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A community consultation survey to evaluate support for and success of the IMMEDIATE trial

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Background The IMMEDIATE (Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment in Emergency care) Trial, a randomized controlled double-blind clinical effectiveness trial of glucose–insulin–potassium (GIK) administered in ambulances in the out-of-hospital setting, used the Exception from Informed Consent Requirements (EFIC) for Emergency Research under Title 21 of the Code of Federal Regulations. EFIC requirements include community consultation that typically involves using a variety of communication methods and venues to inform the public of the research and to receive their feedback. Although not the primary purpose of the community consultation process, a common concern to research sponsors, staff, and institutional review boards (IRBs) is whether there will be a sufficient number of participants to justify mounting a study in their community. Information from community consultation regarding the community acceptance might inform this question.

Purpose We evaluated the utility of telephone survey data done as part of the EFIC process as a way to project the ultimate rate of trial participant enrollment.

Methods A telephone survey community consultation process was undertaken in nine communities planning to be IMMEDIATE Trial sites using a representative sampling of the target population in the areas covered by participating emergency medical service (EMS) agencies. Survey respondents were read a description of the planned study and its informed consent approach that included the option for patients to decline participation in the trial while being transported for acute care in an ambulance. Survey respondents were then asked whether they would object to participating in the study. At the conclusion of actual trial enrollment, the Coordinating Center compared the survey results with the actual rates of enrollment at each site.

Results Approximately 200 (range = 200–271) respondents completed the survey in each of the study communities. Of 2079 survey respondents, 68% (range = 61%–75%) said that they would not object to participating in the trial if experiencing a heart attack, and 85% (range = 79%–89%) said that they would allow the study to be done in their community. During actual trial enrollment in the communities, 79% (range = 63%–91%) of the 828 potential participants agreed in the ambulance to have the study drug started and provided informed consent at the hospital, an average of 13 percentage-points higher than projected by the survey (95% confidence interval (CI): 9%–17%), 19% higher on a relative scale (CI: 14%–25%).

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Conclusions The survey-based approach to community consultation proved to be an efficient way to obtain representative input from potential clinical trial participants. The survey data generated a relatively good and conservative estimate of the ultimate rate of trial enrollment. This information could be useful to investigators and IRBs in projecting enrollment for clinical trials using EFIC. *Clinical Trials* 2014; **11:** 178–186. http://ctj.sagepub.com

Introduction

In 1996, the US Food and Drug Administration (FDA) and the Department of Health and Human Services developed the FDA regulation entitled Exception from Informed Consent Requirements (EFIC) for Emergency Research, detailed in Title 21 of the Code of Federal Regulations (21CFR50.24) [1,2], to facilitate research on potentially life-saving interventions in emergency situations. This regulation allows for enrollment of patients who are unable to provide prospective informed consent. Emergency research studies using this approach must meet the following criteria: the potential participant has a life-threatening condition for which current treatments are unproven or unsatisfactory, obtaining immediate informed consent in the emergency clinical setting is not feasible, there is a potential for direct benefit to the patient, the intervention must be administered before informed consent could be obtained in order to be effective, and the research otherwise could not be done.

Conducting research and ensuring proper consent of patients experiencing a medical emergency in both out-of-hospital and in-hospital emergency settings is challenging, as the requirements of the informed consent process must be balanced with rapidly implementing time-dependent study or actual emergency procedures without compromising care. Even when a patient is fully conscious and able to go through the consent process, the inherent stress of a medical emergency can significantly impair achieving true informed consent, as demonstrated in several studies examining consent in patients experiencing an acute myocardial infarction (AMI). Cognitive testing in a small sample of patients during an AMI has shown that some individuals are cognitively impaired in this stressful emergency situation, calling into question their ability to be fully informed and autonomous while signing a consent form [3]. Another study of a larger sample of patients with AMI found that many of those who consented did not actually read the consent form until later, while those who did read it reported less-than-ideal comprehension of the material [4]. A third study conducted interviews at three to four weeks after enrollment and found gross misunderstandings around the consent process; in particular, participants having an AMI found it difficult to understand the paper consent form [5]. Given the sub-optimal comprehension of the consent process and together with the unstable emergency environment of the ambulance or emergency department, such conditions are not conducive to a full discussion of the study and informed consent. When possible, the opt-out requirement of EFIC allows patients the opportunity to object to participation and may be appropriate in conscious individuals having an AMI, balancing the need for emergency research with the desire of participants to have a say in the research process.

In carrying out research using the EFIC process, consultation with the community is required to inform the institutional review board's (IRB) approval process prior to initiation of a study. Community consultation involves the exchange of information between the investigators and the community and gathers feedback from both the geographic community in which the research will be done, as well as from the target enrollment group. The IRB uses the information generated by community consultation in deciding whether it will (1) approve implementation of the study, (2) require changes in the study before approval, (3) not approve the study under EFIC regulation, or (4) mandate additional community consultation before making a decision. Federal guidelines place the responsibility for what community consultation activities are appropriate on the IRB. However, many IRBs have little or no experience with this regulation and often are in need of guidance in incorporating EFIC requirements into the approval process.

The most commonly reported methods for conducting community consultations involve research team members attending regularly scheduled meetings (e.g., support groups, town council meetings) or organizing specific community consultation meetings about the proposed study [6–8]. Other methods have included developing study-specific web sites linked to questionnaires, interviewing individuals in emergency department waiting rooms or at public events, interviewing patients being

treated for the condition being studied, making presentations to disease advocacy organizations, and participating in call-in radio programs [9–14]. Typically, these approaches are based on convenience sampling and are less likely to be generalizeable to the geographic community, whereas a survey-based approach allows for a random selection and a better chance of being representative of the community population [15].

The IMMEDIATE (Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment in Emergency care) Trial was a National Institutes of Health (NIH)-funded multicenter randomized placebo-controlled effectiveness trial evaluating the use of emergency medical service (EMS) administered intravenous glucose–insulin–potassium (GIK) solution to patients with signs and symptoms of acute coronary syndromes (ACS) [16]. The goal of this multicenter trial was to determine whether very early infusion of GIK reduced progression of ACS, cardiac arrest and mortality, and size of myocardial infarction [16]. Because of the rapid pathophysiologic and clinical course of ACS, the expected beneficial impacts of GIK are likely to be successful only when its administration is initiated immediately after the onset of ACS symptoms, prior to arrival at the hospital, before a diagnosis can be confirmed [17]. Enrolling patients with ACS (i.e., unstable angina pectoris or AMI) into a clinical trial in the out-of-hospital emergency setting posed challenges regarding obtaining informed consent. EFIC research typically involves patients who are unconscious, but in the IMMEDIATE Trial, all patients were conscious. Nonetheless, obtaining informed consent in the out-of-hospital setting prior to initiating the GIK infusion was not feasible or appropriate due to the acuity of the patient's possible ACS and the time-sensitive nature of the study drug's therapeutic effect. In consultation with the FDA, the NIH National Heart, Lung, and Blood Institute (NHLBI), and the Office of Human Research Protection (OHRP), it was determined that conducting this study under the EFIC conditions would be the best approach. To translate the need for immediate treatment into clinical practice for the trial, we implemented an out-of-hospital EMS-based tiered approach to consent. In responding to 9-1-1 calls, paramedics followed a standard screening process to determine a patient's likelihood of ACS and eligibility for inclusion in the trial. Patients who met the eligibility criteria were informed about the study by EMS personnel and were asked for permission to begin the study drug infusion. For those who agreed, the study drug, either GIK or placebo, was started in the ambulance en route to the hospital. Upon hospital arrival, the study drug infusion was continued if the emergency department physician confirmed the presence of ACS and written consent was obtained to confirm the patient's initial agreement.

Methods

The IMMEDIATE Trial began at four sites. Each site developed a plan for the community consultation that was approved by their IRB. These sites adopted similar approaches to community consultation which involved presenting study information at public meetings and events in the communities. Once implemented, however, disadvantages of the approach became apparent. They included time delays, difficulty reaching an adequate number of people, and low attendance by men. With the addition of nine new sites and the need to start enrollment in a timely fashion to meet the study's goals, we elected to change our community consultation process and use a survey method approach. We here report on the nine sites that used the survey approach; a site was defined as the community served by the enrolling EMS systems [18].

The IMMEDIATE Trial Coordinating Center created a standard survey instrument for use for community consultation by all sites, which consisted of a disclosure statement providing an overview of the study and assessment questions. This allowed for consistent data collection and then aggregation across sites to estimate ultimate enrollment. Additionally, survey results would inform IRBs of potential participants' willingness to have the research done in their community and any concerns that should be taken into account in the IRB's approval process. A professional survey vendor was engaged, and the survey was reviewed and critiqued by its project director and 10 of its professional interviewers conducting the interviews, all of whom had experience in administering and conducting telephone interviews. When the survey was used for the first time, the first 20 interviews were considered a pre-test, in that interviewers recorded any problems by respondents and reported these problems to the project director managing the survey. Although the interviewers conducting the survey commented that the disclosure statement was long, given that the respondents showed little difficulty in answering the questions, once the first survey was completed, it remained unchanged and no additional pre-testing was conducted.

A list of landline telephone numbers was purchased for each community based on zip codes covered by the prospective participating EMS agencies. A sample size of 200 offered a margin of error at $\pm 6.8\%$, 95% confidence interval (CI), and a sufficient level of confidence to meet the information needs of the IRBs. In order to ensure the completion of 200 interviews per site, approximately 2000

phone numbers were dialed in each location using a computer-aided system. Each was called at least five times at different times of the day and days of the week before being replaced by a new number. Knowing that we were unable to prospectively identify community members who would later present with symptoms leading to study enrollment, the entire community aged 30 years and older constituted the pool of potential participants. Sampling of the community was done to ensure that the final sample surveyed was representative of the population within each geographic community by age and gender.

The 10-minutes survey, administered in either English or Spanish, began with a disclosure statement that reviewed the essential aspects of the research including goals, objectives, risks, benefits, study drug components, and the procedure for informed consent. Interviewees were informed that written consent would not be obtained prior to participants receiving the study drug, but that there would be an opt-out option (see Appendix A online for complete survey script). Responses to the question, 'If you were having a heart attack and were to be treated by paramedics, would you object to participating in this study?' provided an estimate of the projected study participation rate to be compared to ultimate actual enrollment rates. All comments and concerns raised by respondents were recorded; a toll-free number was provided at the end of the survey to respondents who wanted to follow-up with a study representative.

After completion of the community consultation process and IRB approval, enrollment into the IMMEDIATE Trial began. Paramedics read an IRB-approved abbreviated description of the trial (see Appendix B, online) to patients meeting enrollment criteria. This was designed to provide key information about the study to allow a patient in an emergent situation to make a decision regarding their initial participation. Whenever a patient did not opt-out, the study drug was started. To allow for continuation of the study drug infusion for a total of 12 hours, upon arrival at the hospital written, informed consent was obtained from the participant as soon as was feasible or, for participants who were unable to consent or who died prior to consent, the informed consent process was completed with the family or legally authorized representative.

At the conclusion of IMMEDIATE Trial enrollment, the Coordinating Center compared the projected study participation rates based on the surveys with the actual enrollment rates at each site using a chi-square test. Generalized linear models were used to estimate the differences between the survey-projected and ultimate actual participation rates, weighting by the actual sample sizes and adjusting for site differences. A Pearson correlation coefficient was calculated to assess the relationship between the 10 pairs of survey and actual response rates, one per survey.

Results

The IMMEDIATE Trial enrolled patients at 13 sites from December 2006 through July 2011 [18]. Table 1 shows the demographic characteristics of the respondents in the telephone surveys completed at

Table 1. Self-Reported characteristics of respondents in surveyed communities

					Race				
Site[a]	Number Surveyed	No. aged ≥65 years (%)	No. of women (%)	No. with Hispanic ethnicity (%)	No. of White (%)	No. of Black (%)	No. of Asian or Pacific Islander (%)	No. of American Indian or Alaskan Native (%)	No. of multi-racial/ other/unanswered (%)
Albuquerque	271	54 (20)	141 (52)	53 (20)	193 (71)	2 (1)	0 (0)	3 (1)	20 (7)
Anchorage	201	20 (10)	100 (50)	3 (1)	164 (82)	9 (4)	11 (6)	11 (6)	3 (1)
Bellingham	200	42 (21)	104 (52)	3 (2)	186 (93)	1 (1)	2 (1)	1 (1)	7 (4)
El Paso	200	38 (19)	108 (54)	112 (56)	69 (35)	9 (5)	5 (3)	0 (0)	5 (3)
Hershey	201	52 (26)	107 (53)	4 (2)	183 (91)	5 (3)	1 (1)	3 (2)	5 (3)
Macon	200	44 (22)	110 (55)	2 (1)	137 (69)	53 (27)	1 (1)	0 (0)	7 (4)
New Haven	201	48 (24)	109 (54)	11 (5)	159 (79)	22 (11)	0 (0)	3 (2)	6 (3)
Sioux Falls	201	38 (19)	105 (52)	0 (0)	197 (98)	2 (1)	0 (0)	0 (0)	2 (1)
St. Paul	201	38 (19)	107 (53)	3 (2)	181 (90)	6 (3)	5 (3)	0 (0)	6 (3)
St. Paul – East	203	30 (15)	106 (52)	3 (2)	191 (94)	0 (0)	4 (2)	1 (1)	4 (2)
Overall sample	2079	404 (19)	1102 (53)	194 (9)	1660 (80)	109 (5)	29 (1)	22 (1)	30 (1)

Percentages may not add up to 100 due to rounding.
[a]Sites listed represent those in which a survey was conducted, a subset of all enrolling sites.

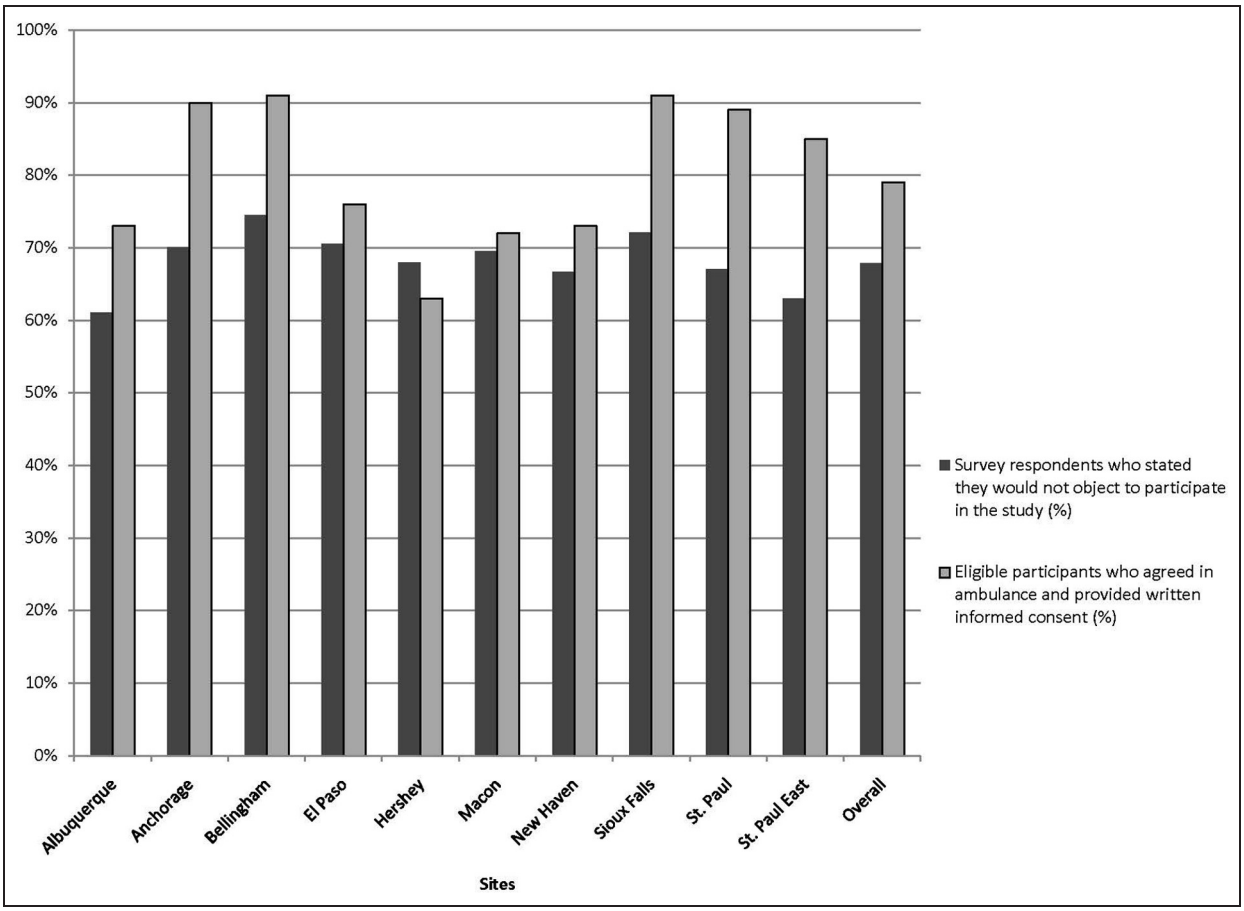

Figure 1. Agreement to participate in the study: survey respondents versus study participants.

nine sites who participated in this survey approach (two surveys were done at one site because after the initial one, an adjacent community was added), showing approximately 200 respondents per survey (range = 200–271), for a total sample size of 2079 individuals.

Table 2 shows that 99% of respondents stated that they understood the purpose of the study, nearly all respondents (range = 97%-100%) said that they understood that the intravenous study solution would be started before obtaining written consent, but that participants would have the option of declining participation. In all, 67% said they had no concerns regarding this approach. The majority (69%) did not voice specific concerns about the study, but 33% (686) did raise concerns, including drug side effects (7%), having diabetes (3%), the potential negative effects of potassium (<1%), the reduced ability to think clearly in an emergency situation (4%) and other issues with research in general (13%).

Of 828 patients who met the IMMEDIATE Trial eligibility criteria at the nine sites where a survey was conducted, 82% had the study drug started and, of those, 97% provided informed consent, such that 79% (range = 63%–91%) of all eligible patients ultimately signed the informed consent agreement. In 9 of the 10 surveys conducted, the survey-derived expected participation rate underestimated the actual enrollment rate (Figure 1). The one exception was the Hershey site where the survey-derived rate was 67% while the actual participation rate was 63%, but this was based on its very small sample (10). The overall 79% participation rate was significantly higher than the survey-derived expected participation rate of 68%, and absolute difference of 13 percentage-points (95% CI: 9%–17%) and a relative difference of 19% higher (95% CI: 14%–25%). There was a positive, although non-significant correlation between each site's survey-derived projected participation rate and the actual enrollment rate (correlation coefficient 0.39, p = 0.27).

Discussion

In preparing to use the EFIC approach for a clinical trial, we used a survey-based community consultation that allowed the process to be completed in one

Table 2. Community consultation survey responses and rates of enrollment: overall and by site

Survey Questions	Overall no. (%)	Albuquerque no. (%)	Anchorage no. (%)	Bellingham no. (%)	El Paso no. (%)	Hershey no. (%)	Macon no. (%)	New Haven no. (%)	Sioux Falls no. (%)	St. Paul no. (%)	St. Paul – East no. (%)
Do you understand what this study is about, based on the information just presented to you? *(answered yes)*	2054 (99)	267 (99)	199 (99)	199 (99)	195 (98)	200 (99)	199 (99)	196 (98)	200 (99)	197 (98)	202 (99)
Do you understand that participants in the study will not be giving their written consent before the study solution is started, but they will have the option to decline participation? *(answered yes)*	2051 (99)	264 (98)	198 (99)	198 (99)	194 (97)	201 (100)	196 (98)	200 (99)	200 (99)	197 (98)	203 (100)
Do you have any concerns about the study solution being started before a patient gives written consent as long as, at that time, the patient will have the option to decline participation? *(answered no concerns)*	1393 (67)	164 (61)	129 (64)	132 (66)	139 (69)	137 (68)	133 (67)	133 (66)	150 (75)	134 (67)	141 (70)
Would you be willing to allow us to do this study in your community? *(answered yes)*	1760 (85)	227 (85)	153 (79)	178 (89)	170 (85)	166 (82)	173 (87)	173 (86)	179 (89)	168 (84)	167 (82)
If you were having a heart attack and were to be treated by paramedics, would you object to participating in this study? *(answered no objection)*	1411 (68)	165 (61)	141 (70)	149 (75)	141 (71)	135 (68)	139 (70)	134 (67)	145 (72)	135 (67)	127 (63)
Enrollment and consent rates	**Overall no. (%)**	**Albuquerque no. (%)**	**Anchorage no. (%)**	**Bellingham no. (%)**	**El Paso no. (%)**	**Hershey no. (%)**	**Macon no. (%)**	**New Haven no. (%)**	**Sioux Falls no. (%)**	**St. Paul no. (%)**	**St. Paul – East no. (%)**
In ambulance, paramedic asked patient if it was ok to start the study drug (n = 828) *(agreed to have study drug started)*	678 (82)	189 (76)	108 (96)	96 (93)	55 (79)	10 (63)	91 (72)	45 (75)	33 (94)	34 (92)	17 (85)
At hospital, patient asked for informed consent (n = 828) *(agreed in ambulance and provided written informed consent)*	656 (79)	182 (73)	101 (90)	94 (91)	53 (76)	10 (63)	91 (72)	44 (73)	31 (91)	33 (89)	17 (85)

week in a sample that was representative of the participating communities. The survey projected that an average of 68% of potential participants would enroll, and the ultimate participation rate was 79%, 19% higher (95% CI: 14%–25%). Thus, such estimates could serve as conservative projections of ultimate trial participation.

The survey approach to community consultation was efficient, allowed collection of comparable data at multiple sites, and it provided information and insights on the opinions and concerns of a representative sample of study-eligible adults that could be generalized to the broad geographic community. It provided quantitative information that was useful for statistical analysis, such as assessing differences among demographic segments. Moreover, the survey provided opportunities to gain insights into potential recruitment issues. Had a very low participation rate been projected by the survey, an IRB might have determined that additional community consultation was needed prior to approval, and this would also have alerted researchers and sponsors of potential challenges for enrollment or continued participation in the post-emergency phase. Alternatively, a high projected participation rate could reassure investigators and the IRB about community acceptance and the likely success of recruitment. Had the survey data *overestimated* the willingness of actual patients to participate, the utility of the survey in providing insight into the opinions and acceptance of the research in the broad community would have been called into question. Our findings that the survey provided conservative estimates of enrollment should be confirmed in future studies.

The survey provided qualitative information regarding the public's concerns and issues with the research. In comparison to in-person community consultation meetings, the survey approach took fewer resources, and it was completed in less than a week with the guarantee of information and insights from at least 200 individuals at each site. By administering the same survey in each IMMEDIATE Trial community, results could be compared across all sites. The near identical participation rates seen in the first few surveys provided a baseline of expectations for new IRBs that were less experienced with EFIC research. It also provided reassurance to researchers about the likelihood of recruitment success which was confirmed during actual recruitment.

Prior studies under EFIC regulations involved participants who were unconscious, making it impossible to determine the actual percentage of respondents who would provide consent to participate before receiving emergency treatment. Lacking this information, it has not been possible to assess the accuracy of survey data in predicting the actual participation rate. Because candidates for the IMMEDIATE Trial were conscious when asked to participate, it was possible to compare survey-projected participation rates with the ultimately realized enrollment rates. In the survey, between 25% and 39% of respondents across the 10 surveys had concerns and would object to having the study drug started in the ambulance, whereas in the actual conduct of the IMMEDIATE Trial, only 18% of patients presented with the study in the ambulance declined to have the study drug started. Whereas the survey data projected that 68% of eligible patients would agree to participate in the research, the actual participation was substantially higher. Importantly, survey data did not overestimate the actual participation rates.

The survey-based approach to community consultation had some limitations. The amount of time available to present information to survey respondents was limited. Although our survey did not specifically target people at the highest risk for ACS, that is, those with a medical history of ACS or specific risk factors, based on the prevalence of heart disease, they were likely included. Questions from survey respondents could not be answered immediately by a study representative as could be done at an in-person community consultation [19]. However, survey respondents were offered a toll-free number to call if they had further questions. Also, a limitation is that quantitative, but not qualitative, data were collected. In the future, this could be added to such a survey or done as later follow-up [20]. In addition, the survey's disclosure statement did not present the full list of potential risks of this trial, which may have contributed to fewer concerns and a higher agreement rate.

Another possible limitation in this study is that the survey personnel called only landline telephone numbers, which could have created sampling bias. According to the National Health Interview Survey sponsored by the Centers for Disease Control and Prevention's National Center for Health Statistics, the number of wireless-only households in 2008 was estimated at 17%, and by 2011, it was up to 34%. Exclusion of wireless-only households from the interview process may diminish the representativeness of the data. Although our surveys were conducted between 2008 and 2010 when wireless-only households were fewer, future surveys likely would benefit from a sampling plan that included wireless-only households and a weighting of the data by the known distribution of wireless-only households within a state [21,22]. Another potential limitation of our survey method is the use of telephone-based caller identification (caller-ID) by those being called, which would have allowed potential respondents to not answer our calls, resulting in lower response rates and potentially increasing non-response bias. However, prior research has shown that caller-ID

displays actually may help to gain respondents and ultimately to improve response rates [23].

As experience accumulates, the research community is learning how best to implement research utilizing the EFIC approach in terms of thoroughness, practicality, effectiveness, and efficiency. In the IMMEDIATE Trial, in which procedures had to be implemented in a wide variety of communities across the nation, traditional approaches to community consultation proved inefficient. Moreover, because the assessment was largely implemented by a survey company with substantial capacity for this work, multiple communities could be surveyed at the same time, a considerable strength when planning a multicenter trial. Thus, this survey-based approach appears to have significant potential for community-based EFIC research.

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Conflict of interest

None declared.

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