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Consulting Communities When Patients Cannot Consent: A Multi-Center Study of Community Consultation for Research in Emergency Settings

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Abstract

*Reprints will not be ordered.

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Objective—To assess the range of responses to community consultation efforts conducted within a large network and the impact of different consultation methods on acceptance of exception from informed consent (EFIC) research and understanding of the proposed study.

Design—A cognitively pre-tested survey instrument was administered to 2,612 community consultation participants at 12 US centers participating in a multi-center trial of treatment for acute traumatic brain injury (TBI).

Setting—Survey nested within community consultation for a Phase III, randomized controlled trial of treatment for acute TBI conducted within a multi-center trial network and using EFIC.

Subjects—Adult participants in community consultation events.

Interventions—Community consultation efforts at participating sites.

Measurements and Main Results—Acceptance of EFIC in general, attitude toward personal EFIC enrollment, and understanding of the study content were assessed. 54% of participants agreed EFIC was acceptable in the proposed study; 71% were accepting of personal EFIC enrollment. Participants in interactive versus non-interactive community consultation events were more accepting of EFIC in general (63% vs. 49%) and personal EFIC inclusion (77% vs. 67%). Interactive community consultation participants had high-level recall of study content significantly more often than non-interactive consultation participants (77% vs. 67%). Participants of interactive consultation were more likely to recall possible study benefits (61% vs. 45%) but less likely to recall potential risks (56% vs. 69%).

Conclusions—Interactive community consultation methods were associated with increased acceptance of EFIC and greater overall recall of study information but lower recall of risks. There was also significant variability in EFIC acceptance among different interactive consultation events. These findings have important implications for IRBs and investigators conducting EFIC research and for community engagement efforts in research more generally.

Keywords

for Indexing: Bioethics; Ethics; Informed Consent; Community Consultation; Research in Emergency Settings

Introduction

Many common acute illnesses lack effective, evidence-based treatment. Unfortunately, the volume of clinical trials directed at improving treatment for many emergent conditions has been inadequate (1), in part due to consent-related challenges. Because informed consent is often impossible in the context of conditions requiring emergent treatment and enrollment, federal regulations were created to allow an exception from informed consent (EFIC) for research in emergency settings (2, 3). Before conducting an EFIC trial, investigators must consult communities where the trial will be conducted. This requirement is consistent with recent emphasis on community engagement in research generally; however, optimal strategies for obtaining and interpreting community views remain poorly defined (4, 5).

Community consultation for research in critical illness may serve multiple goals - from demonstrating respect and fostering trust to providing insight into likely views of enrolled patients and potentially affecting study design - and may involve multiple methods (5-8). Community consultation can be difficult to design, time-consuming, and resource-intensive, and it almost certainly poses a barrier to some studies. Investigators and institutional review boards (IRBs) struggle with defining adequacy, clarifying which communities to consult, and interpreting feedback (3, 9-13). Further, consultation methods range from small focus groups and community panels to population-based surveys (14-16). These methods serve

different goals and require different expertise and investment. Few data exist regarding advantages and disadvantages of different approaches, and no benchmarks or metrics exist for interpreting community consultation results. This is particularly problematic given reported variability in participants' responses to proposed studies using different community consultation methods (17, 18). For one recent EFIC trial, a survey from a large event reported 45% acceptance of personal EFIC enrollment (19). Another study of meeting and focus group-based consultation for the same trial reported 70% acceptance (20). The extent to which this variability is due to population or methodological differences is unclear. Moreover, no consensus exists regarding how to interpret either finding.

Understanding how to conduct and interpret community consultation is integral to successful research on critical illness and to understanding community involvement in research more generally. This project addresses this challenge within a multi-center EFIC trial conducted through the Neurological Emergencies Treatment Trial (NETT) network.

Materials and Methods

Objective and Population

NETT is a multi-center network sponsored by the National Institute of Neurological Disorders and Stroke involving 17 hub sites (referred to as sites), all of which are major academic medical centers and many of which have additional satellite “spokes” (21). This study was nested within the Progesterone for the Treatment of Traumatic Brain Injury III (ProTECT III™) trial, a Phase III, randomized, placebo-controlled trial of progesterone in treatment of moderate and severe TBI. Because study treatment must be started quickly after presentation, most patients are enrolled under EFIC (22). Consent for continued participation is sought when a surrogate is identified.

The nested ProTECT community consultation ancillary study incorporated a standardized survey/assessment tool into community consultation efforts across PROTECT III™ sites. The instrument was developed in consultation with the NETT Human Subjects Protections Working Group. All sites were encouraged to use this instrument as an assessment tool. However, because some sites had independently developed site-specific assessment tools prior to the development of this project, use of this instrument was optional. Importantly, the PROTECT CC study did not affect the type of consultation planned or conducted. Each site developed and executed its own community consultation plans- including choice of methods and target populations- in consultation with NETT staff and local IRBs (23). Additionally, this survey was administered to all consultation participants at participating sites. The study population thus represented the universe of participants at sites using this survey. The 12 participating sites represented all major US geographic regions.

The ProTECT CC study was reviewed and approved by the Emory University School of Medicine IRB. Sites' IRBs reviewed the instrument and local plans for community consultation study participation. Completion of the survey was considered to constitute informed consent, and no identifiable information was collected. At the end of the survey, participants had the option of declining research use of their responses.

Survey instrument

The instrument (supplemental online material, Appendix 1) was designed for descriptive purposes and to test 3 hypotheses:

- More interactive community consultation methods will be associated with greater acceptance of EFIC enrollment in the proposed study both personally and generally.

- More interactive community consultation methods will be associated with greater understanding of study details.
- Greater understanding of relevant study details will be associated with greater acceptance of EFIC and ProTECT III™.

Major survey domains included: prior research experience, personal experience with TBI, knowledge of the study (intervention tested, risks, potential benefits, randomization), views on the ProTECT III™ study, views on personal willingness to be enrolled in ProTECT III™ under EFIC and with family consent, views of the community consultation attended, views of the PROTECT III™ opt-out process, and demographic characteristics.

Five-point Likert scales were used for most response categories regarding attitudes toward EFIC and the PROTECT III study. The instrument was reviewed to ensure face validity by the authors as well as members of the NETT Human Subjects Protections Working Group, a group that contains researchers, ethicists, study coordinators, and other clinical trial staff. Cognitive interviews were then conducted both in-person and by telephone with community members in Atlanta to assure that questions were clear, isolated specific concepts, and could be administered using different consultation methods (24). The instrument was refined as necessary based on these data.

Data Entry and Validation

Sites sent either coded electronic data (n=513) or de-identified hard copy surveys (n=2059) to primary site investigators. 108 (5.3%) of the 2059 hard copy surveys entered at the primary site were double-coded in order to assess accuracy of data entry. The error rate was acceptable (0.57%). Investigators also had access to site-entered aggregated community consultation data from the NETT database.

Statistical Analysis

Analyses were conducted using SAS 9.3 (SAS Institute Inc., Cary, NC, USA). In order to examine effects of community consultation interactivity, methods were dichotomized. Interactive methods were characterized by some form of structured presentation and discussion and included in-person interviews, focus groups, existing group meetings, investigator-initiated meetings, and town halls/open forums. Non-interactive methods included surveys distributed at community events or via web/email and did not entail a structured presentation and discussion, though on many occasions a representative of the study may have been present to answer questions and discuss the proposed trial.

Response categories were collapsed into agree (answers “1” or “2”) and not agree (answers “3,” “4,” or “5”) for multivariable analyses. In order to provide a global assessment of recall of study details, a composite knowledge score was calculated for each participant by summing scored responses to 5 knowledge-based questions. The maximum score for each question was 2 points. For questions with 2 correct answers, 1 point was assigned, for example, if a respondent identified only one of the 2 correct answers. Across the 5 questions, the maximum total score was 10 points.

Simple descriptive statistics were calculated. Chi-square analyses were conducted to examine associations between dichotomous variables. Multivariable logistic regression models were used to assess domains of acceptance and understanding, adjusting for demographic characteristics, TBI experience, method interactivity, and composite knowledge. Due to non-linear distribution of composite knowledge scores, this variable was dichotomized into high (≥ 8) and non-high (<8) for inclusion in these models. In order to examine the impact of multiple covariates (demographic characteristics, TBI experience,

and method interactivity) on the composite knowledge score as a continuous variable, a general linear model for quadratic least squares regression was used. All necessary assumptions for this model were met.

Data from the NETT database were used to assess whether our sample reflected the community consultation population for ProTECT III™ across all sites.

Results

Population

This study included 2,612 community consultation participants from 12 sites. The mean age was 40.2 years, there was a slight female predominance, and 76% were white (Table 1). Additionally, the population was relatively highly educated; 86% completed at least some college. 2991 participants were recorded by participating sites to have attended the 82 events from which we obtained data. The estimated response rate was thus 87.3% (2612/2991).

Community consultation activities across the entire network for the PROTECT III trial (including sites not using the survey for this community consultation sub-study) involved 8835 participants. There were no meaningful differences detected between the demographic characteristics of the study sample and the network-wide community consultation population.

Community Consultation Methods Used

The most prevalent consultation method (by number of events) was attendance at meetings of existing community groups (n= 43 events). This method accounted for the majority of interactive events (see Table 2). Survey administration at community events (typically a booth or table) accounted for the largest number of participants (42.5% of sample). Overall, 39.8% (n= 1039) of participants came from interactive consultation events, and 60.2% (n=1573) of participants came from non-interactive consultation events.

Acceptance of ProTECT III™ and EFIC enrollment

The large majority (92.6%) of respondents agreed ProTECT III™ is “an important study to do,” and 88% agreed it is “acceptable to test this medication in traumatic brain injury patients.” The latter question did not mention EFIC. Acceptance of EFIC enrollment was lower. 54% overall agreed with the statement, “Sometimes no family member can be found to make medical decisions for patients with TBI. It is okay to include those patients in the ProTECT study without consent” (general enrollment). Consistent with other reports, more participants (70.8%) indicated acceptance of personal hypothetical EFIC enrollment in ProTECT, and still more (86.4%) were accepting of enrollment with consent by a family member (19, 25, 26).

While there was some degree of inter-site variability among acceptance (Figure 1), differences between levels of acceptance of personal enrollment versus general enrollment appear relatively consistent across sites.

Relationships between Acceptance and Method

Acceptance of EFIC enrollment in ProTECT III™ was significantly higher among participants in interactive (n=1039) versus non-interactive (n=1573) events (Table 3), both in general (63% vs. 49%, unadjusted OR 1.76 [1.50-2.08]) and for personal inclusion (77% vs. 67%, unadjusted OR 1.60 [1.34-1.92]). Acceptance of enrollment by a family member was also higher in interactive events (89% vs. 85%, unadjusted OR 1.41 [1.11-1.80]), but the difference was less pronounced, suggesting interactivity plays a specific role in EFIC

acceptance. Participants in interactive community consultation events were less often white (68.0% vs 81.7%), were slightly younger (mean age 38.2 years vs. 41.5 years), and more frequently had at least some college education (89.5% vs. 84.3%). However, interactivity remained an independent predictor of acceptance in multivariable models (Table 4) accounting for demographic characteristics (age, gender, race, education, knowing someone with prior TBI, and community type) and recall of study details (by composite knowledge score ≤ 6), with adjusted odds ratios of 2.02 [1.65-2.47] and 1.82 [1.46-2.28] for general and personal EFIC enrollment, respectively. As described below, removing knowledge scores only minimally strengthened the association between interactivity and acceptance. Additionally, in order to assess whether the relationship between method interactivity and EFIC acceptance was driven principally by geographic site, we included both geographic site and an interaction term for site and method interactivity in both models for EFIC acceptance. Neither was significant in the models, while method interactivity remained significant.

We did observe appreciable event-level variability in EFIC acceptance, particularly among the most common interactive method (attendance at existing meetings). Acceptance of general enrollment ranged from 33% to 100% and was reasonably evenly distributed as demonstrated in Figure 2. There was less pronounced variability in acceptance among community consultation survey events, but there were fewer discrete events.

Knowledge and Interactivity of Method

Participants in interactive events were more likely to recall the study medication, to correctly recall study design elements, and to correctly identify potential benefits. However, they were less likely to recall risks (Table 3). This inverse relationship between recall of risks and interactivity persisted in a multivariable model with an adjusted odds ratio of 0.26 [0.20-0.33] for recognition of risks among those in interactive versus non-interactive methods. In contrast, the adjusted odds ratio of correct recall of potential benefits was 2.39 [1.92-2.99].

Interactivity remained a significant predictor of overall study knowledge (by composite score) in multivariable analyses, with an adjusted odds ratio for high-level knowledge (scores 8-10) among participants in interactive versus non-interactive methods of 2.49 [1.97-3.16]. Using a general linear model, interactive methods were associated with a significant increase in the absolute composite knowledge score of 1.03 ($p < .0001$), keeping other variables constant. College education was also significantly associated with an increase of 1.49 ($p < .0001$). Black race was associated with a significant decrease of 0.88 ($p < .0001$). There were no significant relationships between other racial categories, Hispanic ethnicity, or knowing TBI victims personally. Being part of a group consulted because of connection to TBI was associated with lower composite scores (decrease of 0.60, $p = 0.0036$) compared to being part of a group targeted for geographic reasons.

In order to examine whether community consultation interactivity affects acceptance through improving knowledge, regression analyses were performed with and without the composite knowledge score. The addition of the composite score minimally decreased the association between interactivity and acceptance (adjusted OR 2.11 [1.73-2.57] to 2.02 [1.66-2.47] for general acceptance and 1.95 [1.56-2.43] to 1.82 [1.46-2.28] for personal acceptance), suggesting that greater recall of study details minimally contributes to the effect of interactivity on acceptance.

Discussion

The community consultation requirement for EFIC research has been persistently controversial. Investigators and IRBs struggle to conduct and interpret community consultation, and these activities consume significant resources. This study is the first to examine the effect of multiple consultation methods on community responses, study acceptance, and study understanding across a large network.

Our findings support the hypothesis that consultation methods play an important role in shaping responses. In particular, more interactive methods appear to be associated with greater acceptance of EFIC, a difference observed before but not studied across sites (17-20). This difference may be due to the fact that interactive community consultation allows time for participants to learn about a study and develop views on an unfamiliar topic, engage with other participants and presenters, and potentially develop trust. Interactive methods thus may solicit more considered views (27). Survey methodology, on the other hand, likely provides insight into more “surface-level” public reactions. It is also possible that different methods draw people with different levels of community engagement, for example. Though we did not appreciate substantial demographic differences by method, and differences in acceptance by method persisted after adjustment for measured characteristics, there may be unmeasured differences in these populations that play a role in acceptance levels.

The level of variability observed in EFIC acceptance across meeting-based efforts is also remarkable and was not explained by demographic composition of meetings or type of community. Inter-site variability was present but less pronounced. There may be multiple sources of variation in response to interactive community consultation, some unavoidable and even desirable. Different groups, for example, have different values, and capturing those differences is important. On the other hand, presenters likely had varying amounts of time to describe the research, meetings have different formats, and presenters differ in style, persuasiveness, and ability to relate to audiences. Some presenters may be frankly biased. These are more problematic sources of variation and suggest that investigators and IRBs should interpret findings from interactive sessions cautiously and focus more on the substance of feedback than acceptance rates alone.

For the reasons cited above, it was expected that participants in interactive sessions would more accurately recall study information, but it was not expected that they would less accurately recall study risks. It is unlikely to be the case that risks were simply not disclosed in some interactive sessions given general agreement about the importance of risk disclosure, regulatory requirements for such disclosure, and the use of standardized presentation materials. However, it is possible that presenters were biased or overly positive toward the study. If so, this is concerning, but there are other plausible causes of this association that may be less obviously problematic. For example, if risk information was presented at the beginning of a lengthy meeting and other study elements were the focus of subsequent discussion, recall may be predictably lower. This is not unlikely given that the drug under study is believed to be relatively safe, particularly in light of potential benefits and TBI-associated morbidity. Alternatively, non-interactive survey respondents may have looked back at disclosure materials included in self-administered forms to find “the answer” regarding risks. However, it is unclear why they would have looked up risk information alone.

Further research is necessary to ascertain whether these method-related differences in recall of risk and other information persist in other studies as well as to clarify the source and implications of this discrepancy. Some may argue that this finding indicates that non-

interactive methods are superior because they may be less biased and more likely to produce conservative estimates of community acceptance. But if opinions solicited in non-interactive community consultation methods are less informed regarding other important elements of the study, it is not clear how meaningful they are. Moreover, non-interactive methods clearly provide less opportunity for exploring the nature of participants' views and concerns in ways that advance goals of community consultation other than estimating acceptance.

Findings regarding racial distinctions in attitude toward EFIC enrollment are relevant given concerns about differential attitudes among minorities and potential targeting or over-representation of minorities in EFIC research (28-31). We did not find a statistically significant difference in acceptance between black and white respondents in regression analysis, but there was significantly lower acceptance among respondents of other races, particularly Asians. Whether these participants accurately reflect the views of actual enrollees is unclear, but it is encouraging that there were not significant differences in acceptance of trial enrollment among the largest racial groups interviewed.

Recently, two reports have been published of studies assessing the responses of individuals actually enrolled in trials of emergent treatment for critical illness without initial consent. Members of our group found that 73% of individuals and surrogates of individuals enrolled under EFIC in the Rapid Anticonvulsant Medication Prior to Arrival Trial (RAMPART) in status epilepticus were accepting of EFIC enrollment, though many patients had limited understanding of the trial and EFIC (26, 32). A survey of Australian patients and surrogates enrolled using “delayed consent” in the Normoglycemia in Intensive Care Evaluation–Survival Using Glucose Algorithm Regulation (NICE-SUGAR) trial reported that 96% “would have consented” to enrollment if they could have been asked initially (33, 34). While these studies' findings and methods differ from each other, both indicate that the community consultation data in this study do not appear to overestimate acceptance of enrollment. A dedicated study of PROTECT III enrollees' and surrogates' views of EFIC enrollment is ongoing and will be helpful in further contextualizing these findings.

Several very practical implications emerge. Perhaps most clearly, investigators and IRBs should recognize that interactive and non-interactive methods serve different goals and produce different results. While interactive methods offer potential for more considered opinions, they are likely to be context-specific. IRBs should avoid focusing solely on overall acceptance rates, and it may be instructive for IRB members to observe interactive consultation sessions to appreciate the nature of presentations, discussion, and feedback. Acceptance rates of less interactive community consultation may be more consistent, but they also may be lower, lack detail, be more focused on risk, and represent less substantive reactions. The absence of consensus or guidance regarding which purposes of community consultation are most important and which methods are most appropriate continues to challenge researchers and IRBs. Given the variability demonstrated in this and other studies, mixed-method approaches may be most informative but are resource intensive.

A second implication is the need for further research on community consultation. This project contributes importantly to our understanding of the strengths and limitations of different consultation methods. However, in order to develop proper benchmarks and standards, it is vital that similar efforts be embedded within future trials, especially those involving large, diverse networks. It will be helpful, for example, to assess whether attitudes vary appreciably from project to project using similar consultation methods. If not, there may be little use in repeating large-scale efforts in subsequent studies. Similarly, IRBs and investigators can develop shared expectations regarding local feedback. If significant variation exists across studies, it will be important to ascertain what study features prompt concerns and design methods focusing on these elements. With regard to interactive

methods, research incorporating direct observation and experimental manipulation could be particularly informative, and further work on phrasing and structure in non-interactive methods is needed (17, 19). Additional research may also elucidate the impact of community consultation data on study design and IRB deliberations. All participating sites' IRBs approved the PROTECT III study, but the role of community consultation data in shaping those decisions is unclear. Questions regarding the meaning of community feedback are inevitable, but continued research in these areas may allow community consultation to be more efficient, more targeted, and less burdensome.

Finally, this study adds to a growing understanding of the general role of community consultation within research. Community engagement has been a focus of the Clinical and Translational Science Awards program and an important component of research in international settings for some time (4, 5). While community consultation serves a unique role in EFIC research given the inability of subjects to speak for themselves, many functions of community consultation, such as building trust, demonstrating respect, optimizing risks and benefits, and promoting shared responsibility for research, are relevant and worthy of further study across multiple contexts.

There are several relevant limitations to this study. First, it did not include all NETT sites, principally because some sites had previously developed their own assessment tools. The population does appear to be representative of the overall ProTECT III™ community consultation population, but random-digit-dialing (RDD), a method used by some ProTECT III™ sites, was not represented. Comparing RDD to other methods is an important future task (16). Also, because sites chose their own consultation methods, some sites only reported using one method (or the large majority of participants from particular sites came from sessions using a single method), and actual conduct of community consultation using a particular method likely varied across sites, our ability to control for site effects is limited.

Additionally, this study only examined responses to one placebo-controlled trial of a new intervention for a condition with poor standard treatment. Moreover, the intervention appears to be relatively safe. Views may differ toward active comparison trials, trials in which standard care is more effective, or trials in which one or more arms carry greater risk. Our instrument also did not assess views of EFIC in the abstract. Other studies have demonstrated lower acceptance when asking respondents about EFIC outside of the context of a particular study (19, 25).

Conclusions

Overall acceptance of personal EFIC enrollment was 70.8% among community consultation participants, consistent with some other published reports. Interactive methods were associated with increased acceptance of EFIC and recall of relevant study details; however, acceptance within interactive methods was highly variable, and participants had lower recall of study risks. Choice of consultation method appears to impact both the nature of feedback and the extent to which participants understand study content. Our findings highlight the need for further research to refine and improve understanding of community consultation methods and facilitate advancement of care for critical illness.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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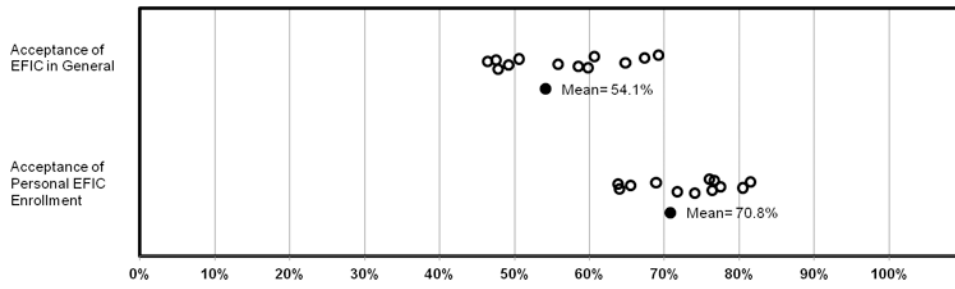


Figure 1. Inter-Site Variability of EFIC Acceptance

○= Mean acceptance by site

●= Mean acceptance of total study population

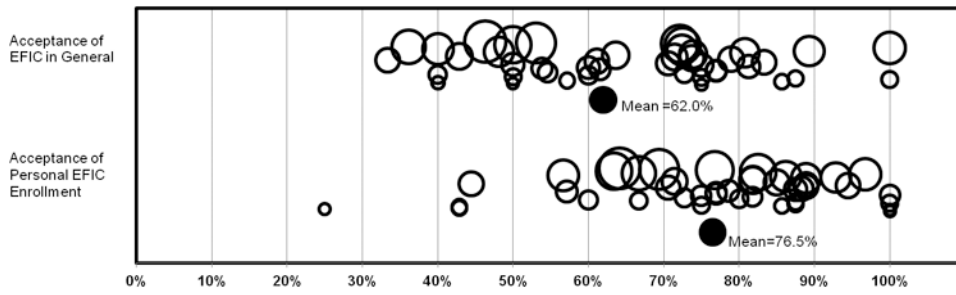


Figure 2. Event-Level Variability of EFIC Acceptance Among Existing Group Meeting Events

○= Mean acceptance by existing meeting group event (circle size reflects number of participants)

●= Mean acceptance of total study population (circle size reflects mean number of participants per event)

Table 1
Population

Demographic Variables	Study Population (n=2612)	Entire ProTECT CC Population (n=8835)
Age, mean (SD)	40.2 (16.6)	40.8 (16.3)
<i>Sex</i>		
Male, No. (%)	1131 (44.0)	3280 (42.3)
Female, No. (%)	1439 (56.0)	4470 (57.7)
<i>Ethnicity^a</i>		
Hispanic, No. (%)	135 (5.4)	395 (7.3)
Not Hispanic, No. (%)	2363 (94.6)	5034 (92.7)
<i>Race</i>		
White, No. (%)	1931 (76.4)	5799 (78.5)
Black, No. (%)	318 (12.6)	1007 (13.6)
Asian, No. (%)	131 (5.2)	227 (3.1)
Other ^b , No. (%)	148 (5.9)	354 (4.8)
<i>Education</i>		
High School Graduate or Less, No. (%)	349 (13.6)	1289 (18.1)
Some College or More, No. (%)	2209 (86.4)	5837 (81.9)
<i>Know Someone With TBI</i>		
Yes (self, family and/or loved one), No. (%)	631 (24.6)	1670 (24.8)
No (other or none), No. (%)	1935 (75.4)	5058 (75.2)

^aHispanic ethnicity separated from race, consistent with U.S. Census Bureau practice

^bIncludes those identifying with more than one race, Native Hawaiian/Pacific Islander, American Indian/Alaskan Native, and those self-identified as race other than those provided

Table 2

Range of Methods

CC Method	Interactive						Non-Interactive		Total
	In-person interview	Focus group	Existing group meeting	Investigator-initiated meeting	Town hall or open forum	Survey at community event	Survey via web or email		
Events, No. (%)	4 (4.9)	5 (6.1)	43 (52.4)	3 (3.7)	4 (4.9)	21 (25.6)	2 (2.4)	82	
Participants, No. (%)	51 (2.0)	43 (1.7)	847 (32.4)	44 (1.7)	54 (2.1)	1111 (42.5) ^a	462 (17.7)	2612	
Sites utilizing	2	2	8	2	2	6	2	12	

^a Responses from participants in existing group meetings at one site could not be distinguished from surveys at community events. Because meeting-based CC participants represented less than 5% of participants from that site, all responses from that site were considered to be from surveys at community events.

Table 3

Bivariate Analyses

Question	Total (n=2612)	Interactive (n=1039)	Non-Interactive (n=1573)	Unadjusted OR [95% CI]
Knowledge of Study Content				
Medication studied correct, No. (%)	2291 (87.7)	978 (94.1)	1313 (83.5)	3.17 [2.37-4.25]
Study design correct, No. (%)	2189 (83.8)	917 (88.3)	1272 (80.9)	1.78 [1.42-2.23]
Randomization correct, No. (%)	2006 (76.8)	848 (81.6)	1158 (73.6)	1.59 [1.31-1.93]
Risks correct, No. (%)	1671 (64.0)	578 (55.6)	1093 (69.5)	0.55 [0.47-0.65]
Benefits correct, No. (%)	1336 (51.2)	634 (61.0)	702 (44.6)	1.94 [1.66-2.28]
Composite knowledge score-high (8-10), No. (%)	1856 (71.1)	801 (77.1)	1055 (67.1)	1.65 [1.38-1.98]
Study Acceptance				
Agree with EFIC in general for ProTECT, No. (%)	1370 (54.1)	622 (62.6)	748 (48.7)	1.76 [1.50-2.08]
Agree with personal EFIC enrollment in ProTECT, No. (%)	1801 (70.8)	762 (76.6)	1039 (67.1)	1.60 [1.34-1.92]
Agree with personal enrollment by a surrogate in ProTECT, No. (%)	2192 (86.4)	881 (88.8)	1311 (84.9)	1.41 [1.11-1.80]
Agree that "received enough information to give an informed opinion" about whether it is OK to do the ProTECT study, No. (%)	2088 (82.5)	871 (87.8)	1217 (79.1)	1.90 [1.52-2.39]

Table 4

Multivariable Logistic Regression Models of Acceptance

Independent Variables	Acceptance of EFIC in General Adjusted OR [95% CI]	Acceptance of Personal EFIC Enrollment Adjusted OR [95% CI]
Interactive vs. Non-interactive	2.02[1.65-2.47]	1.82[1.46-2.28]
Age: Per 5 Year Increase	1.01[1.01-1.02]	1.02[1.02-1.03]
Gender: Female vs. Male	0.95[0.81-1.12]	0.86[0.72-1.04]
Race: Black vs. White	0.86[0.67-1.11]	0.78[0.60-1.03]
Race: Asian vs. White	0.46[0.31-0.68]	0.51[0.34-0.75]
Race: Other vs. White	0.48[0.33-0.70]	0.66[0.45-0.96]
Education: College vs. HS	0.99[0.77-1.27]	1.27[0.98-1.65]
Know TBI Victim(s): Yes vs. No	1.27[1.04-1.55]	1.23[0.98-1.54]
Composite Knowledge: High vs. Low	1.32[1.09-1.60]	1.51[1.23-1.84]
Condition vs. Geographic Community ^a	1.04[0.74-1.47]	0.86[0.58-1.27]
Both vs. Geographic Community ^a	0.47[0.21-1.07]	0.46[0.18-1.14]

^a“Condition” and “geographic” communities refer respectively to whether the CC population was intended to represent the condition under study (by including people with the condition under study or at risk for developing it) or the population in the geographic area where the study was to be conducted. CC sessions categorized as “both” intended to represent both populations.