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Permission Form Synopses to Improve Parents' Understanding of Research: A Randomized Trial

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Abstract

Objective—We hypothesized that, among parents of potential neonatal research subjects, an accompanying cover sheet added to the permission form (intervention) would increase understanding of the research, when compared to a standard form (control).

Study Design—This pilot study enrolled parents approached for one of two index studies: one randomized trial and one observational study. A one-page cover sheet described critical study information. Families were randomized 1:1 to receive the cover sheet or not. Objective and subjective understanding and satisfaction were measured.

Result—Thirty-two parents completed all measures (17 control, 15 intervention). There were no differences in comprehension score (16.8 ± 5.7 v. 16.3 ± 3.5), subjective understanding (median 6.0 v. 6.5), or overall satisfaction with consent (median 7.0 v. 6.5) between control and intervention groups (all p>0.50).

Conclusion—A simplified permission form cover sheet had no effect on parents' understanding of studies for which their newborns were being recruited.

Introduction

The current research informed consent process often fails to fulfill its goal. Several studies of both adult subjects giving consent and of parents giving permission for their children to participate in research have found their understanding of the research to be unsatisfactorily

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low [1-3]. This comprehension may be even lower in high-stress populations, such as the parents of neonatal or pediatric oncology patients [4-7].

One potential contributor to the problem of poor subject understanding of research studies is the written consent/permission form. These forms are often long, complex and difficult to read [8, 9]. Attempts at modifying the written forms have yielded conflicting results of the effect on comprehension [5, 6, 10-14]. One approach, a condensed informed consent document, has been associated with higher comprehension in some studies [11, 12, 15-18], but not all [13, 14, 19]. However, few studies of modified forms have used subjects considering participation in an actual (as opposed to hypothetical) research protocol [6, 11, 15, 17, 20, 21].

In the current regulatory environment, shortened consent/permission forms that omit or abbreviate portions required by federal or local institutional review board (IRB) rules are likely to face opposition. In addition, many parents of children with leukemia completing interviews about the permission process express the wish for more information about the study, rather than less [22].

In a recent commentary, experienced pediatric oncology investigators proposed a preamble to the informed permission document that briefly explained the nature of clinical research and the clinical protocol, and referred the parents to specific portions of the complete document [23]. This approach might allow the complete consent/permission form to remain unabridged, but provide the simplified language that has been shown to be associated with better comprehension.

This study tested a similar mechanism, an abbreviated cover sheet, in a pilot study among a population (parents of premature infants) at high risk for poor consent comprehension. We hypothesized that, among parents of potential neonatal subjects, an accompanying, one page, cover sheet in addition to the standard permission form (intervention) would increase parent understanding of the nature and risks of the research, when compared to parents receiving only a standard permission form (control).

Subjects and Methods

This was a randomized, controlled, single-blind, pilot study. The study was approved by the University of Rochester's Institutional Review Board. Parents of premature infants under 35 weeks' gestation hospitalized in the neonatal intensive care unit (NICU) at Golisano Children's Hospital at the University of Rochester were recruited if their infants were being approached for permission for one of two greater-than-minimal-risk studies. The first of these was a trial of hydrocortisone to decrease bronchopulmonary dysplasia (BPD) (“Hydrocortisone”) and the second was a local, observational protocol including in-hospital and outpatient evaluations, conducted by Rochester site of the Prematurity and Respiratory Outcome Program (“PROP”). The studies (referred to hereafter as the “index” studies) were chosen for entailing greater than minimal risk, but not having significant time pressure for the permission decision. Time from identification of eligibility to enrollment ranged from 7 (PROP) to 14 (Hydrocortisone) days.

Inclusion criteria included being a parent of an infant eligible for one of the index studies, permission being sought for one of the studies and the ability to speak, read and understand English. Parents were excluded if the infant's attending physician felt it would be inappropriate to include them. If parents were approached for both index studies, they were eligible for this study only during the approach for PROP, for which approaches occurred earlier in the hospitalization.

Intervention

The intervention was a one-page cover sheet affixed to the front of the standard permission form for the trial for which permission was being sought (Supplemental Figure 1). The form identified the study as research and contained sections that included investigator contact information, the purpose of the study, a brief description of the study procedures, the alternatives, the voluntary nature, the risks, the potential benefits, privacy and confidentiality, the costs, and the payments. Each section contained a reference to the page in the permission form containing the full description of the topic. The cover sheet was designed to have a reading level no higher than 6^{th} to 8^{th} grade. The Hydrocortisone cover sheet had a Flesch-Kincaid Grade Level of 7.1 and the PROP cover sheet, 6.6. The cover sheet was pre-tested for layout and comprehensibility among the investigators, but not pre-tested among parents. Parents also received the full, standard permission form for the relevant index study. Control parents received the standard, full permission form, without the cover sheet. The full forms' Flesch-Kincaid Grade Levels were 12.0 (Hydrocortisone) and 10.7 (PROP).

All staff (study investigators or research coordinators) obtaining permission for index studies were trained on the use of the cover sheet. The person presenting the permission form for the index study described the study and answered questions from both groups of parents using the standard procedures for each study, which included verbal review of salient points with all parents and page-by-page review of the permission form with parents interested in participation. The only difference in the presentation of the index study between the two study arms was the inclusion of the cover sheet in the intervention group. All interventions and measures occurred in the NICU or maternity ward.

Measures

The main study measure was the Deaconess Informed Consent Comprehension Test (DICCT), a 14-item questionnaire covering study purpose, procedures (2 items), risks, benefits, alternatives, contact information (2 items), compensation for injury (2 items), voluntary nature, freedom to withdraw, lack of participation decision's effect on other care decisions and confidentiality [24]. The DICCT is scored on a 28 point scale, with each of the 14 parameters being scored as 0 = incorrect, 1 = partially correct, 2 = correct, and had face validity, high reliability and preliminary external validity in a previous study [24]. The DICCT was modified as appropriate to each index study, specifically with changes to questions about study procedures (Supplemental Figure 2). The DICCT was administered in an oral format, without a time limit, with a research staff member recording the parent's answers. The participant was allowed to refer to the permission form (and cover sheet, if present) to answer the questions. The participant then completed a short survey that included

self-reported age, gender, race/ethnicity and level of education. The survey also contained two, self-administered, 7-point Likert scales, for satisfaction with the consent/permission process and for perceived understanding of the index study.

Study Procedures

Eligible parents were asked for verbal permission to participate in a study of consent comprehension before initiation of the permission process for the index study. The initial verbal description did not include mention of the cover sheet or the randomization. Parents who refused verbal permission were not enrolled in the cover sheet study and were given a standard (control) permission form for the index study. Parents who gave verbal permission received either the intervention or control index study permission form. The form was taken, in order, from a sealed envelope in a folder in which the order of intervention and control forms had previously been computer randomized (1:1) by the study statistician. Randomization was stratified by index trial. Parents, but not staff, were masked to study group assignment (by virtue of being unaware of the nature of the intervention).

If both parents were present for the approach for permission and both had agreed to participate in the cover sheet study, each parent was considered a subject. Parent pairs were randomized together, as there was no practical way to randomize them separately.

Following the completion of the approach for permission (and their decision regarding allowing their infant to participate in the index study), parents were given an information sheet explaining the study and the surveys (but omitting information about the cover sheet and randomization) and, if they agreed, completed the DICCT and associated survey. This was done as soon as possible after the completion of the consent approach for the index study, but not always the same day. Parents were asked to complete the DICCT and survey whether or not they have agreed to give permission for the trial for their infant. When the parents had completed the DICCT and survey, they were given a post-survey debriefing form that explained the purpose of the cover sheet study and the randomization, and were asked for permission to use their data. Staff administering the measures were specifically trained in their use.

No demographic or other information was collected on parents who did not initially provide verbal agreement, failed to complete the DICCT and/or survey, or opted out after receiving the post-survey information sheet. Parents who initially agreed, but did not complete the DICCT or opted out were replaced until the planned sample size was reached.

Analysis

The DICCT was reviewed by a single reader (CDA), who scored the DICCT using index-study-specific templates based on published criteria [24]. The central reader was unaware of the study group, demographic survey information and whether the parent had given or withheld permission for the index study.

The primary outcome was the score on the post-permission DICCT. The study was powered, with a planned 16 subjects per group, to detect an effect size of 1.0, using $\alpha = 0.05$ and a power of 0.8 – in this case an increase in the mean DICCT score from 20 (the published

mean) to 24, assuming the published standard deviation of 4 points [24]. Secondary outcomes included subjective comprehension, satisfaction and multivariate analysis of primary and secondary outcomes adjusted for covariates.

The DICCT scores were expressed as means and analyzed by Mann-Whitney U test. Likert scale scores were expressed as medians and analyzed by Mann-Whitney U test. Other bivariate analyses used the Mann-Whitney U test or Pearson correlation, as appropriate. ANCOVA tested cover sheet effect on outcomes, after adjusting for index study (PROP vs. Hydrocortisone), consent to index study and parent education. All tests were 2-sided. No *a priori* corrections were made for co-linearity of parent pairs. Analysis was by intention-to-treat.

Results

Study enrollment occurred from March 2012 – April 2013. Sixty-five parents provided verbal permission to participate in this study (Supplemental Figure 3). Thirty-three parents, of whom 23 had refused to have their infants participate in the index study, were unavailable or unwilling to complete the study questionnaires when approached to do so. Of parents who gave a reason, most cited lack of interest in the index study as the reason for declining to complete the questionnaires. Thirty-two of the refusing parents were being approached for the PROP index study; 1 was being approached for Hydrocortisone. Thirty-two parents from 24 families (8 couples included) completed the study questionnaires. Their characteristics are described in Table 1. No participant withdrew consent upon debriefing. Of families with only one parent participating, all participants were women. There were no adverse events.

Use of a cover sheet had no effect on objective understanding of the research permission process, as measured by the DICCT, subjective understanding of research permission or satisfaction with the research permission process (Table 2). Participants nearly uniformly rated their subjective understanding of the study as high, despite their being able, on average, to score about 60% the points possible on the objective measure. When the scores were limited to the elements that other parents of premature infants [25] had indicated were most important to the research permission process (study purpose, procedures and risks, defined as questions 1-4 on the DICCT, which would yield a possible high score of 8), subjects were not able to answer a higher proportion of questions correctly, and there was no difference between groups (No Cover Sheet 5.3 ± 1.7 vs. Cover Sheet 5.1 ± 1.8, $p = 0.91$).

Multivariate analysis using linear regression confirmed no effect of the cover sheet when other variables were controlled (Table 3). Being approached for participation in the Hydrocortisone study and higher educational attainment were each independently correlated with higher DICCT scores, with each accounting for about 4 additional points on the DICCT. *Post hoc* evaluation to assess the independence of family members' scores showed an intra-class correlation coefficient of 0.38 for DICCT scores, consistent with moderate within-class correlation. Repeating the multivariate linear regression for DICCT scores adjusting for within-family correlation showed no difference from the unadjusted analysis (data not shown).

Multivariate linear regression incorporating subjective understanding showed no association of any of the variables with subjective understanding (Supplemental Figure 4). Using a similar regression model, only agreeing to have a child participate in the index study was associated with greater satisfaction with the permission process (mean difference 0.83, 95% CI [0.04, 1.63], p = 0.04) (Supplemental Figure 4). Subjective understanding and satisfaction with the consent process were modestly correlated with one another ($\rho = 0.38$, 95% CI [0.03, 0.64], p = 0.03), but neither showed any significant correlation with DICCT score.

Discussion

In this study of parents of premature infants being approached to have their children participate in actual clinical protocols, we found that adding a simplified cover sheet containing crucial information about the trial did not improve their measured comprehension of the research studies. Overall comprehension in both the experimental and control groups was low, when compared to the norms established for the DICCT in the adult population [24]. The cover sheet also did not affect participants' subjective impression of their understanding of the index study or their satisfaction with the study permission process.

As others have reported [26], educational level was positively associated with measured understanding of the study permission documents. However, it is not possible from our data to ascertain whether education might also affect the general test-taking ability of more highly educated participants, leading them to perform better on the DICCT regardless of their actual level of understanding.

Overall, parents in the current study could demonstrate understanding of only 55-60% of the information tested by the DICCT. This is lower than the 60-90% understanding recorded among adult patients being approached for actual studies reported in a recent metaanalysis of randomized controlled trials of consent interventions [11]. The finding is in keeping with the reports of others that recent parents, including NICU parents, may be at particular risk for poor comprehension of research permission [4, 7, 17]. However, the tools for measurement of understanding, including the DICCT, vary widely, are used infrequently, and have not been standardized, making it difficult to compare studies [27]. True cross-population and cross-intervention comparisons await the advent of standardized, validated, widely-accepted measures of understanding.

Our data raise the possibility that more complex study design and/or presentation (both the PROP study and the PROP consent form were more complex than Hydrocortisone) may impede subjects' understanding of information. Although previous studies suggest that less complex permission forms may improve overall understanding [11, 15-17], it is not clear whether our finding is a result of the information itself or of the definitions we used to quantify understanding. For instance, for a participant to achieve a score of 4 on the DICCT components measuring understanding of study procedures, a participant would have been required to identify at least 6 of 12 procedures and the correct length of the study for PROP, but only the presence of randomization and the correct length of the study for Hydrocortisone. Simplified presentation may not overcome the problems of complex information.

Any factor that decreases understanding of the consent process may consequently diminish potential subjects' autonomous decision making capacity. One recent study among adult cancer patients found that consent forms with higher reading levels were associated with higher likelihood of providing consent to enter a clinical trial [28]. Similarly, a study with adult dental patients found that patients with lower educational levels (who would be expected to have lower understanding) were paradoxically less likely to report consent forms to be confusing [29].

This study has unique strengths. Unlike some previous studies among parents of premature infants [16], the study was performed among parents considering actual (rather than hypothetical) index studies. Parents were also masked as to the nature of the consent intervention until after the study was complete. To our knowledge, such a masked design has never been previously used in this population; it may have decreased bias in our outcomes. The study used a previously published, internally-validated measure [24].

The study also has several weaknesses. It was designed as a pilot study, and thus enrolled a small number of participants, increasing the chance of Type 2 error. Low numbers also hampered subgroup and multivariate analyses. The measures also had potential weaknesses, raising the possibility that the findings represent a failure of the measures rather than failure of the intervention. There is no universally-accepted measure of research participant understanding. Although the DICCT has undergone face, internal and preliminary external validation, there are no standard instruments against which to perform full external validation [24]. In our case, unlike the initial report of the DICCT [24], participants' subjective impression of their understanding was not correlated to the objective measure. Qualitative methods such as cognitive interviewing might have yielded further insight into subjects' understanding. The Likert scales used to measure subjective understanding and satisfaction are prone to an “acquiescence bias” that results in a skew toward high values [30]. The population in this study was relatively highly educated. There were chance variations between study groups in baseline characteristics (e.g. education, index study) that we found to be associated with measured understanding, but this did not seem to favor one study group over the other. Only half of the parents who initially agreed to the study completed the study questionnaires. Parents who did not complete the questionnaires were less likely to have agreed to have their children participate in the index study, were more likely to have been approached for PROP, and may have differed in other ways from those who did not complete the questionnaires. The low study completion rate may thus limit the generalizability of the findings. Finally, it was not possible to mask the research staff members to group assignment. However, there was no evidence of a trend toward higher scores in the Cover Sheet group that might have been expected due to unconscious researcher bias.

In summary, the use of an abbreviated synopsis of critical elements of the research permission form, in the form of a cover sheet, did not improve the measured or subjective understanding of the research or the satisfaction with the permission process among parents of premature infants being approached to give permission for one of two clinical studies. Our findings are consistent with those of others who have shown that attempts to modify consent documents (without necessarily simplifying them) by changing reading levels,

format or organization do not consistently promote understanding of the documents [11, 15]. Specifically, others who have used leaflet or booklet formats, perhaps most similar to this intervention, have reported mixed results [31, 32]. Although this study wasn't designed to assess the complexity of the standard consent form, our data suggest that the overall simplicity of information may improve understanding. This is in keeping with the results of others that suggest shorter, simpler consent forms may promote comprehension [11, 15-17]. Simpler presentation, along with a focus on parental input and the use of other sensory inputs shown to affect comprehension, including verbal presentation, infographics and/or interactive apps on a tablet device, may hold promise as methods for improving understanding in future [7, 11, 12, 16, 25, 33-35].

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline characteristics

Characteristic	No cover sheet (N = 17)	Cover sheet (N = 15)
Number of families	14	10
Parent Age (years)	28 ± 6	27 ± 4
Parent female	14 (82%)	10 (67%)
Parent race		
White	12 (71%)	12 (80%)
Black/African-American	4 (23%)	3 (20%)
More than one race	1 (6%)	0
Parent Latino	2 (12%)	0
Parent with greater than high school education[1]	9 (53%)	10 (67%)
Infant gestation <33 weeks	13 (77%)	9 (60%)
Index study =PROP[2]	10 (59%)	11 (73%)
Consented to index study	12 (71%)	7 (47%)

Results presented as mean ± standard deviation or as N (%)

PROP = Prematurity and Respiratory Outcomes Program

[1]Referent group = High school graduate or less.

[2]Remainder of families in each group were approached for Hydrocortisone index study.

Table 2

Primary and Major Secondary Outcomes

Parameter	No cover sheet	Cover sheet	P value
DICCT Score	16.8 ± 5.7	16.3 ± 3.5	0.85
Subjective Understanding (Likert)	6 [4,7]	6.5 [4,7]	0.53
Satisfaction (Likert)	7 [3,7]	6.5 [4,7]	0.95

Results presented as mean ± standard deviation or median [range]

DICCT = Deaconess Informed Consent Comprehension Test

Table 3

Multivariate Analysis of DICCT Score (ANCOVA).

Parameter	Estimate	95% Confidence	Limits	P value
Cover sheet (Yes)	-0.67	-3.80	2.47	0.67
Consent to index study (Yes)	-0.86	-4.22	2.51	0.61
Hydrocortisone study	3.90	0.60	7.19	0.02
Education (> high school graduate)	3.85	0.66	7.05	0.02

DICCT = Deaconess Informed Consent Comprehension Test