Factors That Influence Parental Decisions to Participate in Clinical Research

Consenters vs Nonconsenters

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Importance: A child’s health, positive perceptions of the research team and consent process, and altruistic motives play significant roles in the decision-making process for parents who consent for their child to enroll in clinical research. This study identifies that nonconsenting parents were better educated, had private insurance, showed lower levels of altruism, and less understanding of study design.

Objective: To determine the factors associated with parental consent for their child’s participation in a randomized, placebo-controlled trial.

Design: Cross-sectional survey conducted from July 2008 to May 2011. The survey was an ancillary study to the Randomized Intervention for Children with VesicoUreteral Reflux Study.

Setting: Seven children’s hospitals participating in a randomized trial evaluating management of children with vesicoureteral reflux.

Participants: Parents asked to provide consent for their child’s participation in the randomized trial were invited to complete an anonymous online survey about factors influencing their decision. A total of 120 of the 271 (44%) invited completed the survey; 58 of 125 (46%) who had provided consent and 62 of 144 (43%) who had declined consent completed the survey.

Main Outcomes and Measures: A 60-question survey examining child, parent, and study characteristics; parental perception of the study; understanding of the design; external influences; and decision-making process.

Results: Having graduated from college and private health insurance were associated with a lower likelihood of providing consent. Parents who perceived the trial as having a low degree of risk, resulting in greater benefit to their child and other children, causing little interference with standard care, or exhibiting potential for enhanced care, or who perceived the researcher as professional were significantly more likely to consent to participate. Higher levels of understanding of the randomization process, blinding, and right to withdraw were significantly positively associated with consent to participate.

Conclusions and Relevance: Parents who declined consent had a relatively higher socioeconomic status, had more anxiety about their decision, and found it harder to make their decision compared with consenting parents, who had higher levels of trust and altruism, perceived the potential for enhanced care, reflected better understanding of randomization, and exhibited low decisional uncertainty. Consideration of the factors included in the conceptual model should enhance the quality of the informed consent process and improve participation in pediatric clinical trials.

objective was to determine factors associated with parents' decisions to permit their children to participate or not participate in a randomized, placebo-controlled trial and, accordingly, identify strategies to enhance enrollment in pediatric clinical research.

Parents who were asked to provide consent for their child's participation in a randomized trial evaluating the management of children with vesicoureteral reflux (Randomized Intervention for Children with VesicoUreteral Reflux [RIVUR] Study) were eligible to participate in the consent survey. The RIVUR study is a randomized, placebo-controlled, double-blind clinical trial evaluating the efficacy of long-term (24 months) antimicrobial prophylaxis in preventing recurrent urinary tract infections and the occurrence of renal scarring in children ages 2 months to 6 years. The institutional review boards at each of the participating institutions (the Children's Hospitals of Pittsburgh, Philadelphia, Buffalo, and Chicago; Johns Hopkins University; Alfred I. duPont Hospital for Children; and Children's National Medical Center) determined this survey study to be exempt under rule 45 CFR 46.101(b)(2); investigators were required to read to parents an institutional review board–approved script that contained basic elements of informed consent describing the anonymous survey, but no formal written consent was obtained.

The RIVUR study was thoroughly discussed with parents of eligible children over the phone or in person by an investigator, after which consent for their child's participation was sought. Regardless of whether they agreed to their child's participation, parents were asked for permission to e-mail them a link to the survey. Parents were informed the anonymous survey would take approximately 15 minutes to complete and involved questions about age, race/ethnicity, education, family background, and their perceptions about medical research; they were also informed that on completing the survey, they would receive a $10 gift certificate to an online bookstore retailer in appreciation for their time.

At one RIVUR study site (Children's Hospital of Pittsburgh), parents who did not complete the survey within 2 months of being sent the link to the online survey were reminded once; no other sites sent out the link in a second wave, and no further reminders were sent to parents in Pittsburgh.

The framework of our 60-question survey to assess factors influencing parental decisions to participate in clinical research was informed by the conceptual model we developed based on prior studies (Figure).1 Child, parental, and study

Figure. Conceptual model of study. Parenthetical numbers correspond with survey question numbers in the eAppendix. The items in bold are statistically significant. Study characteristics were not investigated.

METHODS

Parents who were asked to provide consent for their child's participation in a randomized trial evaluating the management of children with vesicoureteral reflux (Randomized Intervention for Children with VesicoUreteral Reflux [RIVUR] Study) were eligible to participate in the consent survey. The RIVUR study is a randomized, placebo-controlled, double-blind clinical trial evaluating the efficacy of long-term (24 months) antimicrobial prophylaxis in preventing recurrent urinary tract infections and the occurrence of renal scarring in children ages 2 months to 6 years. The institutional review boards at each of the participating institutions (the Children's Hospitals of Pittsburgh, Philadelphia, Buffalo, and Chicago; Johns Hopkins University; Alfred I. duPont Hospital for Children; and Children's National Medical Center) determined this survey study to be exempt under rule 45 CFR 46.101(b)(2); investigators were required to read to parents an institutional review board–approved script that contained basic elements of informed consent describing the anonymous survey, but no formal written consent was obtained.

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characteristics influence how well parents understand the trial design issues such as equipoise, randomization, blinding, voluntary participation, and the right to withdraw. In turn, this understanding influences parental perceptions regarding the risks and benefits of the trial. The decision to allow participation is also influenced by parental decision-making style and external influences. We were interested in learning how factors in each stage of the decision-making process influenced the final decision to provide or withhold consent. Altogether, we sought to examine 7 constructs governing the decision to provide consent: child characteristics, parental characteristics, study characteristics, parental perception of the study, parental understanding of study design, external influences, and the decision-making process.

The survey questions included all those proposed by Tait et al, although we modified the wording of some questions and added 7 questions assessing parental understanding of the trial. Study characteristics included the level of risk involved, study design, time requirement, and characteristics of the consent environment and the researcher. Because we were only assessing participation in a single trial (RIVUR), we did not investigate the influence of study characteristics on the decision-making process. Child characteristics included age, sex, and whether the child was perceived by the parent to be sicker than other children (vulnerable), whether the child provided assent, and whether the child had previously participated in research. Relevant parental characteristics included demographics (age, sex, ethnicity, and race), socioeconomic status (education and health insurance), sense of altruism, research experience (previous participation and trust), and style of decision making.

Responses to most items were scored using a 5-point Likert scale (5=strongly agree); some items were scored on 0 to 10 visual analog scales (10=high). A complete copy of the survey and response data can be found in the eAppendix (http://www.jamapediatrics.com).

Faculty and staff from the University of Pittsburgh Clinical Translational Science Institute Design, Biostatistics, and Clinical Research Ethics Core, who were not involved in the RIVUR study, were responsible for maintaining the anonymity of survey respondents, implementing the survey, and analyzing the data. Web security met the University of Pittsburgh’s standards of confidentiality.

Basic descriptive statistics and frequencies were used to describe all variables, comparing survey data from parents who consented to enroll their child in the RIVUR study with those who declined consent. To determine which factors were significantly associated with the decision to enroll their child in the RIVUR study, we used univariate analyses: Mann-Whitney U test for comparing continuous variables and $\chi^2$ or Fisher exact tests for categorical variables. Small cell size for some dichotomous variables precluded multivariable logistic regression analysis. We tested each construct for internal reliability using Cronbach alpha; in all cases, values obtained were greater than 0.7, suggesting good internal reliability. All analyses were conducted with SPSS version 19 (SPSS Inc.). $P<.05$ was considered statistically significant.

**RESULTS**

Participants in the RIVUR study were enrolled at 19 participating institutions between May 2006 and May 2011; the survey study (an ancillary study to RIVUR) was conducted at only 7 of the 19 RIVUR participating institutions between July 2008 and May 2011. A total of 271 parents who had been contacted for consent to participate in the RIVUR study at 1 of these 7 sites were e-mailed codes to participate in the online consent survey during the survey study period. Of the 271 parents who were e-mailed codes for the online consent survey, 120 (44%) completed the survey (84% from the Children’s Hospital of Pittsburgh site); 58 of 125 parents (46%) who provided consent and 62 of 144 parents (43%) who declined consent for their child to participate completed the survey; the consent statuses of 2 participants were unknown. The 271 parents who were e-mailed the consent survey at the 7 sites during the 3-year period represented 21% of the approximately 1300 parents approached for their child’s participation at the 19 RIVUR sites during the 5-year period. The 58 parents who consented and filled the survey at the 7 sites during the 3-year period represented approximately 10% of the 607 children enrolled at the 19 RIVUR sites during the 5-year period.

Parental and child demographic characteristics are shown in **Table 1**. Children whose parents consented to their participation in the RIVUR trial were slightly older than those of nonconsenters; parents who consented were younger than nonconsenters. Because vesicoureteral reflux is 3 times more common in white individuals than black individuals, the low minority representation was expected. Having graduated from college and having private health insurance—both proxies for higher socioeconomic status—were associated with a lower likelihood of consenting to their child’s participation in the RIVUR study.

In comparison, the RIVUR cohort of 607 children had a similar median age (1.0 year; range, 0.2–5.9 years) and similar proportions of parents who were at least college graduates (48%) or had public health insurance (29%) as the nonconsenter study group. Compared with each of the 2 survey study groups (consenters and nonconsenters), the RIVUR cohort similarly consisted of female subjects (92%), had a lower proportion of white subjects (81%), and included a higher proportion of subjects of Hispanic ethnicity (13%). **Table 2** summarizes the factors that influenced the decision to provide consent. Parents were significantly more likely to consent to participate if they perceived the researcher as being friendly and professional and/or the RIVUR study as having a low degree of risk, resulting in a greater benefit to their child and other children (higher altruism), causing little interference with standard care, and/or exhibiting a greater potential for enhanced care. External influences (discussing research with others and previous family or friends’ experience with research) appeared not to influence consent to participate. Higher levels of parental understanding of the randomization process, blinding, right to withdraw, and degree of risk were also significantly positively associated with consent to participate; paradoxically, the higher educated nonconsenters displayed significantly lower understanding of study randomization and blinding. We found a relatively low agreement ($\kappa = 0.2$) between parental understanding of randomization and the perception that by participating in the study, their child would receive the best medical care (therapeutic misconception).

Parents who had little decisional uncertainty (low levels of anxiety) were more likely to consent to their child’s participation in the RIVUR study. Conversely, parents who declined participation in the RIVUR study reported higher levels of anxiety and more difficulty making the decision.
We found that parents who declined consent to their child’s participation in the RIVUR trial had a relatively higher socioeconomic status, had more anxiety about their decision, and found it harder to make a decision about the study compared with consenting parents, who exhibited higher levels of trust, altruism, and low decisional uncertainty; perceived the potential for enhanced care; and reflected better understanding of randomization.

The impact of socioeconomic status on research participation has varied. A higher level of education resulted in higher research participation rates in adult human immunodeficiency virus and cancer studies. In contrast, in a randomized pediatric oncology study, parents with a higher socioeconomic status were more likely to refuse participation, and parents with a bachelor’s degree or higher were less likely to endorse research in an emergency setting than were parents with less than a bachelor’s degree. In our study, better-educated nonconsenters may have felt a need to explain why they did not consent to the RIVUR trial, making them more likely to participate in this survey. It is also possible that nonconsenters with lower levels of education were more likely to ignore the request to participate in the survey. Accordingly, caution should be applied when considering the influence of education on the consent decision based on these data. In general, our findings may also be limited because we solicited participation at just 7 of 19 study sites for only 3 of the 5 years during which the RIVUR study was open for enrollment, and even among this selected sample, less than 50% of parents who were invited completed the survey.

Previous reports have noted the significant influence of the child’s health on parental decisions to provide consent. A strength of our study was that we surveyed consenting and nonconsenting parents whose children were otherwise healthy, apart from vesicoureteral reflux, and who were approached for participation in an actual rather than hypothetical clinical trial.

Three prior studies compared the motivations of consenting and nonconsenting parents. Tait et al identified low perceived risk, degree to which the parent read the consent document, characteristics of the consent document, parental understanding, perceived importance of the study, and perceived benefits as predictors of providing consent. In a British study of oral vs intravenous treatment for community-acquired pneumonia in previously well children, altruism was the major motivation for parental consent; parents who declined consent were unwilling to undergo randomization as they believed one treatment arm (intravenous treatment) was superior, suggesting lack of understanding about clinical trial design (equipoise). Harth et al reported that the psychologic profile of volunteering parents differed from that of nonvolunteering parents in the context of a randomized trial of an asthma drug. Volunteering parents valued benevolence, were more introverted, had lower self-esteem, and exhibited greater anxiety than nonvolunteering parents, who tended to have higher levels of education, held professional/administrative jobs, and exhibited greater social confidence and emotional stability. Our parents in both categories did not differ in how they assessed equipoise (“Doctors do not really know which of the 2 treatments is better”) and voluntary participation (“I felt like the decision to have my child take part in the study was up to me”). In contrast, responses that reflected understanding of study design issues—randomization, blinding, risk level, right to withdraw (eg, “My child has an equal chance of getting either treatment”), altruism, and potential benefit to others—were significantly higher among consenters (Table 2).

In studies conducted only among parents who had provided consent, factors influencing this decision included altruistic motivation and a desire to learn more about their child’s disease. In one study, the availability of a financial stipend or the parent’s educational level were not

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**Table 1. Parental and Child Demographic Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Nonconsenters (n = 62)</th>
<th>Consenters (n = 58)</th>
<th>P  Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range), y</td>
<td>1.00 (0-5)</td>
<td>1.50 (0-7)</td>
<td>.05</td>
</tr>
<tr>
<td>Parent</td>
<td>33 (20-43)</td>
<td>31 (22-46)</td>
<td>.02</td>
</tr>
<tr>
<td>Child’s sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3 (4.8)</td>
<td>3 (5.2)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Female</td>
<td>59 (95.2)</td>
<td>55 (94.8)</td>
<td></td>
</tr>
<tr>
<td>Parent relationship to child</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>58 (93.5)</td>
<td>52 (89.7)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Father</td>
<td>4 (6.5)</td>
<td>6 (10.3)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (3.2)</td>
<td>3 (5.2)</td>
<td>.67</td>
</tr>
<tr>
<td>No</td>
<td>60 (98.8)</td>
<td>55 (94.8)</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian</td>
<td>0 (0)</td>
<td>1 (1.7)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0)</td>
<td>1 (1.7)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>1 (1.6)</td>
<td>3 (5.2)</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>White</td>
<td>60 (98.4)</td>
<td>57 (98.3)</td>
<td></td>
</tr>
<tr>
<td>Preferred not to answer</td>
<td>1 (1.6)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Level of education</td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>≤ High school or GED or some college/technical</td>
<td>7 (11.3)</td>
<td>29 (50)</td>
<td></td>
</tr>
<tr>
<td>≥ College graduate</td>
<td>55 (88.7)</td>
<td>29 (50)</td>
<td></td>
</tr>
<tr>
<td>Health insurance status</td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Private</td>
<td>56 (90.3)</td>
<td>36 (62.1)</td>
<td></td>
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<tr>
<td>Public</td>
<td>6 (9.7)</td>
<td>21 (36.2)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>0 (0)</td>
<td>1 (1.7)</td>
<td></td>
</tr>
<tr>
<td>English as first language</td>
<td></td>
<td></td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Yes</td>
<td>60 (98.8)</td>
<td>57 (98.3)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2 (3.2)</td>
<td>1 (1.7)</td>
<td></td>
</tr>
<tr>
<td>If no, was language a problem for you to understand the study?</td>
<td>Yes</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Abbreviation: GED, General Education Development.
felt to influence the consent decision, although obtaining free medication became more important as socioeconomic status declined. Among educated research-naive parents who had consented to their child’s participation in placebo-controlled gastrointestinal trials, motivation for consent derived from altruism and the setting and manner in which consent had been sought; perceived risks (adverse effects and receipt of placebo) and financial incentives did not play significant roles.

Finally, in agreement with previous reports, we found that positive parental perception of the researcher was associated with greater likelihood to consent. Specifically, parents were asked if the “person who presented the study” was friendly, was professional, made them feel comfortable, and “did a good job explaining the study.” These researcher characteristics could have contributed to the consenting parents’ greater understanding of and comfort with the clinical trial and its potential to benefit other children. Perez et al noted that comfort with the research team was high among all parents who enrolled their children in a placebo-controlled trial but was lower among parents whose children did not complete the study, emphasizing the importance of this initial encounter.

In conclusion, findings from our survey may be used to improve participation in pediatric clinical research. Among our families, important modifiable factors that influenced the consent process included the involvement of a researcher who made them feel comfortable and proper understanding of the study (ie, low risk, lack of interference with standard of care, and better understanding of randomization and blinding). Our findings emphasize the importance of clearly explaining how risk is minimized, how participation affects standard of care, blinding and randomization, the right to withdraw at any time, and the benefits (if any) to the child and other children. Our finding of a high level of decisional anxiety among the more educated and higher socioeconomic status parents provides an opportunity to acknowledge, empathize, and support parents who may struggle with the decision. Careful consideration of the various factors included in the conceptual model should enhance the quality of the informed consent process and improve participation in pediatric clinical trials.
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Additional Information: The Randomized Intervention for Children with VesicoUreteral Reflux Study website is located at http://www.cscn.unc.edu/tivur/.

REFERENCES