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2 **Approaches to Community Consultation in Exception from Informed Consent:**
3 **Analysis of Scope, Efficiency, and Cost at Two Centers**
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7 Louis Eubank¹, Kwan S. Lee², David B. Seder¹, Tania Strout¹, Matthew Darrow²,
8 Catherine McDonald², Teresa May¹, Richard R. Riker¹, and Karl B. Kern²
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11 1. Departments of Critical Care Services and Emergency Medicine, Maine Medical Center,
12 Portland, Maine
13 2. Division of Cardiology, University of Arizona, Sarver Heart Center, Tucson, Arizona
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26 Corresponding author:

27 Karl B. Kern, MD

28 Professor of Medicine

29 The Gordon A. Ewy, M.D. Distinguished Endowed Chair of Cardiovascular Medicine

30 Sarver Heart Center

31 University of Arizona

32 1501 N. Campbell Avenue

33 Tucson, Arizona 85724

34 USA

35 **Abstract**

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

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

47 **Results:** Among 2185 survey respondents, approval rates were high for community involvement and
48 personal participation without individual consent. Community consultation using in-person, online,
49 and mailed surveys offered slightly different approval rates, and the rate of responses by modality
50 differed by age and education level but not ethnicity. Print advertising was the least cost effective at
51 \$442 per completed survey.

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

55 **Introduction**

56 Informed consent is considered the bedrock of medical research¹, yet emergency research is
57 challenging to conduct under traditional informed consent due to a patient’s decreased level of
58 consciousness and the absence of an appropriate surrogate decision maker. This is particularly true in
59 cardiac arrest, stroke, and trauma – each of which has often been described as a public health crisis in
60 need of ongoing research into new treatments and therapeutic approaches²⁻⁴. This conundrum led the
61 Food and Drug Administration to develop and in 1996 enact Regulation 21 CFR 50.24: Exception
62 from Informed Consent (EFIC) Requirements for Emergency Research. EFIC is intended to allow for
63 medical research in circumstances of grave need when true informed consent cannot be obtained. It
64 functions by allowing such research after community dialogue, IRB approval to proceed, with
65 attempted individual consent post enrollment. Specifics as to how community consultation should be
66 performed have been left vague to allow for interpretation by local Institutional Review Boards
67 (IRBs), the evolution of standard practices, and development of precedent.

68 There are no guidelines regarding the modalities employed and extent of the community
69 consultation that must be performed in EFIC, including the number of surveys performed, need for
70 focus groups and interviews, or required percentages of community members who must agree with and
71 accept the research in a general sense or in terms of their own participation. The FDA addressed this in
72 the addendum guidelines to 21 CFR 50:24: *“How much community consultation activity is necessary?
73 There is no single acceptable way to accomplish or fulfill the community consultation requirements,
74 nor will all studies require the same amount, type, or extent of community consultation activities.”*⁵
75 This puts investigators and IRBs in the position of developing their own process for each trial, and
76 continuously defining standards of acceptance, which can be quite variable from community to
77 community. For example, one review of nine IRB-approved EFIC trials⁶ found that surveyed
78 community members’ personal acceptance rates (the respondent theoretically accepts the possibility of

79 being enrolled in the trial without consent if they fall ill) varied from 45% of the survey population to
80 93%, with a mean of 68% ($\pm 12.9\%$, $n = 9,036$). Community acceptances (the respondent theoretically
81 accepts that the research trial be conducted in their community) ranged from 74% to 100% with a
82 mean of 78% (SD 10.3%, $n = 3,797$). Within these studies, community consultation involved such
83 methods as administering surveys at a state fair, community meetings or other local events, online
84 surveys, telephone surveys via random digit dialing, in-person interviews, and focus groups. Whether
85 these methods yield similar or adequate results is largely unknown, and the labor and expense
86 involved varies greatly, making budgetary planning for EFIC trials difficult.

87 This project is an analysis of the effectiveness and cost of two EFIC community consent
88 processes related to the randomized **P**ilot Clinical Trial for **E**arly Coronary **A**ngiography Versus No
89 Early Coronary Angiography for Post-Cardiac **A**Rrest Patient with No ST Segment **E**levation on their
90 ECG (**P**EARL) trial (NCT02387398) at University of Arizona, Tucson, Arizona (Arizona) and Maine
91 Medical Center, Portland, Maine (Maine).

92

93

94 **Methods**

95 **Study Design**

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

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

111

112 **University of Arizona**

113 *Online process*

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

116 *Print Media Advertisements*

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

120 *Direct administration of surveys*

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

126

127 **Maine Medical Center**

128 *Online process*

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

135 *Direct administration of surveys*

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

138 *Targeted mailing of surveys*

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

143

144 **Human Subjects**

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

152

153 **Statistical Methods**

154 Survey and cost data were entered into a Microsoft Excel (Microsoft Corp., Redmond, WA)
155 spreadsheet program for cleaning and were analyzed using SPSS v. 24.0 for Windows statistical
156 software (SPSS, Inc., Chicago, IL). No formal strategy was used to the sample size for the survey. We
157 used a convenience sample of individuals willing to participate. We note that previously acceptable
158 community surveys averaged 500 individuals (NIH ROC EFIC studies). To maximize sample size,
159 missing data were excluded on a case-by-case basis. Descriptive statistics were employed to evaluate
160 the characteristics of the study participants and are reported as numbers and percentages. Categorical
161 comparisons were made using Pearson’s chi-square or Fisher’s exact test, as appropriate. Racial and

162 ethnic minorities were collapsed into dichotomous categories (White, non-White; Hispanic/Latino,
163 non-Hispanic/Latino) due to small numbers. Education level was similarly collapsed (less than high
164 school, high school/equivalency degree or higher). For continuous data, comparisons were made using
165 the independent samples *t*-test or analysis of variance, as appropriate for the number of groups being
166 evaluated. Spearman's rho was employed to examine the relationships between categorical variables.
167 For the binary outcome variables representing personal and community acceptance of the EFIC trial,
168 logistic regression analyses were conducted to identify participant characteristics associated with EFIC
169 acceptance. We accepted a 2-tailed alpha of ≤ 0.05 as significant and computed 95% confidence
170 intervals using the exact method. To adjust for multiple comparisons, Bonferroni's correction was
171 applied.

172

173 **Results**

174 Demographic characteristics of survey participants are provided in **Table 1**.

175 *Demographic Differences amongst Survey Modalities and Comparisons to County Demographics*

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

183 In the Maine cohort, the 60+ age group (vs. the 18-59 year age group) was better represented
184 by mail participants (established patients of the local cardiology groups) than in-person and online
185 modalities (85% mail, 27% in person, 27% online; $\chi^2 = 470.358$, $df = 2$, $p < 0.001$). In addition, the
186 proportion of participants with at least a high school diploma was greater with the online modality
187 (100%) compared to the in-person (96%) and mailing (95%) methodologies ($\chi^2 = 12.9$, $df = 2$, $p =$
188 0.0016).

189 *EFIC Acceptance and Differences by Survey Modality*

190 Across participants, the majority favored the conduct of EFIC research in their communities
191 (2017/2185, 92%) These data are shown in **Figure 1**). Younger age correlated with personal
192 acceptance for the trial ($\rho = 0.131$, $p < 0.001$). In addition, higher educational level was associated
193 with EFIC participation ($\rho = -0.109$, $p < 0.001$). Race and ethnicity were not independently associated
194 with support for EFIC in the community.

195 *Cost-benefit analysis of various modalities*

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

200

201 **Discussion:**

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

216 Most published EFIC studies have utilized community meetings, random-digit-dialing, and/or
217 surveys for community consent. Community meetings about the specific trial facilitate longer and
218 more involved discussions with community members, and dissemination of complicated information
219 to a number of people at one time. Unfortunately, the reported experience with this approach is
220 uniformly poor.⁷⁻⁹ Attendance is typically low (often less than 25 individuals), and the feedback and
221 support obtained may not be representative of the study population. These biases were supported
222 anecdotally by our experiences.

223 In contrast, presenting the proposed trial at existing community events outside the hospital
224 offers researchers a unique opportunity to engage the community. Though attendance was small when
225 our investigators presented to the Portland, Maine city council, they were able to speak to critical
226 constituent stakeholders including city counselors, media, and the Fire and Police Chiefs, all of whom
227 strongly supported the trial. This approval is especially important when one considers the likelihood of
228 media coverage when EFIC trials are reported, and the importance of logistical support from civic
229 leaders.¹⁰

230 Prior studies have found random-digit-dialing is more successful than community meetings –
231 response rates of almost 50% have occasionally been reported.¹¹ However, there are a concerns about
232 sampling error given increasing variability in landlines in peoples’ homes., and the increasing adoption
233 of “no call” lists^{12,13} In addition, there may not be a professional surveying company available,
234 capable, or willing, as was the case with Maine, and may often be the case when a research question is
235 complex. Even if said company is available, the cost may be prohibitive: in Arizona a company
236 estimated \$30,000 for 500 completed PEARL surveys. This would have made random-digit-dialing
237 four times as expensive per survey as any other approach.

238 Surveys, both online and in person, have been included in many EFIC trials, and compare
239 favorably to community meetings and random-digit-dialing^{6-11, 14-21}. Survey data exist in the literature
240 for comparison, its costs are substantially lower, and the public is more likely to participate since it
241 takes less time than a community meeting¹⁴ and is less personally disruptive than random digit dialing.
242 Our community approval data echo the heterogeneity of other published studies of community
243 consent. In fourteen prior studies, eight^{7,15-21} showed no relationship of age or educational level to
244 study approval, however three^{7,15,21} did note racial differences in EFIC approval. Two trials^{11,22}
245 showed greater EFIC acceptance among younger and more educated patients while two other trials^{23,24}

246 showed increased acceptance with increasing age, one²⁵ showed increased acceptance with less
247 education, and one²⁶ showed increased acceptance with middle age, and less acceptance in the young
248 and elderly groups as well as a racial difference in acceptance.

249 *Online surveys*

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

262 *Survey Mailing*

263 The directed survey mailing brought in the greatest overall number of respondents, many of
264 whom were potential study participants, but also generated many telephone calls from confused
265 patients who could not understand the survey materials without coaching from the research staff. This
266 highlighted how face-to-face surveying allowed respondents to get answers to their questions
267 immediately. In the mailed surveys, respondents sometimes wrote in questions, provided comments
268 that were difficult to interpret, or did not fill in all areas of the survey correctly, necessitating still more

269 phone calls from the research staff. These issues made the mailing of surveys useful, but time-
270 consuming and expensive. Nonetheless, such responses by study staff provide an important avenue of
271 continued dialogue and effort to reach out to the community where such EFIC trials are being
272 conducted.

273 **Limitations**

274 There are limitations to our study. Although the number of community members consulted was
275 high and approval levels in our samples were significantly higher than many prior EFIC trials, in each
276 case the number was still less than 1% of the county population, raising the question of whether the
277 sample size was adequate. Community consultation, however, was never intended achieve perfect
278 acceptance²⁹ nor to be an exhaustive survey of a community's population³⁰. We believe, and our IRBs
279 concurred, that this sampling reflected an adequate community consultation, and showed an
280 appropriate level of acceptance of the trial.

281 Although the Maine and Arizona survey populations are consistent with their respective county
282 demographics, our findings may not be generalizable to other racial and ethnic communities, including
283 Native Americans in Arizona and African refugees in Maine. Additionally, as an editorial to a
284 previous trial mentioned,³¹ there is a concern that the survey text is poorly understood by respondents,
285 some of whom wrote comments such as "...definitely enroll me, I want the best chance to survive!".
286 However, we feel that these comments could be construed as less about therapeutic misconception
287 than difficulty comprehending equipoise and randomization³². This is borne out by a number of people
288 writing comments such as "I don't care which group I'm in, I want to be in the one that has the best
289 survival" and "Why randomize me? Just put me in the one that will give me the best chance of
290 success!"

291 The PEARL trial is a comparatively small extension of current best practice (catheterization of
292 those patients with STEMI post-ROSC). Therefore, our data may not be applicable to EFIC trials that
293 have a relatively larger deviation from best practice, employ more invasive or experimental therapies,
294 or are targeted at vulnerable populations. Finally, this study may have little to no generalizability for
295 neurologic or trauma studies, as there have been no studies to date looking at EFIC acceptance
296 stratified by etiology of injury.

297

298 **Conclusions**

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

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317

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411 **Figure Legends**

412 Figure 1.

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

414

415 Figure 2.

416 Community and personal acceptance of EFIC stratified by age or education in Maine and

417 Arizona. CA=community acceptance, PA=personal acceptance

418