

Commentary: SES, Ethnicity and Goodness-of-Fit in Clinician-Parent Communication during Pediatric Cancer Trials

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Creating appropriate parental permission contexts for clinical trials involving newly diagnosed pediatric cancer patients is uniquely challenging. Unlike most other childhood disorders, pediatric cancer is most often treated through participation in oncology research or in hospital settings in which such research is actively conducted (Ablett & Pinkerton, 2003; Aleksa & Koren, 2002; Bleyer, 2002; Pletsch & Stevens, 2001). In addition, because treatment decisions must be made very quickly after diagnosis, parents are often asked to enter their child in a clinical protocol within hours or just a few days after learning their child's diagnosis. Thus, consent to research participation occurs during one of the most stressful periods in a family's life and before parents have an opportunity to accept or learn about the disease and alternative treatments (Levi, Marsick, Drotar, & Kodish, 2000). Finally, because of the life-threatening nature of the disease and the adverse, sometimes permanent, side effects of many current interventions, treatment and research goals may be blurred not only by parents but by investigators, clinicians, and other care providers (Kodish et al., 1998). Informed consent for pediatric cancer trials takes on added ethical complexity when patient families are diverse with respect to income, education, culture, and language. In such contexts, investigators need to be sensitive to the unique consent requirements of different parent populations as well as their own professional attitudes toward socio-demographic differences (Fisher & Wallace, 2000; Fisher et al., 2002).

Miller, Drotar, Burant, & Kodish et al. (in press) have contributed much needed data to the small but growing body of empirical research on factors affecting the adequacy of the informed consent conference (ICC) for newly diagnosed acute lymphoblastic and myeloid

leukemia. In particular, their findings should encourage other investigators to evaluate the multidimensional factors influencing whether parental permission for children's participation in cancer trials is informed, rationale, and voluntary. First, they selected sites that enabled examination of ICC assets and barriers posed by parent socioeconomic status and ethnicity. Second, they developed a model to test previously unexamined causal links among parent demographics, clinician communication styles, parental questions during the ICC, and parental emotional reactions to and understanding of ICC communication about pediatric cancer trials. Third, they used a multi-method approach to provide both contemporaneous behavioral and retrospective attitudinal data relevant to the effectiveness of the ICC. Finally, drawing upon previous measures of clinician efficacy and parental distress, they operationalized partnership building, rapport building, information-giving, and information-seeking into measurable clinician and parent behaviors and obtained quantifiable self-reports of parental anxiety and control. Their approach is a model of theory testing that takes into account the contributions of both parent and clinician factors to family understanding and anxiety following informed consent.

Direct Effects of SES and Ethnicity

Miller et al.'s (this issue) clearest findings are that both SES (socioeconomic status) and membership in a minority ethnic group (largely Hispanic) have a negative main effect on informed-consent comprehension irrespective of clinician-parent communication factors. It is not surprising that parental SES, typically classified from a calculation of job categories and highest level of education, independently predicted understanding of consent

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information. For example, parents in clerical or manual-labor positions with a high school diploma as their highest degree would be expected to have less familiarity with medical terms and scientific concepts associated with clinical trials than parents in professional positions with college educations. Similarly, that minority ethnicity (a grouping of Hispanics, Blacks, and Asians in the present study, but overwhelmingly Hispanic) predicted poorer understanding of consent information could be anticipated given the fact that more than half of the ethnic minority parents who participated were non-English speaking, suggesting these parents had less familiarity with American medical science as well as treatment terms and procedures. It is important that readers of Miller et al.'s article take into account these critical language characteristics of the sample and do not wrongly infer from the findings that ethnic minority membership in and of itself predicts poor understanding of clinical trials.

Effects of SES and Ethnicity on Clinician Communication

What is surprising in the Miller et al. (in press) data is the direct and inverse effect parent SES and ethnicity had on investigator information-giving. Clinicians provided less information during the ICC to parents of lower SES and ethnic minority status. Clinicians were also less likely to ask parents of lower SES for their opinions or encourage them to ask questions (partnership building). Thus, those parents who were least likely to be familiar with medical research procedures and terminology received the least information about facts critical to this important family decision. On the other hand, all parents received clinician empathy and reassurance (rapport building).

Why did clinical investigators with obvious empathy and concern for all participating parents of cancer patients offer less information about pediatric oncology research trials to those with less education and less English language skills? One might speculate on at least two answers to this question.

Communication Barriers

One interpretation of clinician responses to parental SES and ethnicity may be that the stark educational, cultural, and language differences between highly trained clinicians and families from lower SES and diverse cultural and language groups are too difficult for both clinicians and parents to overcome, therefore stifling clinician information-giving and parental information-seeking. In

addition, traditional attitudes within the medical establishment favoring an ethic of paternalism (Beauchamp & Childress, 1994) may be triggered when clinical scientists are confronted with educational and cultural informed-consent vulnerabilities. The investigators attempted to reduce such barriers by having interviews available in both English and Spanish. However, matching interviewer-parent language (or ethnic group membership) does not in and of itself assure that such procedures can overcome informed-consent obstacles created by different socioeconomic and ethno-cultural communication styles. Drawing upon feedback from clinical staff, future research might explore different communication options for different parent groups so that research teams can be trained in the cultural competencies best suited for ICC with diverse groups (Fisher et al., 2002).

Goodness-of-Fit

Additional patterns of parent responses to the ICC suggest an alternative explanation for less information-giving to lower SES and ethnic minority parents. Two of the more striking findings of the Miller et al. (in press) study were that less clinician information-giving during the ICC and lower SES predicted less parental anxiety and greater sense of parental control. This raises the intriguing possibility that rather than reacting to communication barriers or acting on pre-existing biases, clinicians were sensitive to the particular consent needs of parents from different SES and cultural/language groups, tailoring the amount of information-giving and question seeking to the emotional and psychological needs of individual parents.

A Goodness-of-Fit Ethic for Informed Consent

The ICC for pediatric oncology trials raises unique emotional and psychological reactions that need to be fitted to individual family decisional and health crises-coping styles. Parents are emotionally responding to having just learned of their child's cancer diagnosis. They must place their trust in clinicians who are relative strangers and rapidly take in information about the risks, benefits, and scientific purpose of randomized clinical trials. And, they must do all of this in the unfamiliar setting of the hospital.

Two common coping styles observed when adults are confronted with what they appraise as uncontrollable healthcare situations are information-seeking and information-avoiding. Parents who use an information-seeking coping style attempt to obtain as much information as possible about the situation to provide a brief

sense of control. Parents who are most comfortable with an information-avoiding style apply behavioral or cognitive strategies aimed at distancing themselves from stressful information to provide a short-term means of emotionally mastering periods of uncertainty (Lazarus & Folkman, 1984; Moos & Schaefer, 1993; Wisselo, Stuart, & Muris, 2004). Parental permission procedures for pediatric clinical trials frequently do not take into account these varying parental coping styles.

I have argued elsewhere that respectful consent procedures require scientists to strive for goodness-of-fit between participant decision-making styles and the consent context (Fisher, 2003a, 2003b). A goodness-of-fit ethic describes scientists' efforts to go beyond simply protecting parents from making participation decisions that would be counter to the best interests of pediatric patients. Rather, investigators must be willing to reconfigure the ICC to reduce decisional and emotional vulnerabilities that may emerge from the ICC itself. This family-context reframing may involve remedial efforts to enhance consent comprehension coupled with efforts to attain mutual understandings and support among parents, investigator, and patient (Fisher & Brokowski, 2004; Fisher & Masty, in press).

In pediatric oncology, investigator-clinicians can reduce consent vulnerabilities by providing family members with age and language-appropriate pre-consent educational materials, improve the readability and format of written consent and assent documents, be willing to repeat information and institute a respectful process of checking parent comprehension, provide families with an audio tape of the consent conference, and encourage them to review materials at home and consult with trusted others before making an informed decision (American Academy of Pediatrics, 1995; Kupst et al., 2003; Ruccione et al., 1991). Miller et al.'s (this issue) provocative findings suggest that for some families appropriate ICC communication may call for clinician sensitivity to the level of detail that is best fitted to each family's decision-making styles and modified to minimize those aspects of the consent context that may be stress provoking.

Conclusion

Miller et al.'s (this issue) model testing is a significant empirical step forward in conceptualizing post-ICC parental knowledge and distress as the product of both parental and investigator characteristics and behaviors. Their data suggest that effective informed-consent procedures must include empathic, respectful, and informa-

tive communications fitted to individual differences in parental socioeconomic status and ethnicity. From a goodness-of-fit perspective, consent vulnerability is not defined solely in terms of the socioeconomic, ethnocultural, psychological, or social characteristics of individual family members (Fisher, 1999; Goodin, 1985). Rather the degree to which parents are able to make informed, rational, and voluntary research decisions for their children depends upon the willingness of pediatric oncology investigators to fit the consent context to the unique informational needs of each family.

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References

- Ablett, S., & Pinkerton, C. R. (2003). Recruiting children into cancer trials – role of the United Kingdom Children's Cancer Study Group (UKCCSG). *British Journal of Cancer*, 88, 1661–1665.
- Aleksa, K., & Koren, G. (2002). Ethical issues in including pediatric cancer patients in drug development trials. *Pediatric Drugs*, 4, 267–265.
- American Academy of Pediatrics. (1995). Informed consent, parental permission, and assent in pediatric practice. *Pediatrics*, 95, 314–317.
- Beauchamp, T., & Childress, J. (1994). *Principles of Biomedical Ethics*. New York: Oxford.
- Bleyer, A. (2002). Older adolescents with cancer in North America deficits in outcome and research. *Pediatric Clinics of North America*, 49, 1027–1042.
- Fisher, C. B. (1999). Relational ethics and research with vulnerable populations. Reports on research involving persons with mental disorders that may affect decision-making capacity, Vol. II 29–49. Rockville, Maryland: Commissioned Papers by the National Bioethics Advisory Commission.
- Fisher, C. B. (2003a). A goodness-of-fit ethic for child assent to non-beneficial research. *American Journal of Bioethics*, 3, 27–28.
- Fisher, C. B. (2003b). A goodness-of-fit ethic for informed consent to research involving persons with mental retardation and developmental disabilities. *Mental Retardation and Developmental Disabilities Research Reviews*, 9, 27–31.
- Fisher, C. B., & Brokowski, C. (2004). Cancer patients, adolescent: involvement in clinical trials decision making. In C. B. Fisher, & R. M. Lerner (Eds.), *Applied Developmental Science: an Encyclopedia of Research, Policies, and Programs* (Vol 1, pp. 199–202). Thousand Oaks, CA: Sage Publications.

- Fisher, C. B., Hoagwood, K., Boyce, C., Duster, T., Frank, D. A., Grisso, T., Levine, R. J., Macklin, R., Spencer, M. B., Takanishi, R., Trimble, J. E., & Zayas, L. H. (2002). Research ethics for mental health science involving ethnic minority children and youths. *American Psychologist*, *57*, 1024–1040.
- Fisher, C. B., & Mastay, J. K. (in press). A Goodness-of-Fit Ethic for Informed Consent to Pediatric Cancer Research. In R. T. Brown (Ed.), *Pediatric Hematology/Oncology: a Biopsychosocial Approach*. New York: Oxford University Press.
- Fisher, C. B., & Wallace, S. A. (2000). Through the community looking glass: Re-evaluating the ethical and policy implications of research on adolescent risk and psychopathology. *Ethics and Behavior*, *10*, 99–118.
- Goodin, R. E. (1985). *Protecting the Vulnerable*. Chicago, IL: University of Chicago Press.
- Kodish, E. D., Pentz, R. D., Noll, R. B., Ruccione, K., Buckley, J., & Lange, B. J. (1998). Informed consent in the children's cancer group: Results of preliminary research. *Cancer*, *82*, 2467–2481.
- Kupst, M. J., Patenaude, A. F., Walco, G. A., & Sterling, C. (2003). Clinical trials in pediatric cancer: Parental perspectives on informed consent. *Journal of Pediatric Hematology and Oncology*, *25*, 787–790.
- Lazarus, R., & Folkman, S. (1984). *Stress, Appraisal and Coping*. New York: Springer Publishing Co.
- Levi, R. B., Marsick, R., Drotar, D., & Kodish, E. D. (2000). Diagnosis, disclosure, and informed consent: Learning from parents of children with cancer. *Journal of Pediatric Hematology and Oncology*, *22*, 3–12.
- Miller, V. A., Drotar, D., Burant, C., & Kodish, E. (in press). Clinician-Parent Communication During Informed Consent for Pediatric Leukemia Trials.
- Moos, R., & Schaefer, J. A. (1993). Coping resources and processes: Current concepts and measures. In L. Goldberg, & S. Breznitz (Eds.), *Handbook of Stress: Theoretical and Clinical Aspects*, (2nd edn, pp. 234–257). New York: Free Press.
- Pletsch, P. K., & Stevens, P. E. (2001). Children in research: Informed consent and critical factors affecting mothers. *Journal of Family Nursing*, *7*, 50–70.
- Ruccione, K., Kramer, R. F., Moore, I. K., & Perin, G. (1991). Informed consent for treatment of childhood cancer: Factors affecting parents' decision making. *Journal of Pediatric Oncology Nursing*, *8*, 112–121.
- Wisselo, T. L., Stuart, C., & Muris, P. (2004). Providing parents with information before anaesthesia: what do they really want to know? *Paediatric Anaesthesia*, *14*, 299–207.