

Improving the Readability and Processability of an Informed Consent Document for Pediatric Anesthesia Research: Effects on Parents' Understanding and Satisfaction

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Introduction: It is estimated that 40 million Americans are barely literate and another 45 million have very poor literacy skills. Despite this, the majority of informed consent documents are written well above the recommended 8th grade level and, as such, may be difficult for the average subject to understand (1). Simply reducing the grade reading level of a document, however, may not improve comprehension since it does not take into account the processability of the information i.e., incorporation of explicit information, mental images, context clues, and layout (2). This study, therefore, was designed to examine the effects of improved readability and processability on parents' understanding of a pediatric informed consent document.

Methods: The study population consisted of parents of children (0-18 yrs) who were scheduled for an elective surgical procedure. We selected a standard consent form for a pediatric study of postoperative nausea and vomiting (PONV) previously carried out in our department. The consent form (standard form) was modified by a reading expert to meet the federal literacy guidelines for readability and processability (3) i.e., $\leq 8^{\text{th}}$ grade reading level and a processability score of >60 out of 100 (modified form). Parents were randomized to receive consent information in one of four ways: 1) Standard consent form alone; 2) Standard consent form plus verbal disclosure; 3) Modified consent form alone, and; 4) Modified form plus verbal disclosure.

Although the children were not actually enrolled in the PONV study, the information was presented to simulate our standard practice regarding the timing of consent, the time allotted for disclosure and decision-making, and the environment in which consent is typically sought. Parents were interviewed to determine their understanding of the 11 required elements of consent including the purpose, protocol, risks, benefits, alternatives, etc. Parents' understanding of these elements were scored by two independent assessors who were blinded to the parents' group assignment. The parents also completed a short questionnaire regarding their satisfaction with the quality and layout of the consent form and, if applicable, the verbal disclosure. At the end, parents were shown both forms and asked which one they preferred.

Results: This study was approved by our institutional IRB. To date, we have interviewed 186 parents. There were no differences between the demographics of the parents or children between groups. Although parents in each group perceived their overall understanding to be high (9.2 ± 1.1 out of 10), this represented a significant over-estimation compared to the assessors' measures of parental understanding (6.9 ± 1.4 , $P < 0.001$). Understanding of the protocol and study duration, together with overall understanding was greater among group 4 parents compared to group 2 parents (Table). Additionally, parents reported that the modified form had greater clarity and improved layout compared to the standard form ($P < 0.01$). Group 4 parents also reported greater satisfaction with the overall consent process compared to group 2 parents ($P = 0.053$). When shown both forms, parents overwhelmingly chose the modified form (84%) stating that it was "less intimidating," "easier to read," "friendlier," and was enhanced by the use of pictures.

Discussion: These data demonstrate that a consent document written to meet the federal literacy guidelines for readability and processability resulted in improved parental understanding and acceptance of study information. These results will be important to investigators in developing reader-friendly and understandable consent documents.

Table: Parental understanding

	Standard + verbal (n=46)	Modified + verbal (n=46)	P value
Study protocol	5.4 ± 3.6	7.3 ± 3.3	0.012
Study duration	2.1 ± 3.7	6.8 ± 4.5	<0.001
Overall understanding	6.7 ± 1.6	7.4 ± 1.2	0.013

Data are mean \pm SD on a scale of 0-10 where 10=complete understanding

Refs:

1. Murgatroyd, RJ, et al., Am J Hosp Pharm, 1991
2. Philipson SJ, et al., J Invest Med, 1995
3. Kirsch I, et al., Nat Center Educ Stats, 1993