Theory-guided Assessment of Barriers and Facilitators to Adequate Informed Consent for Childhood Cancer Clinical Trials: Using the *Exploration, Preparation, Implementation, Sustainment* (EPIS) Framework

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ABSTRACT

BACKGROUND. To participate in childhood cancer clinical trials, parents/legal guardians must provide informed consent, which is a fundamental ethical right. However, barriers to achieving valid informed consent have been reported in the literature and include the use of medical jargon, misunderstanding about clinical trials procedures, tremendous emotional distress surrounding the initial cancer diagnosis, and the complexity and length of the inform consent forms. There are scarce data on using theory to assess perspectives of parents of children with cancer on barriers and facilitators for adequate informed consent in diverse populations.

OBJECTIVE. Using implementation science theory and methods, we assessed parent-reported barriers and facilitators to adequate informed consent, in a convenience sample that included a significant number of Hispanic parents.

METHODS. Twelve qualitative semi-structured interviews and 224 open-ended surveys were conducted with 236 parents of children with newly diagnosed cancer at Rady Children's Hospital San Diego, a large quaternary children's hospital in California. Fifty-three percent of participants were Hispanic and 38% of Hispanics used Spanish for medical communication. We utilized the implementation science *Exploration, Preparation, Implementation, Sustainment* (EPIS) Framework, specifically domains of outer context, inner context, bridging and innovation factors to assess barriers and facilitators to adequate informed consent. Four main codes (informed consent concepts and delivery; desired clinical trial information; motivations and emotions related to clinical trial enrollment; and potential areas for interventions) were used as a coding guide for analysis. Interviews and surveys were transcribed and coded for thematic analysis by three independent coders trained in qualitative methods to identify key barriers and facilitators.

RESULTS. Four main themes were identified as barriers: 1) Complexity of the informed consent forms and discussion (lengthy, confusing, not available in Spanish, and use of medical jargon); 2) parents feeling emotionally overwhelmed, anxious, and pressured around the informed consent; 3) parents viewing the clinical trial as the only treatment option; and 4) mistrust and fear of clinical trial procedures. Four informed consent facilitators were identified: 1) simpler explanations of study procedures; 2) provider training and flexibility for accommodations when delivering the informed consent, including additional time for decision-making and psychosocial support; 3) active promotion of voluntariness and trust; and 4) supplemental education in lay language, including request for peer-education, decision aids, and navigation to "bridge the provider-patient gap."

CONCLUSIONS. Our implementation science approach identified multiple barriers and facilitators to adequate informed consent in a diverse sample of parents. Findings can inform potential interventions to enhance informed consent for childhood cancer clinical trials, including the use of decision aids, peer-navigation, and interventions tailored to the language and culture of the individual.