ARTICLE

Improving the Readability and Processability of a Pediatric Informed Consent Document

Effects on Parents' Understanding

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Objective: To examine whether a consent document modified to conform with the federal guidelines for readability and processability would result in greater parental understanding compared with a standard form.

Design: Randomized clinical study.

Setting: The preoperative waiting area of a larger tertiary care children's hospital.

Participants: A total of 305 parents of children scheduled for minor elective surgical procedures.

Interventions: Parents were randomized to receive information about a clinical study in 1 of 4 ways: (1) standard consent form alone, (2) standard consent form with verbal disclosure, (3) modified form alone (standard form modified to meet the federal guidelines for readability and processability), and (4) modified form with verbal disclosure.

Main Outcome Measures: Parents were interviewed to determine their understanding of 11 elements of consent, including study purpose, protocol, risks, benefits to child (direct), benefit to others (indirect), freedom to withdraw, alternatives, duration of study, voluntariness, confidentiality, and whom to contact. Their responses were scored by 2 independent assessors.

Results: Understanding of the protocol, study duration, risks, and direct benefits, together with overall understanding, was greater among parents who received the modified form ($P<.001$). Additionally, parents reported that the modified form had greater clarity ($P=.009$) and improved layout compared with the standard form ($P<.001$). When parents were shown both forms, 81.2% preferred the modified version.

Conclusions: Results suggest that a consent form written according to federal guidelines for readability and processability can improve parent understanding and thus will be important in enhancing the informed consent process.

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An estimated 95 million Americans have poor literacy skills.[1] Since poor literacy has been consistently associated with poor health status,[2,3] a significant number of these individuals will at some time become eligible to participate in clinical research. Furthermore, current research priorities that involve children (and parents) rely on the understanding of individuals with varying levels of literacy and comprehension.[4] Indeed, recent studies[5-8] suggest that many parents and children have poor understanding of study information, particularly as it applies to their understanding of the protocol, purpose, and benefits of the study. This is concerning, since a lack of understanding may render patients vulnerable in all aspects of health care, including compliance with treatment regimens, preventive care, and participation in clinical research.[2,9]

Despite these concerns, most informed consent documents are typically written well above the recommended eighth-grade reading level[10-13] and that of the average reader. Although simply reducing the grade reading level has been shown to decrease anxiety and increase acceptance of information, it does not guarantee improved understanding.[14-16] Several reading experts suggest that to improve reading comprehension one must improve both the readability (reading level) and the processability of the information (ie, incorporation of explicit information, layout, mental images, and context clues).[17-19] With this in mind, we designed this study to test the hypothesis that a consent document modified to conform with the federal guidelines for readability and processability

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Standard Consent Form

What exactly will be done to my child if I agree to let him/her participate in this study?

Following the routine preoperative physical exam and medical history, all children will receive the standard anesthetic for surgery including an intravenous (IV) line placed after the child is asleep. Fifteen minutes before the end of the operation each patient will receive in a randomized fashion either the study medicine in one of two doses, or normal saline through the IV line. Before your child wakes up we will take a small blood sample through the IV to see how much of the active study medicine is in the blood. Postoperative care will be managed as usual. Children who vomit after surgery will receive a standard medication following the normal guidelines. Lastly, parents will be asked a few questions about the child's nausea and vomiting during a follow-up phone call the next day.

Modified Consent Form

What things will be done as a part of the study?

1. Medical history. It is important to give a lot of detailed information about your child's health.

2. Physical exam

3. Your child will get the usual anesthetic, and, once asleep, an IV (intravenous line) placed in his/her arm. 15 minutes before the end of surgery, each child will receive the **study drug**.

2 out of 3 children will get the study medicine in one of two doses, and 1 out of 3 will get a placebo (not the medicine, but looks like the medicine).

Study drug either 12.5 mg or 0.35 mg/kg

Placebo (no drug)

Who gets what is decided before the study in a random way. No one will know if your child is getting the active drug or not until after the study is over.

4. Before your child wakes up, we will take a small **blood sample** through the IV to see how much of the active drug is in the blood.

5. The care after the operation will be the same as for children who are not in the study.

6. Follow-up visit or phone call, the day after surgery.

Figure 1. Example excerpts of text and formatting of the standard and modified consent forms.

would result in greater parental understanding compared with a standard form.

METHODS

The University of Michigan's institutional review board approved this study, and verbal consent was obtained from all parents before participation. The study population included 305 parents of children (newborn to 17 years old) who had been scheduled for elective surgery. Per our usual practice, parents were recruited on the day of their child's surgery. Parents completed all research activities either before or during their child's surgery. Previous work suggests that for minimal risk studies this approach does not engender additional anxiety.

MODIFICATION OF STANDARD CONSENT DOCUMENT

We selected a standard consent form for a pediatric study of postoperative nausea and vomiting (PONV) formerly performed in our department (standard form). This former study was written using our standard institutional consent format at a reading level of approximately the 11th grade. The standard form was evaluated by a reading consultant (S.J.P.) as currently written for readability and processability using the format developed by Irwin and Davis[20] and adapted by Philipson et al[18] for use with consent forms. The format comprises 20 items that identify the 5 components of comprehension: microprocessing, integrative processing, macroprocessing, elaborative processing, and metacognitive processing. Each item was scored using a 1- to 5-point Likert scale, where 1 indicates unacceptable (criteria absent); 2, poor (most criteria absent); 3, minimally acceptable (meets half of the criteria); 4, good (meets most of the criteria); and 5, excellent (meets all criteria). Scores for each item were added to obtain an overall readability and processability score (typical range, 20-100). Desired target levels for readability as determined by the federal government's report on literacy are reading grade levels of 7 to 8 and processability scores of either 61 to 80 (good) or 81 to 100 (excellent).[1]

Based on the readability and processability analysis of the standard consent form, the form was modified to conform to the recommended target levels (eighth grade reading level or lower and a processability score of approximately 70). In modifying the consent document, we incorporated the methods described by Philipson et al[17,18] together with recommendations from the literature on preparing patient education materials.[9,21,22] Care was taken to ensure that the modified form had retained all the required elements of consent. Excerpts of the standard and modified consent forms are shown in **Figure 1**. In modifying the standard form, dense paragraphs were eliminated and the type size increased from 12 to 14 points. Improved understanding of text often requires that the reader is able to process elaboratively (ie, form vivid mental images of the events of the study). As such, bullets and pictographs were used for clarity. Houts et al[23] showed that the use of pictographs significantly improved understanding of medical information among patients with low literacy. In all sections of the modified consent document, boldfacing and underlining were added for emphasis and the sentences rewritten with a more readable sentence structure (microprocessing) and in column format for reading ease.[9,21]

Although we were interested in examining the effect of an improved consent form alone on understanding, the standard process of obtaining consent also requires discussion and verbal disclosure. Thus, to evaluate the modified form alone and in the context of the consent process, parents were randomized (using tables of random numbers) to 1 of 4 groups as follows: group 1, standard consent form alone; group 2, standard consent form with verbal disclosure; group 3, modified consent form alone; and group 4, modified consent form with verbal disclosure. Parents were told that their child would not be participating in the actual PONV study but that they should consider the information just as if the study were real. Although the study represented a sham study, it was nevertheless presented to simulate our standard practice with respect to the time allotted for the parent to read the consent information and the environment in which consent was sought.

Verbal disclosure (groups 2 and 4) followed a standardized script but allowed for questions and interaction with the researcher. Parents were given as long as they needed to read the consent document (typically 10 to 20 minutes). The quality of the interaction was also evaluated using items adapted from the work of Kodish.[24]

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MEASUREMENT OF PARENTAL UNDERSTANDING

Parents were interviewed to determine their understanding of the 11 required elements of consent.[25] These included the study purpose, protocol, risks, benefits to child (direct), benefit to others (indirect), freedom to withdraw, alternatives, duration of study, voluntariness, confidentiality, and whom to contact. The interview was presented in a semistructured fashion, and the parents' open-ended responses were copied verbatim by trained research assistants. Interviewers were allowed to prompt the parents for further information but were not allowed to guide their responses. The parents' levels of understanding of these individual elements were scored independently by 2 assessors who were blinded to the parents' group assignment. The interview process and method of scoring are described in detail elsewhere.[6]

Following the interview, parents completed a short questionnaire that examined their perceptions of the risks, benefits, and importance of the study, measured using 0- to 10-point visual analog scales (10 indicates high). In addition, parents reported on the clarity and quality of the consent document and their overall satisfaction with the consent process. Parents were also asked if, under real circumstances, they would have been willing to allow their child to participate in the PONV study. At the end, parents were shown both consent documents and asked which they preferred.

PSYCHOSOCIAL MEASURES

Parents completed 2 validated instruments for measuring literacy and need for cognition (NFC). Literacy was measured using the shortened form of the Slosson Oral Reading Test–Revised.[26] This shortened version requires the individual to read aloud from a list of words arranged in ascending order of difficulty and has demonstrated excellent test-retest reliability (0.99) and criterion validity (0.9).[27,28]

Parents also completed the 18-item shortened version of the NFC form,[29] which measures the tendency of an individual to engage in and enjoy effortful thinking. Items include statements such as "I would prefer complex to simple problems" and "I only think as hard as I have to." Each item is scored on a 1- to 5-point Likert scale, where 1 indicates "not at all like me" and 5 indicates "very much like me."

STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS statistical software (SPSS Inc, Chicago, Ill). Sample size determination was based on a previous study that showed that parents' understanding of a standard consent form was 7.3±1.8 (0-10 scale, where 10 indicates complete understanding).[6] Accepting a 10% improvement in understanding as the smallest difference that we believed to be clinically important to detect, we required a sample size of 75 parents per group ($\alpha=.05$, $\beta=.20$, 2-sided). Comparisons of parametric data between groups were analyzed using analysis of variance. Post hoc analysis was performed using either the Tukey or Dunnett C tests, depending on the equality of variances. Nonparametric data were analyzed using Mann-Whitney U, χ^2, and Fisher exact tests, as appropriate. Interrater reliability and levels of agreement between the assessors were performed using the Spearman correlation coefficient (ρ) and κ statistics, respectively. Both κ and ρ values of 0.40 or more and 0.70 or more, respectively, were considered to represent acceptable levels of agreement and correlation. Corrections for multiple comparisons were made using the Bonferroni technique. $P<.01$ was considered statistically significant.

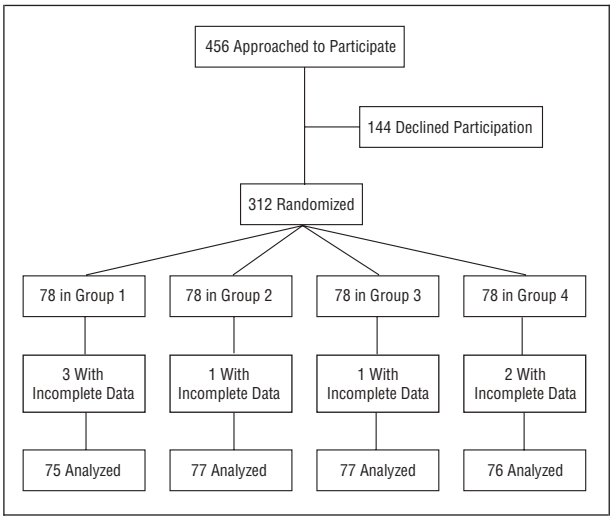

Figure 2. Flow diagram of participant progress through the phases of study.

RESULTS

Four hundred fifty-six parents of children scheduled for elective surgery were approached to participate. Of these, 144 parents declined and 7 were unable to complete all the research measures owing to lack of time (**Figure 2**). Of those who declined to participate, 86.1% were white, 8.3% African American, 2.1% Hispanic, and 1.4% Asian. These demographics reflected those of the final study sample. The primary reasons for not participating were that the parents simply did not want to or felt that they did not have enough time. As a result, we present complete data from 305 parents.

No differences existed in the demographics of each of the study groups (**Table 1**). The grade reading levels and processability scores for the standard and modified consent were approximately 11.2 and 52 and 7 and 70, respectively. Measures of interrater reliability for scores of understanding between the 2 assessors revealed excellent correlations. Spearman ρ and κ values for each core element ranged from 0.80 to 1.0 ($P<.001$) and 0.71 to 1.0 ($P<.001$), respectively.

Overall, the parents' perceptions of their understanding of the consent information were high (mean±SD, 9.2±1.1 of 10); however, this represented a significant overestimation compared with the assessors' measures of understanding (mean±SD, 6.9±1.5, $P<.001$). These results are similar to those observed in a previous study and thus substantiate our findings.[6] There was an overall trend toward greater understanding of all the elements of consent among those parents who received the modified consent form. Specifically, overall understanding and understanding of the protocol, risks, direct benefits, and duration of their child's involvement were significantly improved among the modified groups (**Table 2**).

The average reading ability of the parents was at the 11.3 grade (range, grades 4 to >12), which was similar among groups (Table 1). Across all groups, reading ability was significantly correlated with understanding

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Table 1. Parent and Child Demographics*

Demographics	Standard Form (n = 75)	Standard Verbal Form (n = 77)	Modified Form (n = 77)	Modified Verbal Form (n = 76)
Parent's age, mean ± SD, y	37.9 ± 7.7	37.3 ± 8.1	37.6 ± 9.1	38.1 ± 9.7
Child's age, mean ± SD, y	7.2 ± 5.3	6.6 ± 5.0	7.1 ± 5.8	6.1 ± 5.1
Child's health, mean ± SD†	8.2 ± 1.9	8.4 ± 1.8	8.4 ± 1.8	8.4 ± 1.9
Parents' anxiety score, mean ± SD‡	6.5 ± 2.9	6.6 ± 3.3	6.9 ± 2.7	6.6 ± 2.8
Race, No. (%)				
White	66 (90.4)	59 (77.6)	67 (87.0)	66 (90.4)
African American	4 (5.5)	11 (14.5)	7 (9.1)	7 (9.6)
Hispanic	1 (1.4)	2 (2.6)	1 (1.3)	0 (0.0)
Other	2 (2.7)	4 (5.3)	2 (2.6)	0 (0.0)
Education level, No. (%)				
≤High school graduate	17 (23.6)	14 (18.7)	16 (21.9)	13 (17.8)
Some college	21 (29.2)	26 (34.7)	21 (28.8)	29 (39.7)
≥College graduate	34 (47.2)	35 (46.6)	36 (49.3)	31 (42.5)
Prior child research subject, No. (%)	12 (16.9)	7 (9.3)	12 (16.0)	7 (9.5)
Prior parent research subject, No. (%)	14 (19.2)	19 (25.3)	16 (21.1)	19 (25.7)
SORT-R3 score, mean ± SD§	187.1 ± 13.5	189.4 ± 11.9	185.3 ± 18.6	184.9 ± 21.1
Need for cognition score, mean ± SD‖	50.8 ± 6.2	50.5 ± 5.9	49.9 ± 6.2	49.4 ± 6.8

Abbreviation: SORT-R3, Slosson Oral Reading Test–Revised.[26]

*Study groups included (1) standard consent form alone, (2) standard consent form with verbal disclosure, (3) modified form alone, and (4) modified form with verbal disclosure. Percentages are based on the number of participants who provided information.

†Based on a 0- to 10-point visual analog scale, where 10 indicates extremely healthy.

‡Based on a 0- to 10-point visual analog scale, where 10 indicates extremely anxious.

§Based on a 0- to 200-point scale, where 200 indicates high literacy.

‖Based on the 18- to 90-point Need for Cognition Form,[29] where 90 indicates high need for cognition.

Table 2. Parental Understanding*

Consent Element	Standard Form (n = 75)	Standard Verbal Form (n = 77)	Modified Form (n = 77)	Modified Verbal Form (n = 76)	ANOVA *P* Value
Protocol	4.8 ± 3.3	5.8 ± 3.7	6.4 ± 3.4†	7.1 ± 3.2†	<.001
Duration	2.3 ± 3.8	2.7 ± 4.3	6.4 ± 4.6†‡	7.4 ± 4.3†‡	<.001
Benefits child	7.0 ± 3.9	7.4 ± 3.8	7.5 ± 3.7†	8.8 ± 2.6†	.02
Benefits others	4.5 ± 2.9	5.8 ± 3.0	4.5 ± 2.0‡	5.4 ± 2.7	.007
Contact	9.1 ± 2.6	7.7 ± 4.1	9.4 ± 1.9‡	8.8 ± 3.0	.003
Risks	4.7 ± 3.7	5.8 ± 3.4	5.6 ± 3.6	6.7 ± 3.4†	.006
Overall	6.4 ± 1.4	6.6 ± 1.6	7.2 ± 1.5†	7.6 ± 1.3†‡	<.001

Abbreviation: ANOVA, analysis of variance.

*Study groups included (1) standard consent form alone, (2) standard consent form with verbal disclosure, (3) modified form alone, and (4) modified form with verbal disclosure. Percentages are based on the number of participants who provided information. Data are mean ± SD based on 0- to 10-point scales, where 10 indicates complete understanding.

†$P<.001$ vs standard alone.

‡$P<.001$ vs standard plus verbal.

($r=0.33$, $P<.001$). Additionally, among parents whose grade reading ability was eighth grade or less, those who received the modified form had significantly greater understanding compared with those who received the standard form (mean ± SD, 6.7 ± 1.9 vs 4.3 ± 1.2, $P=.003$).

Despite the observed differences in understanding between the groups, this did not influence the parents' hypothetical decisions to consent to the PONV study. For example, 50% and 48.3% of parents who received the standard and modified forms, respectively, reported that they would have allowed their child to participate had it been a real study. There were no differences in the parents' perceptions of the benefits (direct and indirect) between groups. However, parents who received information using the standard consent form alone perceived the risks to be significantly lower than those who received the modified consent form ($P<.001$).

The parents' perceptions of the quality of the 2 consent forms are given in **Table 3**. As shown, the modified form was perceived to be clearer, to be easier to read, and to have a superior layout. However, no differences existed in parents' satisfaction with the consent process among groups. Overall, 85.3% of parents perceived the amount of information that they received to be "just right." Interestingly, parents who perceived the information as "too little" had significantly higher NFC scores than those who viewed the information as "too much" (mean ± SD, 52.6 ± 4.9 vs 48.2 ± 4.9, $P=.03$).

The verbal disclosures in groups 2 and 4 were rated highly (mean ± SD, 8.6 ± 1.6 of 10) and were similar between the groups. Overall, 73.6% believed that the verbal information was "very clear," and 90.5% per-

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ceived the amount of verbal information to be "just right."

When shown both consent forms, parents overwhelmingly chose the modified form (81.2%). Eighty-five percent of those who were originally shown the modified form preferred it to the standard form. Of those who received the standard consent form, 77.3% reported a preference for the modified version. Those who preferred the modified form stated that it was "easier to read," "less intimidating," and "friendlier"; had a "better layout"; and was enhanced by the use of pictures. Those preferring the standard form believed that it was "more professional," "shorter in length," and "more serious."

Table 3. Consent Form Quality

Form Quality	Standard Form (n = 152)	Modified Form (n = 153)	*P* Value
Very clear, %	63.6	77.2	.009
Easy to read, %	64.7	85.5	<.001
Layout quality, mean ± SD*	7.7 ± 2.0	8.5 ± 1.6	<.001
Overall quality, mean ± SD*	8.1 ± 1.8	8.6 ± 1.5	.03
Overall satisfaction, mean ± SD*	8.0 ± 1.8	8.4 ± 1.4	.08

*Based on a 0- to 10-point scale, where 10 indicates high.

COMMENT

Owing to regulatory and medicolegal issues, the consent document has become the standard vehicle for presentation of consent information[25]; thus, it is imperative that it be written at a level consistent with a layperson's reading ability and presented in a format that is readily understandable. As stated, many consent forms do not meet the federal standards for readability and processability[18] and are often written in a "one size fits all" format that does not take into account important differences in individuals' cognitive abilities, learning styles, or preferences.[30] In one study, Philipson et al[17] identified several problems with readability and processability that would preclude the average participant from fully comprehending study information. Intuitively, one would think that simply reducing the grade reading level would correct the problem, yet Hochhauser[19] argues that even if consent forms are written at the eighth-grade reading level, they may still be incomprehensible if they are written poorly. Previous studies aimed at simplifying consent documents have produced mixed results. Easier-to-read forms have been shown to be better received than standard forms[14,16,31,32] and may decrease anxiety[15,33] but do not necessarily improve comprehension.[14,15]

In a study by Tait et al,[34] several factors were identified as predictors of parental understanding of consent information. These included the parents' levels of education, the degree to which the parent read the consent, and the perceived clarity of the information. Furthermore, we showed that parents' assessments of the risks and benefits of a study were influenced by the perceived clarity and amount of information and the environment in which consent was sought (ie, time, privacy).[35] Our results support these earlier findings and reinforce the observation that not only is the informational content important but the manner in which it is presented is also important. It is unclear why parents' perceived understanding differed from their real understanding; however, this finding suggests that simply asking parents if they understand may be insufficient and reinforces the need to reiterate and clarify their understanding of the most important elements before informed consent is obtained.

The observation that parents who perceived the information as "too little" were those with higher NFC is important, because it reinforces the importance of presenting information that is sufficient to ensure understanding. For example, individuals with low NFC may be overwhelmed by large amounts of information, and conversely, those with higher NFC may require more detailed disclosure. Indeed, recent studies[8,35] suggest that the amount of information has important implications for understanding and for the assessment of risks and benefits.

Although it was clear that the format alone had an independent effect on understanding, parents who received additional verbal information showed improved understanding of the material. Although these improvements were not statistically significant, they highlight the importance of the verbal interaction as a means to educate the individual, answer questions, and instill trust. In one study,[6] the degree to which parents listened and interacted with the researcher was shown to predict improved understanding.

Despite improved understanding among parents who received the modified consent document, this did not translate into a greater, albeit hypothetical, willingness to participate in the PONV study. Although this may reflect the fact that parents were not actually enrolling their child into a real study, Coyne et al[15] showed that accrual rates for a pediatric cancer study were also unaffected by the use of a simplified consent form. In any case, one should bear in mind that the goal of providing understandable consent forms is to ensure that the individual is truly informed and not simply as a means to improve participant accrual.

A few points regarding the study design merit discussion. Although we measured parents' understanding of an actual study, it was presented in a sham format. This choice was based on the rationale that since we were presenting information using a modified and untested consent form, it would be inappropriate to recruit children for a real study. One concern with the use of sham studies is that they may not fully reflect the real-life situation. However, to obviate this concern, we presented the study under similar circumstances (time and environment) to our standard consent process. Furthermore, several studies[36,37] have confirmed the ability of sham studies to predict real behaviors. Robinson and Clore[38] showed that sham methods play an integral part in emotional theory construction, and Jago and Vroom[39] showed a significant correlation between behavior based on real vs hypothetical situations. We also recognize that these results represent one consent document from one institution and, as such, may not be generalizable to all consent documents or to those from other institutions.

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Results from this study show that a consent document written according to federal guidelines for readability and processability results in improved understanding and acceptance of the study information. As such, these data may be important in helping investigators develop more user-friendly and understandable consent documents and may also serve as a guide when presenting information to patients about anesthesia and other medical or surgical procedures.

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