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Assent Described: Exploring Perspectives From the Inside[1,2,3,4,5]

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Informed consent;
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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 that 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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Involving children in decision making about participation in clinical research is mandated in this country by the Code of Federal Regulations (CFRs) and is manifested 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 (Best Pharmaceuticals for Children Act, 2002; National Institutes of Health, 1998; Pediatric Research Equity Act, 2003) 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

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[4] Conflict of Interest: none.

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(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 (Coyne, 2006; Miller, Drotar, & Kodish, 2004), 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 et al., 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 et al., 2007; Johnson et al., 2015; Resnik, Peddada, Atilio, Wang, & Menikoff, 2008). 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 4000 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 that 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 et al., 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 that 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, Cook, Cleary, Clark, & Weeks, 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, & Brandberg, 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).

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