Approaches to Community Consultation in Exception from Informed Consent: 
Analysis of Scope, Efficiency, and Cost at Two Centers

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Abstract

Objectives: Community consultation (CC) is fundamental to the Exception from Informed Consent (EFIC) process for emergency research, designed to inform and receive feedback from the target study population about potential risks and benefits. To better understand the effectiveness of different techniques for CC, we evaluated EFIC processes at two centers participating in a trial of early cardiac catheterization following out-of-hospital cardiac arrest.

Methods: We studied the Institutional Review Board-approved CC activities at Maine Medical Center (MMC) and University of Arizona (AZ) in support of NCT02387398. In Maine, the public was consulted by survey at a professional basketball game and in the emergency department waiting room (in-person group), by multimedia direction to an online website (online group), and by mail (mailing group). Arizona respondents were either approached at a county fair (in-person group) or were directed to an online survey (online group) via social media advertising.

Results: Among 2185 survey respondents, approval rates were high for community involvement and personal participation without individual consent. Community consultation using in-person, online, and mailed surveys offered slightly different approval rates, and the rate of responses by modality differed by age and education level but not ethnicity. Print advertising was the least cost effective at $442 per completed survey.

Conclusions: Canvassing at public events was the most efficient mode of performing CC, with approval rates similar to mailings, online surveys, and canvassing in other locations. Print advertisements in local papers had a low yield and cost more than other approaches.
Introduction

Informed consent is considered the bedrock of medical research\(^1\), yet emergency research is challenging to conduct under traditional informed consent due to a patient’s decreased level of consciousness and the absence of an appropriate surrogate decision maker. This is particularly true in cardiac arrest, stroke, and trauma – each of which has often been described as a public health crisis in need of ongoing research into new treatments and therapeutic approaches\(^2-^4\). This conundrum led the Food and Drug Administration to develop and in 1996 enact Regulation 21 CFR 50.24: Exception from Informed Consent (EFIC) Requirements for Emergency Research. EFIC is intended to allow for medical research in circumstances of grave need when true informed consent cannot be obtained. It functions by allowing such research after community dialogue, IRB approval to proceed, with attempted individual consent post enrollment. Specifics as to how community consultation should be performed have been left vague to allow for interpretation by local Institutional Review Boards (IRBs), the evolution of standard practices, and development of precedent.

There are no guidelines regarding the modalities employed and extent of the community consultation that must be performed in EFIC, including the number of surveys performed, need for focus groups and interviews, or required percentages of community members who must agree with and accept the research in a general sense or in terms of their own participation. The FDA addressed this in the addendum guidelines to 21 CFR 50:24: “How much community consultation activity is necessary? There is no single acceptable way to accomplish or fulfill the community consultation requirements, nor will all studies require the same amount, type, or extent of community consultation activities.”\(^5\) This puts investigators and IRBs in the position of developing their own process for each trial, and continuously defining standards of acceptance, which can be quite variable from community to community. For example, one review of nine IRB-approved EFIC trials\(^6\) found that surveyed community members’ personal acceptance rates (the respondent theoretically accepts the possibility of
being enrolled in the trial without consent if they fall ill) varied from 45% of the survey population to 93%, with a mean of 68% (±12.9%, n = 9,036). Community acceptances (the respondent theoretically accepts that the research trial be conducted in their community) ranged from 74% to 100% with a mean of 78% (SD 10.3%, n = 3,797). Within these studies, community consultation involved such methods as administering surveys at a state fair, community meetings or other local events, online surveys, telephone surveys via random digit dialing, in-person interviews, and focus groups. Whether these methods yield similar or adequate results is largely unknown, and the labor and expense involved varies greatly, making budgetary planning for EFIC trials difficult.

This project is an analysis of the effectiveness and cost of two EFIC community consent processes related to the randomized Pilot Clinical Trial for Early Coronary Angiography Versus No Early Coronary Angiography for Post-Cardiac ARrest Patient with No ST Segment ELevation on their ECG (PEARL) trial (NCT02387398) at University of Arizona, Tucson, Arizona (Arizona) and Maine Medical Center, Portland, Maine (Maine).
Methods

Study Design

Both UAZ and MMC received IRB approval - first to conduct their proposed community consultation, the results of which were later considered in the final IRB approval to conduct the trial under EFIC regulations. There were differences in what each IRB required for community consultation – the University of Arizona, approved a plan of in-person canvassing at a County Fair, supplemented by online surveys and print newspaper advertisements. At Maine Medical Center, the IRB requested diverse community consultation in the form of presentation at community meetings, online surveys, mailed surveys, and canvassing in multiple locations.

Both medical centers informed and surveyed adult community members about the proposed clinical trial, assessing whether respondents thought such a trial was warranted, and the consent mechanism adequate (see Appendix 1 for the survey). Including respondent’s zip codes in the survey helped to confirm that many of them lived in the geographic catchment areas of the participating medical centers. The survey also provided respondents the opportunity to put their names on an “opt out” list. Aside from an oral presentation to the Portland City Council, the administration of these surveys was the primary means of eliciting feedback and quantitating approval from the communities. Random number dialing was not part of either EFIC plan due to its expense.12,13

University of Arizona

Online process

Facebook was the main online tool for alerting the public of this potential study in their community and eliciting survey responses. Twitter was also utilized in this effort.

Print Media Advertisements
Regional and local newspapers, including two Spanish language papers, were paid to run advertisements. They described the PEARL study and directed potential respondents to the Facebook survey site.

Direct administration of surveys

A booth was obtained at the Pima County Fair where compression-only cardiopulmonary resuscitation was being taught to interested fair-goers. Participants and spectators were then asked if they would be willing to participate in a survey about an upcoming trial at the Arizona Heart Center. Surveys were administered in-person by research staff and investigators (Spanish interpreters were available).

Maine Medical Center

Online process

Public disclosures and advertisements directed community members to an online web page and survey site. Flyers were posted at the town halls & libraries in twenty towns and cities within the MMC patient catchment area. Advertisements directing the public to the survey web page were posted on the hospital’s Facebook page. Public Service Announcements were made on local radio stations, and print advertisements were placed in local area newspapers directing interested individuals to go to the survey website, or to call and speak to research staff.

Direct administration of surveys

Surveys were administered in-person by research staff and investigators at a local professional basketball game and in Maine Medical Center’s Emergency Department waiting room.

Targeted mailing of surveys
Six thousand, eight hundred letters were mailed to active patients of the primary local Cardiology practice. The mailing included a survey, a self-addressed stamped envelope, and the research office telephone number for direct assistance in interpreting and completing the survey. Completed surveys were returned by mail.

**Human Subjects**

Institutional Review Boards (IRBs) at UAZ and MMC approved the local PEARL community consultation plans. The protocol at both institutions (and general protocol for conducting EFIC research across most IRBs in the United States) includes an initial presentation wherein the IRB is informed of the research, especially the justification for performing such research under “Exception From Informed Consent” regulations, and the planned community consultation process. The researchers then conducted community consultation and reported their findings to the IRB prior to final approval of the trial.

**Statistical Methods**

Survey and cost data were entered into a Microsoft Excel (Microsoft Corp., Redmond, WA) spreadsheet program for cleaning and were analyzed using SPSS v. 24.0 for Windows statistical software (SPSS, Inc., Chicago, IL). No formal strategy was used to the sample size for the survey. We used a convenience sample of individuals willing to participate. We note that previously acceptable community surveys averaged 500 individuals (NIH ROC EFIC studies). To maximize sample size, missing data were excluded on a case-by-case basis. Descriptive statistics were employed to evaluate the characteristics of the study participants and are reported as numbers and percentages. Categorical comparisons were made using Pearson’s chi-square or Fisher’s exact test, as appropriate. Racial and
ethnic minorities were collapsed into dichotomous categories (White, non-White; Hispanic/Latino, non-Hispanic/Latino) due to small numbers. Education level was similarly collapsed (less than high school, high school/equivalency degree or higher). For continuous data, comparisons were made using the independent samples $t$-test or analysis of variance, as appropriate for the number of groups being evaluated. Spearman’s rho was employed to examine the relationships between categorical variables. For the binary outcome variables representing personal and community acceptance of the EFIC trial, logistic regression analyses were conducted to identify participant characteristics associated with EFIC acceptance. We accepted a 2-tailed alpha of $\leq 0.05$ as significant and computed 95% confidence intervals using the exact method. To adjust for multiple comparisons, Bonferroni’s correction was applied.
Results

Demographic characteristics of survey participants are provided in Table 1.

Demographic Differences amongst Survey Modalities and Comparisons to County Demographics

There were differences between the age of the study participants, the racial composition of the sample, reported ethnic identity, and education level when compared to available local demographic characteristics for the relevant counties ($p$-value range: 0.0404 -<0.0001) (see Table 2). Maine respondents were older, less racially and ethnically diverse, and more educated than the county-at-large. Arizona participants were significantly younger and also better educated than their respective county demographics. Within the site-specific modalities, in-person survey response groups most closely approximated county demographics.

In the Maine cohort, the 60+ age group (vs. the 18-59 year age group) was better represented by mail participants (established patients of the local cardiology groups) than in-person and online modalities (85% mail, 27% in person, 27% online; $\chi^2 = 470.358$, $df = 2$, $p < 0.001$). In addition, the proportion of participants with at least a high school diploma was greater with the online modality (100%) compared to the in-person (96%) and mailing (95%) methodologies ($\chi^2 = 12.9$, $df = 2$, $p = 0.0016$).

EFIC Acceptance and Differences by Survey Modality

Across participants, the majority favored the conduct of EFIC research in their communities (2017/2185, 92%) These data are shown in Figure 1). Younger age correlated with personal acceptance for the trial ($\rho = 0.131$, $p < 0.001$). In addition, higher educational level was associated with EFIC participation ($\rho = -0.109$, $p < 0.001$). Race and ethnicity were not independently associated with support for EFIC in the community.
Cost-benefit analysis of various modalities

Estimated costs of soliciting and receiving EFIC feedback through different modalities are shown in Table 3 and Figure 2. Financial costs refer to direct expenditures only. Estimates of hours spent vary by modality - online and mailing groups are an aggregate of time over multiple weeks while the in-person group is time actively spent administering surveys.
Discussion:

The IRB-approved methodologies differed significantly at two large, regional referral centers conducting emergency research under the Exception from Informed Consent (EFIC) rubric. Community consultation was performed largely by surveys, and respondents to surveys differed demographically from the local population in age, race, ethnicity, and educational level. In-person surveys produced the closest matches to the demographics of their county and were the least expensive and most time-efficient way to perform EFIC consultation. Younger respondents were more likely to respond to online surveys and to approve of EFIC research than older ones, who responded more often by mail than online. Study approval did not vary by race or ethnicity. Online and in-person surveys performed in hospital waiting rooms were the most time-consuming way to obtain community feedback per response obtained. In terms of “hard costs” for advertising and mailings, directing respondents to online surveys by print, radio, and online advertisements cost twice as much per response as the mailings, while in-person surveying at large events carried minimal direct expenses. These data may be helpful for clinical researchers and Institutional Review Boards planning clinical trials that will employ the EFIC process.

Most published EFIC studies have utilized community meetings, random-digit-dialing, and/or surveys for community consent. Community meetings about the specific trial facilitate longer and more involved discussions with community members, and dissemination of complicated information to a number of people at one time. Unfortunately, the reported experience with this approach is uniformly poor. Attendance is typically low (often less than 25 individuals), and the feedback and support obtained may not be representative of the study population. These biases were supported anectdally by our experiences.
In contrast, presenting the proposed trial at existing community events outside the hospital offers researchers a unique opportunity to engage the community. Though attendance was small when our investigators presented to the Portland, Maine city council, they were able to speak to critical constituent stakeholders including city counselors, media, and the Fire and Police Chiefs, all of whom strongly supported the trial. This approval is especially important when one considers the likelihood of media coverage when EFIC trials are reported, and the importance of logistical support from civic leaders.

Prior studies have found random-digit-dialing is more successful than community meetings – response rates of almost 50% have occasionally been reported. However, there are a concerns about sampling error given increasing variability in landlines in peoples’ homes, and the increasing adoption of “no call” lists. In addition, there may not be a professional surveying company available, capable, or willing, as was the case with Maine, and may often be the case when a research question is complex. Even if said company is available, the cost may be prohibitive: in Arizona a company estimated $30,000 for 500 completed PEARL surveys. This would have made random-digit-dialing four times as expensive per survey as any other approach.

Surveys, both online and in person, have been included in many EFIC trials, and compare favorably to community meetings and random-digit-dialing. Survey data exist in the literature for comparison, its costs are substantially lower, and the public is more likely to participate since it takes less time than a community meeting and is less personally disruptive than random digit dialing.

Our community approval data echo the heterogeneity of other published studies of community consent. In fourteen prior studies, eight showed no relationship of age or educational level to study approval, however three did note racial differences in EFIC approval. Two trials showed greater EFIC acceptance among younger and more educated patients while two other trials
showed increased acceptance with increasing age, one\textsuperscript{25} showed increased acceptance with less education, and one\textsuperscript{26} showed increased acceptance with middle age, and less acceptance in the young and elderly groups as well as a racial difference in acceptance.

\textit{Online surveys}

Soliciting and obtaining an online group of respondents was the most expensive method of community consent at $15.63 per completed survey and was not time-efficient. However, directing respondents to online surveys offers the advantages of being able to post a considerable amount of information about the specific trial and EFIC in general in the website, which could be further stratified by reading level or interest. On-line surveys can continue during the trial and provide on-going feedback from the community and patient base. An additional benefit of the information is that both the IRB and researchers can be assured that there is at least one public location where factual data are available – especially important if local media depict EFIC trials in a negative light or report inaccurately.\textsuperscript{10} Finally, online surveys offer access to individuals who are homebound for medical or social reasons, increasing the diversity of respondents to the community consultation process. Given these benefits we believe online consultation to be useful, and a better-calibrated use of advertising on social media might significantly reduce the cost per survey\textsuperscript{8,28}.

\textit{Survey Mailing}

The directed survey mailing brought in the greatest overall number of respondents, many of whom were potential study participants, but also generated many telephone calls from confused patients who could not understand the survey materials without coaching from the research staff. This highlighted how face-to-face surveying allowed respondents to get answers to their questions immediately. In the mailed surveys, respondents sometimes wrote in questions, provided comments that were difficult to interpret, or did not fill in all areas of the survey correctly, necessitating still more
phone calls from the research staff. These issues made the mailing of surveys useful, but time-
consuming and expensive. Nonetheless, such responses by study staff provide an important avenue of
continued dialogue and effort to reach out to the community where such EFIC trials are being
conducted.

Limitations

There are limitations to our study. Although the number of community members consulted was
high and approval levels in our samples were significantly higher than many prior EFIC trials, in each
case the number was still less than 1% of the county population, raising the question of whether the
sample size was adequate. Community consultation, however, was never intended achieve perfect
acceptance\textsuperscript{29} nor to be an exhaustive survey of a community’s population\textsuperscript{30}. We believe, and our IRBs
concurred, that this sampling reflected an adequate community consultation, and showed an
appropriate level of acceptance of the trial.

Although the Maine and Arizona survey populations are consistent with their respective county
demographics, our findings may not be generalizable to other racial and ethnic communities, including
Native Americans in Arizona and African refugees in Maine. Additionally, as an editorial to a
previous trial mentioned,\textsuperscript{31} there is a concern that the survey text is poorly understood by respondents,
some of whom wrote comments such as “…definitely enroll me, I want the best chance to survive!”.
However, we feel that these comments could be construed as less about therapeutic misconception
than difficulty comprehending equipoise and randomization\textsuperscript{32}. This is borne out by a number of people
writing comments such as “I don’t care which group I’m in, I want to be in the one that has the best
survival” and “Why randomize me? Just put me in the one that will give me the best chance of
success!”
The PEARL trial is a comparatively small extension of current best practice (catheterization of those patients with STEMI post-ROSC). Therefore, our data may not be applicable to EFIC trials that have a relatively larger deviation from best practice, employ more invasive or experimental therapies, or are targeted at vulnerable populations. Finally, this study may have little to no generalizability for neurologic or trauma studies, as there have been no studies to date looking at EFIC acceptance stratified by etiology of injury.

Conclusions

Community consultations were performed using in-person, print media, online, and mailed surveys supported by clinical researchers. Survey respondents differed in some demographics from the general public and did not perfectly reflect the target study population. In-person consultations at large public events offered advantages in terms of cost and time commitment of researchers, while providing respondent demographics closest to potential study community demographics. After two decades of EFIC, improved guidelines for community consultation methodology should be developed and discussed. Such guidelines could help both local IRBs and researchers with future EFIC trials.
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Figure Legends

Figure 1. Summation of community and personal acceptances by modality in Maine and Arizona.

Figure 2. Community and personal acceptance of EFIC stratified by age or education in Maine and Arizona. CA=community acceptance, PA=personal acceptance