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Children's Decision Making Involvement about Research Participation: Associations with Perceived Fairness and Self-Efficacy

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Abstract

The primary objective of this study was to examine the associations of children's involvement in decisions about research participation with their perceptions of the decision making process and self-efficacy. Participants were children (ages 8–17) who enrolled in research studies in the prior two months. Children completed a questionnaire that yielded three decision making involvement subscales: Researcher Engages Child; Researcher Supports Autonomy; and Child Participates. Children reported on fairness of the decision making process and health-related decision self-efficacy. After adjusting for age, higher scores on Researcher Engages Child were associated with greater self-efficacy, and higher scores on Researcher Supports Autonomy were associated with greater perceived fairness. These data underscore the potential importance of researcher-child interactions about research participation when assent is sought, including proactively involving children in the decision by asking for their opinions and communicating their central role in the decision, which are likely to be more meaningful to children than receiving information or signing a form.

Keywords

ethics; assent; informed consent; decision making

For children to participate in research, both parental permission and child assent, defined as agreement to participate, must be obtained. The assent requirement can be waived if the research has the possibility of direct benefit to the child that can only be obtained in the research context, or if the child is judged incapable of assent (Federal Policy for the Protection of Human Subjects, 2001). There has been debate as to what constitutes assent and when children are capable of providing it. Perhaps as a result of equating assent with the

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requirements for informed consent with adults (Miller & Nelson, 2006; Wilfond & Diekema, 2012), prior research has been based primarily on a model that focuses on cognitive capabilities; this research has examined children's understanding of research and the factors that influence their understanding (Dorn, Susman, & Fletcher, 1995; Fogas, Oesterheld, & Shader, 2001; Tait, Voepel-Lewis, & Malviya, 2003).

An alternative model of child assent focuses on the relational context of children's decision making (Broome & Richards, 2003; Geller, Tambor, Bernhardt, Fraser, & Wissow, 2003; Miller, Reynolds, & Nelson, 2008). The relational model reflects the view that children can be involved in decisions in various ways (Baylis, Downie, & Kenny, 1999; Broome & Richards, 2003; Joffe, 2003; McCabe, 1996) and that parents and other adults play an important role as sources of support and advice across the child's development. For example, children can be provided with information about the pros and cons of different options or be asked for their opinion, or they may play a more verbal role by asking questions or expressing concerns.

Decision making involvement is hypothesized to teach children what factors to consider when making decisions and increase satisfaction and cooperation with treatment (McCabe, 1996; Schmidt, Petersen, & Bullinger, 2003; Walker & Doyon, 2001). Furthermore, while the assent process is important for conforming to research regulations, it can also be used to enhance self-efficacy, defined as confidence in one's ability to perform the actions needed to produce desired outcomes (Bandura, 1977). Self-efficacy is important for predicting health-related behaviors and outcomes in children and adolescents (Bartholomew, Parcel, Swank, & Czyzewski, 1993; Iannotti et al., 2006). Although potentially important, the possible benefits of children's involvement in research enrollment decisions have not been empirically examined. Evidence that such involvement is beneficial would support the development and evaluation of novel strategies to enhance the assent process for pediatric medical research and may also have implications for children's involvement in other types of decisions.

In the present study, we assessed children within two months of enrolling in medical research studies and utilized a recently developed tool to quantify children's perceived involvement in decision making. First, we expected that involvement would be positively associated with age. Second, we expected that more involvement in the decision about research participation would be associated with higher perceived decision self-efficacy, after adjusting for age (due to the potential effects of child age on both involvement in decision making and perceived self-efficacy). We also expected that more involvement would be associated with greater perceived fairness of the decision making process, based on the assumption that when adults talk to children directly and listen to their concerns and opinions, children will be more likely to accept the process by which a decision was made (Bluebond-Langner, DeCicco, & Belasco, 2005). This is important because among children who participate in research, children's favorable views of the decision to enroll may shape their experience of research participation, compliance with research procedures, and willingness to participate in future studies.

Methods

Recruitment

We contacted principal investigators (PIs) across the institution, a tertiary pediatric academic medical center in the Northeast, to determine eligibility and enrollment status of their current studies and ask if they would be willing to refer participants. If the PI and research staff were supportive, then research staff would give us names of participants who enrolled in their research protocols (called “target protocols”). After receiving a name, we attempted to contact the parent by phone or in person to explain our study and solicit their willingness to participate. Inclusion criteria included that the child was between the ages 8 and 17 years and that both the parent and child were English-speaking. We excluded participants if the child had no knowledge or could not recall that he or she was enrolled in the target protocol, had a new cancer diagnosis (at the request of our oncologist colleagues), had moderate to severe developmental delay or pervasive developmental disorder, or had a psychiatric hospitalization within the past six months.

We attempted to contact 112 principal investigators who appeared to be conducting eligible clinical research studies based on lists we obtained from the Institutional Review Board at our institution. Sixty-seven (60%) of these PIs were excluded from our study for these reasons: 33 (49%) did not respond to our e-mails; 25 (37%) did not have eligible or enrolling studies; 7 (10%) did not agree to refer participants; 2 (3%) agreed to support the study but attempts to contact their research coordinators were unsuccessful. We ended up with 45 (40%) “on board” PIs, representing 105 target protocols.

We received 1278 participant referrals between June 2012 and August 2014. We did not attempt to contact 573 (45%)¹ and could not reach 439 (34%) of these referrals. We were able to contact 266 parents, but 15 (5.6%) were not eligible, and 35 (13.2%) declined before eligibility could be assessed. Of the 216 who were eligible, 3 (1.4%) declined because the child was not interested, and 213 (98.6%) agreed to participate. Of these, 180 (84.5%) completed the assessment. A comparison of those who were eligible 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. Non-participants were more likely to be from a racial minority group compared to participants ($\chi^2_{(1)} = 13.08, p < .001$).

Procedures

The study was approved by the Institutional Review Board. Research staff conducted the assessments over the phone ($n = 134, 74\%$) or in person ($n = 46, 26\%$), if the family was scheduled for a research or clinical visit and they preferred to meet in person. After obtaining parental permission and child assent, research staff administered the questionnaires separately to parents and children. Each child and parent participant received

¹Of these, 410 (72%) were referrals from a genetic biobanking study with a high enrollment goal (>100,000). When research team members for the present study had multiple referrals at a given time, they prioritized contacting referrals from the other protocols, so that the sample did not end up skewed with participants from the genetic biobanking study. The team also prioritized referrals that were closer to the consent date for the target protocol.

\$20 after the assessment. Raw data were entered and managed using REDCap (Research Electronic Data Capture)(Harris et al., 2009).

Measures

Demographics—Parents completed a demographic questionnaire to document child sex, age, race, ethnicity, and prior research experience (yes/no) and parent highest educational grade and family structure. We also documented whether the child had a chronic condition that was the focus of the target protocol (e.g., child with inflammatory bowel disease (IBD) enrolled in a study to understand the intestinal immune system in individuals with IBD), a chronic condition that was not the focus of the target protocol, or no chronic condition.

Decision Making Involvement—Children completed the *Research Decision Making Involvement Scale- Researcher/Child* (RDMIS-R/C), which was adapted from the Decision Making Involvement Scale (Miller & Harris, 2012; Miller & Jawad, 2014) to assess child and researcher behaviors that reflect different ways for the child to be involved in the decision about research participation. The original Decision Making Involvement Scale (DMIS) was developed to assess parent-child interactions about chronic illness management decisions in youth with type 1 diabetes, cystic fibrosis, or asthma and demonstrated excellent psychometric properties and preliminary support for validity. The DMIS items were adapted to reflect researcher-child interactions and the specific decision about research enrollment. For each of 21 items the child indicated the extent to which the child or researcher engaged in a specific behavior during the discussion about research. Because the scale was adapted, we conducted exploratory factor analyses, using principal axis factoring and oblique promax rotation, based on the Pearson correlation matrix. Criteria for the number of factors to retain included consideration of eigenvalues greater than 1.0, scree plots, and interpretability (Ford, MacCallum, & Tait, 1986). The results of the factor analysis are described below.

Fairness of Decision Making Process—Children responded to three items to assess perceptions of the fairness of the decision making process, voice in the decision making process, and satisfaction with the decision making process (Cascardi, Poythress, & Hall, 2000). Each item had a 4-point Likert-type response scale ranging from 1 to 4. A Fairness score for each child was created by adding his/her responses to each of the three items, with a possible range from 3 to 12. The Cronbach's alpha of .54 was somewhat low, but this could be due to the small number of items. An alternative to alpha is to examine the interitem correlations, which should be moderate (.15 to .50) and cluster around the mean value (Clark & Watson, 1995). In this sample, the three items had interitem correlations ranging from .27 to .31, with a mean of .29.

Self-Efficacy—Children completed a 13-item adaptation of the *Decision Self-Efficacy Scale* (Bunn & O'Connor, 1996; Cranney et al., 2002), which assesses self-efficacy for making informed health-related decisions. Adaptations included rewording of existing items to improve comprehension, addition of five items related to seeking help from and understanding information provided by parents, and removal of four items that the study team deemed less relevant to the research assent context. An example item is, "When it comes to taking care of your health, how confident are you that you can understand what

your doctors/nurses tell you?” Items were averaged to create a final score, which could range from 1 to 4. Cronbach’s alpha of the adapted scale in our sample was .87.

Assent and Permission Details—Parents responded to questions about the permission and assent process for the target protocol (e.g., who was the primary person who spoke to the child about the research study; duration of conversation with the child), which were used for descriptive purposes.

Protocol Details—For each participant, we used the consent form for the target protocol to document protocol characteristics (e.g., was the study interventional or observational) for descriptive purposes. All protocol details were documented by a research assistant and verified by the first author.

Statistical Analysis

We used SAS software, Version 9.3, Copyright 2002–2012 by SAS Institute Inc., Cary, NC, USA, for all statistical analyses. Spearman correlations were used to examine the associations of age with the decision making involvement subscales. We utilized regressions to test hypotheses related to the associations of the decision making involvement subscales with fairness and decision self-efficacy. Prior to running the regressions, we utilized independent samples t-tests and Spearman correlations to examine whether child race, sex, prior research experience, and days since assent to target protocol should be included as covariates. We then ran two regressions to determine which of the RDMIS-R/C subscales were significantly associated with our two outcomes of interest, perceptions of fairness and decision self-efficacy, after adjusting for age. To test for potential collinearity among the independent variables, a correlation matrix of the independent variables (Spearman) was examined first. No significant large associations were seen among the independent variables. For each regression the independent variables were age and the three RDMIS-R/C subscales. To yield a parsimonious model with as few predictors as possible, model selection based on Akaike’s Information Criteria (AIC) was utilized. AIC measures the difference between a given model and the estimated “true” model based on the observed data and has been shown to be superior to forward, backward, and stepwise regression (Beal, 2005). For our analysis, AIC produced estimates of the relative quality of 16 possible combinations of models with the four independent variables. The selection of the final model was based on the smallest AIC estimates produced for each of the 16 possible models.

Results

Participants

The participants in the complete sample were 180 children ages 8–17 years ($M = 12.56$, $SD = 2.82$), representing 42 target protocols, and their parents (Table 1). The majority of children were enrolled in observational ($N = 136$, 76%) and minimal risk ($N = 147$, 82%) protocols. Of the 44 participants enrolled in intervention studies, most ($N = 30$, 68%) were involved in drug-related protocols. Table 2 provides additional protocol details for the enrolled participants. The mean number of days from assent to the target protocol to our assessment was 14.97 ($SD = 11.52$, range 0–64). Based on parent report research personnel

talked directly to 167 of the child participants (93%); these participants completed the RDMIS-R/C and are the focus of the regression analyses described below. Additional details about the assent process, as well as descriptive statistics for the fairness and decision self-efficacy scores, are in Table 3.

Descriptive Findings Related to Fairness Items

Most children perceived the decision making process about research participation favorably. Of the 180 participants, 64% ($N = 116$) reported that the process was “very fair,” 58% ($N = 104$) perceived that they had “a lot” of voice, and 69% ($N = 123$) were “very satisfied.”

Factor Analysis of the RDMIS-R/C

Based on the exploratory factor analysis, three items were removed because they had factor loadings less than .40 (“I listened to what the researcher had to say” and “The researcher tried to teach me something about research”) or did not fit conceptually with the other items on its factor (“The researcher tried to teach me something about my illness/health;” this item, which is focused on the researcher’s behavior, loaded on the factor comprised of child behaviors). We ended up with 18 items on three subscales (Table 4): Researcher Engages Child, Researcher Supports Autonomy, and Child Participates. The Researcher Engages Child subscale contains items that reflect listening to the child and facilitating the child’s involvement via soliciting questions, explaining the research, checking for understanding, and asking for the child’s questions, opinions, and concerns. The Researcher Supports Autonomy subscale reflects behaviors that situate the child as central to the decision regarding research participation. The Child Participates subscale reflects the child’s active verbal participation in the discussion, such as expressing an opinion and asking questions. Cronbach’s alpha, a measure of the internal consistency of the items on a subscale, were 0.82, 0.73, and 0.80, respectively. Inter-factor correlations ranged from 0.26 to 0.54. A confirmatory factor analysis indicated acceptable fit based on the root mean squared error of approximation (RMSEA) of 0.07 and borderline acceptable fit based on the comparative fit index (CFI) of 0.89 (Bentler & Chou, 1987; Browne & Cudeck, 1993).

Associations of Involvement with Age

Older children reported higher scores on the Researcher Engages Child ($r = .22, p = .005$) and Researcher Supports Autonomy ($r = .25, p = .001$) subscales. In other words, older children reported that researchers engaged them and supported their autonomy to a greater degree compared to younger children. Age was not associated with scores on the Child Participates subscale.

Associations of Involvement with Fairness and Decision Self-Efficacy

Child race, sex, prior research experience, and days since assent to target protocol were not associated with fairness or decision self-efficacy, so they were not included in the regression analyses. Table 5 displays the results of the two final regression models examining associations of decision making involvement with perceived fairness and decision self-efficacy. For the prediction of fairness, both age and Researcher Supports Autonomy were positively associated with fairness in the final model, accounting for 20% of the variance in

fairness scores. Older children and adolescents and those who perceived that the researcher communicated that the child was central to the decision perceived that the decision making process was more fair. Scores on the Researcher Engages Child and Child Participates subscales were not significantly associated with fairness. For the prediction of decision self-efficacy, both age and Researcher Engages Child were positively associated with self-efficacy in the final model, accounting for 14% of the variance in self-efficacy scores. Older children and adolescents and those who perceived that the researcher engaged them more in the discussion (i.e., soliciting questions, explaining the research, checking for understanding, and asking for the child's questions, opinions, and concerns) reported greater decision self-efficacy. Scores on the Researcher Supports Autonomy and Child Participates subscales were not significantly associated with decision self-efficacy.

Discussion

Although obtaining assent from children is a cornerstone of ethical research in pediatrics, there has been much discussion about what the purpose and process of assent should be. Consistent with the American Academy of Pediatrics and others (American Academy of Pediatrics (AAP) Policy Statement, 1995; Bartholome, 1989; Joffe, 2003; Wilfond & Diekema, 2012), we conceptualized assent as more than information disclosure and affirmative agreement to participate. The assent process may benefit children when it is used to engage children in the discussion about research, solicit children's questions and concerns, and emphasize that the child is central to the decision. The RDMIS-R/C contains items on three subscales, two of which assess specific verbal communication behaviors that can guide researchers who routinely obtain assent from children. The results of this study indicated that when children perceived that researchers proactively engaged them by soliciting questions and asking for an opinion, children reported greater decision self-efficacy. In addition, when children perceived that researchers supported their autonomy by situating the child as central to the decision, they also perceived that the decision making process was more fair. Such data underscore the potential importance of these specific aspects of decision making involvement during the assent process, which are likely to be more meaningful to children than receiving information or signing a form (Miller & Nelson, 2005).

These findings are consistent with prior research with adults, which has found that patient perceptions of physicians' efforts to facilitate involvement in decision making are associated with control, satisfaction, and adherence to treatment (Martin, DiMatteo, & Lepper, 2001; Shabason, Mao, Frankel, & Vapiwala, 2014). In research with adolescents, aspects of physician communication, such as perceived support and a "motivating" or patient-centered style (e.g., asking, listening, and taking notice of teen's opinion), have been associated with visit satisfaction (Freed, Ellen, Irwin, & Millstein, 1998), adherence (Kyngas, Hentinen, & Barlow, 1998; Kyngas & Rissanen, 2001), and perceptions of control and competence (Croom et al., 2011). Indeed, our finding that children's perceptions of greater researcher facilitation of their involvement in the discussion were associated with greater perceived self-efficacy underscores that there may be benefits to involving children in decision making. These interactions with children send the message that the child is capable of handling such involvement and may also enhance children's abilities to participate in health-

related decisions over time. Alternatively, it is possible that higher scores on the Research Engages Child subscale of the RDMIS-R/C subscales reflect generalized perceptions of more effective researcher communication, and not specific efforts to facilitate the child's involvement. Additional research is needed to tease out the effects of general communication quality versus the researcher's efforts to engage the child in decision making.

While scores on the Researcher Engages Child subscale were associated with self-efficacy, scores on the Researcher Supports Autonomy subscale were associated with perceived fairness of the decision making process. Items on this subscale reflect communication from the researcher that indicates that the child is central to the decision about research participation. This finding is not surprising, given that prior research has found that children and adolescents think that they should have a prominent role in decision making about research participation (Geller et al., 2003; Grady et al., 2014; Unguru, Sill, & Kamani, 2010). Interestingly, all of the target protocols that were represented in the present study required assent of the child. However, the way in which research personnel implement this requirement in their interactions with children and parents will vary, and some may be less explicit than others regarding the child's role in the decision. Furthermore, it is important to note that while children have the right to decline when assent is sought, the final decision does not fully rest with the child because parental permission is also typically required. In other words, even if a child desires to participate, a parent's refusal to provide permission would override the child's wishes. Nevertheless, our findings underscore that, among children who enroll in research studies, explicit communication that addresses the child's right to decline participation is associated with more favorable views of the decision making process.

Children's verbal participation in the assent discussion (e.g., expressing an opinion, asking questions) was not associated with perceptions of fairness or self-efficacy. Overall levels of child and adolescent verbal participation in clinical and research settings are low (Cox, Smith, Brown, & Fitzpatrick, 2009; Miller, Baker, Leek, Drotar, & Kodish, 2014; Sleath et al., 2011; van Staa & On Your Own Feet Research Group, 2011; Wassmer et al., 2004). Youth may not speak up in health care settings for a variety of reasons (Young, Dixon-Woods, Windridge, & Heney, 2003), and other factors, such as how the clinician or researcher speaks to them, may be more important in shaping their perceptions of the decision making process. Similarly, it could be that as long as children listen attentively to the researcher or perceive that the researcher is trying to engage them, their own verbal participation is not crucial. Alternatively, the RDMIS-R/C may not be sensitive enough to detect variations in children's verbal contributions to the research assent process.

The present findings should be interpreted in light of several limitations. First, there are several sources of bias in our sample, a limitation that affects empirical work on informed consent more broadly (Agre, Rapkin, Dougherty, & Wilson, 2002). One is that we included children who agreed to participate in the target protocol and their parents, and not those who ultimately did not enroll. Thus, our participants may have viewed research more favorably, and our findings cannot be generalized to children who declined the target protocols. However, a focus on participants is justified if the goal is to ensure that children who participate in research perceive that they had voice in the decision to do so. A second bias is

that research staff of the target protocols may not have referred families who were distressed or struggled with the participation decision, to avoid burdening the family or prevent negative effects on retention efforts for the target protocol (e.g., completion of follow-up assessments). A third bias rests with our “on board” PIs and research staff. These individuals may have been those most invested in child assent, which may have been reflected in the assent processes for the target protocols.

Second, there was variability with respect to characteristics of the sample and the target protocols (although, notably, most target protocols were observational and minimal risk). Although this variability increases the generalizability of our findings, it may have limited our ability to detect associations among the primary variables of interest. Third, the measures of the primary variables were all based on youth self-report, so we cannot rule out shared method variance as an explanation for the significant associations (Podsakoff, MacKenzie, Lee, & Podsakoff, 2003). Fourth, there are potential limitations in the methods we used for the factor analysis of the RDMIS-R/C. For example, use of parallel analysis for choosing the number of factors to retain might have yielded different findings regarding the factor structure of the instrument. In addition, while the factor analyses of the original DMIS and the RDMIS-R/C were based on the Pearson correlation matrix, use of the polychoric correlation matrix might be more appropriate given the ordinal nature of the items. These methods should be considered in future research using the RDMIS-R/C. Finally, although the mean number of days from assent for the target protocol to our assessment was 15, some participants completed our study as long as two months later. Recall bias may have affected participants’ responses (Grimes & Schulz, 2002); however, time since assent was not associated with either outcome.

Best Practices

These findings, although preliminary, suggest that an assent process characterized by soliciting the child’s questions and concerns in the decision is associated with the child’s perceived self-efficacy. As such, these communication behaviors may be more meaningful to children than those that focus on providing detailed information about the research study and may be beneficial for children. Research personnel should consider implementing these specific communication strategies during the assent process. Furthermore, because communicating that the child was central to the decision was associated with more favorable perceptions of the decision making process, research personnel should consider including explicit statements regarding the child’s role in the decision during the assent process, such as saying that it is okay to decline and asking if the child wants to do the research study or not. However, research personnel should always be clear that, even if the child desires to participate, the parent’s permission is also required and therefore, the parent may override the child’s wishes.

Research Agenda

Future research is needed on several fronts related to children’s involvement in decision making about research participation. First, research should seek to understand the impact of different forms of decision making involvement on other outcomes such as satisfaction with

research participation, adherence to research procedures, and retention in longitudinal studies. Second, it will be important to broaden the sampling frame that was used in the present study, by assessing decision making involvement in more ethnically diverse samples. Furthermore, reducing variability in the target protocols may help to isolate the effects of decision making involvement on specific outcomes. Third, prior research in the clinical care context suggests that the dynamics of the child-parent-researcher triad may be important for future efforts to understand and facilitate assent to research participation (Savage & Callery, 2007; Tate, Meeuwesen, Elbers, & Bensing, 2002; van Staa & On Your Own Feet Research Group, 2011; Wassmer et al., 2004). Fourth, future research should utilize observational methods to measure children's involvement (Miller et al., 2014; Olechnowicz, Eder, Simon, Zyzanski, & Kodish, 2002) and assess children immediately after the assent discussion, to reduce the potential effects of shared method variance and recall bias on the results. Finally, research is needed to develop, implement, and test interventions to increase direct, autonomy-supportive communication with children during the assent process and enhance children's favorable views of decision making, in ways that do not unduly burden research personnel time and resources.

Educational Implications

Educational implications include assent-related training for investigators and research staff that addresses specific strategies that can be used to facilitate children's involvement in discussions about potential research enrollment and communicating to children that they are central to the decision. Such trainings should underscore that explaining the research and providing an assent form are merely the starting point for assent and that the assent process is enhanced when investigators and research staff listen to children, show an interest in their concerns and questions, check for their understanding of what has been explained to them, and indicate that the child has an important role to play in the decision about research participation. While it is important for assent-related trainings to address the regulatory requirements regarding child assent, such trainings should also emphasize that the assent process can be used to benefit children (e.g., enhancing self-efficacy) and that children's favorable perceptions of decision making about research participation may have other benefits, such as facilitating compliance with research procedures and study retention.

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Biographies

Victoria A. Miller is a pediatric psychologist and associate professor of pediatrics in the Division of Adolescent Medicine at The Children's Hospital of Philadelphia and Perelman

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Chris Feudtner is a pediatrician, epidemiologist, historian, and ethicist at The Children's Hospital of Philadelphia and a professor of pediatrics, medical ethics and health policy at the Perelman School of Medicine at the University of Pennsylvania. His primary research focus has been decision making in the setting of life-threatening pediatric illness. This research has been informed by his clinical practice in pediatric ethics consultation and pediatric palliative care. Dr. Feudtner critically reviewed and revised the manuscript.

Abbas Jawad is a statistician and associate professor of pediatrics at The Children's Hospital of Philadelphia and Perelman School of Medicine at the University of Pennsylvania. He has been providing biostatistical support for pediatric medical research for more than 20 years. Dr. Jawad conducted the statistical analysis and critically reviewed and revised the manuscript.

Abbreviations

RDMIS-R/C Research Decision Making Involvement Scale- Researcher/Child

DMIS Decision Making Involvement Scale

PI Principal Investigator

References

- Agre P, Rapkin B, Dougherty J, Wilson R. Barriers encountered conducting informed consent research. *IRB: Ethics & Human Research*. 2002; 24(4):1–5.
- American Academy of Pediatrics (AAP) Policy Statement. Informed consent, parental permission, and assent in pediatric practice (RE9510). *Pediatrics*. 1995; 95:314–317. [PubMed: 7838658]
- Bandura A. Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*. 1977; 84:191–215. [PubMed: 847061]
- Bartholome WG. A new understanding of consent in pediatric practice: Consent, parental permission, and child assent. *Pediatric Annals*. 1989; 18(4):262–265. [PubMed: 2755734]
- Bartholomew LK, Parcel GS, Swank PR, Czyzewski DI. Measuring self-efficacy expectations for the self-management of cystic fibrosis. *Chest*. 1993; 103(5):1524–1530. [PubMed: 8486038]
- Baylis F, Downie J, Kenny N. Children and decisionmaking in health research. *IRB: Ethics & Human Research*. 1999; 21(4):5–10. [PubMed: 11660758]
- Beal, DJ. SAS code to select the best multiple linear regression model for multivariate data using information criteria. Paper presented at the SESUG 2005: The Proceedings of the SouthEast SAS Users Group; Portsmouth, VA. 2005. http://analytics.ncsu.edu/sesug/2005/SA01_05.PDF
- Bentler PM, Chou C. Practical issues in structural modeling. *Sociological Methods and Research*. 1987; 16:78–117.
- Bluebond-Langner, M., DeCicco, A., Belasco, J. Involving children with life-shortening illnesses in decisions about participation in clinical research: A proposal for shuttle diplomacy and negotiation. In: Kodish, E., editor. *Ethics and research with children: A case-based approach*. New York: Oxford; 2005. p. 323-343.

- Broome ME, Richards DJ. The influence of relationships on children's and adolescents' participation in research. *Nursing Research*. 2003; 52(3):191–197. [PubMed: 12792260]
- Browne, MW., Cudeck, R. Alternative ways of assessing model fit. In: Bollen, KA., Long, JS., editors. *Testing structural equation models*. Newbury Park, CA: Sage; 1993. p. 136-162.
- Bunn H, O'Connor A. Validation of client decision-making instruments in the context of psychiatry. *Canadian Journal of Nursing Research*. 1996; 28:13–27. [PubMed: 8997937]
- Cascardi M, Poythress NG, Hall A. Procedural justice in the context of civil commitment: An analogue study. *Behavioral Sciences and the Law*. 2000; 18:731–740. [PubMed: 11180419]
- Clark LA, Watson D. Constructing validity: Basic issues in objective scale development. *Psychological Assessment*. 1995; 7(3):309–319.
- Cox ED, Smith MA, Brown RL, Fitzpatrick MA. Learning to participate: Effect of child age and parental education on participation in pediatric visits. *Health Communications and Informatics*. 2009; 24:249–258.
- Cranney A, O'Connor AM, Jacobsen MJ, Tugwell P, JD A, Ooi DS, et al. Development and pilot testing of a decision aid for postmenopausal women with osteoporosis. *Patient Education and Counseling*. 2002; 47:245–255. [PubMed: 12088603]
- Croom A, Wiebe DJ, Berg CA, Lindsay R, Donaldson D, Foster C, Swinyard MT. Adolescent and parent perceptions of patient-centered communication while managing type 1 diabetes. *Journal of Pediatric Psychology*. 2011; 36(2):206–215. [PubMed: 20719752]
- Dorn L, Susman E, Fletcher JC. Informed consent in children and adolescents: Age, maturation, and psychological state. *Journal of Adolescent Health*. 1995; 16:185–190. [PubMed: 7779827]
- Federal Policy for the Protection of Human Subjects. 45 C.F.R. 2001; 46:408a.
- Fogas B, Oesterheld J, Shader R. A retrospective study of children's perceptions of participation as clinical research subjects in a minimal risk study. *Developmental and Behavioral Pediatrics*. 2001; 22(4):211–216.
- Ford JK, MacCallum RC, Tait M. The application of exploratory factor analysis in applied psychology: A critical review and analysis. *Personnel Psychology*. 1986; 39:291–314.
- Freed LH, Ellen JM, Irwin CE, Millstein SG. Determinants of adolescents' satisfaction with health care providers and intentions to keep follow-up appointments. *Journal of Adolescent Health*. 1998; 22:475–479. [PubMed: 9627818]
- Geller G, Tambor ES, Bernhardt BA, Fraser G, Wissow L. Informed consent for enrolling minors in genetic susceptibility research: A qualitative study of at-risk children's and parents' views about children's role in decision-making. *Journal of Adolescent Health*. 2003; 32:260–271. [PubMed: 12667730]
- Grady C, Wiener L, Abdoler E, Trauernicht E, Zadeh S, Diekema DS, Wendler D. Assent in research: The voices of adolescents. *Journal of Adolescent Health*. 2014; 54:515–520. [PubMed: 24630932]
- Grimes DA, Schulz KF. Bias and causal associations in observational research. *Lancet*. 2002; 359(9302):248–252. [PubMed: 11812579]
- Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics*. 2009; 42(2):377–381. [PubMed: 18929686]
- Iannotti RJ, Schneider S, Nansel TR, Haynie DL, Plotnick LP, Clark LM, Simons-Morton B. Self-efficacy, outcome expectations, and diabetes self-management in adolescents with type 1 diabetes. *Developmental & Behavioral Pediatrics*. 2006; 27(2):98–105.
- Joffe S. Rethink “affirmative agreement,” but abandon “assent”. *American Journal of Bioethics*. 2003; 3(4):9–11. [PubMed: 14744308]
- Kyngas H, Hentinen M, Barlow JH. Adolescents' perceptions of physicians, nurses, parents and friends: help or hindrance in compliance with diabetes self-care. *Journal of Advanced Nursing*. 1998; 27:760–769. [PubMed: 9578206]
- Kyngas H, Rissanen M. Support as a crucial predictor of good compliance of adolescents with a chronic disease. *Journal of Clinical Nursing*. 2001; 10:767–774. [PubMed: 11822848]
- Martin LR, DiMatteo MR, Lepper HS. Facilitation of patient involvement in care: Development and validation of a scale. *Behavioral Medicine*. 2001; 27:111–120. [PubMed: 11985184]

- McCabe MA. Involving children and adolescents in medical decision making: Developmental and clinical considerations. *Journal of Pediatric Psychology*. 1996; 21(4):505–516. [PubMed: 8863460]
- Miller VA, Baker JN, Leek AC, Drotar D, Kodish E. Patient involvement in informed consent for pediatric cancer research. *Journal of Pediatric Hematology and Oncology*. 2014; 36(8):635–640.
- Miller VA, Harris D. Measuring children's decision making involvement regarding chronic illness management. *Journal of Pediatric Psychology*. 2012; 37(3):292–306. [PubMed: 22138318]
- Miller VA, Jawad A. Relationship of youth involvement in diabetes-related decisions to treatment adherence. *Journal of Clinical Psychology in Medical Settings*. 2014; 21:183–189. [PubMed: 24659299]
- Miller VA, Nelson RM. Moving beyond the consent document in research on informed consent. *Archives of Pediatrics and Adolescent Medicine*. 2005; 159:396–397. [PubMed: 15809398]
- Miller VA, Nelson RM. A developmental approach to child assent for non-therapeutic research. *Journal of Pediatrics*. 2006; 149(1, Supp):S25–S30. [PubMed: 16829238]
- Miller VA, Reynolds WW, Nelson RM. Parent-child roles in decision-making about medical research. *Ethics & Behavior*. 2008; 18(2–3):161–181.
- Olechnowicz JQ, Eder M, Simon C, Zyzanski S, Kodish E. Assent observed: Children's involvement in leukemia treatment and research discussions. *Pediatrics*. 2002; 109(5):806–814. [PubMed: 11986440]
- Podsakoff PM, MacKenzie SB, Lee JY, Podsakoff NP. "Common method biases in behavioral research: A critical review of the literature and recommended remedies. *Journal of Applied Psychology*. 2003; 88(5):879–903. [PubMed: 14516251]
- Savage E, Callery P. Clinic consultations with children and parents on the dietary management of cystic fibrosis. *Social Science and Medicine*. 2007; 64:363–374. [PubMed: 17064831]
- Schmidt S, Petersen C, Bullinger M. Coping with chronic disease from the perspective of children and adolescents- a conceptual framework and its implications for participation. *Child: Care, Health & Development*. 2003; 29(1):63–75.
- Shabason JE, Mao JJ, Frankel E, Vapiwala N. Shared decision-making and patient control in radiation oncology. *Cancer*. 2014; 120(12):1863–1870. [PubMed: 24648117]
- Sleath BL, Carpenter DM, Sayner R, Ayala GX, Williams D, Davis S, Yeatts K. Child and caregiver involvement and shared decision making during asthma pediatric visits. *Journal of Asthma*. 2011; 48:1022–1031. [PubMed: 22022958]
- Tait AR, Voepel-Lewis T, Malviya S. Do they understand? (Part II): Assent of children participating in clinical anesthesia and surgery research. *Anesthesiology*. 2003; 98:609–614. [PubMed: 12606902]
- Tates K, Meeuwesen L, Elbers E, Bensing J. 'I've come for his throat': roles and identities in doctor-parent-child communication. *Child: Care, Health & Development*. 2002; 28(1):109–116.
- Unguru Y, Sill AM, Kamani N. The experiences of children enrolled in pediatric oncology research: Implications for assent. *Pediatrics*. 2010; 125(4):e876–e882. [PubMed: 20351001]
- van Staa A, On Your Own Feet Research Group. Unraveling triadic communication in hospital consultations with adolescents with chronic conditions: The added value of mixed methods research. *Patient Education & Counseling*. 2011; 82:455–464. [PubMed: 21194872]
- Walker NE, Doyon T. 'Fairness and reasonableness of the child's decision:' A proposed legal standard for children's participation in decision making. *Behavioral Sciences and the Law*. 2001; 19:611–636. [PubMed: 11787072]
- Wassmer E, Minnaar G, Aal NA, Atkinson M, Gupta E, Yuen S, Rylance G. How do pediatricians communicate with children and parents? *Acta Paediatrica*. 2004; 93:1501–1506. [PubMed: 15513580]
- Wilfond BS, Diekema DS. Engaging children in genomics research: decoding the meaning of assent in research. *Genetics in Medicine*. 2012; 14(4):437–443. [PubMed: 22323071]
- Young B, Dixon-Woods M, Windridge KC, Heney D. Managing communication with young people who have a potentially life threatening chronic illness: Qualitative study of patients and parents. *British Medical Journal*. 2003; 326:305–309. [PubMed: 12574042]

Table 1

Demographics (complete sample of N = 180)

	<i>n</i> (%); or mean (<i>SD</i>), range
Child age (years)	12.56 (2.82), 8–17
Child sex: Female	93 (52%)
Child race	
White	106 (59%)
Black or African American	60 (33%)
Other	10 (6%)
Asian	3 (2%)
Missing	1 (1%)
Is child Hispanic or Latino?	
No	172 (95%)
Yes	7 (4%)
Missing	1 (1%)
Child has prior research experience	57 (32%)
Chronic condition status	
Child has chronic condition <i>related</i> to target protocol	116 (64%)
Child has chronic condition <i>not related</i> to target protocol	22 (12%)
Child does not have chronic condition	42 (23%)
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 (complete sample of N = 180)

	<i>n</i> (%)
Division	
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%)
Type of intervention	
Drug	30 (68%)
Website portal	9 (21%)
Peanut desensitization	2 (5%)
Device	1 (2%)
Vitamin	1 (2%)
Procedure	1 (2%)
Risk category	
Minimal	147 (82%)
Minor increase over minimal	27 (15%)
Greater than minimal	6 (3%)
Does the study provide incentives for participation?	
No	78 (43%)
Yes	102 (57%)

Table 3

Descriptive Information for Permission and Assent Details for Target Protocol, Fairness Score, and Decision Self-Efficacy (complete sample of N = 180)

	<i>n</i> (%) or Mean (<i>SD</i>), range
Days since permission/assent for target protocol	14.97 (11.52), 0–64
Did research personnel talk directly to the child?	
No	13 (7%)
Yes	167 (93%)
If yes, who was the primary person who talked to the child?	
Research assistant/coordinator	104 (62%)
Nurse	6 (4%)
Child's own physician	7 (4%)
Physician- researcher	5 (3%)
Other (Medical Assistant)	45 (27%)
How long did this person talk to the child? (minutes)	19.19 (27.12), 2–180
Did parent talk directly to the child about the study?	
No	32 (18%)
Yes	148 (82%)
If yes, how long did parent talk to the child? (minutes)	17.77 (23.85), 1–120
Fairness score	10.57 (1.52), 5.00–12.00
Decision self-efficacy	3.38 (0.53), 1.38–4.00

Table 4
Factor Loadings of the Final RDMIS-R/C Items Based on Exploratory Factor Analysis (N = 167)

Subscales and Items	Factor 1	Factor 2	Factor 3	Cronbach's α	mean (SD), range
<i>Researcher Engages Child (Factor 1)</i>				0.82	3.29 (0.58), 1.13–4.00
The researcher listened to what I had to say	.77	-.18	.13		
The researcher asked me what I thought about the research	.64	.01	.15		
The researcher checked to see if I understood the research	.62	-.09	.03		
The researcher asked me if I had any questions about the research	.60	.15	.13		
The researcher asked me if I had any worries about the research	.56	.04	.08		
The researcher asked me how I felt about the research	.51	.11	.19		
The researcher explained the research to me	.44	.12	.02		
The researcher told me my opinion was important	.40	.21	.11		
<i>Researcher Supports Autonomy (Factor 2)</i>				0.73	2.66 (0.53), 1.00–4.00
The researcher told me it was okay to say no to the research study	-.12	.73	.01		
The researcher told me it was my decision	.15	.62	-.02		
The researcher told me that he/she wouldn't be mad if I didn't want to participate in the research study	-.07	.55	.04		
The researcher asked me if I wanted to do the research study or not	.32	.53	-.14		
<i>Child Participates (Factor 3)</i>				0.80	2.14 (0.74), 1.00–4.00
I told the researcher how I felt about the research	.00	.08	.73		
I asked for the researcher's advice or opinion about the research	-.08	.01	.72		
I asked the researcher if I should do the research study or not	-.13	.01	.58		
I asked the researcher for information about the research	.07	-.03	.58		
I asked the researcher questions about the research	.08	-.12	.57		
I told the researcher what I thought about the research	.21	.03	.55		

Note: Values in bold typeface indicate that factor onto which each item loaded.

Table 5

Multivariate Regressions Predicting Fairness and Decision Self-Efficacy (N = 167)

Models	<i>F</i>	<i>B</i>	95% CI for <i>B</i>	Adj. <i>R</i> ²
Dependent Variable: Fairness				
1.	21.09 ***			.20
Child age		.19 ***	.11–.26	
Researcher Supports Autonomy		.65 **	.24–1.05	
Dependent Variable: Decision Self-Efficacy				
2.	13.92 ***			.14
Child age		.03 *	.01–.06	
Researcher Engages Child		.24 ***	.13–.37	

p < .0001**
p < .002*
p < .02

Note: “*F*” refers to the overall test of significance of the regression model, “*B*” refers to the unstandardized regression coefficient for the relationship between the independent and dependent variable, “CI” refers to the 95% confidence interval around *B*, and “Adj. *R*²” refers to the total variance in the dependent variable accounted for by the independent variables in the model, after adjusting for the number of predictors in the model.