patients and families who were offered phase I trial participation²⁵. Fourth, the sample size was small for analyses that involved parent or patient interview data, and patient interview data were only available for 14- to 21- year-olds. Finally, procedures related to assent may be influenced by institutional policies that were not accounted for, such as whether or not the child is required to provide a signature on the consent form.

Future research is needed to explore reasons for low patient involvement in phase I research discussions, examine outcomes of patient involvement, and identify ways to enhance involvement for those who desire it. Additional analyses are planned to examine aspects of communication that were not captured with our coding scheme, such as the role of hope in the consent discussion and both subtle and overt persuasion during the ICC by physicians and parents. Finally, future research should examine the extent to which these results are comparable to consent discussions about other types of research and in other populations and whether illness-related factors, such as functional status and prognosis, impact physician and parent communication with patients about research participation.

The results of this study have potential clinical implications with respect to child and adolescent involvement in the ICC. One way to intervene is to educate physicians about low levels of patient communication during ICCs despite their desire to be involved in decision making. Physicians could be encouraged to solicit children's questions and opinions about the decision to be made^{5, 29, 30}. Spending part of the ICC alone with older children and adolescents³¹ may facilitate rapport and increase patients' comfort with expressing concerns and worries. In the context of end of life decisions, such as phase I trial enrollment, children and adolescents may keep these concerns to themselves in the presence of parents, to protect them from distress^{3, 11}. We also suggest that asking for a signature on the consent form should be accompanied by, at a minimum, a solicitation of the child's opinion and concerns about research participation.

Patients and parents could also be the target of intervention. For example, anticipatory guidance prior to the ICC could include a description of the purpose of the ICC and types of information that will be covered and encouragement of active participation during the discussion³². Giving children and adolescents permission ahead of time to play an active role may have positive effects on their willingness to give voice to their questions and concerns during the ICC³³. However, end-of-life decisions, including phase I trial enrollment, involve additional complexities and emotional factors that are likely to shape how families manage information sharing and decision making^{3 10}. As such, physicians will need to partner with parents to examine their preferred patterns of decision making, explore how the patient is likely to respond to different types of information, and discuss ways to facilitate patient involvement.

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Abbreviations

ICC informed consent conference

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Table I**Communication Categories**

Broad Domains and Specific Categories of Communication	Description
<i>Gives Information</i>	
Gives information	Provide information, instruction, orientation
Gives decision or opinion (coded for patient-to-physician/parent only)	Express an opinion or decision related to the trial, treatment, or illness
<i>Asking and Checking</i>	
Ask for signature (coded for physician- or parent-to-patient only)	Ask patient for signature on consent form
Ask question	Ask question
Check that self understands	Ensure understanding of what other has said
<i>Socio-emotional</i>	
Agree	Show agreement or understanding
Approval	Compliments, praise, admiration
Concern	Worry, concern, or distress, including current symptoms or pain
Joke	Jokes, teasing
Empathy	Interpret, recognize, or name the other's emotional state
Reassurance	Show encouragement, optimism, or reassurance
Legitimize	Validate patient feeling or opinion
Disapproval	Disagreement or disapproval of what the other has said
<i>Partnership</i> (coded for physician- or parent-to-patient only)	
Partnership	Indicate alliance with the patient in terms of support or decision making related to trial, treatment, or illness
Back-channel	Back-talk when not holding the speaking floor (e.g., "uh-huh")
Ask for decision or opinion	Ask patient for opinion or decision related to the trial, treatment, or illness
Check that patient understands	Check that patient understands what was said
Quiz	Check that patient understands something, specifically by quizzing him or her
Solicit questions	Ask patient if he/she has any questions
<i>Social/Personal</i>	Chit-chat and social niceties

Table II

Participant and ICC Characteristics

Variable	<i>N (%) or M (SD, range)</i>
Years of age *	13.34 (4.13, 7–21)
Male sex	42 (69%)
Cancer type	
Bone or soft tissue	24 (39%)
Brain/CNS	21 (34%)
Neuroblastoma	9 (15%)
Other	4 (7%)
Leukemia	3 (5%)
Years from diagnosis to ICC	3.30 (2.59, 0.27–12.46)
Duration of ICC, minutes	43.33 (18.59, 15–128)
Dominant physician during ICC	
Attending	57 (93%)
Fellow	4 (7%)
Enrolled in phase I trial	57 (93%)

* $n = 13$ (21%) participants were 18–21 years old

Table III

Patient Interview Data (age 14–21 years)

Variable	<i>N</i> (%) or <i>M</i> (<i>SD</i> , range)
Difficulty understanding, from 0 (very easy) to 10 (very confusing)	1.94 (1.30, 0-4)
Pressure to participate, from 0 (no pressure) to 10 (much pressure)	2.06 (2.88, 0-10)
Difficulty of decision	
Easy	11 (61%)
Somewhat difficult	6 (33%)
Very difficult	1 (6%)

Table IV

Proportion of Communication for Each Exchange Pair from Each Category (M [SD, range])

	Gives Information	Asking and Checking	Socio-emotional	Partnership*	Social/Personal
Patient to Physician	41.33 (23.58, 0–100)	27.01 (22.81, 0–100)	18.73 (16.47, 0–100)	N/A	12.01 (16.70, 0–69.23)
Patient to Parent	45.11 (34.88, 0–100)	15.43 (22.05, 0–100)	22.63 (27.23, 0–100)	N/A	16.41 (27.23, 0–93.18)
Physician to Patient	73.28 (25.63, 0–100)	8.73 (11.59, 0–60)	7.34 (9.49, 0–53.03)	5.74 (12.35, 0–75)	4.80 (8.02, 0–33.65)
Parent to Patient	45.30 (28.08, 0–100)	19.80 (26.03, 0–100)	12.60 (15.96, 0–79.55)	13.18 (20.52, 0–100)	9.07 (17.86, 0–78.37)

* Coded for physician-to-patient or parent-to-patient only