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Parent and Child Perceptions of the Benefits of Research Participation

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Abstract

The primary objective of this study was to describe parents' and children's perceptions of the health benefits of research participation. We assessed 180 children ages 8 to 17 years who recently enrolled in medical research and their parents. Of the 136 parents with children on observational protocols, 41% indicated that there would be a health benefit to the child. Their descriptions of benefits revealed that many envisioned a future health benefit to the child arising from improvements in treatment due to the research. There was no difference in ratings of likelihood or importance of benefit between parents of children enrolled in observational protocols versus interventional protocols. Children enrolled in observational protocols were more likely to respond "don't know" to the question about potential health benefit compared to children on interventional protocols. For both observational and interventional protocols, the informed consent process may be enhanced when research personnel explicitly differentiate between different types of potential benefits, including heretofore-unrecognized future direct health benefits.

Keywords

Informed consent; assent; benefit; therapeutic misconception

Prior research suggests that potential risks and benefits are the most important factors parents consider when making a decision about enrolling children in research studies[1]. Misunderstanding the potential risks and benefits may threaten informed decision making about research participation. Ethical concerns have been raised regarding the extent to which participants attribute therapeutic intent to research procedures, typically referred to as the therapeutic misconception[2]. More recently, the therapeutic misconception has been differentiated from therapeutic optimism, which refers to the hope for personal benefit as a result of research participation[3]. Prior research found that only 57% of parents of children enrolled in clinical anesthesia research had complete understanding of direct benefit[4]. Direct benefits refer to those that arise because of an intervention being studied, while collateral

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benefits refer to benefits that might accrue simply by being a research participant[5]. For parents of children enrolled in asthma clinical trials, the highest ranked motivating factor for participation was for the child to learn more about the child's disease, followed by improving medical knowledge and receiving new medications[6]. Prior research suggests that the way in which questions about benefit are asked influences participants' responses. For example, in one study 93% of parents whose children were enrolled previously in a biobanking study answered correctly that there "may not be direct benefit" to study participation. However, 42% responded that one of the main purposes of the study was to treat the child, and 63% responded that participation might help doctors treat the child[7]. In addition, many children and adolescents do not understand that their research participation might not or will not benefit them and are motivated to participate because of hope for a positive clinical effect[8].

To our knowledge, prior studies have not examined parent and child perceptions of benefit for observational research. Such perceptions may have implications for optimizing the informed consent process and helping parents and families to make decisions that are consistent with their values and goals. This paper describes a secondary analysis of a dataset designed to examine children's involvement in research participation decisions. The goal of the overall study was to assess decision making involvement and perceptions of fairness, satisfaction, and voice in children ages 8–17 years who recently enrolled in a variety of different observational and interventional research protocols. The primary objective of the present analysis was to describe the perceptions of both parents and children of the potential health benefits of research participation for the child.

METHODS

Recruitment

We contacted principal investigators (PIs) across the institution, a tertiary pediatric academic medical center in the Northeast, to determine if they had eligible and enrolling studies and solicit their willingness to refer participants. Eligible studies included any study that was currently enrolling children ages 8 thru 17 years. Studies enrolling children with pervasive developmental disorder, developmental delay, psychiatric disorders, or newly diagnosed cancer were ineligible. If both the PI and research coordinator were supportive, then we followed-up with the research coordinator on a recurring basis to ask if any new participants had enrolled in their studies (called "target research studies") since our last contact with the coordinator. We then attempted to contact parents of these new participants by phone or in person to explain our study and solicit their willingness to participate. Participants were eligible if the child was between the ages 8 and 17 years and enrolled in a target research study, and if the parent and child were both English-speaking. Participants were ineligible if the child had no knowledge or could not recall that he or she was enrolled in a research study, had a new cancer diagnosis, had moderate to severe developmental delay or pervasive developmental disorder, or had a psychiatric hospitalization within the past six months. We assessed parents and children within two months of their consent to the target study, in order to reduce recall bias and potential effects of ongoing target study participation on responses to the questionnaires.

We received 1278 participant referrals from target research studies being conducted in general pediatrics and numerous sub-specialty areas (Table 2) between June 2012 and August 2014. 1012 (79.2%) of these were not contacted (i.e., there were not enough research staff to contact all referrals) or could not be reached (i.e., research personnel tried to call and/or left messages). Of the 266 who were contacted, 12 (4.5%) were not eligible and 35 (13.2%) declined before eligibility could be assessed. Of the 219 who were eligible, 3 (1.4%) declined to participate because the child was not interested, and 216 (98.6%) agreed to participate. Fourteen (6.5%) of these could not be scheduled or reached again, 7 (3.2%) started but did not complete the assessment, and 195 (90.3%) completed the assessment. Of those who completed the assessment, 15 were later withdrawn (e.g., not meeting eligibility criteria, incomplete data). The final sample for analysis consisted of 180 children and their parents.

A comparison of those who were eligible for our study but declined participation or did not complete the assessment (n = 36) to the participants in the final dataset (n = 180) showed that they did not differ with respect to child age, sex, or ethnicity. Children who did not participate in our study were more likely to be from a minority group compared to children who did participate ($\chi^2(1)= 13.08$, $p < .0001$).

Procedures

The study was approved by the IRB and procedures were in accordance with international guidelines for the ethical conduct of human subjects research. The procedures and measures were piloted with four parent-child dyads prior to the start of formal recruitment. As a result of piloting, we made minor item edits to increase clarity. Assessments were conducted over the phone (n = 134, 74%) or in person (n = 46, 26%). We provided a thorough explanation of the study to parents and a developmentally-appropriate explanation to the child. After obtaining parental permission and child assent, parents and children were interviewed and administered the questionnaires separately. Each child and parent participant received $20 after completing the assessment. Raw data were entered and managed using REDCap (Research Electronic Data Capture)[9].

Measures

Demographics—Parents completed a demographic questionnaire. Child data included sex, age, race, and ethnicity. Parent/family data included sex, age, race, ethnicity, highest educational grade, income, employment status, and marital status.

Perceived Research Characteristics—Parents and children completed items developed for this study to assess perceptions of the risks, benefits, and other characteristics of the target research study. Items relevant to this analysis included those asking about the potential for health benefit for the child and the likelihood and importance of those health benefits; items were analyzed separately. For parents, the first item asked, “Are there any potential health benefits to your child by participating in this study?” (yes or no). If the parent answered yes, there were three follow-up questions: “Do you think that your child will experience any of the potential health benefits?” (definitely yes, probably yes, probably not, definitely not); “How important are these potential health benefits for your child?” (not

very important, a little bit important, quite important, very important); and "What are the potential health benefits?" (open-ended). Children were asked, "Could the target research study be good for your health?" (yes or no), and, if children answered yes, they were asked, "How so?" Parent and child responses to the open-ended item were coded by a research assistant; all coding was reviewed by the first author. Questionable codes were discussed by the team (two research assistants and the first author) until consensus was reached.

Protocol Details—For each participant, we used the consent form for the target study to document protocol characteristics. All protocol details were documented by a research assistant and verified by the first author. The item relevant for this analysis was whether or not the protocol was observational or interventional.

Analytic Plan

Descriptive statistics and proportions were used to describe the sample and responses to questions about health benefit for the child. We utilized an independent samples t-test to compare the age of children who described a direct health benefit to participation to those who only described other types of benefits. For the closed ended question about health benefit, we used a chi-square test to compare the frequency of "don't know" responses for children on interventional versus observational target research studies.

RESULTS

Participants

The participants in our study were 180 children ages 8–17 years and their parents. Of these, 64% (n = 116) had a chronic condition that was the focus of the target protocol, 12% (n = 22) had a chronic condition that was not the focus of the target protocol, and 23% (n = 42) did not have any chronic condition. Additional demographics are in Table 1. Protocol characteristics are displayed in Table 2.

Perceptions of Benefit of Participants Enrolled in Interventional Protocols

Of the 44 parents whose children were enrolled in an interventional protocol, 40 (91%) responded "yes" to the question, "Are there any potential health benefits to your child by participating in the target research study?" and the remainder (n = 4, 9%) responded "no" (Table 3). Of those who answered "yes," the majority (n = 36, 90%) responded that the child would "probably" or "definitely" experience these health benefits, and all responded that these health benefits were "quite" or "very" important for the child.

Those who answered "yes" were asked an open-ended question, "What are the potential health benefits?" and responses were coded (Table 4; examples of responses provided in the Appendix). The majority (n = 32, 80%) described a direct health benefit to participation (i.e., a benefit that arises from an intervention being studied[10]). The next most frequent categories of benefit were that the child would reap a health benefit in the future, because of improvements in treatment or care due to the research (n = 4, 10%) and improvements in quality of life (n = 3, 8%) and the child's or family's understanding the condition (n = 3, 8%).

Of the 44 children enrolled in an interventional protocol, 1 (2%) responded “no” to the question, “Could the target research study be good for your health?”, 39 (89%) responded “yes,” and 4 (9%) said “don’t know” (Table 3). Those who answered “yes” were asked, “How so?” and responses were coded (Table 4). Most children (n = 29, 74%) described a direct health benefit to participation.

Perceptions of Benefit of Participants Enrolled in Observational Protocols

Of the 136 parents whose children were enrolled in an observational protocol, 56 (41%) responded “yes” to the question about potential health benefits and the remainder (n = 80, 59%) responded “no” (Table 5). Of those who answered “yes,” the majority responded that the child would “probably” or “definitely” experience these health benefits (n = 48, 86%) and that these health benefits were “quite” or “very” important for the child (n = 52, 93%). For the open ended question about benefit, the most frequent response (n = 23, 41%) was that the child would reap a health benefit in the future, because of improvements in treatment or care due to the research (Table 4). The second most frequent response (n = 17, 30%) was finding out if or why the child had a particular condition (due to testing that was part of the research protocol). The third most frequent response (n = 5, 9%) was that research participation would improve the child’s or family’s understanding of the child’s medical condition. Very few parents (n = 3, 5%) described an actual direct health benefit.

Of the 136 children enrolled in an observational protocol, 78 (57%) responded “yes” to the question about potential health benefits, 17 (13%) answered “no,” and 41 (30%) answered “don’t know” (Table 5). Children enrolled in observational protocols were more likely to respond “don’t know” to this question than children enrolled in interventional protocols ($\chi^2(2)= 14.38$, $p < .001$). For the open ended question about benefit, the most frequent response category was contributing to medical knowledge (n = 17, 22%) (Table 4), followed by direct health benefits (n = 16, 21%) and finding out if or why the child had a particular condition (n = 16, 21%). The next most frequent response (n = 12, 15%) was that the child would reap a health benefit in the future. We compared the age of children who described a direct health benefit versus those who only described other types of benefits and found that those who described a direct health benefit were younger than the children who did not (11.9 versus 13.9 years; $t(64)= -3.26$, $p= .002$).

DISCUSSION

In this study of perceptions of the potential health benefits of pediatric research participation, we drew on what has been learned in previous studies while seeking to advance our understanding by assessing participants within two months of enrollment, including participants enrolled in observational protocols, and exploring what participants meant when they indicated that the target study would benefit the child’s health. Most parents and children on interventional protocols indicated that research participation may benefit the child’s health directly as a result of the intervention being delivered. A sizable proportion of both parents and children on observational protocols responded that research participation may benefit the child’s health. However, an exploration of parents’ and

children's descriptions of the benefits revealed that most described other types of benefits, not direct health benefits per se.

Almost half of parents and 15% of children enrolled in observational protocols described that the child would benefit in the future due to improvements in treatment. These expectations of future benefit may be reasonable and do not necessarily imply misunderstanding. One implication of this finding, consistent with prior work[11], is that the way in which participants respond to questions about research may be different than what we intend to assess. Furthermore, the regulatory guidelines focus on the potential for direct health benefit, which typically means immediate or short-term health benefit as a result of the intervention being studied[12]. However, some parents and children conceive of the possibility of delayed or long-term health benefits, and this understudied concept may shape participation decisions.

Parents and children enrolled in observational protocols described numerous health benefits that are typically considered collateral benefits of research participation. Similar to what has been found in prior research with parents[13], these benefits included finding out if or why the child had a specific condition, emotional benefits of participation, and monitoring of the child's health or illness. Such collateral benefits are difficult to define, and there are no guidelines with respect to whether and how such potential benefits should be described in consent forms or during the consent process. When participants expect a collateral benefit, they may experience regret or resentment when it turns out that the child does not benefit[14], especially if they perceived such benefit as likely or important. Indeed, the majority of parents also perceived that the likelihood of health benefit was high and that it was "quite" or "very" important for the child's health. Their ratings of likelihood and importance did not differ from those of parents whose children were enrolled in interventional protocols, suggesting that even collateral benefits are salient for families and may impact decision making.

Children who were enrolled in observational studies were more likely to answer "don't know" to the closed-ended question about health benefit, compared to children who were on interventional protocols (30% versus 9%). This finding is consistent with prior research suggesting that adolescents are unsure of how to rate the potential benefits of research participation[15]. Furthermore, 21% of children who said "yes" to the question about direct health benefit had open-ended responses that actually described a direct health benefit of participation. While concerns about participants' expectations of benefit have typically been discussed with respect to clinical trials, these findings suggest that expectations of direct health benefit are present for a subset of children enrolled in observational protocols..

Limitations of this study include that we only enrolled children who agreed to participate in the target study and their parents, and not those who declined participation. Furthermore, research coordinators may not have referred participants who were distressed or struggled with the decision about participation. Therefore, we likely had a biased sample of individuals who viewed research favorably. Second, we did not assess to what extent perceptions of benefit contributed to the decision to participate. However, prior research supports that perceptions of benefit impact parental permission[16]. Third, there is wide

variability in terms of sample and protocol characteristics. Finally, non-participants in this study were more likely to be from a minority group compared to children who did participate in our study, so our results may not be generalizable to non-White children who participate in medical research studies.

Several implications of this study are worth noting. First, the finding that parents and children described future health benefits for the child from research participation is novel. The informed consent process may be enhanced when research personnel explicitly differentiate between the different types of benefits, including future health benefits. Such an explicit discussion of benefits may not only ensure that potential participants understand the actual potential for immediate health benefit, but also help them to make a decision based on their goals and relative weighing of benefits. Second, research that examines understanding of informed consent should distinguish between types of benefit. When assessing expectations of benefit, probes should be used to explore whether the participant's response reflects a misunderstanding or merely a different concept of benefit. Finally, future research should employ a combination of observational methods and participant self reports to delineate the relative effects of various factors, such as researcher communication, on participants' understanding, perceptions, and satisfaction related to informed consent for research participation.

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APPENDIX: Examples of responses to open-ended item about potential benefits

	Parent responses	Child responses
Direct health benefit	"Would like to see it cured but just to help it not get any worse." "Cured of peanut allergy."	"Improve lung functioning; get mucous out of my lungs." (age 17) "I have a bleeding problem and they might be able to fix it." (age 11)

	Parent responses	**Child responses**
Future health benefit	"In the global sense of health, whenever you do research, treatments may be improved and benefit you in the future." "General research at the hospital could eventually help your child."	"Maybe they will find better treatments that will directly benefit me in the future." (age 13) "Possibly in the future by helping doctors find a cure." (age 17)
Improve understanding of condition	"Better understanding of his condition."	"Because then I could learn more information about asthma." (age 11)
Quality of life	"Quality of life."	"I will be able to sit at any part of the table at lunch at school, because I won't be allergic anymore." (age 8)
Help others	"They could end up finding a diagnosis or treatment that could be beneficial to a lot of people."	"Help other children." (age 9)
Contribute to medical knowledge	"Increased knowledge."	"'Cause it could teach the doctor something, help them figure out stuff (medical team)." (age 11) "Help researchers figure out the best way to do it." (age 13)
Emotional benefit	"Helping her feel like she is doing something positive with a condition she didn't choose to have."	"Help me be more active, bring mood back to where it was before I got sick." (age 17)
Find out if/why child has condition	"Can find out why she bleeds."	"If they get more tests done they could probably find out what causes it." (age 14)
Monitor child's health	"It will keep me up to date about her health."	"Can monitor your health." (age 17)
Access to new/better/more thorough treatments	"Having an extra set of eyes, more thorough, longer echo."	N/A

Table 1

Child and Parent Demographics

Variable	***n* (%); or mean *(SD)*, range**
Child age	12.56 (2.82), 8–17
Parent age	42.26 (7.23), 27–65
Child sex: Female	93 (52%)
Parent sex: Female	166 (92%)
Child race	
Black or African American	60 (33%)
Asian	3 (2%)
White	106 (59%)
Other	10 (6%)
Missing	1 (1%)
Is child Hispanic or Latino?	
No	172 (95%)
Yes	7 (4%)
Missing	1 (1%)
Income	
Less than 19,999	26 (14%)
20,000–39,999	33 (18%)
40,000–59,999	19 (11%)
60,000–79,999	12 (7%)
80,000–99,999	18 (10%)
More than 100,000	55 (31%)
Prefer not to answer	17 (9%)
Parent education	
Some high school	8 (4%)
Completed high school	36 (20%)
Some college or technical school after high school	47 (26%)
College graduate	49 (27%)
Some post-college graduate education	10 (6%)
Masters, PhD., MD, law degree	30 (17%)
Family structure	
Two parents	116 (64%)
Two parents- Step family	10 (6%)
Single parent	54 (30%)

Table 2

Protocol Details for Enrolled Participants (n = 180)

Division	***n* (%)**
Allergy/Immunology	17 (9%)
Cardiology	9 (5%)
Endocrinology	7 (4%)
Gastroenterology, Hepatology, & Nutrition	18 (10%)
General Pediatrics	58 (32%)
Hematology	4 (2%)
Nephrology	3 (2%)
Neurology	6 (3%)
Oncology	1 (1%)
Orthopedic Surgery	5 (3%)
Pulmonary	23 (13%)
Radiology	1 (1%)
Rheumatology	28 (16%)
Is the study interventional or observational?	
Interventional	44 (24%)
Observational	136 (76%)
For interventional studies only:	
Allocation	
Single arm	6 (14%)
Randomized controlled trial	37 (84%)
Non-randomized trial	1 (2%)
Risk category	
Minimal	147 (82%)
Minor increase over minimal	27 (15%)
Greater than minimal	6 (3%)

Table 3

Perceptions of Benefit for Participants Enrolled in Interventional Protocols

	Parent	Child
	1) "Are there any potential health benefits to your child by participating in the study?" (n = 44)	1) "Could the target research study be good for your health?" (n = 44)
No	4 (9%)	1 (2%)
Yes	40 (91%)	39 (89%)
Don't know	N/A	4 (9%)
	2) If answered yes to #1, "Do you think that your child will experience any of the potential health benefits?"[1] (n = 40)	-
Definitely not	0	-
Probably not	3 (8%)	-
Probably yes	29 (73%)	-
Definitely yes	7 (18%)	-
	3) If answered yes to #1, "How important are these potential health benefits to your child?" (n = 39)	-
Not very important	0	-
A little bit important	0	-
Quite important	5 (13%)	-
Very important	35 (88%)	-

[1]Does not add up to 100% because one participant did not respond to the item.

Table 4

Coded Response Frequencies for Open-Ended Item about Potential Benefits[1]

Variable, n (%)	Parent	Child
Participants Enrolled in Interventional Protocols[2] (n = 40 parents; 39 children)		
Direct health benefit	32 (80%)	29 (74%)
Future health benefit	4 (10%)	1 (3%)
Improve understanding of condition	3 (8%)	3 (8%)
Quality of life	3 (8%)	3 (8%)
Help others	1 (3%)	1 (3%)
Contribute to medical knowledge	1 (3%)	3 (8%)
Other	1 (3%)	0
Emotional benefit	0	3 (8%)
Find out if/why child has condition	0	0
Monitor child's health	0	0
Access to new/better/more thorough treatments	0	0
Not sure, don't remember, hard to explain	0	1 (3%)
Participants Enrolled in Observational Protocols[2] (n = 56 parents; 78 children)		
Direct health benefit	3 (5%)	16 (21%)
Future health benefit	23 (41%)	12 (15%)
Improve understanding of condition	5 (9%)	2 (3%)
Quality of life	2 (4%)	0
Help others	2 (4%)	7 (9%)
Contribute to medical knowledge	2 (4%)	17 (22%)
Other	1 (2%)	2 (3%)
Emotional benefit	3 (5%)	0
Find out if/why child has condition	17 (30%)	16 (21%)
Monitor child's health	3 (5%)	1 (1%)
Access to new/better/more thorough treatments	3 (5%)	0
Not sure, don't remember, hard to explain	0	7 (9%)

[1] Numbers add up to more than 100% because participants sometimes gave multiple responses

[2] Limited to participants who said "yes" to question about whether there would be a health benefit.

Table 5

Perceptions of Benefit for Participants Enrolled in Observational Protocols

	Parent	Child
	1) “Are there any potential health benefits to your child by participating in the study?” (n = 136)	1) “Could the target research study be good for your health?” (n = 136)
No	80 (59%)	17 (13%)
Yes	56 (41%)	78 (57%)
Don’t know	N/A	41 (30%)
	2) If answered yes to #1, “Do you think that your child will experience any of the potential health benefits?” (n = 56)	-
Definitely not	0	-
Probably not	8 (14%)	-
Probably yes	27 (48%)	-
Definitely yes	21 (38%)	-
	3) If answered yes to #1, “How important are these potential health benefits to your child?” (n = 56)	-
Not very important	1 (2%)	-
A little bit important	3 (5%)	-
Quite important	11 (20%)	-
Very important	41 (73%)	-