Clinician–Parent Communication during Informed Consent for Pediatric Leukemia Trials

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Objective To address the need to describe informed consent in pediatric settings and to identify barriers to parent understanding, this study assessed how aspects of clinician–parent communication during the informed consent conference (ICC) relate to parent understanding of informed consent and parent perception of the impact of the ICC on their anxiety and control. **Methods** Parents of 127 children with newly diagnosed leukemia who were eligible for clinical trials were the participants. The study used comprehensive methods including both observational and self-report assessment methods. **Results** Structural equation modeling demonstrated that parent race and socioeconomic status (SES) were powerful predictors of clinician–parent communication, parent anxiety and control as a result of the ICC, and parent understanding. Clinician information giving and partnership building predicted parent participation during the ICC. **Conclusions** These findings may be used to design interventions that increase the effectiveness of the ICC by identifying specific elements of the conference that influence parent affect and understanding.

Key words informed consent; pediatrics; leukemia; communication; research ethics.

Effective communication is the cornerstone of the clinician–patient and clinician–parent relationship and effective health care delivery (DiMatteo, 1994). The way in which clinicians communicate about research participation is particularly important and provides the foundation of adequate informed consent. The empirical examination of informed consent is important not only for psychologists who conduct research with pediatric populations, but also because there is a need for psychological perspectives to be included in such research. Psychological research and theory can inform policy and guidelines regarding informed consent, especially because there is a significant gap between what has been documented in scientific research and actual policies for informed consent (Stanley, Sieber, & Melton, 1987). There is also a need to understand the psychological impact of research to protect human subjects and reduce the risk of exploitation (Rae & Fournier, 1986). In addition, there are many psychological factors that are potentially relevant for both clinician–parent communication in general and informed consent in particular, such as parents' emotional state, physicians' attitudes and beliefs toward parents and families, and parent and physician decision-making concerning treatment and research.

The informed consent conference (ICC) for the medical treatment of pediatric cancer is a unique context in which to empirically examine the process of informed consent. Nearly all children with cancer are eligible for clinical research trials, and most children with cancer enroll in such clinical trials (NCCN, 1996). In this context, parents and clinicians face many barriers to informed consent, such as inadequate patient understanding, time constraints, the stress induced by decision-making, and

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problematic clinician–patient communication. Previous research in pediatric settings has demonstrated inadequate recall of key aspects of informed consent (Dermatis & Lesko, 1990; Harth & Thong, 1995).

One of the most important potential barriers to informed consent is the parents' high level of distress at the time of their child's diagnosis of cancer (Levi, Marsick, Drotar, & Kodish, 2000; Sloper, 2000). The distress of parents of children with newly diagnosed cancer may affect their understanding of information regarding options for their child's treatment which are complex (Janis, 1993) and, consequently, may limit their ability to make informed treatment decisions, especially within a highly compressed time frame. Parents' sense of control over the process of informed consent may also be related to the degree to which parents actively engage in decision-making about research treatment options.

In addition to the impact of parent anxiety and control on the informed consent process, less than optimal clinician–parent communication may also compromise parental understanding of informed consent for research concerning the treatment of childhood cancer. At the time of the diagnosis of pediatric cancer, clinicians have the task of providing complex medical information to parents and patients, providing support, and guiding parents through the treatment decision-making process, including the decision about the option to enroll in a clinical trial (Levi et al., 2000). The way in which both clinicians and parents communicate during this highly stressful time may influence the degree to which parents understand the clinical trial, as well as their level of anxiety and sense of control over their situation. However, to our knowledge, the nature and impact of clinician–parent communication during the ICC for research on the treatment of childhood cancer have not been studied.

The purpose of this study was to assess how aspects of clinician–parent communication during the ICC for pediatric leukemia trials (clinician information giving, partnership building, and rapport building, as well as parent participation) relate to parent understanding of informed consent and parent perceptions of the impact of the ICC on their anxiety and control. This study addressed several limitations of previous research on informed consent. First, the study sites were chosen to recruit a substantial number of ethnic minority and non–English-speaking parents to identify barriers to informed consent for vulnerable individuals, which has been described as a research priority (Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999). Second, previous research in this area has relied on retrospective reports of what occurs during the ICC, which may not accurately reflect what actually transpires and do not provide the level of detail that is necessary for understanding clinician–parent communication during the ICC. This study utilized observational methods, which are more accurate than retrospective reports, to describe what actually happens during the ICC and how clinicians communicate with parents and families in this context. Third, this study broadened the measurement of factors that may affect the informed consent process by documenting parent affect, as well as parents' participation during the ICC, which is important insofar as it reflects the parents' autonomy in the informed consent process. Moreover, well-established components of physician–parent communication were measured during the actual consent conference (e.g., information giving, partnership, rapport, and parent participation).

This study also builds on the literature on clinician–parent communication by examining communication in the unique context of pediatric cancer, which may be more stressful compared to other contexts because of the possibility of death, time pressure, and the complexity of the medical information (Siminoff & Fetting, 1991). The examination of situation-specific components of clinician–parent communication has been identified as a research priority (Nobile & Drotar, 2003). In addition, although prior research on clinician–parent communication has relied on correlation and regression techniques, this study utilized structural equation modeling (SEM) to test the primary hypotheses. The benefits of SEM include the ability to test causal relationships between variables, assess both direct and indirect effects on explained variables, deal with more than one explained variable at a time, and measure the overall fit of a model to the data (Biddle & Marlin, 1987).

A model of hypothesized relationships is presented in Figure 1. Clinician information giving can include the amount of information provided by clinicians, the level of detail of this information, and the clarity of the information provided (Hall, Roter, & Katz, 1988; Siminoff, 1992). More information giving by clinicians was expected to relate to greater parental understanding of informed consent (Hall et al., 1988; Siminoff, 1992) because it would equip parents with more information about the child's condition, treatment, and potential clinical trial participation. Furthermore, more information giving by clinicians was expected to relate to less anxiety and more control as a result of the ICC because parents have information and resources to cope with a stressful situation, participate in decision-making, and take action (Dediarian, 1987; Dermatis & Lesko, 1990).

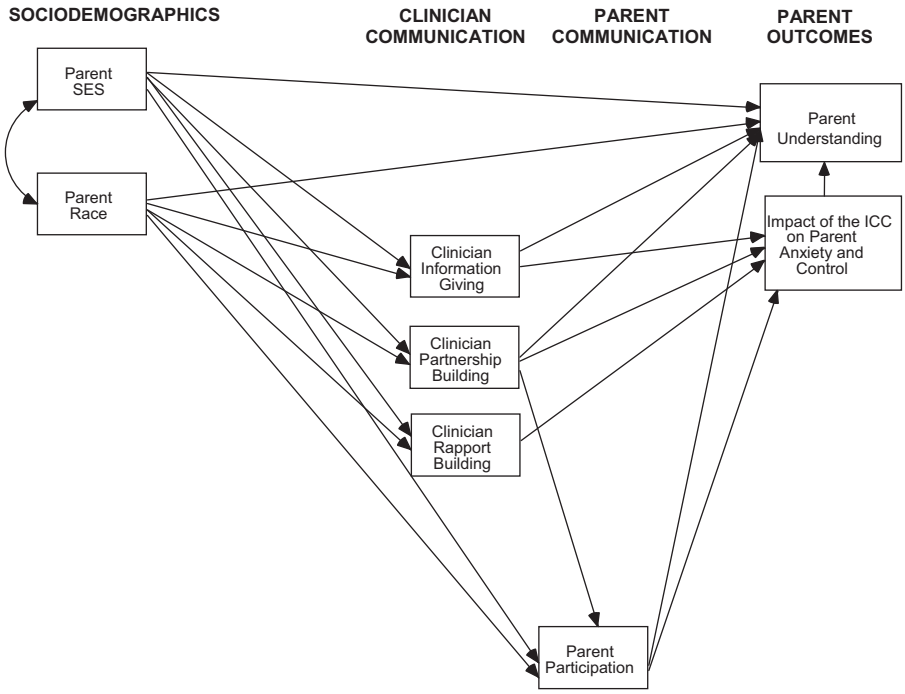

Figure 1. Hypothesized model.

Partnership building consists of clinicians asking for the parents' opinions and questions and facilitating the parents' response (Roter, 2000; Roter, Hall, & Katz, 1988). Clinician partnership building was expected to relate to more parent participation in the ICC and greater parental understanding of informed consent (Golin, DiMatteo, & Gelberg, 1996; Hall et al., 1988) because partnership statements solicit parent involvement and actively assess for parental understanding throughout the conversation. Partnership building was also expected to relate to less anxiety and more control as a result of the ICC: When clinicians show respect to parents and facilitate their involvement in the informed-consent process, parents may be more likely to feel that their needs are being met and that they are empowered to deal with a distressing situation, which, in turn, may decrease anxiety and increase their sense of control (Avis, 1994; Golin et al., 1996; Roter, 2000).

Rapport building involves conversation that is explicitly emotional, such as statements of empathy, concern, and reassurance (Wissow et al., 1998). Clinician rapport building was expected to relate to less anxiety and more control as a result of the ICC (Roter, 2000), as it may enhance the parent's belief that the clinician is caring and sensitive, which may enable parents to assert their needs. Moreover, at a time when parents often feel overwhelmed, knowing that someone recognizes and understands their emotions may decrease parents' anxiety and improve their sense of control over a difficult situation.

The researchers expected parent participation during the ICC to be related to greater understanding of informed consent, because greater participation may enable parents to obtain the information they want and need from the clinician (Siminoff, Ravdin, Colabianchi, & Sturm, 2000). Parent participation was also expected to relate to less anxiety and more control as a result of the ICC (Avis, 1994; Golin et al., 1996; Roter, 1977), as parents who are more involved in the informed consent process would be expected to feel empowered and more in control of the encounter and their situation in general. Moreover, the researchers expected less anxiety and more control as a result of the ICC to relate to greater parent understanding (Edwards, Lilford, Thornton, & Hewison, 1998; Janis, 1993; Siminoff, 1989), on the basis of previous findings demonstrating that stress has deleterious effects on patient understanding (Barnlund, 1976) and decision-making processes (Janis, 1993).

Moreover, on the basis of previous findings (Kodish et al., 2004), both parent race and socioeconomic status (SES) were expected to predict clinician–parent communication and parent-related outcomes in the proposed model (e.g., higher SES and majority status were expected to relate to greater participation in the conference and greater understanding).

Methods

Procedures

This study was part of a larger study examining the informed consent process for participation in randomized clinical trials (RCTs) for treatment of pediatric leukemia. Previous published reports have described parental understanding of randomization (Kodish et al., 2004), clinician perspectives on the informed consent process (Simon et al., 2001), and the effect of patient presence on the ICC (Olechnowicz, Eder, Simon, Zyzanski, & Kodish, 2002). Subjects were recruited from six Children's Cancer Group (CCG) institutions that routinely treat children with acute leukemia. The study was approved by the Institutional Review Board at each site.

Parents of children with newly diagnosed acute lymphoblastic leukemia (ALL) or acute myeloid leukemia (AML) were the participants in this study. The participants were eligible for one of four different Phase III clinical trials for the treatment of ALL or AML. Each of these studies consisted of several different treatment arms, including standard treatment. The experimental arms generally involved minor alterations to standard treatment, the aim of which was to either improve the cure rate with tolerable toxicity or maintain the cure rate with less toxicity than the standard arm.

Potential participants were approached by a research assistant, who explained the study and offered participation. This usually occurred within hours or days of the child's initial diagnosis. Although the consent document for this study communicated the essential elements of the study design, it did not cue parents with respect to what specific behaviors would be assessed. If parents consented, the ICC was observed and audiotaped by trained research assistants.

Of the 164 parents who were asked to participate in this study, 85% (N = 140) consented. Parents generally declined to participate because they felt too overwhelmed by the news that their child had cancer, did not feel comfortable with additional people being in the room during the ICC, or did not like the idea of their conversations being tape-recorded. There were no differences between participants and nonparticipants for parent race, parent SES, patient age, patient gender, or decision to enroll in the clinical trial.

Within 48 hr after the ICC, parents were interviewed using a semistructured interview designed to assess parents' perceptions of what was discussed in the ICC, understanding of treatment options and what trial participation entails, and their reaction to the ICC. Both open-ended (e.g., "What were all the different treatment options that you discussed with doctor?") and closed-end (e.g., "Did you feel that you were under any pressure to permit your child to enroll in the clinical research study: No pressure, Some pressure, or Much Pressure?") questions were asked, as well as questions that required a response on a visual analogue scale (e.g., "How risky is therapy in the clinical research study compared to standard therapy?"). The interviews were conducted by the same research assistant who observed the ICC. The interviews were available in English and Spanish. The taped ICCs were transcribed into a word-processing program.

Table I. Parent Characteristics ($N = 127$)

	M (*SD*)
Parent age (range 19–51)	35.6 years (7.4)
Child age (range 1–18)	7.2 years (4.8)
	N (%)
Parent race	
Caucasian	75 (59.1)
Hispanic	32 (25.2)
African-American	9 (7.1)
Asian	6 (4.7)
Other	5 (3.9)
Hollingshead category (1, higher SES; 5, lower SES)	
1	11 (8.7)
2	22 (17.3)
3	46 (36.2)
4	30 (23.6)
5	18 (14.2)

Participants

Demographic characteristics are presented in Table I. For the purpose of statistical analyses, the data set was subjected to a listwise deletion for the primary variables in the study, resulting in a sample of 127 for the present analyses (91% of the original sample). The sample consisted of 40.9% racial minority parents representing several different subgroups ($n = 32$, Hispanic; $n = 9$, African-American; $n = 6$, Asian; $n = 5$, Other). These subgroups were combined to provide enough power to examine potential differences in the informed consent process for racial minority and Caucasian parents (Kodish et al., 2004). In addition, 18.1% of parents were non–English-speaking ($n = 22$, Spanish; $n = 1$, Cantonese). Translators were present for 16.5% of cases ($n = 21$). Two cases were conducted entirely in Spanish by the clinician. Of the 127 parents who participated in this study, 84.3% consented to participate in the RCT, whereas 15.8% chose standard treatment.

Seventy-six physicians participated in this study. Most of the clinicians (69.7%) were Caucasian. Most of the conferences (70.7%) included two physicians; the remainder included only one physician.

Measures

Clinician–Parent Communication Variables

Clinician Information Giving Following the ICC, the research assistant coded the audiotape of the conference, using the Observer Checklist (OC), an instrument developed to code behaviors specific to clinical discussions related to cancer (Siminoff & Fetting, 1991). The OC lists specific information categories as either occurring or not occurring and as being initiated by the physician, the patient, or the patient's family. The percentage of information-based items on the OC that were addressed by the physician in each ICC was calculated as a measure of information giving. The items used in the percentage were conceptually derived, on the basis of whether the item reflected a statement of fact or opinion related to diagnosis, treatment, or the clinical trial. These items were related to the child's condition, prognosis, standard treatment, and the clinical trial (e.g., discussed the child's condition, discussed test results, discussed concept of induction, explained randomization, explained that trial participation is voluntary, etc.). Twenty items were related to the child's condition and treatment (54%), and 17 (46%) were specifically related to the clinical trial. The items used in the percentage can be distinguished from other items on the OC that reflect different types of communication, such as eliciting parents' opinions or questions, using medical jargon, and drawing a diagram to explain the clinical trial. The percentage of items that were addressed during the ICC was then calculated, based on 37 possible items. This percentage was used as a measure of the amount of information provided by physicians. A higher percentage indicates that the clinician covered more items during the ICC. All items from the OC were independently coded by three researchers and then reconciled according to a rule book designed to limit misinterpretation of each coded item. The mean kappa across all items before reconciling was .62 (SD = .19).

Clinician Partnership Building and Rapport Building Transcripts of the ICCs were coded to measure partnership building and rapport building. The coding scheme was based on the Roter Interaction Analysis System (RIAS; Roter, 1977). The RIAS was designed to measure specific clinician and patient communication behaviors during adult medical office visits. In the original system, each clinician and patient utterance is categorized into 38 mutually exclusive and exhaustive categories. These include categories such as biomedical information, psychological information, orientation or instructions, social conversation, disapproval, and criticism. Unlike the original RIAS, transcripts rather than audiotapes were used to code communication statements in this study. Furthermore, only communication statements reflecting partnership building and rapport building were coded. Rapport building includes statements of worry and concern, reassurance, empathy, legitimation, self-disclosure, and approval (Roter, 2000). Partnership building involves facilitation of patient participation and understanding and includes asking for parents' opinions and checking for understanding (Roter et al., 1988). Frequencies of each type of statement were calculated for physicians and summed to yield a total partnership-building score and a total rapport-building score (Wissow et al., 1998).

Twenty-eight cases were double-coded so that interrater reliability could be measured. Intraclass correlation coefficients, using a two-way random effect model, were calculated. The coefficient for the total partnership-building scale was .99. The coefficient for the total rapport-building scale was .86.

Parent Participation during the ICC Parent participation during the ICC was measured by counting the number of questions they asked during audiotape review of the conference. Patient questions have been used as a measure of patient communication in previous research (Roter, 1977; Siminoff et al., 2000).

Parent Outcomes

Impact of the ICC on Parent Anxiety and Control Parents' retrospective reports of anxiety and perceived control following the ICC were measured using two items from the parent interviews. The first was "Did the informed consent information make you feel less anxious, more anxious, or have no effect?" For this item, a "1" was scored if the parent reported that the informed consent information made him or her feel less anxious, a "2" was scored if the parent reported that the ICC had no effect on his or her anxiety, and a "3" was scored if the parent reported that the ICC made him or her feel more anxious. The second item was "Did the informed consent information make you feel more in control, less in control or have no effect?" For this item, a "1" was scored if the parent reported that the informed consent information made him or her feel more in control, a "2" was scored if the parent reported that the conference had no effect on his or her sense of control, and a "3" was scored if the parent reported that the ICC made him or her feel less in control. These two items were summed to create a score for "impact of the ICC on parent anxiety and control," with lower numbers indicating less anxiety and more control following the ICC. The alpha for this summary score was low (.39), which is not surprising given the small number of items. However, the positive

correlation between theses two items, $r = .25$, $p < .01$, justifies summing the two items to yield a single score.

Parent Understanding of Informed Consent Parent understanding of informed consent was measured using items from the parent interviews. The items were conceptually derived, on the basis of the critical elements of informed consent (e.g., voluntary participation, randomization, the possibility of other treatment options, and the freedom to withdraw from the study at any time). One point was scored for each of the following criteria that were met: (1) "Did the parent answer 'No' to the question?" and "Do you feel your child has to participate in this clinical research study to get treated here?" (voluntariness), (2) "Did the parent answer 'Yes' to the question, 'If your child starts to participate in this clinical research study, can you stop this participation at any point?' " (withdrawal), (3) "Based on the entire Parent Interview I, is there evidence of understanding the existence of different treatment arms *and* understanding of randomization?" (randomization), and (4) "Based on the entire Parent Interview I, did the parent recognize that treatment options include both a clinical trial *and* standard treatment?" (alternative treatments or treatment choice).

All of the coding was done by one person, on the basis of explicit rules that were developed as a group (Kodish et al., 2004). For the last two items, parents' answers to all of the interview items were analyzed for evidence of understanding, which gave parents multiple opportunities to demonstrate comprehension. The criteria for understanding of these items were as follows: For understanding of treatment choice, parents must have at some point during the interview indicated that both standard treatment and the clinical trial were options that were available to them. Therefore, included in the group of parents who did not understand treatment choice are those who did not recollect discussing the clinical trial and those who did not know the alternatives to trial participation. For understanding of randomization, parents must have at some point during the interview indicated that if they chose to enroll in the clinical trial, their child would be assigned by chance to one of multiple treatment groups. When there were questions about the coding for a specific case, the principal investigator was consulted.

To meet the criteria for SEM, the investigators summed the scores for the four items to yield a total understanding score, ranging from 0 to 4, with higher scores indicating greater understanding of informed consent. The Kuder–Richardson 20 reliability coefficient was rather low (.58). This was not surprising, because the elements of informed consent are heterogeneous, with different dimensions that vary in conceptual complexity. However, most of the intercorrelations between these items were significant.

Results

SEM was used to test the hypothesized relationships described earlier (Figure 1). On the basis of Pearson product–moment correlations, eight insignificant paths were removed and four significant paths were added to this model. The resulting model was the first to be tested in AMOS-5 (Analysis of Moment Structures, Version 5). Estimates of error variances were fixed and assumed to be equal to zero. Output from the AMOS program includes tests of the significance of the predicted paths, as well as tests of the significance of unpredicted paths found in the modification indices. Several indices were used to assess the fit of the data to the proposed model, which is in accord with current standards (Bentler & Chou, 1987; Browne & Cudeck, 1993). These included (a) a chi-square index to assess the degree of nonfit between the estimated and observed covariance matrices, (b) the Comparative Fit Index (CFI; >.90 acceptable, >.95 excellent), (c) the Tucker Lewis Index (TLI; >.90 acceptable, >.95 excellent), (d) the Root Mean Square of Approximation (RMSEA; <.08 acceptable, .05 excellent), and (e) the Standardized Root Mean Square Residual (RMR; <.08 acceptable).

The initial test of the model provided a good fit with the data, $\chi^2 = 10.12$ (12), $p = .609$; CFI = 1.00; TLI = 1.03; RMSEA = .000; RMR = .054. However, three regression paths were nonsignificant (parent participation to parent understanding, parent race to impact of the ICC on parent anxiety and control, and clinician information giving to parent understanding). These paths were removed one at a time, and the model was retested each time. Although the significance of the path from clinician information giving to impact of the ICC on parent anxiety and control in the final model was equal to .06, this path was kept in the final model because removing it resulted in instability in the model (e.g., the model fit less well to the data when this path was removed). The final model yielded an excellent fit to the data. Evidence of the goodness-of-fit of the model to the data include the chi-square, $\chi^2 = 13.46$, $df = 15$, $p = .57$, the CFI (1.00), the TLI (1.02), the RMSEA (.000), and the RMR (.06).

The final model is illustrated in Figure 2, and parameter estimates are presented in Table II. The final model explained 36% of the variance in parent understanding, 11% of the variance in impact of the ICC on

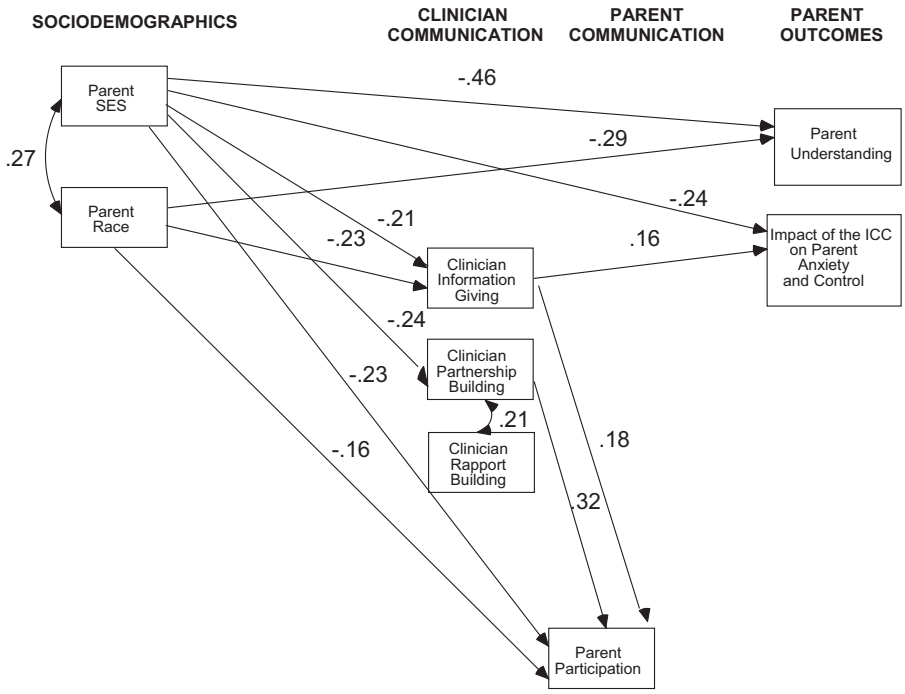

Figure 2. Final model. For Parent SES: 1, higher SES; 5, lower SES. For Parent Race: 1, majority status; 2, minority status. For Impact of the ICC on Parent Anxiety and Control, lower scores indicate less anxiety and more control as a result of the informed consent conference (ICC).

Table II. Parameter Estimates of the Final Model

Regression Path	Unstandardized β	Standardized β	SE	Critical ratio	*p*
SES to clinician information giving	−2.076	−.214	.841	−2.469	.014
SES to clinician partnership	−7.261	−.239	2.568	−2.828	.005
SES to parent participation	−6.541	−.234	2.241	−2.919	.004
SES to parent understanding	−.445	−.456	.072	−6.175	<.0001
SES to parent anxiety and control	−.237	−.243	.085	−2.779	.005
Parent race to clinician information giving	−5.089	−.227	1.944	−2.618	.009
Parent race to parent participation	−10.194	−.158	5.062	−2.014	.044
Parent race to parent understanding	−.649	−.288	.166	−3.897	<.0001
Clinician information giving to parent participation	.513	.178	.226	2.273	.023
Clinician information giving to parent anxiety and control	.016	.164	.009	1.876	.061
Clinician partnership to parent participation	.294	.319	.070	4.214	<.0001

parent anxiety and control, and 32% of the variance in parent participation. Overall, the demographic variables were more important in predicting the outcomes compared to the communication variables. It was hypothesized that parent minority status, lower parent SES, and less information giving and partnership building by clinicians would predict lower parent understanding of informed consent. As expected, minority status and lower SES were related to lower understanding of informed consent. Clinician information giving and partnership building did not predict parent understanding.

It was also hypothesized that more information giving, partnership building, and rapport building by clinicians and more parent participation during the ICC would predict less anxiety and more control as a result of the ICC. The final model indicated that lower SES was related to less anxiety and more control. In addition, there was a weak relationship between clinician information giving and impact of the ICC on parent anxiety and control, but this was in the opposite direction than what was hypothesized. Less information given by clinicians predicted less anxiety and more control as a result of the ICC. Clinician partnership building, clinician rapport building, and parent participation were not related to impact of the ICC on parent anxiety and control.

Minority status, lower SES, and less clinician partnership building predicted less parent participation during the ICC, a finding that was consistent with the hypotheses. In addition, more information giving by clinicians predicted greater parent participation.

As expected, lower SES was related to less clinician information giving and less partnership building. However, SES did not predict clinician rapport building. Also consistent with the hypotheses was the finding that minority status predicted less information giving by clinicians. Parent race did not predict clinician partnership building or rapport building, a finding that was contrary to expectations.

Discussion

This study addressed salient limitations of previous research on both clinician–parent communication and the informed consent process in childhood cancer by including a large number of minority participants, using observational methods, measuring both clinician and parent communication during the ICC, and testing the impact of the ICC on parent anxiety and control and understanding of informed consent using SEM.

Race and SES were powerful and independent predictors of clinician–parent communication in this study. Clinicians provided less information to minority parents and to those from a lower SES and expressed fewer partnership-building statements to lower SES parents. Moreover, parents from ethnic minority groups and those from a lower SES participated less during the ICC. This finding is consistent with prior research that demonstrated that Caucasian ethnicity and higher SES are related to preferences for participation in medical decision-making (Ende, Kazis, Ash, & Moskowitz, 1989; Strull, Lo, & Charles, 1984). Individual differences in parents, such as race and SES, may influence beliefs about rules that should govern communication between clinicians and patients (Golin et al., 1996). Parents who are intimidated by the hospital setting or are sensitive to the power differential between clinicians and patients (e.g., the notion of "respeto" in Latino culture; Flores, 2000) may participate less in interactions with health care professionals. Alternatively, it is possible that clinicians' beliefs and attitudes toward patients influence patient communication with clinicians (Street, 1991).

More information giving and partnership building by clinicians predicted greater parent participation during the ICC. This finding is important because of the theoretical and ethical significance of the notion of patient (or in this case, parent) autonomy in the informed consent process (Beauchamp & Childress, 1994). To the extent that parents are actively involved in decision-making related to their child's treatment, the ideal of informed consent is more closely achieved (Avis, 1994).

Another interesting finding was that there was a trend for more information giving to be related to more parent anxiety and less parent control as a result of the ICC, which is consistent with the idea of information overload (Levi et al., 2000; Simon et al., 2001) (e.g., too much information may result in parents feeling more distressed and less in control). In addition, some of the nature of the information given in the conference was threatening (e.g., survival rates and toxic side effects of treatment), which would be expected to increase parental distress (Roling, Pressgrove, Keeffe, & Raffin, 1977).

In contrast to prior research that has demonstrated significant relationships between physician-patient communication and various patient-related outcomes such as understanding and anxiety (e.g. Hall et al., 1988; Dermatis & Lesko, 1990; Avis, 1994; Siminoff et al., 2000; Roter, 1977), several hypothesized relationships were not significant in the final model. In general, the communication variables were not predictive of the two primary outcomes, parent understanding and impact of the ICC on parent anxiety and control. However, it should be noted that prior studies of physician–patient and physician–parent communication have not examined both demographics and communication variables in a single model. Furthermore, the role of demographic variables has not been well documented in the literature on informed consent, particularly in pediatric settings. In addition, the context of clinician–parent communication in this study included a preponderance of distressing and complex information, which is very different from typical primary care visits, in which much of the research on physician–patient communication has been conducted.

This study has several limitations. First, cross-sectional data limits the degree to which one can interpret cause and effect. For example, although the researchers hypothesized that too much information giving may have resulted in more anxiety and less control as a result of the ICC, it is also possible that when parents appeared distressed, clinicians may have tried to impart more information in an effort to assuage their anxiety (Street, 1991). Second, the measurement of parent anxiety and control was limited in several ways and may have impacted the present findings. The measure included only two items that assessed the specific impact of the ICC and did not include other components of emotional state, such as hopelessness, anger, and sadness. In addition, parent responses to these items could have been affected by a response set, such that parents might have been inclined to say that they were not negatively impacted by the ICC. Future studies should include

standardized and comprehensive measures of parents' emotional state, such as the State-Trait Anxiety Inventory (Spielberger, 1983), which may be more sensitive at detecting relationships between key aspects of the ICC and parent-related outcomes such as understanding of informed consent. In addition, assessing parent anxiety prospectively may provide useful information about how parents' emotional state prior to the ICC influences clinician and parent communication, as well as parent-related outcomes, and how parents' emotional state changes throughout the informed consent process. Third, the measurement of parent understanding in this study was based on the coding of parents' responses to a semistructured interview, which could have been vulnerable to inference by the coder. Furthermore, only four specific components of clinical trial participation were included in the parent understanding score. Although these are important components of informed consent, they represent a subset of the information that can be presented during the ICC for the treatment of pediatric cancer. Other important aspects of parent understanding include the purpose, procedures, risks, and benefits of research (Edwards et al., 1998). Future studies of informed consent should develop and incorporate standardized and comprehensive measures of patient and parent understanding.

The findings from this study highlight several other potentially important areas for future research. First, additional research is needed to more fully explain the relationships between SES, minority status, clinician–parent communication, and parent understanding of informed consent. A related point is that some prior research suggests that it is the similarity of the patient's ethnicity to the health care provider that influences patient–provider communication (Cooper-Patrick et al., 1999). To our knowledge, this issue has not been examined in the context of either pediatrics or informed consent but may shed light on the process of clinician–parent communication in these unique contexts. Second, a prospective study of the clinician–parent relationship would identify those aspects of physician–parent communication at the time of cancer diagnosis that predict later communication as well as parental emotional state, understanding, and satisfaction with their child's care. Although the findings related to clinician communication were generally insignificant in this study, it is possible that specific clinician communication behaviors become more important following the initial stages of the diagnosis of cancer and its treatment. Third, future studies should incorporate variables that potentially moderate or mediate the relationships between clinician–parent communication and parent-related outcomes. For example, it is possible that a parent's coping style (e.g., information-seeker versus information-avoider) moderates the relationship between clinician information giving and parent anxiety.

Finally, future studies should identify ways in which the ICC can be improved. On the basis of findings from this study, several areas might be targets of future interventions, some of which are currently being tested by this research group. These include improving physician–parent communication during the ICC and increasing parent understanding of informed consent. For example, by adapting their communication style to the needs of parents, physicians may be able to alleviate parent anxiety and increase their understanding. In addition, a two-stage model of informed consent, where information about cancer and its treatment is presented in one meeting, followed by information about research and the clinical trial in a second meeting, may alleviate parents' distress and enhance their decision-making capacity (Angiolillo et al., 2004). This format for informed consent provides the family with multiple opportunities for receiving, seeking, and understanding information about treatment and the clinical trial.

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