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A Goodness-of-Fit Approach to Informed Consent for Pediatric Intervention Research

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Abstract

As children and adolescents receive increased research attention, ethical issues related to obtaining informed consent for pediatric intervention research have come into greater focus. In this paper, we conceptualize parent permission and child assent within a goodness-of-fit framework that encourages investigators to create consent procedures "fitted" to the research context, the child's cognitive and emotional maturity, and the family system. Drawing upon relevant literature and a hypothetical case example, we highlight four factors investigators may consider when constructing consent procedures that best reflect participants' rights, concerns, and well-being: (1) The child's current assent capacity and the likely impact of study information on the child's mental and physical development; (2) parents' understanding of their child's treatment needs and distinctions between treatment and clinical trials research; (3) the family's history of shared decision-making, and (4) the child's strivings for autonomy within the context of their parents' duty to make decisions in the child's best interest; and.

Key words: informed consent, assent, goodness of fit, pediatric intervention research, pediatric oncology

The unique characteristics of children with behavioral and biomedical disorders create special challenges for investigators seeking to test the efficacy of pediatric interventions. Obtaining informed consent for child participation in such research is particularly challenging because minors do not have the legal status to independently consent to research and depending on the age of the child they may lack the cognitive maturity or experience to make an informed participation decision. For research with the prospect of direct benefit (hereafter referred as "intervention research"), U. S. Federal Regulations require that at least one parent of a potential pediatric research participant give permission for the child to participate in the research. Investigators are also strongly encouraged to obtain assent, or a statement of agreement, from the child. The assent requirement may be waived when the child's age, maturity, psychological state, or health status indicates an inability to provide informed or rational assent, or when the research offers a benefit to the health of the child which cannot be obtained through treatment outside the context of research (Department of Health and Human Services [DHHS], 2005, 45 CFR 46.408). However, neither federal regulations nor scientific organization ethics codes have laid out explicit procedures directing investigators how to make the determination that child assent should be sought or waived or how to mediate participation disputes within families when both parent permission and child assent are sought (Joffe et al., 2006).

This paper examines the ongoing challenge for investigators to develop informed consent procedures that are sensitive to the research context, the child's developmental capacities and treatment needs, and the parent-child relationship. While there has been some progress in producing empirical data on child involvement in the consent conference for pediatric biomedical trials, such data is lacking for pediatric psychosocial clinical trials. The goal of the paper is to bring together what is known about consent and assent and frame these issues within

a goodness-of-fit model of parental permission and child assent for mental health intervention research involving children.

A Goodness-of-Fit Model for Informed Consent

Fisher has called for a research ethic that conceptualizes informed consent for studies involving participants with questionable consent capacities in terms of the goodness-of-fit among (a) the participant's social-cognitive capacities and disorder-based vulnerabilities; (b) guardians' understanding of the participant's health condition and research terminology; (c) previous preferred modes of health decision-making for the participant; and (4) the unique characteristics of the specific research context (Fisher, 2003a, 2003b). Conceptualizing research risks and benefits as a product of experimental design and participant and guardian attributes shifts judgments regarding ethical procedures away from an exclusive focus on assumed participant or guardian vulnerabilities to an examination of those aspects of the research setting that are creating or exacerbating research vulnerability. When constructing parental permission and child assent procedures, the goodness-of-fit ethic encourages investigators to consider how the consent setting can be modified to produce a process that best reflects (1) the participant's rights, concerns, and welfare (Fisher, 2003a, 2005) and the own researcher's competencies and obligations (Fisher, 1997, 1999).

The usefulness of a goodness-of-fit model has previously been applied to studies involving adults with developmental disabilities, at risk for suicidality, drug use, and from ethnocultural populations as well as to research involving children with cancer and adolescent risk behavior (Fisher, 2003c; Fisher & Goodman, inpress ; Fisher & Masty, 2006; Fisher, Pearson, Kim, & Reynolds, 2002; Fisher & Ragsdale, 2007). When extending the goodness-of-

fit framework to pediatric behavioral intervention research, we propose the investigator can create a "family-fitted" consent process by considering the following dimensions:

1. The child's current cognitive capacity to understand and emotional readiness to make participation decisions about the issues posed by the specific research problems and design;
2. Contextual factors and characteristics that might affect parents' understanding of the nature of the child's disorder and the distinction between medical or mental health treatment and intervention research;
3. The family's history of shared decision-making for the child's health-related matters.
4. The child's autonomy strivings balanced with parents' duty and responsibility to make decisions in their child's best interest; and

In the sections that follow we provide an overview of current knowledge and suggestions for how to apply the goodness-of-fit to each of these dimensions.

Fitting Assent Procedures to Child's Cognitive and Emotional Readiness

In deciding how to involve the child participant in the consent conference, investigators working within the goodness-of-fit framework will first consider the assent capacity of the child. Truly "informed" assent to pediatric research rests on children's ability to comprehend information presented during the consent conference and their emotional preparedness to process facts about their condition.

Age Differences in Assent Capacity

The age at which parents and investigators feel minors are able to take part in the consent conference will among other factors depend upon the developmental changes in cognitive reasoning skills. The growing body of literature on children's capacity to understand

their research rights and the nature of research provides a broad outline of age changes in these abilities. For example, Nannis (1991) found that third and fifth graders had difficulty understanding that the research they took part in was designed to assess their ability to detect math errors, not to help them improve their math skills. Abramovitch and her colleagues found that 5- to 12-year olds understand the purpose and procedures of nonclincial research, but they have poor understanding of the risks and benefits of research, their right to withdraw, the voluntariness of research participation, and confidentiality (Abramovitch, Freedman, Henry, & Van Brunschot, 1995; Abramovitch, Freedman, Thoden, & Nikolich, 1991). Similarly, Bruzzese and Fisher (2003) observed that fourth grade children had difficulty understanding the purpose of research and both fourth and seventh graders did not fully comprehend their right to withdraw from research. The ability to understand consent information, to define research rights, and to identify rights violations generally increased with age, but tenth graders had an understanding of research rights at an adult level. The authors suggested that deficits in understanding research methods may reflect younger children's difficulty to process multiple informational items simultaneously and systematically while deficits in understanding the voluntary nature of research may be a result of inexperience with independent decision making and the power differential between adults and children. Consistent with this perspective, Melton (1980) found that adolescents view self determination as universally granted, but young children think it is a privilege granted by parents.

Many empirical studies on research consent comprehension involving healthy children and those receiving psychiatric treatment suggest that the ability to fully comprehend both the nature of research and research rights do not fully emerge until mid-adolescence, at

approximately 14 to 15 years of age (Abramovitch et al., 1995; Abramovitch et al., 1991; Bruzzese & Fisher, 2003; Grisso & Vierling, 1978; Lewis, Lewis, & Ifekwungue, 1978; Melton, 1980; Ruck, Abramovitch, & Keating, 1998; Ruck, Keating, Abramovitch, & Koegl, 1998). Weithorn and Campbell (1982) found that 14-year-olds, but not 9-year-olds, were as competent as adults to make decisions about hypothetical medical and psychological treatments. Parents' and childrens' opinions parallel empirical findings. For example, Masty, Fisher, Cruz-Arrieta, and Reisman (2006) reported that children who had participated in a pediatric trial as well as their parents thought the child's age was a significant factor for determining the involvement of a patient in the pediatric consent conference. When Alderson (1993) asked children undergoing orthopedic surgery, their parents, and health professionals about the age at which children should be able to consent to surgery, children and parents suggested that 14 year olds could provide consent, although clinicians suggested 10 years as the threshold. Fisher (2002) reported that parents and adolescents also identified age 14 years as the age at which teenagers could be responsible for making independent consent decisions. These data suggest that fitting assent language to the age level of the child may be a necessary but not sufficient means of assuring that younger children understand the research procedure or their research rights.

Cognitive Factors Associated with the Disorder under Investigation

It is customary that investigators provide minors with an assent form that consists of a simply-worded explanation of the research study, including much of the same information provided in the informed consent form for parents. However, assent content tailored to the developmental level of the child may not be well-fitted to the current cognitive or emotional deficiencies that some children with serious health problems or mental disorders may develop. For example, newly diagnosed pediatric cancer patients demonstrate a decreased ability to

comprehend clinical trials information compared to children of the same age who were diagnosed with diabetes (Broome, Richards, & Hall, 2001; Crisp, Ungerer, & Goodnow, 1996). Childhood psychological disorders may present similar challenges. For example, children who have difficulty attending to the research discussion because of their attention deficit hyperactivity disorder (ADHD) may not be able to fully comprehend the study information or appreciate the implications of their participation options. Cognitive impairments associated with youth drug use and suicidality may also preclude rational assent. .

Children's Reactions to Consent Procedures

The growing commitment among investigators to involve children in clinical trials participation decisions has advanced more rapidly than empirical examination of the mental health consequences of placing this decisional responsibility on children with physical or mental disorders. Careful theoretical consideration of the issue suggests that there is potential for both positive and negative consequences on the prospective participants' health outlook and responsivity to treatment. Child participants' readiness to be informed about the study rationale, inclusion criteria, risks and benefits, and procedures may depend, in part, on the nature of the child's illness. Although empirical data is lacking, the psychological disorders that bring families to the consent conference for behavioral intervention research might yield different reactions to information about the study, especially when the disorder to be treated has be associated with family conflict. . For example, fully disclosing to a child that a study's purpose is to decrease the effects of the child's irritability and depression on family interactions may inadvertently cause the child to experience guilt or fuel dysfunctional power struggles with his or her parents. Moreover, in psychotherapy research, some aspects of clinical trials that are difficult to understand may compromise the therapeutic alliance. For example, asking children for a

participation decision after they have been told that random assignment to a treatment or control condition will not be their choice may be confusing to younger children who have not yet obtained the ability to think recursively and perceived as disingenuous by adolescents.

There is some evidence suggesting that involving children in the consent process can have both short and long-term benefits. Participation in the research decision may increase children's feelings of self-worth, their ability to cope with anxiety regarding illness and treatments, and their long-term emotional and social adjustment (Fletcher, van Eys, & Dorn, 1993; Grodin & Burton, 1988; Varni, Katz, Colgrove, & Dolgin, 1996). Further inviting children to participate in health and research decisions may be a way in which parents can promote their children's sense of self-efficacy. More research on the psychological effects of research-related information and the opportunity to make participation decisions on children's well-being is needed to determine how assent procedures can be appropriately fitted to participant reactivity to consent information.

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Fitting Parental Permission to Parent Information Needs

In deciding how to design the consent conference, an investigator working within the goodness-of-fit framework will also consider the consent strengths and vulnerabilities of the parents or guardians who are legally responsible for the participation decision. Often, during initial visits when researchers screen families for study eligibility, they inquire as to the educational background and language comprehension of parents. Sometimes, a family psychiatric or medical history is taken as well. These characteristics can inform investigators about issues relevant to the consent content and format. Investigators can then "fit" the consent conference to the parents' language level, parents' familiarity and experience with the child's disorder, levels of anxiety about their child's health, their knowledge of the distinctions between

research and treatment, and cultural factors that may shape their understanding and responsivity to the consent conference. Although there is a good deal of research published on parent characteristics in regards to consent, as illustrated in this section most of the studies focus on medical clinical trials. There is a need for this line of research to be extended to psychopharmacological and psychosocial intervention research.

Parental Anxiety

Parents' needs during the consent conference may vary in response to the degree of emotional distress they are experiencing at the time research decisions must be made. This is especially true when prospective child participants have been non-responders to standard treatments. In the case of behavioral research, parents may be desperate to find an intervention that will improve the functioning of the impaired child in school or at home. For example, parents of children with disorders related to school misconduct may be under pressure from school authorities to take steps that will prevent their child's school expulsion. Parents of an adolescent with an eating disorder may not accept their child's behavior as indicative of psychopathology or, in the face of extreme weight loss, may be desperate to seek an intervention that includes hospitalization. Parents of an adolescent hospitalized following a suicide attempt may be asked to enroll their children in a research trial within hours or days of receiving diagnosis of bipolar disorder or major depression. Hence, the timing of the research participation decision can be a confusing and emotional time for families with suffering children (Eiser, Davies, Jenney, & Glaser, 2005; Kodish et al., 1998; Kupst, Patenaude, Walco, & Sterling, 2003).

Under the pressure of stressful circumstances, parents are often unsure about their child's diagnosis, prognosis, and the nature of random assignment to treatment conditions (Eiser et al.,

2005; Kodish et al., 2004). In a study by Kupst et al. (2003), a majority of parents (70%) reported that their high levels of distress during consent discussions for a pediatric oncology trial interfered with their ability to ask questions about the research and their child's illness. Similarly, Ruccione, Kramer, Moore, and Perin (1991) found that parents who experienced high anxiety at the time they provided informed consent for pediatric oncology trials reported that the anxiety was related to an inability to clearly understand the risks associated with the study treatment. Wiley et al. (1999) conducted a case-controlled multi-site study to examine how parents' perceptions and knowledge about randomization in clinical trials impacted their decisions for their children's randomization in pediatric cancer research. They found that parents' perception of randomization as frightening predicted, in part, whether or not they gave permission for their children to participate in a randomized clinical trial.

Distinguishing Treatment from Intervention Research

Many parents have difficulty distinguishing between standard medical treatment and their child's participation in a treatment study, and they often do not understand the term "randomization" (Kodish et al., 2004; Kupst et al., 2003; Levi, Marsick, Drotar, & Kodish, 2000). Wiley et al. (1999) reported that most parents who entered their child in a randomized pediatric oncology study believed that the experimental treatment would benefit their child more than future patients. Of the patients and parents surveyed in the Masty et al. (2006) pilot study who had participated or were currently enrolled in a cancer research study, 56% believed that they had *never* participated in clinical research and 6% were unsure.. Confusion between the nature of treatment and clinical research is also present in pediatric psychopharmacology trials (Vitiello et al., 2005) and in studies on other childhood conditions (Bergler, Pennington, Metcalfe, & Freis, 1980; Lidz & Appelbaum, 2002; Miller & Rosenstein, 2003). Misconceptions

regarding the therapeutic value of clinical trials research has been observed in adult patient populations as well, and was coined the "therapeutic misconception" by (Appelbaum, Roth, Lidz, Benson, and Winslade, 1987) YES. While assumed to be prevalent in pediatric research involving medical disorders, there is little empirical information available regarding parents' understanding of research information or the presence of the therapeutic misconception in pediatric behavioral intervention studies (Lavori, Sugarman, Hays, & Feussner, 1999).

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Cultural, Educational, and Economic Influences

Investigators also need to be sensitive to cultural differences that may affect parents' comfort in asking questions during the consent conference (Fisher, 2005). The type of information investigators provide, in addition to their presentation style, may interact with culturally-derived communication preferences and impact parents' comfort level (Fisher, Hoagwood, et al., 2002). For example, Miller, Drotar, Burant, and Kodish (2005) found that parents of racial minority status and low socioeconomic status asked fewer questions and were more likely to miss or misunderstand consent information for pediatric cancer trials. They also learned that investigators provided less information to these families and made fewer partnership building statements. When parental permission for child participation in intervention research is sought in educational or service delivery settings, language differences, disparities in access to treatment, lack of familiarity with intervention research, or immigration status may elicit fear that failure to consent will result in discontinuation of services. In these situations, parents may also transfer to the researcher their trust in the institution (e.g., school, clinic, hospital, agency) without understanding the difference between the investigator and practitioner roles (Fisher, Hoagwood, et al., 2002).

Family Decision-Making and Disagreements

A family's history of cooperative discussion and shared decision-making may determine the degree to which a child's opinions can be "fitted" to the research participation decisions. In general, when the child is older and more mature, when the disorder is not posing a serious threat to the child's physical or mental well-being, when there are valid treatment options outside the research, and when the family communication style is more open, there will be a greater propensity for pediatric research decisions to be made together as a family (Geller, Tambor, & Bernhardt, 2003). On the other hand, if the family culture is such that the child's input is not sought on a regular basis, the child may not be accustomed to or wish to make health decisions. The child may not fully embrace the idea of assent because he or she has not had the opportunity to learn what decision-making entails, including critical thinking and an examination of possible consequences (Abromavitch et al., 1991; Bruzzese & Fisher, 2003; Scherer, 1991; Susman, Dorn, & Fletcher, 1992). Children may choose to have their parents make the participation decision because that is what is customarily done, or because the child does not want the pressure of making critical health decisions. In some cases, respect for parental authority and confidence in parental decision-making may lead children to actively defer participation decisions to parents. In a survey study, Fisher (2003b) found that approximately 33% of adolescents favored parental permission requirements for research on adolescent risk behaviors, and percentages were higher when the respondents were of African American background and younger in age (Fisher, 2003b).

Child's Best Interest

Although it is assumed that parents will make decisions in their children's best interests, some parents, such as those who abuse or neglect their children, may have conflicting interests for enrolling their children in intervention studies. As Margolin et al. (2005) describe, this can

happen in subtle ways, such as providing inaccurate information about a child such that he or she can qualify for a study that offers free assessments, treatments, or monetary compensation. Inappropriate study entry may result in additional risks or harms to the child, and should be avoided if possible. In cases like this, where it is determined that parents are not making research decisions in the child's best interest, investigators can request an ethics consultation, seek a child advocate, or turn to the IRB for help in identifying the best way to protect the child. In such situations the child's understanding of his or her research rights and research procedures takes on added importance in determining whether or to what degree their assent will be sought.

Parent-Child Disagreements and Expectations

Another ethical challenge is deciding how to navigate the consent decision when parents and children take opposing positions. The literature on pediatric informed consent indicates that disagreements occur a substantial amount of the time. Hawley and Weisz (2003) found that in community clinics, children, parents, and therapists disagreed on primary treatment and research issues three-fourths of the time. Parents and adolescents also tend to differ in their perception of research risks and benefits (Fisher, 2003b). Additionally, children and parents may have different motivations for participating in intervention research (Fisher, Hoagwood, et al., 2002). Incentives such as free treatment, health monitoring, and assessments may motivate parents to enroll their children in intervention research, but these benefits are unlikely to be as important to children. When disagreements arise within the consent conference, the investigator's primary role is to facilitate family discussion, not necessarily to mediate the conflict or render judgment as to whose concerns are more valid.

Parents and children may have different expectations about how such disagreements will be resolved. For example, one study found that both parents and adolescents expected that their

own decision would be prioritized over the other's opinion. Parents said they would acknowledge the child's preferences, although not necessarily allowing the child to make the final decision, but adolescents did not endorse parents' ability to influence them (Brody, Scherer, Annett, & Pearson-Bish, 2003). Perceived power inequities between child and parent, child and investigator, or even parent and investigator may preclude truly voluntary participation in research on behalf of children (Fisher, 2005). Children may believe that they do not have any freedom to choose between treatment and research alternatives, or to provide valid assent or dissent to a particular research study (Brody, Scherer, Annett, & Pearson-Bish, 2003). Furthermore, it is unclear whether children believe that their assent or dissent will be meaningful. In one of the few studies conducted on assent to behavioral research, Abramovitch et al. (1995) found that children aged 7-12 were more likely to voice dissent and stop research participation if they were told that the investigator would not be upset with their decision. Cohn, Ginsburg, Kassam-Adams, and Fein (2005) found that adolescents who gave their assent for an interview on youth violence when in a room without their parents felt freer to make the decision to participate in research. A child's response to the social pressure of investigators and parents depends on multiple factors, including the child's age, the seriousness of the decisions, the nature of the research, and the type of influence that is present (i.e., explicit or implicit; Scherer, 1991). A child's trust in the research process can be undermined when his or her opinion is sought after parents have already given permission for research participation before consulting the child, or when parents decide that the child's opinions about research participation are irrelevant (Koocher, 2003).

Parental Responsibility and Child Autonomy

When conducting the consent conference, investigators working within the goodness-of-fit framework face the dual task of supporting young participants' developing autonomy and parents' responsibility to make decisions in their children's best interest. Investigators routinely seek input from children during the consent process. But the degree and weight of pediatric participation in clinical trial entry and withdrawal decisions is variable (Olechnowicz, Eder, Simon, Zyzanski, & Kodish, 2002). Inviting children with the capacity to assent to participate in health and research decisions is a way in which parents can promote their children's well-being and developing autonomy (Alderson, 1993; Fisher, 2002).

At the same time, parents are responsible for determining what is in their child's best interest and for protecting their child against undue harm that may arise when consent participation is developmentally inappropriate (Melton, 1999). Given some children's limited world experience and lack of a well-formulated life plan, investigators should be wary of reflexively giving child autonomy privileged status over parents' responsibilities to direct the autonomy strivings of their children (Childress, 1990; Fisher & Masty, 2006; Ross, 1997). In some intervention research contexts, parents may be justifiably concerned that assent procedures may increase their child's fear of his or her disorder, pessimism about the treatment, or anxiety about treatment risks. On the other hand, in some instances, failure to involve the child in the participation may stifle children's autonomy development (Kunin, 1997). There is some evidence that children and parents are acutely aware of the tension between child autonomy and parental protection. Masty et al. (2006) found that a majority of both children and parents who had participated in pediatric oncology trials believed that while it was important to respect a child's decision-making abilities, parents had a responsibility to shield their children from anxiety-provoking information and to protect their children from feelings of blame or guilt if participation did not produce positive effects.

Implications of the Child's Condition on Parents' Willingness to Seek Their Involvement

Finally, the family's history of shared decision making may be a consequence of the nature of the child's condition, beyond the extent to which the child's cognitive capacity is affected. Parents of children with life-threatening conditions such as untreated diabetes, asthma, drug overdose, obsessive-compulsive disorder, or major depression with suicidality may have found themselves frequently in the position of making health care decisions for their child that the child may not have agreed to or been unable to make, but are nevertheless necessary for the child's well-being. When these children have not responded to standard treatments, parents (as well as their children) may see it as the parents' responsibility to make the research participation decision. In other situations, the disorder under investigation may itself be associated with parent-child conflict. For example, the anger, irritability, and oppositionality that are characteristic of some common childhood psychological disorders such as ADHD, oppositional defiant disorder (ODD), and conduct disorder, may "cause" children to disagree with parents about research participation. Furthermore, adolescents who suffer from disorders from which they receive some secondary gain, such as eating disorders and drug abuse, may not be motivated to change their behaviors and may not be compliant with research interventions.

The ethical concerns may be most difficult in these cases where the research intervention appears to provide the probability of direct benefit to the child, but because of the nature of the child's illness, the child cannot provide voluntary assent or carry through with research procedures. If parents are prepared to override their child's opposition to participating in a study, investigators may be in the position to tell parents that the child's assent should not be sought. On the other hand, noncompliant children may not be good candidates for some forms of research because the research interventions need to be administered in a standardized way. In

these situations, a caring investigator should provide the family with a referral to obtain effective clinical treatment elsewhere. The impact of psychological disorders on children's ability to give meaningful assent (over and above their capacity to make rational decisions) is another important area of research that needs future study. Nonetheless, investigators can be sensitive to the interaction of patient disorder and parental responsibility to collaborate with parents in fitting the child's role in the research participation decision to these factors.

Goodness-of-Fit Recommendations

The following recommendations draw from the literature reviewed above to assist investigators in best fitting consent and assent procedures to participant, parent and family characteristics and the research context.

1. Consider the Child's Cognitive and Emotional Maturity, Nature of Disorder, and Possible Reactions to Assent Information

A goodness-of-fit approach to assent takes into consideration child characteristics indicative of competence to make decisions, such as age, health, and the nature of the child's disorder. Assent competence is also affected by the child's understanding of his or her condition and characteristic ways of handling difficult situations. Accordingly, investigators may wish to encourage increasing levels of child participation in consent decisions as children approach 14 years of age and when the child's mental or medical condition has not adversely affected cognitive or emotional functioning. A child's previous experience in research, familiarity with his or her diagnosis, and a family history of participating in decisions relevant to his or her health can also support greater assent detail and child participation in the consent context. As suggested by Joffe et al. (2006) assent capacity can also be assessed by evaluating the quality of responses children give when asked why they want to participate in research. Children who show that they

have weighed the pros and cons of participating and can provide plausible justification for enrolling in the study should be considered capable of providing assent.

However, child assent assessments should not be conducted in the absence of parental input and investigators should carefully consider both the benefits and potential pitfalls of over-riding parents' preferences regarding the degree of their child's input on the participation decision (Joffe et al., 2006). Moreover, children should never be asked to assent or dissent to participation if their choice will not be respected. There are a range of levels at which children can be involved in the clinical trials consent decision. Child participation may range from taking the family lead in making the participation decision, to having the opportunity to override the parents' positive participation decision, to having their opinions sought and considered as parents make the final decision, to providing the child with only the information that will best prepare him or her for participation. Consent is a continuing process that does not end when the child initially enters the trial. Children whose age or medical or mental health status was judged to preclude assent involvement at the outset of a study, may improve over the course of the research, especially in longer term studies, providing an opportunity to fit assent information to the child's developing abilities.

2. Fit the Consent Conference to Parent Knowledge and Characteristics

A goodness-of-fit approach to parental permission takes into account the contextual factors that may be affecting the parents' decisional capacities, such as educational background, language fluency, anxiety, and the pressure to rapidly obtain help for their children. Investigators can optimize informed parental decisions by being sensitive to the timing of the consent conference and by being open to delaying the participation decision (when feasible) until parents feel less stress and pressure. The consent discussion can also take place on multiple occasions.

Investigators can take time to repeat main points and encourage active questioning from parents during the consent discussion. When consent is sought in service delivery settings it may be important to clarify the investigators' relationship to the setting and underscore the distinction between service and research roles. Of added importance are clear explanations of the purpose of assessments and interventions conducted to gain scientific knowledge distinguished from those conducted exclusively for receipt of treatments or services (Fisher, Pearson, et al., 2002). To combat misperceptions about the research, it may be beneficial to consider making research information available in alternative formats. In addition to the informed consent form, study information can be presented in brief summary sheets, videos, or computer-based presentations. Investigators can also seek feedback from participants about what they do and do not understand and to use such feedback to fill in the gaps in their knowledge. Some investigators ask parents to complete questionnaires to assess their understanding of the research (Vitiello et al., 2005). By putting forth effort to ally with parents during the stressful times, investigators can develop a rapport that will permit parents to feel more comfortable expressing their concerns and enable investigators to adequately fit consent information and format to the parent characteristics and needs.

3. Consider Each Family's Decision-Making History and Negotiation Process

A goodness-of-fit approach to consent and assent takes into consideration the child-parent dynamic and the characteristic ways in which the family makes other decisions. Investigators should encourage pediatric participants to be actively involved in the consent conference when they are accustomed to doing so. However, investigators should also be aware that some children may prefer that their parents make research decisions for them, and investigators need to curb any urges to push children to take a strong position. Children who

easily agree with their parents' decision to enroll or not enroll in research are often functioning in the role they are most used to. Furthermore, encouraging children to express disagreements with parents in some instances have iatrogenic effects in producing child anxiety or family conflict at a time when the child's health is at issue. To further preserve family harmony, investigators should be attentive to cultural norms that the family embraces regarding family structure and roles.

It is not the investigator's role to talk families into participating in research, nor to solve family conflicts that arise when children and parents disagree. Instead, investigators operating under the goodness-of-fit framework should try to understand the values and priorities of each party and encourage a helpful discussion of the issues. Investigators can explain to parents the conditions under which children can dissent and when parents can overrule the wishes of their children under federal regulations (DHHS, 2005, 45 CFR 46.408), but they should also voice their concerns about the negative impact of invalidating a child's opinion and the methodological problem of potential non-compliance from a child who is vehemently opposed to participating in a behavioral intervention. Investigators can seek advice from their IRBs or encourage families to seek treatment outside of the research context altogether by offering a clinical referral. Ultimately though, the investigator must respect the position of parents, who are legally responsible for the well-being of their children. In an effort to make the consent discussion best "fit" each family's qualities and circumstances, investigators can re-visit the participation decision as time passes and both children and their parents better understand the implications of the initial consent decision.

4. Respect Each Family's Profile of Child Autonomy and Parental Protection

A goodness-of-fit approach to parent permission and assent takes into consideration the developing autonomy of pediatric participants within the context of parents' responsibilities to protect their children and make decisions in their best interest. Many parents strongly believe that it is their duty to shield their children physically and emotionally within the research context. Although investigators generally support this view, in some cases, investigators may empathize with young patients in advocating independence from parental protection. However, in an effort to make the consent discussion best "fit" each family's unique qualities, investigators must be wary of their potential bias to prioritize children's autonomy over parents' desires to shield their children from information or responsibilities they believe will be harmful. Investigators may be unintentionally doing a disservice to patients and their families by encouraging adolescent autonomy before the family system can support it. If parents express concern that a discussion of particular research topics may be distressing to their children, especially when the research holds out a possibility of direct benefit to the child that is not available outside of the research study, investigators may wish to encourage a family discussion so that parents can share this information with children at the level they feel is most appropriate. Investigators need to encourage cooperative decision-making at the point on the autonomy continuum that best suits the family in their current developmental context.

Finding the right balance between valuing child autonomy and parental protection may be a challenge given the changing nature of families. The decisional power of pediatric participants will differ depending on the unique characteristics of individual families. Variations in cultural conceptions of parental authority, individual autonomy, and collective responsibility may call for consideration of different levels of adult and community involvement in consent decisions (Council of National Psychological Associations for the Advancement of Ethnic Minority

Interests, 2000; Fisher, Hoagwood, et al., 2002).When designing informed consent protocols, investigators should make efforts to understand expectations toward guardian permission and child assent reflecting cultural attitudes, values, and histories regarding the roles of family members. In some family settings, the best approach to child involvement may include providing a clear description of the research for the child and encouraging active participation by asking for feedback rather than a participation choice. In this way, investigators highlight the value of the child's independent concerns while respecting the family's decision-making values. Following the child's feedback, investigators can encourage parents to take into account the child's opinion in the final participation decision. Investigators can best serve the future autonomy of young study participants by facilitating the consent conversation such that the study information is conveyed clearly, the child's concerns are validated, and by ensuring that the child's participation is not coerced. Investigators may also wish to express genuine interest in procuring input from participants about positive and negative side effects of the research intervention throughout the research process.

An Illustration of the Goodness-of-Fit Approach: A Case Example

The following is a hypothetical case example of an investigator using the goodness-of-fit framework during a consent conference for a psychosocial intervention study.

The Bissee Family

The Bissee family has just arrived at a local university outpatient mental health clinic to complete the informed consent process for their 8-year old son Ned to participate in a randomized, waitlist-controlled psychosocial treatment study for oppositional defiant disorder (ODD). The investigator, Dr. Kalm, explains the purpose of the study and inquires as to their interest in the research.

Recommendation 1: Consider the Child's Cognitive and Emotional Maturity, Nature of Disorder, and Possible Reactions to Assent Information. Dr. Kalm then asks the parents to describe Ned's current functioning so that she can assess whether Ned has the capability to understand the study information. She also engages Ned in a brief conversation about his interests and why he is at the clinic. Ned initially does not respond to Dr. Kalm's questions. Then he complains that this is a waste of his time. With further prompting it becomes clear that Ned is having difficulty understanding what a research study is and continues to associate the clinic with other visits to doctors. In addition to determining that his cognitive level is not mature enough to understand the research, Dr. Kalm is concerned that a discussion about certain aspects of the study may exacerbate Ned's defiance and anxiety about the problems that he is having. Consequently, she explains to the family that, at this point, it might be more comfortable for Ned to play in the outer waiting room.

Recommendation 2: Fit the Consent Conference to Parent Knowledge and Characteristics. Dr. Kalm asks Mr. and Mrs. Bissee about their educational backgrounds, language facility, and prior experience with research [Recommendation 2 - *assessing consent needs and competence*]. Dr. Kalm provides Mr. and Mrs. Bissee with a verbal explanation of the information on the consent forms and encourages the parents to ask questions. To ensure that the Bissees understand the research information, Dr. Kalm asks them to relay back to her the key aspects of the study and their research rights. Mrs. Bissee starts to cry during the discussion of the experimental nature of the treatment and the use of a waitlist condition. Dr. Kalm acknowledges that if Ned is assigned to the waitlist, his behavior could worsen. However, she also explains the ways the researchers minimize risk, and she assures the Bissees that they can withdraw from the study at any time. Noting that they are in mild distress, Dr. Kalm offers to

take a short break or to delay the consent conference until another day. After a five minute break, Mr. and Mrs. Bissee state that they would like to enroll Ned in the study. They express their hope that the research treatment will help Ned. They also like the idea that they will be helping scientists learn about this new treatment.

Recommendation 3. Consider Each Family's Decision-Making History and Negotiation Process. Dr. Kalm asks the Bissees how they usually make family decisions. They report that they rarely invite Ned to make important choices because he typically chooses the opposite of what they think is best for him out of spite. Mr. and Mrs. Bissee assume that Ned will not agree to participate in the study if asked. Ned's oppositional style has also made it difficult to evaluate whether Ned will have sufficient understanding of the research to provide meaningful assent or dissent. Therefore, given the nature of his condition, Ned's non-responsiveness to previous treatments, and the prospect of direct benefit afforded only by this study, and they all agree that the parents will make the enrollment decision and it would be unwise to allow Ned to have a final say or veto power.

Recommendation 4. Respect Each Family's Profile of Child Autonomy and Parental Protection. Dr. Kalm suggests that Ned return to the room so that he can participate in the discussion. Ned sits at the table with a scowl on his face. Dr. Kalm supports Ned's growing autonomy by suggesting to him, "Before your parents make the final decision about enrolling in this study, I'd like to tell you a little more about the study so you can ask some questions and help your parents understand anything about the research that you would like them to consider." Ned says he does not want to miss school to be in a silly study and that since nothing has worked to help him the study will be just another waste of time. Dr. Kalm praises Ned for his comments and assures him that he will attend the sessions after school. She also tells him she understands

his disappointment in other treatments and that while she cannot promise him that being in the research will help with all his problems, he will be helping therapists know what types of treatments work best for children who have problems just like Ned. She then suggests that Mr. and Mrs. Bissee share with Ned their understanding of his concerns and their reasons for why they think it is a good idea for him to participate in the study.

Dr. Kalm then reminds Ned that the decision to participate is up to his parents. Mr. and Mrs. Bissees reiterate to Ned that they think participating in the research is a good idea and the sign the parent permission forms. Ned complains that he did not agree, but Dr. Kalm assures him that there are many decisions he will be able to make throughout the process. “In fact, provided that it is okay with your parents, you can choose the day that you will come back and start the study.” Dr. Kalm encourages the Bissees to contact her at any time if they have questions about the research and tells Ned that she will be checking in with him when he visits the clinic.

Discussion

In the Bissee family case, the goal of the consent conference was not restricted to providing accurate information to Ned and his parents. Instead, using the goodness-of-fit model for parent permission and child assent to research, Dr. Kalm made a special effort to get a sense of each member of the Bissee family’s current level of functioning and their family decision-making culture. With a better understanding of their unique characteristics, she “fit” the consent conference to match the family’s consent informational needs, Ned’s autonomy strivings and his parents’ desire to make decisions in his best interest, and the style in which the family typically makes important decisions within the context of his ODD. Dr. Kalm achieved the delicate balance between fulfilling her responsibilities to the participant and to his legal guardians while also respecting the individual qualities of the Bissee family.

Suggestions for Future Research

The small but growing literature on child and family engagement in the consent process is a critical step in informing goodness-of-fit approaches to child assent and parent permission in pediatric intervention research. One promising avenue of research is to directly explore the attitudes of parents and children toward the ethical challenges discussed above. For example, to examine family attitudes toward child participation in pediatric oncology trials Masty et al. (2006) developed the Family Decision-Making Questionnaire (FDMQ), which consists of 30 items, scored on a 4-point Likert scale, covering 5 main topics: (1) what information adolescent patients should be given regarding the research; (2) which patient and family characteristics affect the decision to allow adolescents to participate in the decision to begin research; (3) the degree to which adolescents should have a say in the decision to participate; (4) how and when adolescents participate in withdrawal decisions; and (5) each individual's previous research experience. A similar approach can be tailored to psychosocial intervention research with particular attention paid to the child's age and disorder. Focus groups are also effective methods for exploring parents' and children's knowledge and attitudes regarding involvement in participation decisions for psychosocial research interventions (for example, see Fisher, 2003b). For different mental health disorders, age groups, and cultural groups a goodness-of-fit ethic points to the need for research on the following questions: (a) To what extent is the child's responsivity to experimental procedures positively or negatively affected by knowledge of randomization, control conditions, or the nature of his or her disorder? (b) Under what conditions is involvement in the participation decision empowering or anxiety producing for children? What approaches would increase empowerment and reduce anxiety? (c) Does the extent to which the consent conference was successfully or unsuccessfully fitted to the

needs of the child and parents have long-term effects on later family decision-making? On parents' trust in the research process? (d) How does application of the goodness-of-fit approach to consent impact research knowledge, study enrollment rates, patient autonomy, family decision-making, and consumer satisfaction in research participation?

Some investigators in fields outside of pediatric oncology and other medical disorders (Vitiello et al., 2005) have begun to explore the effectiveness of consent and assent procedures in conveying important research information. More work on formats to enhance parent and child comprehension of research methodologies (randomization, control groups) and research rights (voluntariness, confidentiality) for pediatric behavioral intervention research are needed. For example, Bruzzese and Fisher (2003) found that a brief 10 minute lesson prior to study participation improved comprehension of research rights in children, adolescents, and young adults from 4th grade through college.

To understand better how the goodness-of-fit model can be adapted for psychosocial intervention studies, it is important to understand what parents do and do not want their children to know about research, the reasons for their concerns, and what steps should or should not be taken to ameliorate these concerns. It is also vital that investigators consider how their values and perceived obligations concerning the role of children in research participation decisions may match or mismatch parental concerns and reasons for differences in perspective when they exist so that so that investigators can more effectively construct parent permission and assent procedures that reflect the values and merit the trust of child participants and their families.

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