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Assent Described: Exploring Perspectives from the Inside

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Abstract

Purpose—The purpose of this study was to describe the informed consent and assent experience for oncology research from the perspective of the participants: adolescents, their parents, and their physician providers.

Design & Methods—This descriptive mixed-methods study included the pilot use of the Quality of Informed Consent Questionnaire (QuIC) with an adolescent population and semi-structured interviews with adolescents, their parents, and their physician providers within 48–72 hours of the informed consent and assent discussion for a pediatric oncology clinical trial and again 6–9 weeks later.

Results—Adolescents and their parents scored considerably lower on Part A of the QuIC than Part B indicating a lower level of objective understanding of key elements of informed consent and assent. Qualitative interviews highlight participants' self-reported poor memory or recollection of key details of the informed consent and assent discussion paralleling the QuIC findings for objective understanding.

Conclusion—Findings from this pilot descriptive study suggest adolescents and their parents feel more informed than they actually are. This dichotomy of experience seems to have been mitigated by a strong sense of trust in and connection with their physician provider.

Practice Implications—Further exploration of adolescent and parent viewpoints regarding what they value as important in the content of the informed consent and assent and how that content is delivered is warranted. Additionally, understanding the origin of participants' misunderstanding of the key elements of consent and assent may illuminate areas for future intervention-based research focused on improving the overall quality of informed consent and assent discussions.

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Keywords

Informed Consent; Assent; Adolescent; Oncology Research

Involving children in decision making about participation in clinical research is mandated in this country by the Code of Federal Regulations (CFRs) and is manifest in the requirement to obtain informed assent from children prior to their participation in clinical research (Requirements for permission by parents or guardians and for assent by children, 1983). Despite a push to include children in clinical research (National Institutes of Health, 1998; Pediatric Research Equity Act, 2003; Best Pharmaceuticals for Children Act, 2002) and to involve them in decisions about their participation, research literature provides little exploration of the voice and perspective of the child in decision making processes, specifically informed consent and assent for oncology clinical trials (Stegenga et al., 2005). Previously, research examining children's understanding of clinical research involvement and preference for participation (assent) has primarily utilized healthy children and hypothetical cases (Angst & Deatrick, 1996; Bradlyn, Kao, Beale, & Cole, 2004; Geller, Tambor, Bernhardt, Fraser, & Wissow, 2003; Kunin, 1997; Rossi, Reynolds, & Nelson, 2003). While researchers have attempted to quantify the child's level of participation in actual consent and assent discussions (Olechnowicz, Eder, Simon, Zyzanski, & Kodish, 2002) and conceptually explore children's competence to participate in research and treatment decision making (Miller, Drotar, & Kodish, 2004; Coyne, 2005), there are few data that directly address the child's self-reported experience. Understanding the perspective of children and their parents involved in these discussions is paramount to research aimed at improving a less than ideal process in actual clinical practice (Hinds, 2009; Sugarman, 1999).

Background

Ethicists and clinicians involved in human subjects research have been concerned with participants' misperceptions of elements of the informed consent process for years. Clinical trial participants across the world have consistently shown a lack of comprehension of essential informed consent elements, most notably randomization and placebo design elements (Mandava, Pace, Campbell, Emanuel, & Grady, 2012). Challenges to describing key elements of consent and assent in actual clinical research practice have led to a number of investigative studies (Burman, Breese, Weis, Bock, Bernardo, Vernon, 2003; Resnik, Peddada, Atilio, Wang, & Menikoff, 2008; Johnson et al., 2015). While much empirical research literature on informed consent has focused on poor understanding and created and tested interventions to improve the overall quality of informed consent, success at improving understanding of the key elements of informed consent has been very limited (Flory & Emanuel, 2004).

In the context of pediatric oncology research, clinical trial involvement is high and accounts for substantial improvement in survival rates, with the 5 year relative survival rate up from 58% for children diagnosed between 1975–1977 to 83% for children diagnosed between 2004–2010 (Seigel, Miller, & Jemal, 2015). Approximately 4,000 children diagnosed with

cancer enroll in a Children's Oncology Group sponsored clinical trial each year making this population a primary focus for informed consent and assent research (National Cancer Institute, 2014). Findings suggest adolescents may feel pressure from the clinical research team and their parents to enroll in clinical trials (Grady et al, 2014). Contrasting findings from adolescents in Phase I clinical trials suggest that the majority understand the concept of voluntariness and see themselves as the final decision-maker (Miller et al., 2013). Understanding how and why parents and adolescents make decisions about clinical trial participation is key in oncology research. Research indicates that factors influencing family decision making in clinical trials include: child characteristics such as health and developmental status, parent-child relationship, context of the research, and investigator characteristics (Broome, Kodish, Geller & Siminoff, 2003). Navigating key factors influencing family decision making in informed consent and assent, especially in oncology, requires involvement of key stakeholders in the discussion to include providers. Physicians in pediatric oncology report little previous formal training in facilitating informed consent and assent discussions, instead relying on modeling their mentors and attending physicians in the absence of a formal institutional protocol for consent processes (Kodish, Pentz, Noll, Ruccione, Buckley & Lange, 1998). Identifying content of these informed consent discussions can illuminate directions for further study. Dialogue in most informed consent conferences in pediatric oncology is devoted to the discussion of disease and treatment issues, with little time devoted to study discussion, risks/benefits and voluntariness of clinical trial participation (Olechnowicz et al., 2002).

Oncology patients have shown poor understanding of the design and purpose of clinical trials (Daugherty et al., 1995). Research with adults focused on the quality of the informed consent process utilizing the Quality of Informed Consent Questionnaire (QuIC) showed the majority of oncology patients were satisfied with the consent process yet had little understanding of key elements of the process outlined in the Code of Federal Regulations (General requirements for informed consent, 2005; Joffe et al., 2001). Similar results using the QuIC with adult participants demonstrated little understanding of concepts of clinical trial participation related to it not being standard treatment, having additional risk when compared to standard treatment, and the protocol being unproven (Barrett, 2005; Bergenmar, Molin, Wilking, and Brandbery, 2008). Pediatric oncology patients of the age of assent (>7 years) involved in oncology clinical research similarly voiced poor understanding or recollection that their treatment was considered research, outlined little or no role in deciding to enroll in their trial, and expressed a feeling of being unable to dissent to trial enrollment (Ungaro, Sill, & Kamani, 2010).

Understanding the perspectives of participants can aid research aimed at improving the overall process from the perspective of the participants. Clarifying whether and how the federal regulations that guide this discussion are being operationalized and perceived by the participants in clinical research is a key next step to moving this area of research forward. The primary purpose of this descriptive mixed-methods study was to describe the informed consent and assent experience from the perspective of the participants: adolescents, their parents, and the physician providers participating in discussions for oncology clinical trials.

Methods

Study Design

This was a descriptive, longitudinal, mixed-methods research study with a heavily weighted qualitative approach. Concurrent qualitative (semi-structured interviews with adolescents, their parents/guardians, and their physician provider) and quantitative data collection (QuIC completed by adolescents and their parents/guardians) was utilized to form a baseline description of participants experiences of informed consent and assent. A longitudinal look at the informed consent and assent experiences for adolescents and their parents took place 6–9 weeks after their initial informed consent and assent discussion (ICD/IAD).

Study Procedures

Study approval was obtained from the local Institutional Review Boards prior to subject enrollment. Potential research participants were identified by the clinical staff in the pediatric oncology clinics. Eligible research participants consented/assented to participate in this research study within 48–72 hours of the formal informed consent and assent discussion for the cancer clinical research trial. In Step 1, adolescents and their parents/guardians participated in either separate or joint audio-recorded qualitative interviews lasting approximately one hour. Adolescents and their parents/guardians were asked to provide a narrative of their informed consent and assent discussion experience (see Table 1 for sample interview structure). After the completion of the qualitative interviews, the parent/guardian and adolescent subjects completed short demographic forms and the study instrument (QuIC). The researcher completed a short descriptive form that captured relevant elements such as the clinical diagnosis of the adolescent participants. A member of the research staff that participated in the informed consent and assent process for the cancer clinical trial also participated in an audio-recorded qualitative interview with the researcher at this initial time point. A second qualitative interview was conducted with adolescents and their parents/guardians approximately six to nine weeks after the completion of the induction phase for the cancer clinical trial.

Sample and Setting

Data were collected from a convenience sample of adolescent patients, their parents/guardians, and their physician providers at two separate pediatric oncology clinics in academic medical centers located in the Mid-Atlantic United States. Specific eligibility criteria for adolescent participants included 1) being age 12 to <18 years at time of study entry with a new diagnosis of cancer; 2) completed informed assent discussion for Phase II-III pediatric oncology research trial; and 3) ability to understand written and spoken English. Exclusion criterion for adolescents and their parents included any cognitive deficit that would have made either of them eligible for a waiver of consent or assent for the cancer clinical research trial based on physician investigator judgment. Specific eligibility criteria for parent/guardian participants included 1) parental status (biological or legal guardian) of an adolescent who participated in the informed consent and assent discussion for a Phase II-III pediatric oncology clinical research trial, and 2) ability to understand written and spoken English. The physician provider/physician investigator who facilitated the ICD/IAD for the

oncology clinical trial for the adolescent and parent/guardian dyads was approached for participation. There were no exclusion criteria for providers.

Quantitative Measure: QuIC

The QuIC questionnaire developed by Joffe, Cook, Cleary, Clark, and Weeks (2001) measures actual (objective) and perceived (subjective) understanding of the informed consent process. Eight relevant domains for measurement of the quality of informed consent were derived from federal regulations outlined in the Code of Federal Regulations (General requirements for informed consent, 2005). Part A measures objective understanding with item responses ranging from disagree (1), unsure (2), or agree (3) to statements such as “The main reason cancer clinical trials are done is to improve the treatment of future cancer patients” (Joffe et al., 2001, A2). Part B measures subjective understanding, or perception of understanding, with item responses ranging from “I didn’t understand this at all” (1), to “I understood this very well” (5), to statements such as “I understand the possible risks and discomforts of participating in a clinical trial” (Joffe et al., 2001, B6). With a summary score range of 0–100, higher scores on Part A (a criterion-referenced measure) indicated a higher level of understanding of clinical trials or objective knowledge. With a summary score range of 0–100, scores on Part B (a norm-referenced measure) indicated a higher level of perception of understanding of clinical trials or subjective knowledge. Face and content validity of the QuIC were established via two independent expert panel reviews with experts in statistics, oncology, clinical trial design and bioethics. Test-retest reliability was established with intraclass coefficients (ICC) of .66 on Part A (objective understanding) and .77 on Part B (subjective understanding) (Joffe, et al, 2001).

Feasibility (to include evaluation of acceptability and timing) of QuIC use with adolescent participants occurred in this study via adolescent verbal reports following completion of the instrument. The brevity and readability level supported ease of adaptation of the instrument for an adolescent sample. Estimated time for completion was seven minutes.

Qualitative Measure: Semi-Structured Interviews

Adolescents, their parents/guardians, and a member of the clinical research staff participated in separate or joint audio-recorded qualitative interviews about their informed consent and assent experience lasting approximately one hour within 72 hours of the initial ICD/IAD for the oncology clinical trial. Adolescents, their parents/guardians, and physician providers were asked to tell the story of their informed consent and assent experience. Adolescents and their parents also participated in additional interviews 6–9 weeks later to reflect on what they remembered about the ICD/IAD.

Analysis Techniques

Qualitative and quantitative data were collected concurrently during Step 1 of the study, analyzed separately, and then examined for areas of convergence and difference in the interpretation phase. Transcripts of the qualitative interviews were analyzed using the following steps: data immersion, data transformation or reduction for relevant content, identification of strips, grouping of similar strips, identification of groups of strips into themes, and finally thematic analysis (Cohen, Kahn, & Steeves, 2000). Trustworthiness was

addressed by multiple design and analysis strategies. The researcher kept a reflective journal with field notes completed at the end of each interview in an attempt to enhance self-awareness and credibility (Guba & Lincoln, 1989). Member checks were completed with each participant throughout their interviews to ensure authentic reports of their experiences (Guba & Lincoln, 1985). An audit trail was maintained throughout the data analysis phase to ensure ease of access to evaluate coding choices and definitions for larger categories and themes, enhancing dependability of the study (Guba & Lincoln, 1985).

Important themes and key elements of the ICD/IAD from the participants' standpoint as highlighted during qualitative interviews were compared to participants' scores on the QuIC to highlight similarities and differences. The QuIC, demographic data, and chart abstraction data were the secondary forms of data providing supportive explication of the qualitative data collected in participant interviews, thus a heavily weighted qualitative approach. Comparison of qualitative data (interviews), quantitative data (QuIC), demographic data, and chart data occurred side by side in the data interpretation phase of the study and is explored in the discussion of results.

Results

Participant Characteristics

The sample included 4 participant triads (adolescent, parent, clinician). Demographic information is summarized in Tables 2 & 3.

QuIC Results

In this study, the adolescents and their parents scored 72 or lower on a scale of 100 on Part A, indicating a low level of objective understanding of the essential elements of the informed consent and assent (see Table 4 for summary scores). Mean summary score for adolescents on Part A of the QuIC was 64.25 (SD 5.6) with a range of 53–72. Mean summary score for parents was 59.0 (SD 9.5) with a range of 47–70. Three out of four adolescents' summary scores of 82 or higher for Part B, indicating they subjectively felt well informed. All four parents felt well informed with summary scores of 86 or higher for Part B. Mean summary score for adolescents on Part B of the QuIC was 79.25 (SD 9.6) with a range of 60–89. Mean summary score for parents on Part B was 93.0 (SD 7.0) with a range of 86–100.

Initial Interview Themes

Analysis of the transcriptions from interviews with adolescents, their parents and physician providers revealed seven key themes: *Altruism, Overwhelmed, Fear and Lack of Control, Physician Provider Communication, Timeline and the Rush, the Protocol Roadmap, and Poor Memory* (see Table 5 for definitions of themes and key examples of participant quotes demonstrating theme).

Altruism—Adolescent and parents highlighted their desire to give back as a motive for clinical trial participation. This was clearly a source of pride as they volunteered why they decided to participate in the cancer clinical trial. Adolescents described their desire to help others in a similar situation with reference to an idea of solidarity among those who have a

new oncology diagnosis and are new to clinical trials. Mothers spoke of their own family's strengths and pride in their adolescent for "*giving something back*" when they spoke about their altruistic motives for participating in a clinical trial. Physician providers highlighted the purpose of the trial as "*gathering data for the future (patients) of the world*" which adolescents and parents translated as a motive for participation.

Overwhelmed—As adolescents and their mothers settled into the narrative descriptions of the informed consent and assent discussions they often began with a description of how they felt like they were being inundated with a large amount of information to include a new oncology diagnosis and subsequent complex informed consent and assent discussion that involved complex concepts and words. Adolescents and parents highlighted the complex, medically sophisticated language involved in oncology clinical trial discussions. Adolescents often referenced what they called "*big word*" or "*giant words*" used by the physician providers as an example of where they often became "*lost*" in the informed consent discussion.

Fear and Lack of Control—Adolescents and parents often expressed trepidation and lack of ability to manage a new oncology diagnosis and subsequent treatment options and decisions including the possibility of clinical trial participation. Adolescents were often hesitant to admit fear in the presence of their parents but often alluded to it as they discussed the future beyond their initial enrollment in the clinical trial. Mother's expressed clear feelings of panic and lack of control as they faced the unknown with their child. Mother's often did not express this fear in front of their child and elaborated that this was a defense to shield their child from what they perceived as a weakness in the face of a new oncology diagnosis and clinical trial participation. Physician providers did not provide any discussion related to observations of fear or lack of control on their part or from the perspective of the family within the context of the ICD/IAD.

Physician Provider Communication—Adolescents and mothers identified key characteristics of physician provider interactions and behaviors that influenced their positive perception of the consent and assent experience. They often highlighted how well their physician provider's characteristics and habits of communication matched their own preference for receiving difficulty information in such a complex experience. One adolescent liked his physician provider and the "*fact that he didn't jump around the bush, and he told me straight forward*." Parents also noted their satisfaction with physician providers who demonstrated commitment to their child as an individual and utilized positive communication techniques that made them feel like they were "*part of the conversation*", highlighting a patient centered approach. Mothers highlighted their satisfaction with their physician provider's use of "*layman terms*" as a way to make complex medical concepts and terms more understandable. Similarly physician providers pointed to their strategy to utilize "*layman terms*" in an attempt to help adolescents and parents make sense of the complex medical content within their own context of experience. Descriptions from physician providers often began with details related to the consent and assent environment, describing the landscape of consent and assent in an attempt to illustrate establishing a connection with patients and their families. For one physician provider it was especially important to

illustrate the implied relationships between physician provider, patient, parent, and nurse by outlining where everyone was sitting for this discussion. The fact that all were on generally the same eye level for the discussion was both literally and metaphorically important for this physician provider to highlight an attempt to establish a connection with the patient and the patient's family. The positions of those involved in the discussion were outlined to demonstrate a symbolic equal footing as they began this important discussion, therefore, eliminating any physical signs of power differentials.

Timeline and the Rush—Adolescents, mothers and physician providers all expressed a frustration with the quickened and pressured pace necessary to make decisions and implement a plan for treatment and clinical trial participation so soon after a new oncology diagnosis. This left adolescents feeling they did not have enough time to process all that was happening. Parents wished physician providers took more time during these discussions. Physician providers also expressed conflict between wanting to move quickly to provide their patient with the best possible outcome and wanting to take more time to go over key information.

Roadmap—Parents and adolescents outlined the necessary steps in the process for oncology clinical trial participation to include calendars, medications, procedures, and other trial specific time points. They were able to organize their thoughts about the consent and assent experience around what they called the *roadmap* or the visual interpretation of their treatment protocol and the different paths they could take. Understanding their treatment protocol and the order of activities in their new cancer dominated lives was important to adolescents and parents. The roadmap provided the structure to help them understand and move through this process. The roadmap stemmed from the physician provider's presentation of what they call the necessary "*schema*" of how the clinical trial protocols work. Essential elements of the consent and assent discussion for physician providers centered on the actual roadmap for the protocol as dictated by the individual's cancer clinical trial. The physician providers' memories of the roadmap were more detailed than the memories that the mothers and adolescents provided.

Poor Memory—Parents and adolescents described an inability to remember specific content of the informed consent and assent discussions. They described their own *poor memory* about specific details about the ICD/IAD, specifically what was said and by whom. One mother felt she understood the discussion while it was happening, but once the discussion was over, her memory of what was actually said was sparse. Adolescents were open and nonchalant about their lack of specific memory related to consent and assent discussion details. When adolescents and parents attempted to recall specific content of the informed consent and assent forms, they often expressed frustration about what they could not remember. A sense of being overwhelmed and deluged with technical information in a foreign language (medical terminology) were often blamed for their "*bad memory*". Physician provider comments did not highlight this particular theme.

Themes from Follow-Up Interviews with Adolescents/Parents

During interviews 6–9 weeks after the initial ICD/IAD for their cancer clinical trial, adolescents and their mothers described what they remembered about the initial ICD/IAD. Both had a difficult time remembering key details about the content of the ICD/IAD, but were able to recall how they were feeling during that time and contrast it to their present day lives. Their feelings of *fear and lack of control* and general sense of being *overwhelmed* had waned as they saw themselves moving forward and achieving milestones within their individual protocols. Adolescents proudly recited details about the *roadmap* for their clinical trial and were precise in their descriptions of where they were on the *roadmap*. Adolescents and mothers spoke with greater confidence about their knowledge of drugs and treatments and expressed continued confidence in their physician providers. All continued to be satisfied with the ICD/IAD and attributed this to their confidence and positive connection with their physician provider.

Convergent and Divergent Findings: Integrating the Data

A comparison of findings from the semi-structured interviews and the QuIC highlights a dichotomy between how well adolescents and their parents felt the actual ICD/IAD went versus how much they actually understood key elements of informed consent and assent. Parents and adolescents showed a considerably higher level of subjective understanding than objective understanding of the essential informed consent and assent elements, meaning they perceived themselves more informed than they actually were. Both adolescents and parents scored low (<70%) in domains addressing individual understanding of foreseeable risks and discomforts as a result of clinical trial participation; potential benefits to self and others; available appropriate alternatives to clinical trial participation; different levels of confidentiality related to clinical trial participation; potential compensation for injury or illness related to clinical trial participation; and whom to contact with questions related to participation in a cancer clinical trial. In six out of eight domains of informed consent and assent outlined in the CFRs, participants averaged less than 70% in their overall scores related to understanding these elements. Seven out of eight adolescents and parents scored above 80% for subjective understanding of the key elements of informed consent and assent with no scores less than 50%. This provides an interesting contrast between participants' actual or objective understanding and their subjective of the same elements of consent and assent. Adolescents and parent participants felt more informed than they actually were which parallels similar work in oncology consent research with adults who were generally satisfied with the informed consent experience but demonstrated less than clear understanding of key elements (Joffe et al., 2001).

QuIC findings for Part A indicated a low level of objective understanding of the essential elements of consent and assent that seems to match the participants' description of "*bad memory*" or poor recollection of ICD/IAD details and lack of reference to the essential elements of the ICD/IAD in their narratives. The fact that both adolescents and parents described difficulty and frustration at not being able to recall details of the ICD/IAD parallels the low scores for objective understanding of the technical elements of the consent and assent discussion.

However, "*bad memory*" or poor recollection of the actual details of the ICD/IAD seems to contrast their overall positive perception of the process and their physician provider. Physician providers that were straightforward and spoke in clear *layman's terms* were appreciated and hailed as a positive part of the ICD/IAD. The ability for physician providers to match their delivery style and communication with the preferences and needs of adolescents and parents was considered part of the success of the overall ICD/IAD.

Divergent findings include the idea that when asked to describe their overall informed consent and assent experience, adolescents and parents focused on more subjective perceptions of the experience. Adolescents and parents moved beyond descriptions of the consent and assent environment, perhaps as a defense against their poor recollection of key concepts in the ICD/IAD. Instead, they focused on what went well during the discussion. This may indicate superficial misconception of understanding that was not identified by their physician provider during the actual ICD/IAD or an experience of being inundated with complex information and inability or lack of time to process clinical trial participation in the face of a new oncology diagnosis. As adolescents and mothers discussed memories of the consent and assent environment, they provided details about their providers that seemed to influence their experience of in a positive way. Physician providers who were forthcoming with adolescents and their families and used language they could understand, were appreciated. Physician providers who did not appear rushed were highlighted as good providers. Additionally, physician providers who helped families feel included in this decision-making process created strong connections that helped to establish a sense of trust and rapport.

Creating time and space between discussions related to diagnoses and discussions related to consent and assent was important to physician providers and families alike. Physician providers indicated that their preference was to spread out the discussions over several days to allow for adequate time for families to process the new information. Yet, they expressed frustration at the necessary rushed pace that must be kept to give adolescents their best chance at a positive outcome.

Some of the negative aspects of the ICD/IAD were related to the inability of adolescents and their mothers to recall all that they wanted to about the ICD/IADs. Adolescents and their mothers focused on their own functional memory as an important element of their ICD/IAD and described their memory as "*bad*", sometimes expressing fear and concern related to what they could not remember about the discussion. This highlights the necessity of revisiting the elements of the ICD/IAD with patients and families throughout their participation in a clinical trial. The idea that consent and assent are ongoing processes is one well documented in clinical research ethics literature (Capron, 2008), yet the reality of clinical practice does not often reflect this in any formalized pattern.

Altruism seemed to motivate some of the adolescents' and mothers' participation decisions, allowing them to feel some level of pride in their decision to participate in a cancer clinical trial and, to some extent, softening the devastating news of a new cancer diagnosis. Adolescents and mothers expressed gratitude at being able to "tell their story" and wanted to share with future cancer patients the message that they are not alone.

Participants' descriptions of their individual *roadmaps* comprised an important component of how they remembered the ICD/IAD and illustrated what elements of that discussion seemed to stick out as important to remember. Although physician providers also highlighted the roadmap, mothers and adolescents seemed to hold onto the details of the roadmap in an effort to regain control in an overwhelming situation.

Discussion

Key Lessons

This study offers a triadic evaluation of informed consent and assent experiences as reported in near real time by adolescent, parent and physician provider. Study measures and initial interviews took place within 48–72 hours of the informed consent and assent discussion for the oncology clinical trial. A rare glimpse into what is happening in these discussions from the perspectives of the participants without the potential biasing effect of an informed consent researcher in the room observing the oncology clinical trial informed consent discussion provides a new lens for evaluating this complex experience.

Discrepancies between the QuIC results and perceptions articulated during interviews with adolescents, parents and physician providers demonstrate a conflict between participants **feeling** informed and actually **being** informed. Adolescents and their parents generally felt more informed than they actually were. Part B summary scores of the QuIC for both adolescents and their parents indicated higher subjective understanding of key elements of informed consent which parallels their excellent perceptions of the overall experience as described in their interviews and indicates that they felt informed. Contrasting results from Part A of the QuIC indicated that they were less informed than they felt were. While these findings do not diverge from the initial QuIC research completed by Joffe and colleagues (2001), they do provide a more nuanced background for interpreting the participant perceptions as articulated by adolescents and their parents in the interviews in this study. It is difficult to separate the experience of distress and uncertainty associated with a new oncology diagnosis and the experience of informed consent and assent in this population as these two complex experiences happen in nearly the same space and time and are often overlapping. Perhaps it is not a realistic expectation for adolescents and their parents to demonstrate clear understanding of the key elements of assent and consent process within the context of a new oncology diagnosis, yet the basic tenets of human subjects' protection must be attended to with valid and meaningful informed consent and assent discussions. This presents real challenges for researchers and clinicians and reflects the complexity of this space in the journey for adolescents and their parents.

Limitations and Strengths

During the recruitment period there was a significant drop in the number of new oncology cases at the primary site as well as an unusually low number of open clinical trials for this particular age group when compared to the previous two years. A total of four eligible triads surfaced and all four eligible triads agreed to participate in this study. Although this represents a small sample size, the study generated a substantial amount of qualitative data for analysis with over 30 hours of interviews for analysis, indicating a high level of

engagement with participants and a significant interest from participants in ‘sharing their story’. This design included a retrospective look at the consent and assent experience. Retrospective descriptions of complex processes can sometimes create skewed representations of the actual process. In this study, the retrospective nature of the interview was a benefit, as participants had time to reflect on their assent experience and provide insights that may not have been available ‘in the moment’ or during their actual consent and assent experience. In addition, the QuIC was piloted with an adolescent sample for the first time in this study. Average time for completion of the QuIC was 10 minutes for adolescents and 12 minutes for parents. All adolescent and parent participants reported that the QuIC was “easy” to complete, although some parent felt that the questions seemed repetitive, as the language used in different questions seemed very similar. This questionnaire may be a feasible tool to use in this population but must be tested in a larger population to provide additional evidence for validity and reliability with this age group.

Conclusions

Implications for Future Research

The original developers of the QuIC indicated that adequate disclosure of information and adequate individual capacity could be assumed for the domains where subjects performed well (Joffe et al., 2001). Further, the QuIC could potentially act as a screen for adequacy of both disclosure and capacity, with lower domain scores indicating problem areas for understanding. Understanding the origin of participants’ misunderstanding of the key elements of consent and assent may illuminate areas for future intervention-based research focused on improving the overall quality of ICD/IADs. Future studies may include the use of the QuIC shortly after the cancer clinical trial ICD/IAD followed by in depth qualitative interviews aimed at exploring the origin of the participants’ misunderstandings of informed consent and assent.

While this study may have uncovered rich descriptions of the consent and assent process from the perspective of the participants, much work is needed to begin building a conceptual framework for further empirical study. Future research designs should involve audio-recording of the actual assent process for the cancer clinical trial coupled with qualitative retrospective interviews after the assent process so that participant perspectives can be compared and integrated with actual content analysis of the ICD/IAD.

Implications for Practice

Findings from this study indicate that this sample of adolescents and their mothers generally felt positively about the physician providers that facilitated the consent and assent discussion. When adolescents and their mothers had a positive impression of their physician providers and their physician providers’ communication style, participants had an overall positive impression of the consent and assent experience. Exploring this notion of connectedness with physician providers as a measure of overall satisfaction in the ICD/IAD for pediatric oncology research can provide focus for the physician provider’s approach to these discussions.

Additionally, adolescent participants in this study demonstrated a need to hear certain elements of the consent and assent discussion in language they could understand. The high level of interaction and engagement on the part of the adolescents in their descriptions of the consent and assent experience illuminates the necessity of involving adolescents in the discussion in a meaningful way that takes into account the wide variation in their developmental level and level of maturity. Providers must be cognizant of the necessity to meet the adolescent where they are and must spend time identifying the specific informational needs of each adolescent and their families.

Final Thoughts

As the number of pediatric clinical research participants continues to rise, researchers are obligated to elevate the science and literature surrounding crucial elements of human subjects protection for this vulnerable population. Children and adolescents are not just small adults, and the study of their experience of consent and assent and involvement in crucial decision-making processes should be focused specifically as their unique set of characteristics make them different from adults. Research that honors the developing autonomy of children and adolescents and takes into account the wide variation in their development and maturation is necessary to create empirically-based guidelines for the operationalization of the concept of consent and assent in real time clinical research practice.

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Highlights

- Despite reporting positive perceptions of their experiences in informed consent and assent, adolescents and their parents have poor recollection of essential elements of informed consent and assent.
- Rushed timelines and vast amounts of information make consent and assent difficult processes to facilitate.
- Adolescents and parents highlight real ‘ connections’ with their providers as markers for a good consent and assent process.

Table 1

Template Utilized for all Semi-Structured Qualitative Interviews for Adolescents and their Parents/Guardians

Opening Statements	
Thank you for agreeing to participate in this conversation with me about your informed consent/assent experience. I would like you to tell me the story about how you decided to (or not to) participate in the cancer clinical trial with Dr. X.	
Questions	
1	Describe what this experience was like for you. What happened on the day of this discussion' Tell me about that particular day.
2	What happened during the informed consent/assent discussion? What was it like? What was The room like? Who was in the room?
3	Who did most of the talking? What did they say? What did you say to them?
4	What was most helpful about this experience? What was least helpful about this experience?

Notes. Derived from Interview #1, which took place within 72 Hours of the Informed Consent Discussion/Informed Assent Discussion for the oncology clinical trial.

Table 2

Adolescent and Parent/Guardian Participant Demographic Characteristics

Characteristic	Adolescents (N)	Parents/Guardians (N)
Gender		
Male	3	0
Female	1	4
Race		
Caucasian	0	0
African-American	4	4
Age		
12–14 years	1	
15–16 years	1	
17-<18 years	2	
25–34 years		0
35–44 years		3
45–54 years		1
Diagnosis		
Acute Myeloid Leukemia	1	
Hodgkin's Lymphoma	1	
Sarcoma	2	
Phase of Cancer Clinical Trial		
Phase II	0	
Phase III	4	
Previous Clinical Research Experience		
None	4	3
1x or >	0	1
Length of Assent Form for Cancer Trial		
1 Page	4	
>1Page	0	
Length of Consent Form for Cancer Trial		
10–19 pages	1	
20–29 pages	2	
30–39 pages	1	

Table 3

Clinical Research Staff Participant Demographic Characteristics

Characteristic	N
Gender	
Male	2
Female	1
Race	
Caucasian	3
African-American	0
Age	
25–34 years	0
35–44 years	3
45–54 years	0
Role of Clinical Research Staff	
Physician/Principal Investigator	3
Years of Clinical Research Experience	
0–5	1
6–10	1
11–20	1
Years of Pediatric Clinical Experience	
0–5	1
11–20	2
Continuing Education Completed in Last 1–3 years	
CITI Training	3
Focused Training on Ethical Conduct in Clinical Research	1
Focused Training on Informed Consent/Assent in Clinical Research	1
Focused Training on Pediatric/Adolescent Participation in Clinical Research	0
Other Continuing Education Activity	1
Continuing Education Experiences over the Lifetime	
CITI Training	3
Focused Training on Ethical Conduct in Clinical Research	3
Focused Training on Informed Consent/Assent in Clinical Research	3
Focused Training on Pediatric/Adolescent Participation in Clinical	1
Research	
Other Continuing Education Activity	1

Table 4

QuIC Summary Scores for Adolescent and Parent Participants

Characteristic	Participants			
	Adolescent 1	**Adolescent 2**	**Adolescent 3**	**Adolescent 4**
Race	AA	AA	AA	AA
Sex	F	M	M	M
QuIC Score (Part A)	72/100	66/100	53/100	66/100
QuIC Score (Part B)	82/100	86/100	60/100	89/100
	Parent 1	Parent 2	Parent 3	Parent 4
Race	AA	AA	AA	AA
Sex	F	F	F	F
QuIC Score (Part A)	47/100	70/100	52/100	67/100
QuIC Score (Part B)	86/100	100/100	100/100	86/100

Note. AA = African American; F = female; M = male; QuIC Score (Part A) > *Objective Understanding Summary Score*; QuIC Score (Part B) > *Subjective Understanding Summary Score*

Table 5

Themes and Key Illustrative Quotes

Theme & Definition	**Key Quotes by Participant Role**		
	Adolescent	**Parent**	**Provider**
Altruism – Participants highlighted their desire to give back as a motive for participating in a clinical trial.	Dr. XX told us about it and I was like, yeah, sure, why not. Because *if it helps someone else* and especially at this time in their lives they should figure out and know that someone else went through it.	Yeah, we're big givers and *we like to give something back* and my son like I said, he cares so much about other people, sometimes he forgets himself. … So that the next time somebody, a child comes in in her situation or similar you know, using her stuff… *contributing what they doing to her to the next person* so that they'll know how to *help the next person*.	And then just basically told them that you know it's totally optional but it's also fairly standard king of therapy…her therapy would essentially be identical whether she was in the study or not. So a lot of this is just *gathering data for the future* (*patients*) of the world.
Overwhelmed – Participants expressed a feeling of being inundated with a large amount of information to include a new oncology diagnosis and subsequent complex informed consent and assent discussion that involved complex concepts and words.	Well, the doctor did most of the talking. I was *a little bit confused* so I just sat and didn't' say much of anything. I didn't really say anything during that conversation. …a *big word* that described one of the medicines, as soon as he said that, that lost me right there. …He used that, he *used a giant word* in every sentence. I didn't know what they meant. Why did the doctors use such *big words*? He said he has to learn all of them so he's going to have somebody listen to them.	It wasn't real, you hear about this, you know people that go through this but you never think that it's going to happen to you and then when it's your child and you have no control over it, it's like, it is *overwhelming* and it's hard. It was just all of the paperwork that I had there signing over the last week or so… It was just *overwhelming* anyway having to read something else long again.	It is always so much new information and such *complex information* that families struggle to absorb. Cancer is so *overwhelming*, there are so many issues that need to be addressed… it's just an *overwhelming amount of information* to talk about, drugs and all of their toxicities and the concepts of clinical trials, the concepts of trying to have to be homebound, changing your entire life for a year, it's a lot for a family to absorb and so I always feel, and this is no exception, that it's very hard because families so frequently express being *overwhelmed*.
Fear and Lack of Control - Participants referenced a sense of trepidation about and lack of ability to manage a new oncology diagnosis and subsequent treatment options and decisions including clinical trial participation.	I was *scared* because I didn't want any more bad news.	Now there is a thin line between sane and insane, and I really, really, really realized that when I found out that my son had cancer, because I was, I was on the verge of just like a mental breakdown. … [W]hen stuff is *out of my control* I just don't know what to do. I panic, I don't know what to do when it's out of my control and you want to do everything you can to make it right because that's what mom is supposed to do.	**Providers did not provide discussion of content related to this theme*
Physician Provider Communication -	I liked the fact that he didn't jump	First of all he kept making eye contact with my son,	So I was sitting on a stool. The patient

Theme & Definition	Key Quotes by Participant Role		
	Adolescent	**Parent**	**Provider**
Participants described positive provider interaction and behaviors during the informed consent and assent discussions.	around the bush, and he told me *straight forward* The way she just *tells it like it is* Like she shows that she cares and that she is *trying her best* to help.	with myself and with his dad. So he made each one of us feel that *we were part of the conversation*, which is very important. She is a very very *to the point* type person. Most people in situations like that they care more about the research than the patient…*She was totally into X* and getting her straight and squared away. He also did not talk to us in so many *medical terms*. You know he did say the medical…information. You know names and treatments and types and different things. But then he gave it to us in layman terms, which was really good.	was on the exam table. Mom was sitting in one of the chairs and the nurse was sitting in the other chair. So we were all seated and the patient was higher than eye level *so at least we were able to sit and all be face to face* essentially in a tiny little circle. I think the hard part is that a lot of families, the consent forms just overwhelm them and they don't get it, for a lot of families I don't think they read the consent forms because they are so overwhelming. So for me I try to really sum up in *layman terms* as possible what the study is about…trying to use examples that would make sense in the day to day rather than in the medical world.
Timeline and the Rush – Participants felt the quickened and pressured pace necessary to implement a plan for treatment and clinical trial participation after a new oncology diagnosis despite their wish for more time to consider clinical trial participation.	I wish everything, I wish everything would slow down. It does *go fast* and some things I would like to slow down…It seems like everything was *moving so fast, I* don't really have time to really think about it all that much.	You *need to take time* especially in these situations with juveniles…Because I mean you have to consider that you know I just thought that he had this upper respiratory thing, bronchitis you know, a bad cold. And in an hour and a half my life change, his life changed…I mean our lives completely changed the moment that doctor said leukemia.	It's hard because it always feels so *rushed* in having to talk about so many things. That day was *chaotic* from the outside of that room. …because I was on hospital service and there were other things going on so I was bouncing around…I think in, you know, the ideal world I would have liked to have had a little bit more face time with X…in some ways it felt *rushed*.
The Protocol Roadmap - Participants outlined the necessary steps in the process for oncology clinical trial participation, to include calendars, medications, procedures, and other trial specific time points.	She called us in that day to tell us about what she's going to be doing and what *type of medicine* I'll be taking and stuff. And *how often* I take it and how, *how many days* of that week will I be in the hospital and *how long* I'll take chemo and radiation. And she	You can see the little *road map* that was there. Because if you did okay, if you did okay with the first one, if it lessened, then it would be either minimum or no radiation.	There is actually kind of a *schema* of how you decide where kids go.

Theme & Definition	Key Quotes by Participant Role		
	Adolescent	**Parent**	**Provider**
	told us if the first cycle doesn't help shrink she'll keep going and going until it can shrink so they can take it out.		
Poor Memory - Participants were unable to remember specific content of the informed consent and assent discussions.	I don't really remember that day; I just have a *bad memory*. I don't remember the content. He told me what my diagnosis was. *I can't remember* what. I can't remember what he said it was. I didn't talk much at all until the end, like after she explained everything. I asked some questions. *I don't remember* what those questions were…I repeated what she said to make sure.	So I just basically, I mean, I think I understood at the time but once she left out the room… *I really didn't remember* what we talked about. Like honestly and that was scaring me too, like I just had a whole conversation about my baby with this lady and honestly *I don't remember* what it was about. I *really don't remember*. I was honestly going through so much, so I hardly remember actually the conversation, honestly. *I can't remember*. She says she gets 12 bouts of chemo or then she starts radiation or….She told me. I *just forgot*.	**Providers did not provide discussion of content related to this theme*