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Parents experience difficulty with consent process in pediatric cancer trials

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Compared with adult cancer patients, parents of children with cancer were more likely to be dissatisfied with the informed consent process for participating in clinical trials, according to a study from Dana-Farber/Children's Hospital Cancer Center. The findings will be presented at the 42nd Congress of the International Society of Paediatric Oncology (SIOP) in Boston on Saturday, Oct. 23.

Parents who had agreed to their children's enrollment in treatment trials said they felt hurried in making the decision, the researchers said. They also perceived themselves as less well-informed about the clinical trial protocols than did adult patients, even though tests showed they understood the issues equally well.

"These findings were consistent with what we suspected, given the different contexts in which adult and pediatric clinical trials are offered," said Steven Joffe, MD, MPH, senior author of the study. "But I didn't expect such large differences."

The researchers administered questionnaires to 47 parents and 204 trial participants within two weeks after the clinical study began.

Results showed that only 64 percent of parents felt they had enough time to learn about the trial, compared to 87 percent of adults. The parents were also less likely (79 percent to 93 percent) to report that they had sufficient opportunity to ask questions.

Even though they scored about the same on objective tests about the trials' particulars, parents of children with cancer rated themselves as less knowledgeable (79.5 percent) than did adult patients (87.8 percent).

Joffe, an ethicist and pediatric hematologist/oncologist at Dana-Farber/Children's Hospital Cancer Center, attributed much of the disparity to the differing contexts in which adults and pediatric patients are offered clinical trial participation.

"The adult patients tended to have solid tumors and had lived with their disease for a long time. Most of the adult patients were offered a trial because they had relapsed or their disease had progressed," he noted.

"For these patients, there wasn't as much urgency in getting started on a protocol, and they had moved beyond the initial crisis of learning that they had cancer."

Conversely, about three-quarters of the pediatric patients were facing a new diagnosis of cancer – usually a blood malignancy like leukemia.

"Often they were in the hospital and their parents had known about the diagnosis only for a day or two, and they had to make urgent decisions at a time of tremendous shock and emotional upheaval," Joffe said. "The parents were often overwhelmed and it made them feel less certain they understood the information they were given about the trial."

Joffe said the study confirms concerns that have already prompted efforts to alleviate the confusion surrounding decisions made in the middle of an emotional crisis. For example, some medical personnel now make a return visit to patients or parents "after the initial storm has passed" to make sure they have understood the protocol correctly.

Also, clinical researchers, in some cases, are relieving clinical study

recruits of the necessity to make decisions on all aspects of a trial right away, he said. "Often there are randomizations to one treatment or another that occur later in the overall trial, and we are delaying the consent process for those aspects rather than asking people to make all those decisions on Day One."

Provided by Dana-Farber Cancer Institute