Clinical trials for childhood cancer drugs are critical, but parents don't always understand them

February 25 2016, by Laura Sedig And Raymond Hutchinson, University Of Michigan

Credit: AI-generated image (disclaimer)

Each week in the United States, about 300 children are diagnosed with cancer. Many of them will be offered treatment as part of a clinical trial that tests different drugs or different ways to give standard drugs.

The dramatic improvements in survival for children with cancer depend on these clinical trials, and these trials depend on parents understanding the possible risks and benefits involved.

But the parents of these young patients are usually unfamiliar with how these clinical trials work and are dealing with factors that make it difficult for them to give informed consent.

Clinical trials for children with cancer are important

Clinical trials work in four phases, each meant to further assess the safety, optimal dose and effectiveness of the drug or treatment regimen. When we talk about clinical trials in this article, we are referring to phase III clinical trials.

Phase III clinical trials compare a newly designed treatment, or "experimental arm," with the current standard of care, or "standard arm." For children with cancer, the standard arm is the current best standard for treatment based on previous research. The experimental arm may involve the addition of a new medication or medications, variation in the doses or a different schedule for giving a medication.

Credit: Vlada Karpovich from Pexels

By the time a new drug is in phase III clinical trials, it will have already been tested in earlier phases for safety and efficacy. The goal of phase III clinical trials is to improve survival and/or decrease side effects when compared to previous treatment regimens. Phase IV clinical trials for a new drug are the continued collection of data after its use is more widespread.

Thanks to phase III clinical research trials, the number of children who are still alive five years after receiving a diagnosis of leukemia has increased from 48 percent in the late 1970s to 84 percent in the 2000s. In the same time period, the percentage of children who are alive five

years after diagnosis of any cancer has improved from 63 percent to 83 percent.

To participate or not: that is the question

After a child is diagnosed with cancer, the physician will discuss treatment options and the possibility of participating in a clinical trial with the child's parents. If the parents choose for their child to participate, they will sign a written consent document provided by the organization coordinating the trial.

Parents have to decide relatively quickly if their child will participate in the trial so that treatment can begin. If parents opt out of the trial, the child receives treatment similar or identical to that offered in the standard arm of the trial, but the child's results won't be recorded for the trial.

Parents don't always understand what participating in a trial means

In this situation, parents often struggle to make the best decision for their child and are fearful of making a wrong decision. Parents have to consider the risks and benefits of treatment overall as well as potential risks and benefits of participating in the trial.

Previous research and our own personal experience as pediatric oncologists finds that parents don't always understand critical elements of how these trials work.

Clinical trial participation is always voluntary, and parents may choose not to have their children participate without fear of consequences. Unfortunately, parents do not always realize that they have a choice.

Additionally, they may find it difficult to say no to the physician now responsible for their child's care.

Children in these clinical trials are randomly assigned by a computer to receive either the standard treatment or the experimental treatment. Neither the physician who is enrolling the patient nor the researchers in charge of the study have any input into which arm a particular child will end up on. Unfortunately, previous research demonstrates that parents struggle to understand how their child will be assigned to the standard arm or the experimental arm.

Phase III clinical trials compare a new treatment with an established one, to look for differences in survival rates and side effects between the two treatments. These differences are unknown at the start of the trial to everyone involved. This is called clinical equipoise and it is the foundation of the research design.

Parents often struggle with the fact that the physicians do not know which treatment is better. We are frequently asked to "do what is best for my child," but we do not know which arm of the study will be better, making it impossible for us to guide the parents. Some parents are comforted that the treatment arm their child is assigned to is randomly assigned and that the better outcome is unknown so that they do not have to make a decision. Others find the uncertainty disconcerting.

Despite the initial uncertainty, if there a big difference in survival or side effects are noticed before the trial is over, the study will be stopped. A participant's treatment will usually then be changed to the arm with better survival or fewer side effects.

Can we make the decision process easier for parents?

These are big issues for parents to understand before they sign the

written consent form and enroll their child in a clinical trial.

Despite these obstacles, many parents want their child to participate in a trial, especially if they feel it is not too burdensome and could be beneficial for their child. Some parents also feel that having their child participate in the trial is a way to give back since their child is benefiting from the previous participation of other children.

Several studies have asked parents for suggestions to improve the consent process. Their ideas include making sure people have enough information but not an overwhelming amount of information, speaking without medical jargon, giving better educational materials and staging the consent so that the discussion spans several meetings.

Additional studies demonstrate that parents who choose to read the entire consent document are more likely to understand randomization. Also, those who understand randomization are more likely to have their child join the clinical trial, suggesting that more understanding is good for both parents and researchers.

Phase III clinical trials are complicated. While there is always the chance of unforeseen events, parents should know what they are signing up for, how it can impact their child and how it can impact future children. Research shows that there is both room to improve how and what parents learn about trials and novel ways to do it.

This article was originally published on The Conversation. *Read the* original article.

Source: The Conversation

Citation: Clinical trials for childhood cancer drugs are critical, but parents don't always

understand them (2016, February 25) retrieved 27 April 2024 from https://medicalxpress.com/news/2016-02-clinical-trials-childhood-cancer-drugs.html