

STRONG CHILDREN'S RESEARCH CENTER

Summer 2014 Research Scholar

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ABSTRACT

Title: Improving Measurements of Parents' Understanding of Research Consent Forms

Background: Current measures of research consent understanding are imperfect. Modifying current measures, such as the DICCT (Deaconess Informed Consent Comprehension Test), may improve the ability to more accurately measure parent understanding.

Objective: The objective for this study was:

- to improve current tools to measure parent understanding of research permission
- The primary and secondary hypotheses included:
- two modified and simplified subsets of questions from the DICCT would retain the test characteristics of the full DICCT
 - test scores would correlate with educational level and perceived understanding
 - the written modified comprehension test will be preferred

Methods: Parents were selected based on the following criteria:

Inclusion criteria: Parents who (1) had infants admitted to the NICU at Strong Memorial Hospital with gestation <32 weeks at birth and, (2) were recovering from neonatal illness, (3) were English-speaking, and (4) were 18 years of age or older.

Exclusion criteria: Illiteracy (unable to read simple forms).

Parents gave verbal consent to the study, and were presented with a sham permission form with attached cover sheet. After reading, participants completed: (1) Likert scale on subjective understanding, (2) the DICCT, the modified written comprehension test, and the modified oral comprehension test in randomized order, (3) Likert scale on cover sheet, and (4) Demographics and post-test survey form. After participants completed all forms regarding the measures of comprehension, researchers presented them with two additional formats (brochure and trifold) of the information found on the cover sheet, and conducted a cognitive interview. Correlation scores between the modified tests and the DICCT were calculated by linear regression. The same procedure was used to calculate the correlation scores between the tests and perceived understanding, and between the tests and education levels.

Results: The relationships among the three comprehension measures varied from weakly to strongly correlated, with $R=0.4977$ ($p=0.003$) for the DICCT vs. modified oral test, $R=0.7779$ ($p\leq 0.00025$) for the DICCT vs. modified written test, and $R=0.3025$ ($p=0.161$) for the two modified tests. The relationships between the comprehension measures and parents' education levels were weakly to moderately correlated ($R=0.6407$ for DICCT, $R=0.2694$ for oral test, and $R=0.5271$ for written test). Similar relationships were found between the comprehension measures and perceived understanding ($R=0.5021$ for DICCT, $R=0.2474$ for oral test, and $R=0.5396$ for written test). Most participants (62.5%) of those who took the written test preferred it to the other tests.

Conclusion: By being highly correlated with a previously established measure of comprehension (DICCT) and being preferred to other tests, the modified written test may be used in the future as a standard measure of parent understanding. The written test has the added benefit of a high inter-rater reliability, and can be used as a teaching tool (parents can learn from the answers provided to the questions). Also, the written test can be self-administered, saving time for study staff.