As pediatric oncologists, we often ask parents to do the unthinkable: grapple with a child’s new cancer diagnosis and participate in a clinical trial informed consent discussion within hours to days of each other. Informed consent is essential to our practice because access to clinical trials is the standard of care in pediatric oncology. These discussions are both emotionally charged and medically complex, adding challenges to effective communication. Nearly 2 decades ago, Kodish and colleagues first examined this process in a cohort of parents consenting to therapeutic trials for children with newly diagnosed acute leukemia and found that only one-third of parents understood the concept of randomization and that non–English-speaking families were less likely than English-speaking families to understand key aspects of informed consent. Since then, our trials and informed consent discussions have become more complex. Aristizabal et al found that these gaps in our informed consent process persist, particularly for historically marginalized groups exposed to adverse social determinants of health.

Aristizabal and colleagues conducted a cross-sectional study in a cohort of English-speaking and Spanish-speaking parents of children with newly diagnosed cancer enrolled in a therapeutic clinical trial at a quaternary pediatric cancer center to understand the associations of specific social determinants of health with informed consent comprehension across 4 domains: (1) purpose, procedures, and randomization; (2) risks and benefits; (3) alternatives; and (4) voluntariness. The authors designed their study questionnaire with rigor, using a validated set of instruments related to informed consent comprehension and applying a comprehensive process of back-translation to instruments that were not previously validated in Spanish. Importantly, the study team comprised bilingual and bicultural staff members and was successful in recruiting an ethnically diverse cohort of 223 parents, 49.8% of whom identified as Hispanic.

The authors report that limited health literacy was independently associated with lower informed consent comprehension overall and across all 4 domains. Preferred Spanish language for medical communication was also independently associated with lower informed consent comprehension overall and lower comprehension in the purpose, procedures, and randomization and voluntariness domains. Interestingly, lower satisfaction with the informed consent process was also independently associated with lower comprehension overall and in the alternatives domain.

These data demonstrate that our current informed consent processes are inadequate to support families with limited health literacy or who do not speak English as their primary language. Despite data reaffirming this inequity over the last 2 decades, there are still no evidence-based interventions focused on improving the informed consent process in pediatric oncology. Notably, Dr Aristizabal is currently conducting a multisite efficacy trial of a peer navigation intervention to improve research literacy among Hispanic parents of children with cancer during the informed consent process.

Another interventional target to improve the informed consent process rests at the practitioner level. The authors of this study suggest that the association of satisfaction with comprehension may be explained by the quality of the informed consent discussions. This hypothesis is supported by prior data demonstrating that pediatric oncologists omit key details, including specifics of the clinical trial and explanations of randomization and the right to withdraw from a trial, during informed consent discussions with parents who do not speak English more than they do in consent discussions with those who speak English. Pediatric oncologists also greatly underestimate the amount of information Black and Hispanic parents want to know about their child’s prognosis, despite the fact...
that most parents want to know as much information as possible, regardless of race and ethnicity.4 Therefore, strategies to enhance practitioner communication and reduce practitioner bias with historically marginalized groups during informed consent discussions are compelling intervention targets and are urgently needed to rectify these demonstrated inequities.

A notable limitation of this study3 is that the authors report data on parents who had already consented to clinical trial participation. Further characterization of parents who declined clinical trial participation or were not offered clinical trials may provide other meaningful targets to advance equity in the informed consent process and in clinical trial representation. This is particularly important in light of national calls to improve access to clinical trials, because clinical trial enrollment does not match the racial and ethnic makeup of the US.5 These disparities are becoming more pressing as the non-Hispanic White population is expected to make up less than 50% of the US population by 2045, largely owing to growth in the Hispanic population.6

Finally, although these results3 shed light on limitations to the current informed consent process for Hispanic children with cancer and their parents, they are not the only group at risk of poor informed consent discussions. First, Black adults have lower health literacy scores than non-Hispanic White adults, putting them at risk of poor informed consent outcomes.7 In addition, practitioners underestimate the prognostic information Black families want even more so than Hispanic families.4 Second, Spanish-speaking families frequently have the benefit of some care team members who are fluent in Spanish, in-person interpreters, and fully translated consent documents, unlike families who speak other languages. Data on informed consent outcomes in children with cancer in those groups are lacking.

Nonetheless, Aristizabal and colleagues3 have taken a critical step in identifying specific risk factors for decreased informed consent comprehension, yet another mechanism by which historically marginalized populations receive inequitable care in pediatric oncology. The onus is now on the pediatric oncology community, including health services investigators, clinical trialists, and our cooperative groups, to move the science of informed consent discussion beyond describing these disparities and toward the development of evidence-based practices to advance equity in informed consent discussions.

ARTICLE INFORMATION
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