

HIGHLIGHT

Jane Hankins, MD, MS*

Should My Child Participate in This Research Study?

(Commentary on Liem et al., page 129)

You identify a clinically significant problem and come up with a great idea for a research study. Then, you assemble a strong team, obtain the best equipment and other important resources, secure funds, and identify a large pool of eligible patients. Unfortunately, once the study opens, recruitment does not go as well as you had planned or is not completed within the projected time frame [1]. This scenario, regrettably, is far from uncommon in studies involving children. Many factors can play a role on why recruitment is insufficient or slow in pediatric studies. Despite a solid overall administrative structure of the clinical project and high level of enthusiasm and commitment of the research team, the interest of the child and parent in making the research commitment may become a key factor that governs participation. Factors that play a role in decision-making regarding participation in research are fascinating and complex. Factors influencing the participation of children with sickle cell disease (SCD) in research studies are virtually unknown, and an improved understanding of this area can help improve the success in accrual and retention in clinical trials of children with SCD.

Parents consider multiple issues while deciding whether their child should take part in a research study. Factors such as benefit to the child, feelings of altruism, and the perception that research is important are weighed against the risks and inconveniences of their child participating in the study. In the current issue of *Pediatric Blood & Cancer*, Liem et al. have examined some important factors that could contribute to the decision of the participation of children with SCD in a research study. A survey investigating the factors influencing the decision process involving research participation was administered to parents of patients in an urban institution (Children's Memorial Hospital, Chicago, IL) that cares for many children with SCD. Although approximately 50% of the total number of families actively followed by the Institution's Sickle Cell Center participated, the sample seemed to be skewed toward families with higher socio-economic status (80% of respondents owned a car and 70% had at least some college education). Importantly, the majority (86%) of families felt that more research was necessary in the field of SCD, but only little over half would allow their child to participate in a medical research study. Further examination of the reasons for this large gap between the perception that research is important and the actual willingness to be part of it revealed that a personal belief that more research was needed and perception that their child was more severely affected were the strongest factors linked with a positive attitude toward research participation. Prior exposure of the respondent to research was also an influential factor, although less significant. Interestingly, attitudes about research participation did not differ significantly between parents born and not born in the US.

Recruitment of minority populations, such as patients with SCD, poses additional challenges that should not be disregarded by investigators. Culturally sensitive investigators are critical to the success of a study, beginning with the first time the family is approached and continuing throughout the study. The time commitment and logistics of study visits (e.g., distance from the participant's home) should be considered carefully, as these have been important in influencing the decision to participate in a Phase III clinical trial for infants with SCD (BABY HUG) [2]. To facilitate research recruitment in a generally disadvantaged and vulnerable population, the BABY HUG trial used recruitment-neutral research subject advocates to insure that the risks and benefits of the trial were clearly presented [3]. In addition, investigators should be careful and avoid preconceived notions of the ideal study participant. For instance, a factor such as low socio-economic status should not be the basis to rule out a study candidate, as this may not affect adherence with taking the study drug or keeping study visits [4].

Another important question is who should make the decision regarding study participation. How much should the child's opinion matter in the final decision? In an interesting study that looked at children's and parents' perceptions of who should be the main driver on deciding study participation, children expressed their desire to be more involved in the decision-making process, and perhaps even the ones governing this decision [5]. A study has shown that adolescents not only express the desire to be more in control of decisions regarding research participation, but their knowledge about the disease and the specifics of the research project are important determinants of their level of interest and consequently of their consenting to study participation [6].

The findings from the survey by Liem et al. highlight the motivating factors for study participation in children with SCD: patients or parents participate in research studies that they perceive as relevant or beneficial and are related to important issues to them [7]. This and further studies investigating specific and unique factors that influence the decision of research participation among patients with SCD are essential for the success of future studies on this population.

Department of Hematology, St. Jude Children's Research Hospital, Memphis, Tennessee

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*Correspondence to: Jane Hankins, Department of Hematology, St. Jude Children's Research Hospital, 262 Danny Thomas Pl, room R 5037, Memphis, TN 38105. E-mail: jane.hankins@stjude.org

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