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Experimental paper

Measuring the cost and effect of current community consultation and public disclosure techniques in emergency care research☆

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ABSTRACT

Aim: U.S. federal regulations for research involving exception from informed consent (EFIC) include stipulations for community consultation (CC) and public disclosure (PD) (FDA 21 CFR 50.24). Published descriptions of PD campaigns include letters to community leaders, media outreach, paid advertising, and community meetings. Whether or not these activities provide measurable impact is unknown, as few prior works have evaluated PD activities with probabilistic polling. The aim of this study is to use polling to assess how much public awareness PD efforts generate.

Methods: A 3-month PD campaign similar in scope and scale to PD campaigns described in several recent publications was implemented across a large urban county (pop. 2.55 million). PD included a study website (www.evktrial.org), letters to 300 community leaders/organizations, bilingual media outreach and also phased roll-outs, weeks apart, of newspaper advertisements, mass e-mail messaging, and paid advertising in Facebook® and Twitter® augmented by volunteer social media outreach. During PD we used repeated zip code-targeted online polling via Google Consumer Surveys® to assess community awareness of the proposed EFIC study.

Results: Over 3-months all-source exposures to > 1 million individuals were estimated, generating ~5,000 website visits (12-month cumulative, ~9000). However, general community awareness evaluated through repeated county-wide polling never rose above baseline measurements. CC/PD campaign costs were estimated at $60,000 (USD).

Conclusion: A PD campaign in scope and scale common for EFIC studies may not provide measurable impact in a community. Investigators, review boards and regulators could consider these findings when re-examining and/or creating policies for PD for EFIC studies.

Introduction

One of the challenges of emergency clinical research is obtaining informed consent during acute critical illness. Under emergent circumstances it may be impossible to obtain informed consent. In the United States, Title 21 Code of Federal Regulations 50.24 (hereafter FDA 21 CFR 50.24) provides for subjects to be enrolled in a study without informed consent [1]. Clinical trials that enroll subjects under these provisions are often described as "Exception From Informed Consent" (EFIC) clinical trials [2]. FDA 21 CFR 50.24 stipulates that EFIC trials must conduct Community Consultation and Public Disclosure (CC/PD) prior to the start of trial enrollment, and additional Public Disclosure describing study results after completion of the clinical trial [2].

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Community Consultation (CC) and Public Disclosure (PD) are distinct activities that share common elements [2]. CC is an effort to consult with the community about the proposed clinical trial, whereas PD is an effort to disclose the proposed research to the broader community [2]. PD campaigns often offer an opportunity for potential subjects to opt out of the study if they wish [2]. Recent EFIC studies describe PD campaigns that include letters to community leaders, email campaigns, print advertising, media outreach, online and social media advertising, and open community meetings [3–6].

Community Consultation with specific groups will be successful (by definition) once the consultation meetings occur. The effectiveness of PD is much less certain. In particular, very little is known about how well PD campaigns generate public awareness of a proposed emergency clinical trial. We are aware of only one study that used a survey to measure a population's familiarity with an EFIC study [6], and no studies that employed probabilistic sampling techniques necessary to assess how broadly information spreads throughout a community. The financial investment required to perform PD can be substantial, so information about how well PD campaigns achieve their ends is important for weighing costs against benefits.

In this study we assess how effectively a PD campaign increases awareness of an EFIC clinical trial. Our study has two key advantages over previous research. First, past studies assess PD with measures such as website visits or meeting attendance that do not reveal the percentage of a population has learned about a proposed EFIC trial from PD. In contrast, we conduct surveys on samples that are representative of the PD catchment to test how broadly information permeates the target population. Second, our PD campaign encompassed multiple waves (newspaper ads, a social media campaign, email messages, and community meetings) to dissemination of information. We measured knowledge increases via a separate survey associated with each wave. As such, our study is the first designed to isolate and compare the effectiveness of different approaches to Public Disclosure.

Methods

Setting and IRB approval

The parent clinical trial, related EFIC processes and the current analyses were approved by the IRB at UT-Southwestern Medical Center (Appendix 1 in the Supplementary material). The parent clinical trial is a study of etomidate versus ketamine administration prior to emergency endotracheal intubation in the setting of acute critical illness (Etomidate versus ketamine for emergency endotracheal intubation: A prospective randomized clinical trial, NCT02643381, UTSW IRB STU#022015-023). The ongoing clinical trial is being conducted at a single high-volume tertiary-care facility and Level I trauma center serving a very diverse county (Dallas County, pop. 2.55 million; 2,354 km^2).

Specifics about CC and PD methodologies

Community consultation

Formal CC began in mid-2015 before IRB approval of the parent trial. CC was held with the Community Advisory Panel at UT-Southwestern Medical Center. This is a group of approximately 30 community members with a specific interest in clinical and health services research and the relationship between the county health system and the communities it serves. This group's activities are independent of the clinical trial, and are formally supported by Center for Patient-Centered Outcomes Research at UT-Southwestern Medical Center (Stakeholder Engagement Core, Agency for Health Research & Quality, R24HS022418). The Community Advisory Panel provided input to guide the subsequent content and strategy of further outreach, website design, frequently asked questions, media outlets to approach and advertise with, and other related matters. Subsequent Community Advisory Panel meetings are being held on an intermittent basis in an effort to effect continued community engagement about the trial. Finally, letters sent to community leaders and organizations (discussed below) were presented as an opportunity for both CC and PD.

Table 1
Timeline of Public Disclosure Outreach Activity and Respective Polling.

Date (2016)	Survey Activity	Outreach Activity
Jan. 25	Survey 1 (Baseline)	–
Feb. 1–15	–	Newspaper advertisements
Feb. 18	Survey 2 (Newspapers)	–
Feb. 24-March 2	–	Social media campaign
March 3	Survey 3 (Social media)	–
March 17–23	–	E-mail campaign
March 23	Survey 4 (E-mail)	–
April 4, 6, 11	–	Community Meetings
April 19	Survey 5 (Community meetings)	–

Public disclosure

Launched in early 2016, PD processes (using English and Spanish) involved four staggered phases implemented weeks apart, over a 3-month period: 1) newspaper advertising; 2) social media; 3) mass e-mailing; and 4) community meetings (Table 1). Investigators purchased newspaper and Facebook® and Twitter® advertisements (Table 2 and Appendix 2 in the Supplementary material), and the study hospital promulgated information through its own Facebook® and Linked-In® sites. Study team-members provided additional promotion through social media platforms, primarily Facebook®. E-mails were distributed to internal and external listserves, including one with 29,000 potential recipients. Most lists had several-hundred to several-thousand potential recipients (resulting estimate of 50,000 to 100,000 total messages delivered). Open community meetings were also convened.

Advertisements included specific information about the clinical trial, and contact information for individuals interested in receiving more information and/or attending public meetings. Online advertising, primarily through Facebook® and Twitter®, was limited to relatively few characters, and featured "EvK" prominently. Sample advertisements, both online and print, are available in Appendix 2 (in the

Table 2
Public Disclosure Instruments and Related Costs.

Newspaper Advertisements[a]	~$5,000.00
Social Media[b]	~$3,000.00 plus in-kind services
Translation Services	~$1,000.00
Printing, mailings, letters, posters	~$3,000.00
Website production, Maintenance, Licensing	~$1,000.00
Meeting space, facility fees, opt-out supplies	~$1,500.00
Project computer, IT support	~$2,000.00
Online Polling via Google Consumer Surveys®	~$3,000.00
Research Coordinator Costs[c]	~$37,000–$48,000
Total Estimated Costs	$60,000 (range $55,000–$66,000)

[a] Advertisements were purchased and placed in the following newspapers with a combined daily circulation of ~645,000): *Dallas Morning News, Al Día Dallas, Dallas Weekly, Dallas Examiner, El Heraldo News, Southern Dallas Magazine and El Hispano News* (which also published a featurette on the study). Advertising included *Al Día Dallas* ($1,000), *Dallas Morning News* ($1,000) and ~$3,000 among the others.

[b] Social media advertisements were purchased and placed in the social media, primarily through Facebook® and Twitter.® The sponsoring Institutions placed additional advertisement on their websites. Investigative team members contributed additional promotions through a varied number of social media platforms.

[c] Estimate based on fair market value estimates derived from other related studies, the cost per hour would have been or an estimated $37–$48 per hour, at a conservative estimate of 975 hours.