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Do They Understand? (Part I)

Parental Consent for Children Participating in Clinical Anesthesia and Surgery Research

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Background: **Central to the tenet of informed consent is the quality of disclosure of information by the investigator and the understanding thereof by the research subject or his or her surrogate. This study was designed to measure parents' understanding of the elements of informed consent for clinical studies in which their children had been approached to participate.**

Methods: **The study sample consisted of 505 parents who had been approached for permission to allow their child to participate in a clinical anesthesia or surgery study. Regardless of whether the parent consented (consenters, n = 411) or declined (nonconsenters, n = 94) to their child's participation in a study, they were interviewed to determine their understanding of 11 elements of consent. Two independent assessors who were familiar with the study protocols scored the parents' levels of understanding.**

Results: **Parents perceived their overall understanding of the elements of consent as high (8.7 ± 1.6; 0–10 scale); however, this represented a significant overestimation compared with the assessors' measures of parental understanding (7.3 ± 1.8; $P < 0.0001$). Furthermore, consenters had greater understanding than nonconsenters (7.6 ± 1.6 *vs.* 6.1 ± 1.9; $P < 0.001$). Several predictors of understanding were identified, including whether the parent consented, education level, clarity of disclosure, child in previous study, age of parent, parent listened to disclosure, and degree to which parent read the consent document. The day on which consent was sought had no impact on the level of understanding.**

Conclusions: **Parents approached for permission to allow their child to participate in a research study had less than optimal understanding of the elements of consent. As such, investigators must make every effort to enhance understanding and ensure that parents have sufficient information to make informed decisions regarding their child's participation in research studies.**

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PARENTS are generally considered the proxy decision-makers for their child's participation in clinical research, although the assent of the child (affirmative agreement) may be required for those children considered competent to give it. Because the parents' role as decision-maker is to protect the interests and safety of the child, it is imperative that they understand the risks, benefits, and consequences of their child's participation as a research subject. In clinical anesthesia, and to a lesser extent, surgery research, consent is often sought just before surgery, a time when the subject and the subject's family may be most anxious. In such a situation, the ability to satisfy the "information element" of consent as described by Beachamp and Childress[1] may be hampered by the unique, often perfunctory, nature of the investigator–subject interaction. Despite this, there is a paucity of information addressing this issue, particularly as it applies to parental decision-making. Although a few studies have addressed understanding of consent for research, none have addressed understanding in a surgical population.[2–4] Therefore, this study was designed to measure parents' real-time understanding of the elements of informed consent for clinical anesthesia and surgery studies in which their children had been approached to participate.

Materials and Methods

The University of Michigan's Institutional Review Board (Ann Arbor, Michigan) approved this study. The study population included parents or guardians who had been approached to allow their child to participate in 1 of 18 ongoing clinical anesthesia or surgery studies. Disclosure of information for informed consent was presented verbally and in written format by investigators, research nurses, or assistants either on the day(s) before surgery or, in the majority of cases, on the day of surgery. The day on which consent was sought, the time spent disclosing information, and the time allotted for the parents to make a decision were recorded. Regardless of whether the parents had consented to allow their child to participate in one of these studies, the parents were invited to complete an interview and questionnaire. The interview was conducted while the child was in surgery and was designed to determine their understanding of 11 required elements (Title 45. Code of

Federal Regulations. Part 46)[5] of the informed consent document. The elements and corresponding interview questions are outlined below.

Study purpose (What is the purpose of the study?)
Protocol (What are the researchers going to do to your child for this study?)
Risks (What are the possible risks or discomforts associated with the study?)
Direct benefits (Describe the possible benefits to your child as a result of this research.)
Indirect benefits (Describe the possible benefits to other children as a result of this research.)
Freedom to withdraw (Could you change your mind about the study once you had agreed to allow your child to participate?)
Alternative treatments or procedures (If you did not allow your child to participate in the study, how would his or her anesthesia and surgery care be different?)
Voluntariness (Was your child's participation in the study voluntary?)
Duration of participation (What is the approximate length of time that your child will be involved in the study?)
Contact (Who can you contact regarding any aspects of your child's involvement in the study?)
Confidentiality (Can you tell me who is allowed to see your child's medical records for this study?)

The questions presented above were adapted from the Deaconess Informed Consent Comprehension Test (DICCT).[6] The interview was presented in a semistructured fashion, and the open-ended responses were written down *verbatim* by trained research assistants who had no knowledge of the details of the study protocols. Research personnel were allowed to clarify questions and prompt the parents for additional information but were unable to offer any specific details of the study. The parents' levels of understanding of these individual elements were scored by two assessors who were familiar with all aspects of each study but who were blinded to the parents' decision to consent or decline their child's participation. Using the format of the DICCT,[6] scores of 2, 1, or 0 were assigned based on whether the parents had complete (correct, complete answer), partial (correct but incomplete answer or "poverty of content"), or no understanding (incorrect or no answer) of each element, respectively. Based on these scores, a composite score was derived and compared with the parents' perceived level of understanding measured on a 0–10 visual analog scale (VAS; 0 = no understanding, 10 = complete understanding). Because the two scales had different metrics, they were normalized to permit comparisons.

After the interview, the parents completed questionnaires, either while their child was in surgery or, if they preferred, at home. The questionnaire was designed to elicit demographic information, including the child's and parents' ages, their race, income, parents' education, and the child's and parents' previous experience as a research subject. Information regarding the parents' perceptions of the environment in which consent was sought (*e.g.*, time, privacy) and the clarity and completeness of the information were elicited together with a measure of parental anxiety measured on a 0–10 VAS (10 = extremely anxious). Although there are more comprehensive measures of anxiety, the VAS represents a simple, yet valid means to obtain a global assessment of anxiety.[7,8] Parents also rated their child's health status using a 0–10 VAS (0 = extremely poor health, 10 = extremely healthy). This global measure has been shown to be a valid assessment of health status.[9] Readability of the informed consent documents for each study was analyzed using the Flesch Reading Ease and the Flesch-Kincaid Grade Level tests.[10]

Statistical Analysis

Statistical analyses were performed using SPSS® statistical software (SPSS Inc., Chicago, IL). Based on pilot data, the assessors' scores of understanding for consenters and nonconsenters were 7.3 ± 1.9 (0–10 scale) *versus* 6.4 ± 1.9, respectively. To detect a difference between groups of at least that large, we would need to study 94 subjects per group ($\alpha = 0.05$, $\beta = 0.1$, two tailed). Descriptive data were analyzed using frequency distributions. Comparisons of parametric data between consenters and nonconsenters were performed using unpaired *t* tests. Nonparametric comparisons were analyzed using chi-square and Mann–Whitney U tests. Interrater reliability and levels of agreement between the two assessors' scores of understanding were determined using Spearman correlation coefficients (ρ) and κ statistics, respectively. The κ statistic is a measure of agreement that allows for observer variability and corrects for chance levels of agreement.[11] Kappa values of 0.4 or greater were considered to represent acceptable agreement. Data are expressed as percentages, mean ± SD. Significance was accepted at the 5% level ($P < 0.05$).

Results

Five hundred sixty-nine parents whose child had been recruited for 1 of 18 clinical anesthesia (n = 13) or surgery (n = 5) studies were approached for interview and completion of the questionnaire. Of these, 505 parents were enrolled; 411 had consented to allow their child to participate in one of the studies (consenters), and 94 had declined their child's participation (nonconsenters). Of the 64 parents who were not included in this study, 14 declined, 24 were not available to be interviewed, 21 did not complete the questionnaire, 3 had language barriers, and 2 did not remember being

Table 1. Parent and Child Demographics

	Consenters (n = 411)	Nonconsenters (n = 94)	All Parents (n = 505)
Parent's age, yr	37.3 ± 7.4	36.1 ± 6.5	37.1 ± 7.3
Child's age, yr	7.6 ± 4.9†	5.1 ± 4.3	7.2 ± 4.9
Child's health*	8.5 ± 1.7	8.6 ± 1.9	8.5 ± 1.8
Child's sex, male/female %	57.7/42.3	68.5/31.5	59.7/40.3
Race, n (%)	—	—	—
Caucasian	355 (89.6)	78 (89.8)	434 (89.6)
African American	16 (4.0)	6 (6.8)	22 (4.5)
Hispanic	7 (1.8)	0 (0.0)	7 (1.4)
Other	18 (4.5)	3 (3.4)	21 (4.3)
Education level, n (%)	—	—	—
≤ High school graduate	107 (26.6)†	13 (14.4)	120 (24.4)
Some college	102 (25.4)	27 (30.0)	129 (26.2)
≥ College graduate	193 (48.0)	50 (55.6)	243 (49.4)
Income level, n (%)	—	—	—
< $0–29,000	72 (19.8)	9 (12.2)	81 (18.5)
$30,000–69,000	140 (38.5)	24 (32.4)	164 (37.4)
> $70,000	152 (41.8)	41 (55.4)	193 (44.1)
Prior research, subject-child	80 (20.0)	17 (18.3)	97 (19.6)
Prior research, subject-parent	98 (24.4)	20 (21.5)	118 (23.9)
Therapeutic/nontherapeutic study	19.8/80.2†	33.7/66.3	22.3/77.7
Consent day of surgery/day(s) prior	91.7/8.3	87.5/12.5	91.0/9.0

Data are expressed as mean ± SD, percent is shown in parentheses.

* Based on a 0–10 scale where 10 = very healthy. † $P < 0.05$ *vs.* nonconsenters.

approached for a study. The demographics of the study sample are described in table 1. Results showed that nonconsenters were less likely to have completed high school, had children who were significantly younger, and were more likely to have been approached for participation in a therapeutic rather than an observational study.

Measures of interrater reliability for scores of understanding between the two assessors revealed excellent correlations. Spearman rank order correlation coefficients and κ values for each core element ranged from 0.82 to 1.0 ($P < 0.0001$) and from 0.75 to 1.0 ($P < 0.0001$), respectively. The mean Flesch Reading Ease and Flesch-Kincaid Grade Level indices for the consent forms were 48.2 (range, 36–54.6) and 11.2 (range, 9.9–12), respectively. Table 2 compares the assessors' measured scores of understanding with the parents' perceived understanding. The percentages of parents who had complete understanding of each element of consent are described in table 3.

Eighty-four percent of parents believed that the amount of information given was "just right," and only 13.4% thought that there was "too little" information. In addition, 59.3% of parents rated the clarity of the information as "very clear," and only 2.1% rated it as "not clear." There were no significant correlations between understanding and the time taken by the research personnel to disclose information; the time allotted for parents to make their decision; the amount of information given; the timing of consent (*i.e.*, day of surgery *vs.* day(s) before surgery); parental race or ethnicity; researcher race or ethnicity, gender, appearance (white coat, scrubs, street clothes), and demeanor (friendly, hurried, pushy); whether child had previous surgery; and which parent gave consent.

However, several factors were shown by univariate analysis to be significantly ($P < 0.01$) associated with greater understanding. These included older parent or guardian (aged > 30 yr); child's participation in a previous study; parent consented to child's participation; higher education level; anxiety; perceived clarity of information; degree that parents had listened to the researcher; degree parents had read the consent document; and parental perception of the study's importance, risks, and benefits. These factors found to be significant by univariate analysis were subsequently en-

Table 2. Comparison of Assessors' Scores and Parents' Perceived Understanding Scores

Understanding Scores	Consenters	Nonconsenters	All Parents
Assessors	7.6 ± 1.6 (7.9)*†	6.1 ± 1.9 (5.9)*	7.3 ± 1.8 (7.7)*
Parents	8.8 ± 1.5 (9.0)†	8.3 ± 1.8 (9.0)	8.7 ± 1.6 (9.0)

* $P < 0.0001$ *vs.* parents, †$P < 0.001$ *vs.* nonconsenters.

Data expressed as mean ± SD, median is shown in parentheses.

Table 3. Parents' Complete Understanding of Eleven Elements of Consent

Elements of Consent	Consenters, %	Nonconsenters, %	All Parents, %
Study purpose	60.6*	48.8	58.5
Protocol/procedures	53.8	47.7	52.7
Risks	74.9*	46.5	70.0
Benefits to child	60.8*	41.2	57.4
Benefit to others	52.0*	26.2	47.5
Freedom to withdraw	82.8*	56.5	78.3
Alternatives	83.7*	70.2	81.4
Voluntariness	99.8*	96.5	99.2
Duration of study	53.5	44.4	51.9
Whom to contact	66.3*	33.7	60.6
Confidentiality	37.3*	12.8	33.0

* $P < 0.02$ *vs.* nonconsenters.

tered into a multiple regression model with stepwise selection. Multivariate analysis of these factors yielded several predictors of parental understanding. Results of these analyses are shown in table 4.

Discussion

The role of the parent or guardian as the proxy decision-maker for his or her child's participation in clinical research is one of protection and, as such, differs from that of the adult subject whose role is one of self-determination.[12] Despite this difference, the information required at disclosure and the understanding thereof is essentially the same.[5] Beauchamp and Childress[1] suggest that one understands "if one has acquired pertinent information and justified, relevant beliefs about the nature and consequences of one's action." However, some would argue that many subjects or their surrogates are unable to comprehend the relevance of information sufficiently to make an informed decision.[13] The nature of the information presented, for example, including the amount, type, clarity, and difficulty, has been shown to impact the subject's ability to comprehend.[14,15] Furthermore, problems with information processing because of incapacity, language difficulties, time constraints, anxiety, or pain may also hinder understanding of informed consent. Results of this study showed that parents approached for permission to allow their child to participate in a clinical study had inadequate understanding of the research. Furthermore, poor understanding was associated with lower education and clarity of information, and although not surprising, it reinforces the need for information to be disclosed at a level consistent with those attributes.

Table 4. Predictors of Understanding of the Elements of Informed Consent

Factor	β	*P*
Consenter	0.27	0.0001
Higher education level	0.18	0.0001
Clarity of disclosure	0.17	0.0001
Child in previous study	0.16	0.0001
Listen to researcher	0.13	0.011
Older parent	0.12	0.013
Read consent document	0.12	0.020

β = standardized coefficient.

Although there are some data regarding understanding of consent by adult subjects,[16–18] there are few data regarding understanding by parents acting as proxies for their children in research.[19] Postlethwaite *et al.*[2] measured understanding and ease of decision-making among parents and children involved in a growth hormone trial. Even though 70% of parents reported no difficulty in making their decision, only 30% had understanding that was rated as very good. In another study, van Stuijvenberg *et al.*[4] showed that only 45% of parents approached for permission to enroll their child in a randomized, placebo-controlled trial were aware of five of six major trial characteristics (*i.e.*, study aim, freedom to withdraw, risks, randomization, reasons for signing, chance of placebo). Snowdon *et al.*[3] showed that parents of neonates enrolled in a randomized trial had poor understanding of the nature of the trial, and many had no perception that randomization would occur. These data suggest that inadequate understanding may jeopardize the ability of the parent to protect the child's interests.

Results of this study showed that parents approached for permission to allow their child to participate in a clinical study had inadequate understanding of the elements of informed consent, particularly with respect to those elements that they perceived to be important to them. In a previous study, parents ranked the risks, benefits to their child, and the protocol as the three most important elements that they believed they needed to understand before making a decision regarding their child's participation in a research study.[20] In this study, 70, 57.4, and 52.7% had complete understanding of these three elements, respectively. Furthermore, nonconsenters had less understanding of these elements than consenters. Although this finding may suggest that improved comprehension may improve consent rates, it may also reflect "early closure" by parents who had already made up their mind to decline participation and were uninterested in any further information.

Federal regulations require that consent forms be written "in a language understandable to the subject (or authorized representative)."[5] However, although the general recommendation is that consent forms be written at an eighth grade reading level, several studies suggest that this is rarely accomplished. In a review of surgical consent forms, Grudner[21] found that the majority of forms were written at the level of a scientific journal. Other studies show reading levels between eleventh and sixteenth grade.[22,23] In our study, the Flesch-Kincaid readability index of the informed consent doc-

uments ranged from a tenth to twelfth grade level. Although we realize that these consent forms did not comply with the readability guidelines, we believed it important to measure understanding as an index of what appears to occur in the real world.

Consent for studies involving surgical populations is unique because consent is often sought on the day of surgery. Although some would argue that consent sought at this time is potentially coercive, studies suggest that consent obtained on the day of surgery is appropriate.[24–26] Furthermore, this study showed that the time taken to disclose information to the parents, the time allotted for them to make a decision, and the day on which consent was sought had no apparent impact on anxiety or understanding. This latter observation is similar to that of Elfant *et al.*,[18] who showed that patients given consent information several days before endoscopic surgery had similar understanding as those given information just before surgery. Despite this, anesthesiologists should make every effort to ensure that the environment in which consent is sought is a private area conducive to decision-making.[27]

In our study, understanding was strongly associated with the perceived clarity of information and the degree to which the parent(s) listened to the disclosure by the investigator. In a study by Muss *et al.*,[14] understanding of chemotherapy regimens by cancer patients was greatly enhanced by the clarity of information. These findings fit nicely with the concept that consent should be an interactive process between researcher and subject involving disclosure, discussion, and understanding.[19]

It was interesting to note that understanding was significantly better when a nonphysician investigator provided information. Although we were unable to identify factors related to the interaction that may have explained this difference, a similar finding was observed by Muss *et al.*[14] regarding understanding of risks associated with chemotherapy regimens. The reason for this is unclear, although one may speculate that the physicians present the information at a level above that of a layperson.

A few points regarding the design of this study merit discussion. Previous studies addressing issues of informed consent in anesthesia have been based on sham studies.[24,28] Although these types of studies may be easier to conduct, they do not reflect the real-life situation. For example, the anxiety of having a child participate in a sham study may be different from that of a real study with real risks and benefits and, so too, the levels of understanding and decision-making. With this in mind, we believed it important to evaluate the parents' understanding of real studies. Although participation in more than one study is not generally advocated, this caveat may be waived if the investigators agree that the second study presents minimal risk, will not harm the subjects, and will not influence the study outcomes, as was the case in our study. Furthermore, although parents were required to consent to both studies, the subjects were technically different, *i.e.*, the child for the initial study and the parent for this study.

We deliberately based our measures of understanding on several studies so that we could examine understanding in the context of different risks and benefits. As such, one could argue that there was no standardization of consent documents used in this study. However, we should note that all consent documents used in this study followed the standard University of Michigan's Institutional Review Board template and included all elements of disclosure. Furthermore, all research personnel are trained to obtain informed consent in a standardized fashion.

It should also be noted that this study represents the experiences of subjects at one institution and, as such, may not be generalizable to all research centers. However, in our department, all research personnel involved with subject recruitment are required to complete the National Institutes of Health's and University of Michigan's web-based training program for research involving human subjects, receive on-the-job training, and undergo periodic quality assessment by investigators and senior research personnel. Furthermore, to reduce any bias attributed to the disclosure style of one person, understanding was based on disclosure of information by several different trained researchers. Based on these factors, it is likely that our findings would be similar to those experienced at most large pediatric research centers.

This study is the first to identify predictors of parental understanding of informed consent and, as such, will be useful in developing strategies to improve understanding for research subjects and their proxies. Results showed that parents of children recruited for anesthesia and surgery studies had less than optimal understanding of the elements of informed consent. Several factors, including lower education level, inattention to the researcher, and unclear information, were associated with poor comprehension. Of note for anesthesia research was the fact that subjects recruited on the day of surgery had similar understanding to those recruited on the previous day(s). Because the role of the parents is to protect the child from any perceived research-related risks, a lack of understanding of the elements of consent may jeopardize the parents' ability to accurately weigh the benefits and risks. As such, these results not only have important implications for this population of children but also for all children involved in clinical research. Because consent without understanding has ethical and legal implications, investigators must make every effort to enhance understanding so the rights of the research subject are protected and preserved.

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