

# Childhood cancer patients enrolled in clinical trials need clearer communication about their role

March 29 2010

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A small study of children with cancer enrolled in therapeutic clinical research trials shows that they don't fully understand what physicians and parents tell them about their participation, nor do they feel they are genuinely involved in the choice to take part.

The study, led by Yoram Unguru, M.D., an associate faculty member at the Johns Hopkins Berman Institute of [Bioethics](#), will be published online March 29 in the journal *Pediatrics*.

While an estimated 70 percent of young cancer patients participate in [clinical trials](#) during their treatment, more than half of the 37 children who were interviewed for the study did not know or recall that their treatment was considered experimental or part of research, the investigators report.

And out of a subset of 22 children, 19 of them did not understand their doctors' explanation at the time they agreed to take part in the clinical trial.

In addition, irrespective of age, every child interviewed with a 69-part questionnaire said they wanted to be involved in decision-making about their care and participation in research. Permission to participate in Unguru's study was sought first from the parents and adult caretakers, and then from the children.

"It was very enlightening to listen to the kids themselves talk," said Unguru, a pediatric hematologist and [oncologist](#) in Baltimore at the Herman and Walter Samuelson Children's Hospital at Sinai. "For the vast majority, their parents were the ones who made decisions and decided what was going to happen."

Longstanding doctrines are in place to ensure that human research subjects understand and consent to participate in advance. Furthermore, federal law explicitly requires that children must "provide their affirmative agreement" to participate in research "whenever possible."

Meanwhile, the American Academy of Pediatrics Committee on Bioethics states that doctors should ascertain that children comprehend information they are given about their treatments. In conjunction with the Belmont Report — a core historical document that lays out ethical principles and guidelines — Unguru says the onus is on physician-investigators to verify that childhood patients understand.

However, it turns out that little rigorous research has been done to determine just how much minors with cancer actually understand about the treatment trials, Unguru says. He explained that, when doctors diagnose a child with cancer, they often also know about clinical research projects that hold promise for treatment and ask their patients and parents if they would like to participate.

Typically, physician-investigators first ask the adult decision-maker, then turn to the child. Unguru said some doctors are very thorough throughout this process, while others aren't.

"Rather than going through the assent process as it was meant to be done, often times the child signs a piece of paper, and all it represents is an empty signature," Unguru said. "The child may not know what he or she is signing because the parents often just say, Sign here."

The study is the result of face-to-face interviews with [cancer patients](#) from age 7 to 18 years and is believed to be the first examination of children's understanding of — and preference for — involvement in research. Unguru says past studies on children's comprehension of research participation have largely relied on hypothetical cases based on surveys of healthy, older adolescents.

Unguru acknowledged that age — or perhaps even the young patients' health, or state of shock and confusion in the face of a cancer diagnosis — might have made it impossible for some of them to fully grasp the concepts of clinical research. But, he insists, that doesn't mean doctors shouldn't at least try to do better.

"I argue that we have to do better, because if we do agree that assent is an important process and an important ideal, then we have no other choice," Unguru said. "The notion of assent is that you're respecting the child's developing sense of autonomy, dignity and future decision-making potential."

While the sample size was small, given the relatively few number of children in the United States who are diagnosed with [cancer](#) every year (12,500), Unguru said the results were consistent and useful as a pilot study and basis for further research.

Provided by Johns Hopkins Medical Institutions

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