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# Do They Understand? (Part II)

## Assent of Children Participating in Clinical Anesthesia and Surgery Research

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***Background:*** **Participation of children in clinical research requires not only parental permission but also the assent of the child. Although there is no fixed age at which assent should be sought, investigators should obtain assent from children considered able to provide it. This study was designed to determine children's understanding of the elements of disclosure for studies in which they had assented to participate.**

***Methods:*** **The study population included 102 children aged 7–18 yr who had given their assent to participate in a clinical anesthesia or surgical study. Children were interviewed using a semistructured format to determine their understanding of eight core elements of disclosure for the study to which they had agreed to participate. Two independent assessors scored the children's levels of understanding of these elements.**

***Results:*** **The children's perceived level of understanding of the elements of disclosure was significantly greater than their measured understanding (7.0 ± 2.4 *vs.* 5.3 ± 2.7, 0–10 scale; $P < 0.0001$). Complete understanding of the elements of disclosure for all children ranged from 30.4 to 89.4%. Children aged more than 11 yr had significantly greater understanding compared with younger children, particularly with respect to understanding of the study protocol, the benefits, and the freedom to withdraw.**

***Conclusions:*** **Children approached for their assent to participate in a clinical anesthesia or surgery study have limited understanding of the elements of disclosure and their role as a research participant, particularly if they are aged less than 11 yr.**

THE issue of assent (affirmative agreement) for children has gained increasing importance given the requirements of the National Institutes of Health (NIH) to incorporate children in clinical research.[1] However, there is some debate regarding the ability of children to make informed decisions about their participation in research and the age or developmental levels at which assent should be sought.[2,3] Traditionally, parents and legal guardians were considered to be the appropriate proxy decision-makers for their child's participation in research; however, many believe that this approach denies the child's right to autonomy and self-determination.[2,4] Zinner[5] suggests that there be a "sliding scale" to ascertain a child's ability to give assent so that those deemed capable of understanding a research study be allowed to make their own decisions. Although permission from one or both parents or guardians is still required, the Code of Federal Regulations (Title 45, CFR, Part 46)[6] also requires that assent be sought from children, "when in the judgment of the Institutional Review Board the children are capable of providing assent." This requires that a judgment be made regarding the child's age, maturity, and psychological state. Unfortunately, there are no set guidelines for obtaining assent. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research suggests that the standard of assent should include at least a description of the protocol and an assurance that participation is voluntary, and acknowledges that this standard requires a lesser degree of comprehension than consent.[7] The Commission also suggests that a child aged 7 yr with normal cognition is capable of providing meaningful assent.[7,8]

Given the importance of assent and the fact that children recruited for clinical anesthesia studies are typically approached on the day of surgery, this study was designed to examine the reasons that children use to make decisions regarding participation in clinical anesthesia and surgery research and their level of understanding of the elements of disclosure.

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## Materials and Methods

The University of Michigan's Institutional Review Board (Ann Arbor, Michigan) approved this study. Children aged 7–18 yr scheduled for an elective surgical procedure and who had given their assent (plus parental permission) to participate in one of six ongoing clinical anesthesia or surgery studies were included. Children with cognitive impairment were excluded from the study. For the most part, children were recruited for these studies on the day of surgery, although some were recruited before this time. Information for each study was provided in written and verbal formats. None of these studies used a separate consent document for children; however, all disclosure documents included information on the salient elements using simplified language. Information regarding who had sought assent, the time spent with the child, and the time taken by the child to make a decision were recorded.

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Children were interviewed at least 24 h after their surgery using a semistructured interview (modified from Ondrusek *et al.*[9]) to determine their understanding of eight core elements of disclosure for the study in which they had agreed to participate. Children were first asked to rate their perception of their understanding of the study on a 0–10 visual analog scale (VAS; 0 = no understanding, 10 = complete understanding). After this, they were asked a series of questions that addressed their understanding of each of the core elements of disclosure. These elements included:

Study purpose (Can you tell me why this study was being done?)
Protocol (What was going to happen to you in this study?)
Risks (What were the possible bad things that might have happened to you by being in the study?)
Direct benefits (What were the possible good things that might have happened to you by being in the study?)
Indirect benefits (What were the possible good things that might have happened to other kids by you being in the study?)
Freedom to withdraw (Would it have been OK to stop the study if you had changed your mind about being in it?)
Alternative treatments or procedures (Do you know what would have been done to you differently if you had decided that you did not want to be in the study?)
Voluntariness (Did you have a choice of whether or not to be in the study?)

Interviews were conducted either face to face if the child was an inpatient or *via* telephone at home. Research assistants who had no knowledge of the study protocols wrote down the open-ended responses *verbatim*. Research personnel were allowed to clarify questions and prompt children for additional information but were unable to offer any specific details of the study. The wording of the questions was adapted to be age appropriate (*e.g.*, stress, worry, fear); however, information was not simplified to the extent that important information was omitted. Whenever possible, we involved the parents in presenting information at a level that they believed was appropriate for their child. Two assessors familiar with all aspects of each study independently scored the children's levels of understanding of these specific elements. The scoring scheme was based on the Deaconess Informed Consent Comprehension Test.[10] Scores of 2, 1, or 0 were assigned to responses that indicated complete (complete, correct 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 child's perceived level of understanding. Because the metrics of these two scales were different, they were normalized to permit comparisons. Information was also elicited as to whether they had read the consent form, who had helped them with their decision, and the reason(s) for participation. In addition, children were asked to rate their level of anxiety (0–10 scale, 10 = extremely anxious) regarding their surgery and whether being asked to participate in a study had increased their anxiety. VAS have been shown to provide a simple, yet valid global measure of anxiety.[11,12] General demographic information was obtained from the parents. Furthermore, parents were asked to rate their child's overall health status using a 0–10 VAS (0 = extremely poor health, 10 = extremely healthy) and to note the age at which they believed children should be asked for assent. Readability of the informed consent documents for each study was analyzed using the Flesch Reading Ease and Flesch-Kincaid Grade Level tests.[13] The Flesch Reading Ease is measured on a 0–100 scale. Higher scores represent improved reading ease. The Flesch-Kincaid Grade Level index indicates the grade reading level.

### *Statistical Analysis*

Statistical analyses were performed using SPSS® statistical software (SPSS Inc., Chicago, IL). Descriptive data were analyzed using frequency distributions. Comparisons of understanding scores between assessors and children were analyzed using Mann–Whitney U tests. Frequency comparisons were analyzed using chi-square and Fisher exact tests, as appropriate. Interrater reliability and levels of agreement between the two assessors' scores of understanding were determined using Spearman $\rho$ and $\kappa$ statistics, respectively. Kappa values of 0.4 or greater were considered to represent acceptable agreement. The sample size for this study was based on a convenience sample of children presenting for elective surgical procedures during a 15-month period. Data are expressed as percentages, mean ± SD, and median. Significance was accepted at the 5% level ($P < 0.05$).

## Results

One hundred thirty children who had assented to one of the anesthesia or surgery studies were approached for interview, and of these, 102 agreed (with parental permission) to be interviewed (78.5%). Of the 28 who were not interviewed, 12 did not remember being recruited for a study, 11 declined, and 5 were not available at the time the interview was sought. Children who could not remember being recruited for a study were significantly younger (9.3 ± 2.4 *vs.* 12.8 ± 2.4 yr; $P < 0.0001$) and had lower health status (8.0 ± 1.3 *vs.* 8.9 ± 1.4, 0–10 scale; $P = 0.03$) than those who acknowledged their participation as a research subject. Furthermore, these children were recruited for nontherapeutic studies and were all approached on the day of surgery. The demographics of the participating subjects are described in table 1.

**Table 1. Demographics**

| | |
|---|---|
| Child's age, yr | 12.8 ± 2.4 |
| Child's gender, male/female % | 50/50 |
| Race, n (%) | — |
| Caucasian | 88 (88.0) |
| African American | 5 (5.0) |
| Hispanic | 1 (1.0) |
| Other | 6 (6.0) |
| English as first language, % | 98.0 |
| Previous surgery, n (%) | 59 (60.8) |
| Previous research subject, n (%) | 13 (13.4) |
| Therapeutic/non-therapeutic study, % | 11.8/88.2 |
| Assent: day of surgery/days before surgery, % | 94.1/5.9 |
| Child's health status* | 8.9 ± 1.4 |
| Child's anxiety level† | 4.5 ± 3.0 |

Data are expressed as mean ± SD and n (%).

* Based on the parents' rating using a 0–10 scale, where 10 = extremely healthy.

† Based on the child's rating using a 0–10 scale, where 10 = extremely anxious.

Measures of interrater reliability for scores of understanding between the two assessors revealed excellent correlations. Spearman rank order correlation coefficients (Spearman $\rho$) and $\kappa$ values for each core element ranged from 0.95 to 0.99 ($P < 0.0001$) and from 0.84 to 0.97 ($P < 0.0001$), respectively. Table 2 compares the children's perceived understanding with the assessors' measured understanding. The extent to which children of different ages had complete understanding of each of the elements of consent is described in table 3. The mean Flesch Reading Ease and Flesch-Kincaid Grade Level indices of the consent forms were 50.2 (range, 36–69.3) and 10.6 (range, grades 7–12), respectively. There were no significant correlations between understanding and the child's gender; the child's race or ethnicity; participation in a previous research study; therapeutic *versus* nontherapeutic study; the time at which assent was sought (*i.e.*, before, or the day of, surgery); the time taken to disclose information; the time allotted to make a decision; and researcher race or ethnicity, gender, appearance (white coat, scrubs, street clothes), demeanor (friendly, pushy, rushed), and title (physician, nurse, research assistant). Furthermore, there were no correlations between the child's understanding and parental understanding (measured by two assessors; see companion article), child's health status, and child's anxiety level. Overall, children who had read the consent form had greater understanding than those who had received verbal information only. However, when broken down by age-specific strata, this was only significant in the youngest age group.

**Table 2. Assessors' Scores and Children's Perceived Understanding Scores By Age**

| Age Group (yr) | Assessor's Score | Children's Score |
|---|---|---|
| 7–10 | 2.2 ± 2.2 (1.7)* | 7.3 ± 1.8 (7.0) |
| 11–14 | 5.1 ± 2.6 (5.0)*† | 6.9 ± 2.6 (7.0) |
| 15–18 | 6.6 ± 2.5 (7.5)†‡ | 6.9 ± 2.9 (8.0) |
| All groups | 5.3 ± 2.7 (5.0)* | 7.0 ± 2.4 (7.0) |

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

Scores based on 0–10 scale where 10 = complete understanding.

* $P < 0.0001$ *vs.* children's score; † $P < 0.0001$ *vs.* 7–10 age group; ‡ $P = 0.02$ *vs.* 11–14 age group.

**Table 3. Percent of Children with Complete Understanding of Elements By Age Group**

| Elements of Consent | 7–<11 (n = 16) | 11–<15 (n = 59) | 15–18 (n = 27) | All Groups (n = 102) |
|---|---|---|---|---|
| Study purpose | 28.6 | 44.4 | 50.0 | 44.1 |
| Study protocol | 7.7 | 40.0* | 63.6* | 41.9 |
| Risks | 35.7 | 47.2 | 64.0 | 50.5 |
| Benefits to self | 0.0 | 31.5* | 43.5* | 30.4 |
| Benefits to others | 7.1 | 44.2* | 56.0* | 42.4 |
| Alternatives | 0.0 | 22.0 | 40.0* | 24.4 |
| Freedom to withdraw | 23.1 | 66.0* | 87.5* | 64.8 |
| Voluntariness | 64.3 | 90.7* | 100* | 89.4 |

* $P < 0.05$ *vs.* 7–<11 age group.

Age alone was shown to be significantly associated with improved understanding ($P < 0.0001$), particularly in children aged more than 11 yr. Interestingly, parents reported that the age at which they believed assent should be sought was 11.7 ± 4.0 yr. Fifty-nine percent of children reported that their parents had been the primary influence in their decision to participate, and although the majority of decisions were made jointly between child and parent(s), 13 (13.8%) each were made solely by the child and parent, respectively. Only 3 (3.1%) children believed that the investigator would be upset if they declined to participate, and none were concerned that their parent(s) would be upset. Children reported relatively low anxiety regarding their surgery (4.5 ± 3.0, 0–10 scale), and only 3 (3.1%) reported feeling more anxious as a result of being recruited for a study. Anxiety was independent of age, whether the study was considered therapeutic, and the time at which assent was sought. Reasons for agreeing to participate as a research subject are described in table 4.

## Discussion

The bioethical credo "respect for persons" is interpreted to require investigators to "show respect for a

**Table 4. Reasons for Participation**

| Reasons | Respondents, % (n = 63) |
|---|---|
| To help | 20.6 |
| The benefits | 17.5 |
| Low risks | 14.3 |
| Don't know | 9.5 |
| Parental decision | 4.8 |
| Miscellaneous* | 33.3 |

* For example: "Cause they asked me"; "For the heck of it"; "Just to try it"; "I was bored"; "Nothing better to do"; "So I could get on and play Nintendo"; "Mom helped design the study!'

potential subject's capacity for self-determination to the extent that it exists."[14] Because children cannot legally provide consent, the principle of respect for persons requires that researchers obtain their assent or affirmative agreement before participation in a research study. Although many consider assent to provide the minor child with the opportunity for self-determination,[15] others would argue that neither assent nor parental permission can be understood from the perspective of self-determination because they serve different functions, *i.e.*, preference on one hand and protection on the other.[16]

The challenge for the investigator is to determine the age or developmental level at which assent should be sought and the age appropriateness of the disclosed information. Although review of the literature, albeit sparse, suggests that most children aged more than 14 yr have sufficient capacity to make decisions regarding their health care,[17] the National Commission recommends that assent be sought for those aged more than 7 yr.[7] However, use of age solely as a criterion may be discriminatory because it does not take into account the individual maturity of the child. Furthermore, there are principles of child development that may differentially affect assent by children.[18]

Given that the definition of assent indicates a preference for participation rather than permission, Weithorn[19] suggests that compared with informed consent, assent should not require the same degree of understanding. However, for assent to be meaningful, it seems reasonable that children understand, at minimum, the core elements of disclosure, *i.e.*, the risks, benefits, and what will be done. We chose to examine children's understanding of what we believed were the most important elements. Although federal regulations have specific requirements for information disclosed for informed consent,[6] there is limited information regarding the nature and amount of information required for assent.[20]

The ability to comprehend the important aspects of a research study likely requires that the child has moved into what Piaget describes as the formal operations stage of development.[21] This generally occurs at or around age 11 yr. Before this level, children are able to think logically and systematically only in reference to tangible objects (concrete operations, ages 7–11 yr). These younger children may be able to grasp specific concepts within the study, such as having blood drawn, but they may not be able to understand why giving a blood sample is necessary. During the formal operation stage of development, however, children are able to think more abstractly and hypothetically. Adolescents at this level should be able to comprehend the purpose of a research study beyond specific procedural components, *e.g.*, how the study will benefit themselves and others. Elements of Piaget's developmental theory may help explain the observed increase in understanding after age 11 yr.

A few studies have examined children's understanding of research.[2,3,9,19,22] Postlethwaite *et al.*[23] measured children's understanding of a trial of growth hormone and found that 21% had "very good" understanding, whereas 36% were unable to understand or recall any information about the trial. In a study of children's consent for hypothetical treatment options, Weithorn and Campbell[19] showed that children aged 9 yr were less capable of understanding consent information than those aged 18 yr but were equally capable of making decisions. Susman *et al.*[3] reported that most children can understand the elements of consent that assess concrete information, such as duration of study; however, few can understand the more abstract elements, such as the purpose of the research. More recently, Ondrusek *et al.*[9] showed that understanding was particularly poor for children aged less than 9 yr. In our study, understanding appeared to improve substantially after age 11 yr. Age was shown to be an independent predictor of understanding for these children.

The manner in which information is disclosed likely influences the child's understanding. In our setting, study information is always presented verbally and in a written document. All research personnel involved with subject recruitment are trained and experienced in interacting with children of all ages. Furthermore, they undergo periodic quality assessment by senior research staff. Verbal information is presented to children in abbreviated, simplified language, yet includes all of the important elements of disclosure. The readability of the consent forms in our study ranged from the seventh to twelfth grade levels, which is at a higher level of education than most of the children in our study. Despite this, even younger children (*i.e.*, aged $< 11$ yr) who read the consent forms had a greater understanding of the study compared with those who did not. Studies in adults have shown that combining verbal and written information improves patient understanding and compliance with discharge instructions.[24,25] Ensuring that children have enough time to read the consent document may similarly improve understanding. We believe that the child's level of understanding in our study was based on appropriately disclosed information that met the criteria of the National Commission.[7] Whether disclosure of information at other research institutions is as comprehensive or more or less age appropriate is unknown. As such, these data may not be generalizable to all research settings.

We deliberately based our measures of understanding on several studies so that we could examine understanding in the context of different risks and benefits. Although each consent document contained different information, their formats were all standardized with respect to the institution's Institutional Review Board template. Furthermore, all research personnel are

trained in giving study information to children in a standardized fashion.

We chose not to interview children before surgery because of time constraints and ethical concerns that we would be overburdening them at a time when they might be most anxious. As such, one may argue that their ability to recall elements of disclosure may have been affected by their anesthetic and surgical experience. Although there are several studies examining the effect of anesthesia on memory of events occurring intraoperatively, anesthesia, in the absence of preoperative anxiolytic agents, does not appear to affect recall and understanding of information presented before surgery (retrograde amnesia).[26–29] Elfant *et al.*[30] showed that understanding of informed consent by adults after endoscopic procedures with sedation was good and was similar regardless of whether the consent had been obtained immediately or several days before the procedure. At our institution, children aged more than 7 yr rarely receive premedicant agents, so none of the children in these studies received preoperative anxiolytic agents. One could argue that because of this, only the least anxious children were included. Although anxiety did not appear to affect understanding in this population, our results may not be generalizable to children who receive sedatives preoperatively. Only 12 children who had been approached could not recall being asked to be in a study. Whether this was related to anxiety, distraction, or some other reason remains unknown because they were not interviewed once it was determined that they could not remember the study. Of the 102 children who could remember being in a study, some had poor understanding of the elements of disclosure, whereas other children of similar ages undergoing similar procedures demonstrated complete understanding of all elements. Therefore, for the majority, understanding may have been more dependent on individual characteristics than anesthetic effects *per se*.

Although some children are capable of providing assent for participation in clinical research, they may be, nevertheless, vulnerable to undue influence because their tendency to defer to authority figures may impede their ability to state their preferences. Several studies suggest that parents have a significant influence on their child's wishes regarding participation in a study.[3,22,31] Scherer *et al.*[31] found that "children" aged to 25 yr reported a deference to parental wishes. In our study, 59% of children reported that their parent(s) were the biggest influence in their decision-making, and 13.8% stated that their parent(s) alone had made the decision for them. However, none believed that their parents would be upset if they had declined participation in the study. Parental influence and decision-making decreased inversely with their child's age.

Although our Institutional Review Board does not advocate participation of subjects in more than one study at a time, this caveat can be waived if the investigators agree that the second study presents no more than minimal risk, that the subjects will not be harmed, and that outcomes will not be affected. Because the present study depended on participation of children in a previous study and fulfilled these criteria, the Institutional Review Board granted a waiver for dual enrollment. The alternative would have been to base the children's understanding on hypothetical studies, which we believe does not adequately mimic the real situation.

This study marks the first to examine assent in a surgical population of children and is unique in that understanding was based on real-life studies rather than hypothetical ones. Results of this study suggest that children approached for their assent to participate in clinical anesthesia and surgery studies have limited understanding of the elements of disclosure, particularly if they are younger and did not read the disclosure information. Whether this reflects a generalized inability of children to assimilate this type of information or whether this reflects the unique circumstances under which surgical populations of children are typically recruited for studies remains to be seen. In any case, although assent does not require the same level of understanding as consent, every attempt should be made to ensure that the subject has sufficient information and understanding to formulate a preference for participation. If assent in children is to be meaningful, it behooves the investigator to present age-appropriate disclosure in an ethically sensitive manner that is conducive to understanding.

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