Integration of Social Media With Targeted Emails And In-Person Outreach For Exception From Informed Consent Community Consultation

Cindy H. Hsu, MD, PhD,[1,2] Jennifer Fowler,[1] James A. Cranford, PhD,[1] Michael P. Thomas, MD,[3] Robert W. Neumar, MD, PhD[1,2]

[1]Department of Emergency Medicine, [2]Michigan Center for Integrative Research in Critical Care, [3]Division of Cardiovascular Medicine, Interventional Cardiology, University of Michigan, Ann Arbor, MI

Corresponding author:
Cindy H. Hsu, MD, PhD
Assistant Professor
Department of Emergency Medicine
Department of Surgery
Michigan Center for Integrative Research in Critical Care
University of Michigan Medical School
NCRC B026-309N
2800 Plymouth Road
Ann Arbor, MI 48109-2800
Phone: (734) 764-3691
Email: hcindy@med.umich.edu

Jennifer Fowler, RN, BSN
Department of Emergency Medicine
University of Michigan Medical School
B1-204 Taubman Center

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/acem.14377

1500 E. Medical Center Drive
Ann Arbor, MI 48109-5301
Email: jenfow@med.umich.edu

James A. Cranford, PhD
Department of Emergency Medicine
University of Michigan Medical School
Room 3316, Domino's Farms
24 Frank Lloyd Wright Drive
Ann Arbor, MI 48105
Email: jcranfor@med.umich.edu

Michael P. Thomas, MD
Department of Cardiology
University of Michigan Medical School
Floor 3 Reception C
1500 E Medical Center Dr SPC 5856
Ann Arbor, MI 48109-5856
Email: michptho@med.umich.edu

Robert W. Neumar, MD, PhD
Department of Emergency Medicine
Michigan Center for Integrative Research in Critical Care
University of Michigan Medical School
1500 E. Medical Center Drive
TC B1220
Ann Arbor, MI 48109-5301
Email: neumar@med.umich.edu

Running title (<50 characters): Social media for EFIC community consultation

Keywords: Exception from informed consent, community consultation, social media, targeted interviews, email, cardiac arrest

Manuscript word count: 3629

Abstract word count: 292

CONFLICTS OF INTEREST

All authors have no conflicts of interest to disclose.

DISCLOSURE

CHH had NIH support in the form of K12HL133304-01. RWN has NIH support in the form of NIH-R01HL133129 and R34HL130738. There was no funding or financial sponsorship directly for this project.

PRESENTATIONS

This work was previously presented at the 2018 Resuscitation Science Symposium (Chicago, IL) as a posterior presentation and 2018 Resuscitation in Motion Conference (Toronto, ON) as an oral presentation.

AUTHOR CONTRIBUTIONS

CHH contributed to the study concept and design. CHH, JF, and MPT contributed to acquisition of the data. CHH, JF, JAC, and RWN contributed to the analysis and interpretation of the data. JAC provided statistical expertise. All authors were responsible for the drafting of the manuscript and critical revision of the manuscript for important intellectual content.

Received Date:

Revised Date:

Accepted Date:

Article Type: The Biros Section on Research Ethics

ABSTRACT

Background: Exception from informed consent (EFIC) enables the enrollment of research subjects with emergent conditions to clinical trials without prior consent. EFIC study approval requires community consultation and public disclosure. We hypothesized that the integration of social media with targeted emails and in-person outreach is an effective community consultation strategy.

Methods: We utilized social media with targeted emails and in-person outreach for the community consultation of the ACCESS cardiac arrest trial. Study advertisements were disseminated using Facebook and Instagram, and targeted emails were sent to emergency medicine, prehospital and cardiology providers. We also interviewed at-risk individuals with cardiac conditions, their caretakers, and patient advocacy groups. Participants were asked to complete a survey about their opinions about the study.

Results: We collected 559 surveys over an 8-week period, and 70.5% of the surveys were obtained using social media. The mean age of survey respondents was 45 years; 89.9% were white and 60.1% were women. 91.3% believed ACCESS was an important study. Compared to the in-person group, more from social media (81.8% vs 63.3%, $p < 0.05$) and targeted email (77.4% vs 63.3%, $p < 0.05$) groups said they would include their loved ones in the study. More from the in-person group believed that their opinion would be considered seriously compared to the social media (75.9% vs 62.6%, $p < 0.05$) and targeted email (75.9% vs 54.5%, $p < 0.05$) groups. The incorporation of social media and targeted emails for community consultation reduced the cost per survey by 4-fold compared to an in-person only strategy.

Conclusions: The integration of social media with targeted emails and in-person outreach was a feasible and cost-saving approach for EFIC community consultation. Future work is necessary to determine the perception and best utilization of social media for community consultation.

INTRODUCTION

The time-sensitive nature of acute illnesses limits the ability to rapidly enroll research subjects using the traditional informed consent method. The subjects are often incapacitated, and their legally authorized representatives are either not present or too distressed to consider enrollment in research studies on behalf of the subjects.[1-3] In 1996, the Food and Drug Administration (FDA) and the Department of Health and Human Services developed the Final Rules (21 CFR 50.24), which included a regulation known as exception from informed consent (EFIC) to enable research without informed consent in emergency circumstances.[4] In order to utilize EFIC for a research study, investigators need to demonstrate that: 1) the subject has an acutely life-threatening condition; 2) currently available treatments are untested or unsatisfactory; 3) the potential subject cannot consent because of the acute condition; 4) there must not be time within the proposed therapeutic window to contact the legally authorized representatives to obtain prospective consent; and 5) the subject might directly benefit from participation.[4,5]

The FDA mandates that all study sites complete community consultation and public disclosure before an EFIC study can be approved to start enrollment. Community consultation is a two-way process involving the investigators and community representatives designed to provide the institutional review boards with community attitude and cultural beliefs regarding the research. Public disclosure is a one-way process by which the investigators inform the potential study population about the study.[6] EFIC studies from the past two decades have enrolled patients into clinical trials in cardiac arrest, trauma, status epilepticus, stroke, and acute coronary syndrome.[7] Yet, there is a continued lack of standardized approach to community consultation in part due to differences in perception about its goals and metrics. The implementation of community consultation is often challenged by significant cost[8-10] and ineffective community engagement.[9] Furthermore, significant variabilities in approach occur even within the sites of the same trial due to differences in interpretation by institutional review boards.[6,9,11] As such, little is known regarding the best strategies to implement EFIC community consultation. This problem became even more evident during the COVID-19 pandemic, during which direct contact with the

community was substantially reduced due to social distancing and restrictions in human subjects research.

We hypothesized that the integration of social media with targeted emails and in-person outreach would be a feasible and effective strategy to conduct EFIC community consultation. We report our experience implementing this multifaceted approach for the community consultation of the ACCESS Trial, a multicenter randomized controlled study that examined the effect of immediate versus delayed cardiac catheterization for patients who suffered from ventricular fibrillation out-of-hospital cardiac arrest.

METHODS

Study Design

We utilized social media, targeted emails, and in-person outreach for the EFIC community consultation of the ACCESS to the Cardiac Catheterization Laboratory in Patients Without ST-Segment Elevation Myocardial Infarction Resuscitated From Out-of-hospital Ventricular Fibrillation Cardiac Arrest Trial (NCT03119571). This study was approved by the institutional review board of the University of Michigan.

Social Media

We disseminated Facebook and Instagram study advertisements (Figure 1) to subscribers who resided in Washtenaw (population 367,601; density 488/sq mi)[12] and Livingston counties (population 191,995; density 320/sq mi)[13] in Michigan. Facebook and Instagram determine the location of its subscribers when users enable location services voluntarily, through checking-in and tagging of posts and pictures, and from Internet Protocol (IP) addresses.[14] The advertisements contained a link to an electronic survey that provided information about the study and an opt-out option on the study website. There were two methods for opting out of ACCESS – through a Medic Alert™ membership or by calling the study team to request an Opt Out bracelet. The survey also inquired about the participants' opinions about the study and their demographic information (Table 1). The American Heart Association also posted the link to the advertisements on its Facebook page. The survey was developed using Qualtrics (Provo, UT).

Targeted Emails

The electronic survey was sent to emergency department staff including physicians, physician assistants, nurses, technicians, and clerical staff via a group email. Separate survey links were also sent to cardiologists and prehospital providers through their email distribution lists. These separate links allowed us to differentiate their responses from that of the general population.

Targeted In-Person Outreach

We approached individuals with cardiac conditions and their caretakers in the waiting room area of our cardiology clinic to disseminate information about ACCESS over a period of 4 days. We did the same to two patient family advisory groups during two 30-minute sessions. All individuals were given the opportunity to ask questions about the study. We also asked the in-person participants to complete the same study survey in a paper format.

Cost Analysis

To estimate the cost of the social media campaign, we compared the total costs and cost per survey of community consultation for ACCESS to that for the Extracorporeal CPR for Refractory Out-of-Hospital Cardiac Arrest (EROCA) Trial (NCT03065647).[15] EROCA was a single-center, pilot Phase 2 cardiac arrest EFIC study with similar community at-risk and eligibility criteria that had relied solely on in-person outreach for community consultation. We defined the total cost as the sum of personnel cost and direct expenditures (i.e. social media charge) associated with community consultation. The personnel costs were calculated by multiplying the personnel effort in hours by their respective hourly salaries. The hourly salaries were estimated by dividing the annual salaries by annual work hours, which were 1,920 hours for a research coordinator and 1,152 hours for an investigator (full-time assistant professor in emergency medicine). The personnel annual salaries were $87,204.95 for research coordinator and $225,000 for investigator. A $350 direct expenditure for Facebook/Instagram (cost of $0.80 per opened link for total of 438 opened survey links) was also added to the cost of social media campaign. The total costs of community consultation and cost per completed survey were then calculated for both trials.

Qualitative Analysis

The answers to the open-ended question, "Please provide below, any additional comments, concerns or questions you would like to share with the ACCESS study team" were coded iteratively and analyzed thematically by two of the authors (CHH and JF).

Statistical Analysis

To ensure independence of observations, survey responses were checked to ensure that there were no duplicates or multiple responses by the same individual using their IP addresses and response ID. The normality of continuous variables (e.g. age) was assessed with Shapiro-Wilk test and found to depart from normality due to its right skewness. Thus, Krusal-Wallis with post-hoc Dunn test was used to compare the age between groups. Between-group comparisons of proportions were tested using modified chi-squared tests for small sample size, and statistically significant chi-squared tests were followed-up with post-hoc comparisons of proportions.[16] Statistical analyses were conducted using SAS 9.4 (Cary, NC). For all analyses, $p < 0.05$ was considered statistically significant.

RESULTS

Community consultation for the ACCESS Trial was conducted using combination of social media, targeted emails, and targeted in-person outreach over an eight-week period, from February 28th to April 30th, 2018. A total of 559 surveys were collected, with 394 (70.5%) surveys obtained using social media, 84 (15%) using targeted emails, and 81 (14.5%) using in-person outreach. Out of these surveys, 200 respondents answered only the first question, "Have you or has anyone you know ever experienced a sudden cardiac arrest?" More respondents from the social media group completed only the first question (169 [42.9%]) than the targeted email (30 [35.7%]) and in-person group (1 [1.2%]; $p < 0.0001$; Table 2). Of the 359 remaining survey respondents, all of them answered at least one close-ended questions and 22% at least one open-ended question. The reach of our Facebook study advertisements, or the number of times the advertisements was opened, was 24,742 subscribers. The impression, or the number of times the advertisements was displayed, was 49,683. The frequency, or average number of times our advertisement was served to each person, was 2.01.

Demographic data were available for 98-99% (352 to 356 of 359) of the completed surveys (Table 2). The overall median age of survey respondents was 44 years (interquartile range [IQR]

33-57); 89.7% were white and 60.1% were women. The in-person group was older (median age 59) than social media (median age 39) and targeted email groups (median age 44; $p < 0.0001$). There were more women in the social media group (72.5%) than in the targeted email (18.5%) and in-person groups (57.1%; $p < 0.0001$). No one opted out from the study.

Of all the survey respondents, 35% had loved ones or knew of someone who suffered from sudden cardiac arrest, and 2% were cardiac arrest victims (Table 3). The in-person group had more loved ones with cardiac arrest than the social media (50% vs 36.7%, $p < 0.05$) or targeted email (50% vs 23.6%, $p < 0.005$) group. Of the completed surveys, 91.3% believed that ACCESS was an important study. Compared to the in-person group, more from social media (81.8% vs 63.3%, $p < 0.05$) and targeted email (77.4% vs 63.3, $p < 0.05$) groups said they would include their loved ones in the study. More from the in-person group believed that their opinion would be considered seriously compared to the social media (75.9% vs 62.6%, $p < 0.05$) and targeted email (75.9% vs 54.5%, $p < 0.05$) groups.

Several important themes emerged from answers to the open-ended question, "Please provide below, any additional comments, concerns or questions you would like to share with the ACCESS study team" (Table 4). Overall, the social media group provided the most qualitative comments to this question. The survey respondents from all three groups raised several concerns regarding the study, including the lack of informed consent as well as uncertainty about clinical equipoise of the treatments and randomization. Specifically, several respondents questioned whether immediate and delayed cardiac catherization after ventricular fibrillation out-of-hospital cardiac arrest should both be considered as standards of care, and whether randomization could potentially deprive themselves or their loved ones from the appropriate care. Some respondents were confused about the study design, while others pointed out survey design issues including the lack of study details and flaws to the questions. Finally, the remaining respondents supported the study, commented on the study eligibility criteria, made recommendations for study improvement, knew cardiac arrest survivors, and clarified their demographics.

To estimate the cost-savings achieved by incorporating the social media and targeted email strategies, we compared the total cost for ACCESS community consultation to that for the EROCA Trial (NCT03065647)[17] (Table 5). EROCA community consultation required 51 hours

of study coordinator time and 8.5 hours of investigator time, which yielded 137 surveys. In contrast, ACCESS needed 30 hours of study coordinator time and 3.5 hours of investigator time, and yielded 359 completed surveys. Importantly, we were also able to reduce the time our study coordinators spent unsuccessfully soliciting community groups' permission to present the study from 20 hours for EROCA to 8 hours for ACCESS. We found that the incorporation of social media and targeted email strategies reduced the cost per survey by 4-fold, from $29.03 per survey for EROCA to $7.56 per survey for ACCESS. In addition, the social media campaign was the least expensive strategy for ACCESS at $3.63 per survey, compared to $4.46 per survey for targeted email and $20.69 per survey for in-person outreach.

DISCUSSION

This study compared our community's opinions toward an EFIC study solicited using different methods of community consultation. To our knowledge, our study was also the first to incorporate and compare the opinions of healthcare staff with other members of the community at-risk for EFIC community consultation. We showed that our Facebook/Instagram campaign reached more members in our communities than the targeted emails or in-person approach. The majority surveyed thought that ACCES was an important study (91.3%) and would agree to enroll themselves (77.1%) or their loved ones (74.9%). These findings were consistent with a systematic review of dockets from 27 EFIC trials submitted to the FDA from 1996 to 2017,[7] which found that more people were willing to approve initiation of EFIC trials in their community (86.5%) than personal enrollment (73%), enrollment of a family member (68.6%), or principle of enrollment without consent (58.4%). Interestingly, more survey respondents from our social media group said they would enroll their loved ones in the study than the in-person group, while more from the in-person group believed that their opinion would be considered seriously. The etiology of these differences in opinion is likely multifactorial and requires further investigation.

It is possible that the social media respondents felt less informed about the study and less engaged with the study investigators. The fact that more respondents from the in-person group believed that their opinion would be considered seriously compared to the other two groups may reflect the differences in the level of community engagement. Based on the open-ended responses, several respondents from the social media group expressed concerns about the lack of

informed consent and clinical equipoise between the two treatment arms. They also brought up issues about the survey design and lack of details about the study. Although the in-person group also raised similar concerns, some of these issues could have been addressed by the study team in person or with more interactive virtual platforms. For example, Zoom or Facebook Live can be used to engage the community in real time. Multimedia platforms such as YouTube or Vimeo can be used to disseminate informational videos, which can be incorporated within electronic surveys.

The results of our study add to emerging evidence that a multifaceted approach to community consultation may be less costly than traditional in-person approach[9,18] or random digital dialing.[8,19] Our findings are consistent with those from prior studies, which showed that social media campaign for EFIC community consultation could increase the number of community members reached at a reduced cost.[19-22] However, while some of these prior studies[20-22] utilized Facebook for their community consultation, their study advertisements only provided links to study websites rather than surveys. Therefore, they were only able to assess average time spent viewing the sites, not community engagement nor opinions toward the study. Our cost analysis results differed from that of Eubank et al,[19] who found in-person outreach at two large public events to have lower cost per survey than online surveys. However, they only included direct expenditures in their cost analysis,[19] therefore likely to have significantly underestimated the cost of their in-person outreach events. It is important to note that the cost and level of community engagement from in-person events could differ between small gatherings such as those in our study and large public group events such as fairs and sporting events like those in Eubank et al.[19]

It is worth noting that 19.1% of our survey respondents did not want to participate in the study, yet no one opted out from the study. This finding was consistent with prior EFIC trials, with one study reporting only a 3.6% opt-out rate out of 4,335 patients from 15 study sites.[9] It is unclear whether this discrepancy was due to sampling error, logistic barriers, or the survey respondents not feeling strongly enough to opt out of ACCESS. The inconsistency between survey results and opt-out rates also suggests that the survey instrument and opt-out process can be better optimized. For example, future surveys can automatically direct survey respondents to the study website that provide instructions on how to opt out of the study if they express desire to not participate in the study. While community consultation should not be mistaken for community

consent, they are not mutually exclusive. Consulting with a community includes soliciting feedback, criticism, and suggestions, but does not include asking for approval or permission.[23] As such, community consultation is designed to recognize and accommodate the relevant particularities of a given community for a specific project. Dickert and Sugarman proposed the ethical goals of community consultation as enhanced protection, enhanced benefits, legitimacy, and shared responsibility.[23] The question remains, can social media help to achieve both regulatory and ethical goals of community consultation through enhancement of community outreach and engagement?

Recent evidence suggested that social media utilization has steadily increased in recent years. In 2019, 72% of the U.S. adults used at least one social media site.[24] In the same year, 69% used Facebook in 2019, with more women (75%) using Facebook than men (63%). However, only 40% of 65+ year-old used social media, compared to 90% of 18-29 year-old, 82% 30-49 year-old, and 69% 50-64 year-old.[24] As such, if the community at-risk includes those above 65 years of age, relying solely on social media for community consultation will likely be insufficient.[25] In that scenario, our approach of integrating social media with targeted in-person outreach may be more effective. Potential socioeconomic and racial disparities should also be considered when utilizing social media for community consultation, as access to smartphones and internet may be more limited in certain populations.

The COVID-19 pandemic introduced additional barriers to conduct in-person outreach for community consultation due to social distancing and restrictions in human research conduct. Just as the pandemic has transformed how healthcare is delivered by shifting toward telehealth,[26] future studies can explore how different virtual platforms can be strategically incorporated to conduct effective EFIC community consultation virtually. Specific platforms can be utilized to target particular demographics based on the community at-risk, such as using Facebook to solicit more opinions from women, or using Twitter, TikTok, and Snapchat to disseminate study information to those aged 12-34, since only 34% in this age group identified Facebook as their social media platform of choice in 2020.[27] Google Analytics can be used to monitor website visitor traffic and demographics. The ability to leave comments on all these platforms would enable two-way communications between community members and study investigators.

It is important to accurately define and identify the community at-risk prior to initiation of community consultation process. Federal regulations require consultation with "representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn."[4] How the at-risk community is defined, however, is dependent upon the institution conducting the research based on geography, patient characteristics, or population served by participating emergency medical services or hospitals.[5] Understanding the target audience is essential for the determination of the most effective community consultation and public disclosure approaches. For example, the mean age of out-of-hospital cardiac arrest victims was 62.4 years and 61.7% were men from 2013 to 2019.[28] Feldman et al[7] found in their systematic review that African Americans made up 29.3% of those enrolled in EFIC trials that reported data on race, but only 16.7% of those surveyed for community consultation. Men made up 42.9% of the surveyed population but 65.6% of those enrolled in EFIC trials. Groups surveyed with higher proportions of African Americans and male respondents had lower rates of EFIC approval.[7] It is also important to note that legally authorized representatives, which often include the spouses or adult children of the research subjects, are more likely to be women and of different age demographic than the population at-risk. Our study demonstrated no statistically significant differences in racial distributions between groups, but the sample sizes were relatively small. It is possible that there were proportionally fewer Black/African American respondents in the social media and targeted email groups compared to the in-person group. These differences could also reflect the underlying demographic differences between our two counties, as Black/African Americans consist of 12.3% of the population in Washtenaw county and 0.7% in Livingston county.[12,13]

LIMITATIONS

This study has several limitations. It is a single-center study with relatively small sample size, thus limiting our ability to perform multivariable analysis to determine the associations between the method of community consultation and opinion toward the ACCESS Trial and EFIC. Due to the lack of preliminary data on using social media and targeted email strategies for EFIC community consultation in our community at-risk, our study was designed as a pilot study. As such, a power analysis to detect a discrete difference in our primary outcomes using well-defined variability was not feasible. The surveys were distributed to convenience samples, and results might not reflect the overall opinion of our community at-risk due to selection bias and sampling

error. Furthermore, we only utilized Facebook and Instagram as our social media platforms, which might have limited engagement of certain demographics such as those who were older than 65 years of age.

We distributed the survey electronically via Qualtrics to the social media and targeted email groups while handed out paper surveys to the in-person group, thereby introducing a potential confounder. In addition, we were not able assess the reasons why participants failed to complete certain survey questions. Given that we utilized the survey obtained from the study sponsor, we were unable to modify its content and format to enhance the survey validity and respondent engagement. It was likely that 200 respondents answered only the first question because a lengthy study description was located between the first and second question, leading to attrition. Finally, our cost analysis was limited to comparison with a single prior study conducted at a single center. Future validation studies are necessary to confirm the cost and cost-saving of social media integration for other sites and EFIC studies. As multicenter emergency care trials shift from individual to centralized institutional review boards with oversight of a robust network infrastructure such as the Strategies to Innovate Emergency Care Clinical Trials Network, future EFIC community consultation efforts will benefit from standardized survey instruments, reporting, and clarification of the survey function in the trial protocol development and modification.[7]

CONCLUSIONS

The integration of social media with targeted emails and in-person outreach was a feasible and cost-saving approach for EFIC community consultation. Future research is necessary to determine the community's perception toward the use of social media for community consultation, strategies to optimize virtual platforms to improve study dissemination and community engagement, and to identify potential disparities in these approaches.

REFERENCES

1. Dutton RP, Stansbury LG, Hemlock B, Hess JR, Scalea TM. Impediments to obtaining informed consent for clinical research in trauma patients. J Trauma 2008;64:1106-12.

2. Hsieh M, Dailey MW, Callaway CW. Surrogate consent by family members for out-of-hospital cardiac arrest research. Acad Emerg Med 2001;8:851-3.
3. Sava J, Ciesla D, Williams M, Street J, 3rd, White P, Wang D. Is informed consent in trauma a lost cause? A prospective evaluation of acutely injured patients' ability to give consent. J Am Coll Surg 2007;205:405-8.
4. Administration DoHaHSUSFaD. Protection of human subjects: informed consent and waiver of informed consent requirements in certain emergency research; final rules. 21 CFR part 50.24. 1996:51497–531.
5. Tisherman SA. Defining "Community" and "Consultation" for Emergency Research that Requires an Exception from Informed Consent. AMA J Ethics 2018;20:467-74.
6. Tisherman SA, Powell JL, Schmidt TA, et al. Regulatory challenges for the resuscitation outcomes consortium. Circulation 2008;118:1585-92.
7. Feldman WB, Hey SP, Franklin JM, Kesselheim AS. Public Approval of Exception From Informed Consent in Emergency Clinical Trials: A Systematic Review of Community Consultation Surveys. JAMA Netw Open 2019;2:e197591.
8. Bulger EM, Schmidt TA, Cook AJ, et al. The random dialing survey as a tool for community consultation for research involving the emergency medicine exception from informed consent. Ann Emerg Med 2009;53:341-50, 50 e1-2.
9. Holsti M, Zemek R, Baren J, et al. Variation of community consultation and public disclosure for a pediatric multi-centered "Exception from Informed Consent" trial. Clin Trials 2015;12:67-76.
10. Matchett G, Ryan TJ, Sunna MC, Lee SC, Pepe PE, Ev KCTG. Measuring the cost and effect of current community consultation and public disclosure techniques in emergency care research. Resuscitation 2018;128:37-42.
11. Carlson JN, Zive D, Griffiths D, et al. Variations in the application of exception from informed consent in a multicenter clinical trial. Resuscitation 2019;135:1-5.
12. Quick Facts - Washtenaw County, Michigan. 2019. (Accessed March 10th, 2021, at https://www.census.gov/quickfacts/washtenawcountymichigan.)
13. Quick Facts - Livingston County, Michigan. 2019. (Accessed March 10th, 2021, at https://www.census.gov/quickfacts/livingstoncountymichigan.)
14. Chauhan S. Facebook reveals it can track users location even if they turn off location services. TechRadar2019.
15. Hsu CH, Meurer WJ, Domeier R, et al. Extracorporeal Cardiopulmonary Resuscitation for Refractory Out-of-Hospital Cardiac Arrest (EROCA): Results of a Randomized Feasibility Trial of Expedited Out-of-Hospital Transport. Ann Emerg Med 2021;78:92-101.

16. Campbell I. Chi-squared and Fisher-Irwin tests of two-by-two tables with small sample recommendations. Stat Med 2007;26:3661-75.
17. Hsu CH, Meurer WJ, Domeier R, et al. Extracorporeal Cardiopulmonary Resuscitation for Refractory Out-of-Hospital Cardiac Arrest (EROCA): Results of a Randomized Feasibility Trial of Expedited Out-of-Hospital Transport. Ann Emerg Med 2021.
18. Biros MH, Sargent C, Miller K. Community attitudes towards emergency research and exception from informed consent. Resuscitation 2009;80:1382-7.
19. Eubank L, Lee KS, Seder DB, et al. Approaches to community consultation in exception from informed consent: Analysis of scope, efficiency, and cost at two centers. Resuscitation 2018;130:81-7.
20. Harvin JA, Podbielski JM, Vincent LE, et al. Impact of Social Media on Community Consultation in Exception From Informed Consent Clinical Trials. J Surg Res 2019;234:65-71.
21. Stephens SW, Williams C, Gray R, Kerby JD, Wang HE. Preliminary experience with social media for community consultation and public disclosure in exception from informed consent trials. Circulation 2013;128:267-70.
22. Stephens SW, Williams C, Gray R, Kerby JD, Wang HE, Bosarge PL. Using social media for community consultation and public disclosure in exception from informed consent trials. J Trauma Acute Care Surg 2016;80:1005-9.
23. Dickert N, Sugarman J. Ethical goals of community consultation in research. Am J Public Health 2005;95:1123-7.
24. Social Media Fact Sheet. (Accessed March 1st, 2021, at https://www.pewresearch.org/internet/fact-sheet/social-media/.)
25. Galbraith KL. Practical and ethical considerations for using social media in community consultation and public disclosure activities. Acad Emerg Med 2014;21:1151-7.
26. Chao GF, Li KY, Zhu Z, et al. Use of Telehealth by Surgical Specialties During the COVID-19 Pandemic. JAMA Surg 2021.
27. 20 Facebook stats to guide your 2021 Facebook strategy. 2021. (Accessed March 1st, 2021, at https://sproutsocial.com/insights/facebook-stats-for-marketers/#general)https://www.statista.com/topics/751/facebook/.)
28. CARES. CARES Summary Report, Demographic and Survival Characteristics of OHCA2020 April 15, 2020.

Table 1. Survey Questions

1. Have you or has anyone you know ever experienced a sudden cardiac arrest? (check all that apply): [Me, A family member or loved one, Someone else, No]

2. ACCESS is an important study to do: [Strongly agree, Agree, Neutral, Disagree, Strongly Disagree]

3. If you had an out-of-hospital cardiac arrest, you would be okay with being included in ACCESS? [Strongly agree, Agree, Neutral, Disagree, Strongly Disagree]

4. If a loved one had an out-of-hospital cardiac arrest, you would be okay with including your loved one in ACCESS? [Strongly agree, Agree, Neutral, Disagree, Strongly Disagree]

5. Do you think that ACCESS researchers will seriously consider what community members like you have to say about this study before starting it? *[Yes, No, I don't know]*

6a. Do you feel that you have been given enough information to give your informed opinion about whether you think it is ok for researchers to do the ACCESS study? [Yes, No]

6b. What additional information would you still like to know? [Free text]

7. Would you like to tell doctors that you do not want to participate in ACCESS? [Yes, No]

8. Lastly, so that we can make sure we are hearing from a wide range of residents in the Washtenaw and Livingston County area, please complete the following final five questions about yourself. What is your age (in years)? [Free text]

9. Are you: [Male, Female]

10. Are you Hispanic or Latino? [Yes, No]

11. Which one or more of the following would you say is your race: (Check all that apply) [White, Black or African American, American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, Other (please list)]

12. What is the highest grade or year of school you completed? [Never attended school or only attended kindergarten, Grades 1 through 8 (Elementary), Grades 9 through 11 (Some high school), College 1 year to 3 years (Some college or technical school), College 4 years or more (College graduate)]

13. Please provide below, any additional comments, concerns or questions you would like to share with the ACCESS study team: [Free text]

Table 2. Survey Respondent Demographics

	Overall	Social Media	Targeted Email	In-Person	P value
Collected surveys	559	394 (70.5%)	84 (15%)	81 (14.5%)	<0.0001
Answered question 1 only, n (%)	200	169 (42.9%)	30 (35.7%)	1 (1.2%)	<0.0001
Completed surveys					
Age, years	(N=356)	(n=222)	(n=54)	(n=80)	
Median (IQR)	44 (33-57)	39 (31-53)	44 (36-56)	59 (46-68)	<0.0001
Gender, n (%)	(N=353)	(n=222)	(n=54)	(n=77)	<0.0001
Women	215 (60.1%)	161 (72.5%)	10 (18.5%)	44 (57.1%)	
Men	138 (39.1%)	61 (27.5%)	44 (81.5%)	33 (42.9%)	
Race, n (%)	(N=351)	(n=221)	(n=54)	(n=76)	0.0797

White	315 (89.7%)	201 (91%)	50 (93%)	64 (84%)	
Black/African American	13 (3.7%)	4 (2%)	1 (2%)	8 (11%)	
Asian	10 (2.8%)	7 (3%)	2 (4%)	1 (1%)	
Native Hawaiian/ Pacific Islander	1 (0.3%)	1 (<1%)	0 (0%)	0 (0%)	
American Indian/Alaskan Native	5 (1.4%)	5 (2%)	0 (0%)	0 (0%)	
Hispanic/Latino	11 (3.1%)	8 (4%)	1 (2%)	2 (3%)	
Other race	7 (2.0%)	3 (1%)	1 (2%)	3 (4%)	
Education, n (%)	(N=352)	(n=222)	(n=54)	(n=76)	<0.0001
College 1 year to 3 years (Some college or technical school)	95 (27.0%)	50 (23%)	25 (46%)	20 (26%)	
College 4 years or more (College graduate)	242 (68.8%)	167 (74%)	28 (52%)	47 (62%)	
Grade 12 or GED (High school graduate)	16 (4.5%)	8 (4%)	0 (0%)	8 (11%)	
Grades 9 through 11 (Some high school)	1 (0.3%)	0 (0%)	0 (0%)	1 (1%)	
Never attended school or only attended kindergarten	1 (0.3%)	0 (0%)	1 (2%)	0 (0%)	

Krusal-Wallis with post-hoc Dunn test was used to compare the median age between groups. Modified chi-square tests for small sample size were used for between-group comparisons of proportions. IQR = interquartile range.

Table 3. Comparisons of Opinions about the ACCESS Trial Between Different Groups

Opinions about the ACCESS Trial	n	Overall	Group			p value		
			Social Media	Targeted Emails	In-Person	A	B	C
Had family member or loved ones who suffered from sudden cardiac arrest	521	194 (37%)	143/390 (36.7%)	13/55 (23.6%)	38/76 (50.0%)	0.06	0.03	0.002
Agreed that ACCESS is an important study to do	356	325 (91.3%)	206/223 (92.4%)	47/55 (85.5%)	72/78 (92.3%)	0.11	0.98	0.21
Agreed to being included in ACCESS if they had an out-of-hospital cardiac arrest	354	273 (77.1%)	175/222 (78.8%)	45/55 (81.8%)	53/77 (68.8%)	0.62	0.08	0.09
Agreed to include loved ones in ACCESS if their loved ones had an out-of-hospital cardiac arrest	355	266 (74.9%)	171/221 (77.4%)	45/55 (81.8%)	50/79 (63.3%)	0.48	0.01	0.02
Thought ACCESS researchers would seriously consider what community members have to say about the study before starting it	356	229 (64.3%)	139/222 (62.6%)	30/55 (54.5%)	60/79 (75.9%)	0.21	0.03	0.01
Did not feel that they were given enough information to give an informed opinion	352	70 (19.9%)	52/222 (23.4%)	8/54 (14.5%)	10/75 (13.3%)	0.15	0.06	0.84
Would tell their doctors that they did not want to participate in ACCESS	346	66 (19.1%)	36/214 (16.8%)	10/54 (18.5%)	20/78 (25.6%)	0.77	0.09	0.34

Modified chi-square tests for small sample size were used for between-group comparisons of proportions. Statistically significant chi-squared tests were followed up with post-hoc comparisons of proportions. A = Social Media vs Targeted Email; B = Social Media vs In-Person; C = Targeted Email vs In-Person.

Table 4. Thematic responses to the question, "Please provide below, any additional comments, concerns or questions you would like to share with the ACCESS study team"

Themes	Social Media	Targeted Email	In-Person
Concerns about lack of informed consent	• I do NOT (want) doctors, CNAs, RNs/LPN, PAs, or any other medical professional performing anything to my body without prior consent! • I think informed consent is an absolutely critical thing. If you can't get informed consent from a patient or family member, they shouldn't be a part of the study, no matter how important it is. • It would be my preference for myself or my loved one to be taken to the Cath lab if their cardiac arrest met those requirements and for that reason would prefer not to be enrolled.	• Code status should be determined first. Informed consent whenever possible from next of kin. If both are not possible, send to the most appropriate area for intervention.	None
Concerns about clinical equipoise and randomization	• ACCESS is a bad idea and people will die because they are not receiving treatment they may need • I think it would help if, in this survey, you explained more about a) what is the difference between the two treatments and b) why there is a reason someone would Decline to enroll in the survey. • I would want the best option for my loved one and would be concerned that I might not be	• I'm wondering why if you say v-fib cardiac arrest patients can actually have a clot that doesn't show up on the ekg, why wouldn't you always do the catherization that can actually save the heart? Send them to the ICU only after it is proven there is no clot. That is the only treatment I would agree to.	• Concerned that the study is choosing my care. • Very experienced ICU RN with 29 years and not sure I am a fan of randomizing care when it can be so life threatening • V-Fib [is a] strong predictor of coronary occlusion

	given the best choice if in the study • How are the outcomes with both of these treatments in the past? Has one already shown to be superior? • For myself/loved one for whom I was Health POA, I would authorize that treatment(s) that provided greatest chance of survival and quality of life. • This hardly gives me any information about the study. I don't know what the procedures are for either standard treatment. If they're existing treatments, there also must be some data for their outcomes... • They will be randomly assigned to one of two treatment options. Random means assigned by chance, like the flip of a coin. THIS STATEMENT CONCERNS ME BECAUSE IT SOUNDS LIKE YOU MAY NOT DELIVER THE BEST TREATMENT OPTION BASED ON SYMPTOMS BUT BASED ON A "COIN TOSS". UNDER THESE CIRCUMSTANCES, I WOULD NOT WANT TO PARTICIPATE OR GIVE CONSENT FOR A LOVED ONE. IF THEY WERE GIVEN		

	THE BEST TREATMENT POSSIBLE AND DATA COULD STILL BE COLLECTED, THAT'S A DIFFERENT STORY.		
Confusion about study design	• I don't see language in this proposal as to patient privacy practices, is this a controlled, randomized study, double-blind study, what or who is the control (group) for this study?	• Publish a transparent article describing the equipoise of the two treatment options and financial implications of each arm assignment. This may be better described as comparative effectiveness research.	• I would like to see ACCESS referred to as a "Study" and not "trial" or "research" which both trigger out of the norm treatments. • Be clear that this is comparison of standard of care procedures
Comments about eligibility criteria	• I don't even want out of hospital CPR, otherwise would be happy to participate.	• I think there should be an age limit. Having worked pre-hospital as a Paramedic for 10 years and in the ED for 10 years I feel that more times than not the elderly just want to be "let go".	• Young people < 45 years old less likely to have CAD so why randomize them? (Drug effect, ?arrhythmias, etc)
Survey design issues	• CHANGE/CLARIFY the wording of this question: "Would you like to tell doctors that you do not want to participate in ACCESS?";	• I was asked my background such as age, gender, race, education, etc. how would this information	• I find this questionnaire confusing • Not enough information for decision making

	instead, say "Would you be willing to participate in ACCESS? Yes or No" • I think it would help if, in this survey, you explained more about a) what is the difference between the two treatments and b) why there is a reason someone would Decline to enroll in the survey. • Is cardiac arrest the same as a heart attack? • I wanted to re-read information but the survey wouldn't let me go back one or more pages. Even whey I went out of survey and came back, it put me back in the same spot I began. As a result, my answers may be impacted by lack of understanding. • I think this survey should go into more detail to provide a better explanation. • Your survey design is flawed, if strongly agree is an option, strongly disagree should be included as well.	impact ACCESS selection if allegedly it doesn't impact the treatment selection (lab vs ICU) choice. Treatment transparency relative to Insurance coverage limits is my great concern with ACCESS.	
Suggestions for study improvement	None	None	• A video or website would be helpful • Would like to see a better system in place to opt-out, such as a database to query before approaching

			patient
Support the study	• Great idea! Great study! Good luck! • I believe this is an important study. The rate of survival of someone having a cardiac arrest is low, so it's important to know and understand how we can increase the survival rate and the most effective treatment. • I think this is important in order to help someone. I have had high enzymes and had to go in but no heart attack. I have got some plaque buildup. It is concerning. • Important study	• I think this is an important study anything to improve the out of hospital cardiac arrest patient is beneficial	• Best wishes on your study • Good Luck!
Knew someone who suffered from cardiac arrest	• My father died of cardiac arrest walking through the store. I'm sure he would have signed up for any research that would have allowed him to live longer! He was 59. • My dad had v fib w cardiac arrest and is lucky to be alive today!	None	None
Clarification of survey respondents' demographics	• I don't live in Washtenaw or Livingston Counties - I live in West Michigan but work for C.S. Mott Congenital Heart Center so spend a fair amount of time in Ann Arbor.	• I am an ER doctor at UMICH	• I am a Cath Lab Registered Nurse • I am multiracial • Race is N European

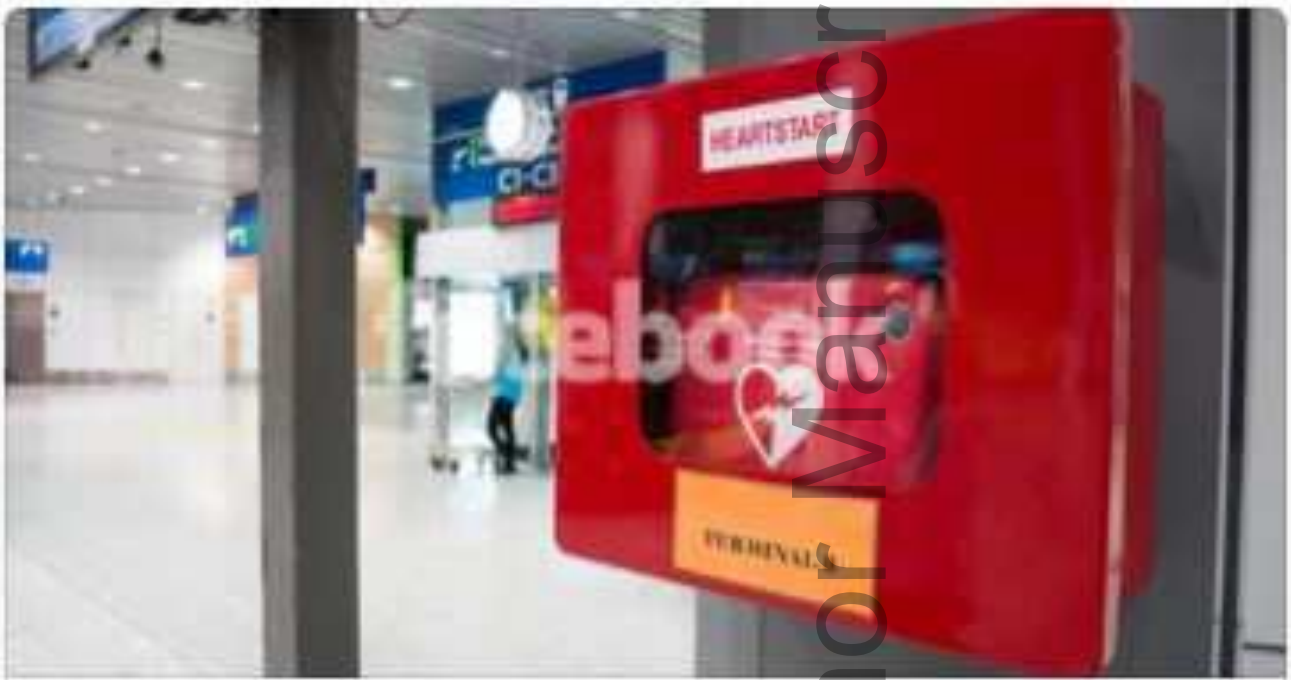
Table 5. Cost Analysis of Community Consultation for ACCESS and EROCA Trials

ACCESS Trial	Research Coordinator Effort			Investigator Effort			Social Media Cost	Total Cost	Surveys Collected	Cost Per Survey
	Hourly salary	Hours	Cost	Hourly Salary	Hours	Cost				
Social Media	$45.42	6	$ 272.52	$195.31	1	$ 195.31	$350	$ 817.83	225	$ 3.63
Targeted Email	$45.42	1	$ 45.42	$195.31	1	$ 195.31	NA	$ 240.73	54	$ 4.46
In-Person	$45.42	30	$ 1,362.60	$195.31	1.5	$ 292.97	NA	$ 1,655.57	80	$ 20.69
Total		37	$ 1,680.54		3.5	$ 683.59		**$ 2,714.13**	**359**	**$ 7.56**
EROCA Trial										
In-Person	$45.42	51	$ 2,316.42	$195.31	8.5	$ 1,660.14	NA	**$3,976.56**	**137**	**$ 29.03**

U-M Health Research

Sponsored

Michigan Medicine needs your opinion about an emergency cardiology research study.

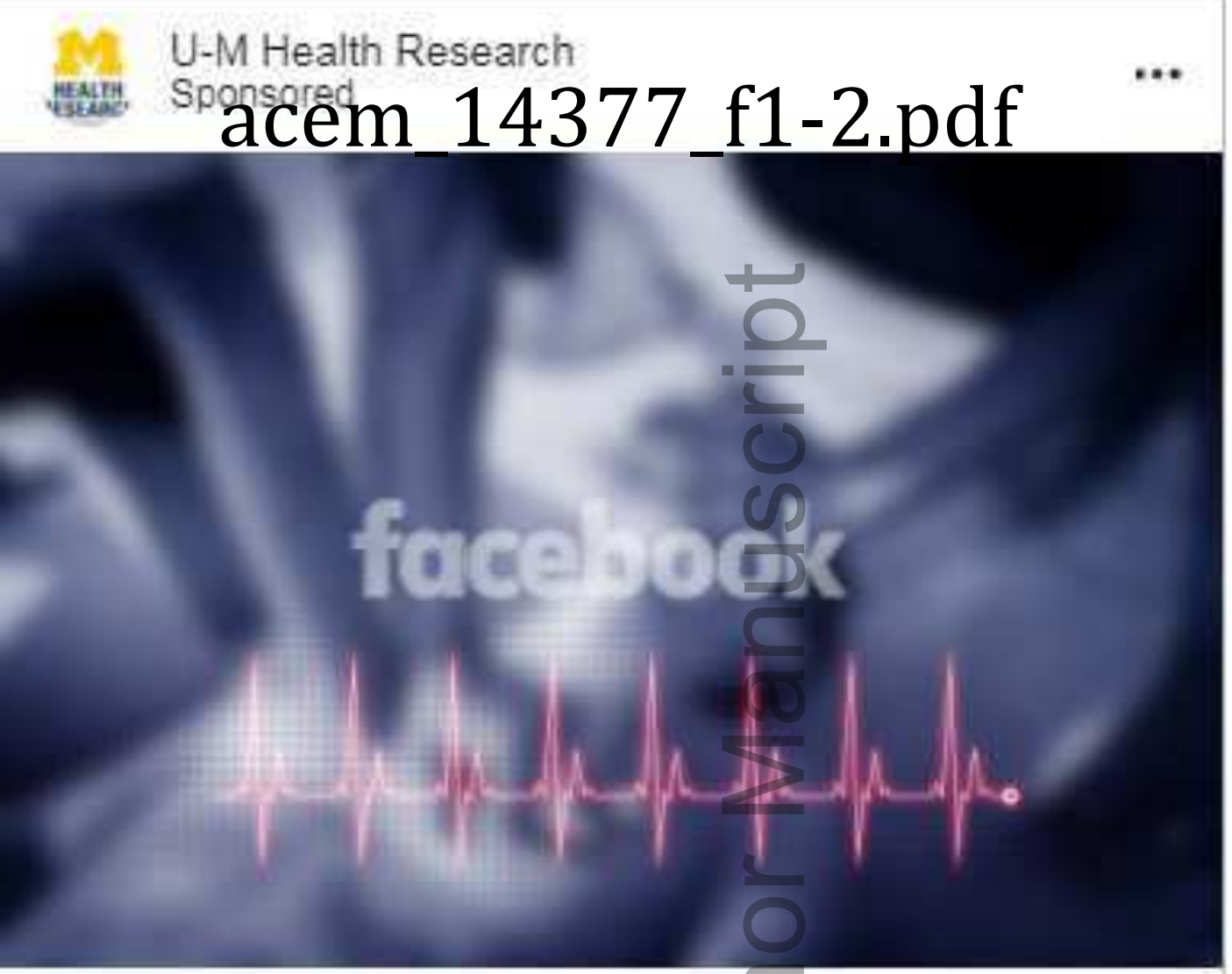


A survey about ACCESS: an emergency cardiac study

umhealthresearch.org

Learn More

Like Comment Share



U-M Health Research

Sponsored

Michigan Medicine needs your opinion about an emergency cardiology research study.

A survey about ACCESS: an emergency cardiac study

umhealthresearch.org

Learn More

Like Comment Share

U-M Health Research

Like Page

Sponsored

Michigan Medicine needs your opinion about an emergency cardiology research study.

A survey about ACCESS: an emergency cardiac study

Volunteers needed to participate in a survey.

UMHEALTHRESEARCH.ORG

Learn More

Like Comment Share

U-M Health Research

Like Page

Sponsored

Michigan Medicine needs your opinion about an emergency cardiology research study.

A survey about ACCESS: an emergency cardiac study

Volunteers needed to participate in a survey.

UMHEALTHRESEARCH.ORG

Learn More

Like Comment Share