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Utilizing Social Media for Community Consultation and Public Disclosure in Exception from Informed Consent Trials

Shannon W. Stephens, EMTP¹, Carolyn Williams, RN, BSME¹, Randal Gray, EMTP, MEd¹, Jeffrey D. Kerby, MD, PhD², Henry E. Wang, MD, MS¹, and Patrick L. Bosarge, MD²

Shannon W. Stephens: swstephens@uabmc.edu; Carolyn Williams: cswilliams@uabmc.edu; Randal Gray: rgray@uabmc.edu; Jeffrey D. Kerby: jkerby@uabmc.edu; Henry E. Wang: hwang@uabmc.edu; Patrick L. Bosarge: pbosarge@uabmc.edu

¹Department of Emergency Medicine, University of Alabama at Birmingham, Birmingham, AL

²Division of Trauma, Burns, and Surgical Critical Care, Department of Surgery, University of Alabama School of Medicine, Birmingham, AL

Abstract

Background—The U.S. Food and Drug Administration and Department of Health and Human Services outline regulations allowing an Exception From Informed Consent (EFIC) for research conducted in an emergency settings. Acute care clinical trials utilizing EFIC must include community consultation and public disclosure (CC/PD) activities. We describe our experience using social media to facilitate the CC/PD process in two trauma resuscitation clinical trials.

Methods—We conducted local CC/PD activities for two multicenter trauma clinical trials, Pragmatic, Randomized Optimal Platelet and Plasma Ratios (PROPPR) and Prehospital Tranexamic Acid Use for Traumatic Brain Injury (ROC-TXA). As part of the CC/PD process, we developed research study advertisements using the social media website Facebook. The Facebook advertisements directed users to a regional study website that contained trial information. We targeted the advertisements to specific demographic users, in specific geographic areas. We analyzed the data using descriptive statistics.

Results—During the study periods, the PROPPR Facebook advertisement was displayed 5,001,520 times, (12 displays per target population) with 374 individuals selected the advertisement. The ROC-TXA Facebook advertisement was displayed 3,806,448 times (8 per target population) with 790 individuals selecting the advertisement. Respondents to both Facebook advertisements were mostly male (52.6%), with the highest proportion between the ages 15-24 (28.2%). Collectively, 26.9% of individuals that clicked on the Facebook advertisement, spent > 3 minutes on the study website [3min – 49 min]. Commonly accessed webpages were “Contact Us” (PROPPR 5.5%, TXA 7.7%), “Study-specific FAQs” (PROPPR 2.4%), ROC-TXA 6.7%) and

Correspondence & address for reprints: Shannon Stephens, EMTP, Department of Emergency Medicine, University of Alabama at Birmingham, OHB 251 619 19th Ave. South Birmingham, AL 35294-7013, Tel: 205-934-5890, Fax: 205-996-5019, ; Email: swstephens@uabmc.edu.

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“Opt-Out of Research” (PROPPR 2.5%, ROC-TXA 3.8%). Of 51 total individuals viewing the opt-out of research information (PROPPR 19, ROC-TXA 32), Time spent on that specific page was modest (PROPPR 62 seconds, ROC-TXA 55 seconds), with no individuals requesting to opt-out of either study participation.

Conclusion—In clinical trauma trials, using EFIC, social media may provide a viable option for facilitating the CC/PD process.

Level Of Evidence—Descriptive Study, Level IV.

Keywords

Consent; Social Media; Community Consultation; Ethics; Resuscitation

Background

Injury is the leading cause of death in the United States, for individuals between the ages of 1-46 years and an additional 2,000,000 suffer a serious traumatic injury requiring hospitalization.^{1, 2} Clinical advances in acute trauma care have been limited because of the paucity of scientific evidence guiding resuscitation practices. Prospective clinical trials are important for advancing the knowledge base, however because of the emergent nature and the inability of these critically injured subjects to provide informed consent, investigators must often conduct clinical trials of trauma under federal regulations for Exception from Informed Consent (EFIC).

The U.S. Department of Health and Human Services and the Food and Drug Administration (FDA) have issued guidelines for the execution of clinical studies using EFIC.^{3, 4} One of the key steps for EFIC research is “community consultation and public disclosure” (CC/PD), a process that involves consultation between the principal investigator, the institutional review board (IRB), and community members where the research will be conducted. However, the regulations provide little guidance on how to accomplish these key goals. While traditional methods for CC/PD include public meetings and telephone-based surveys, the ability of these modalities to access the target populations, to effectively deliver information about the study, and to elicit useful feedback remain unclear.

The objective of this study was to describe our experience using social media to facilitate the CC/PD process for two trauma resuscitation clinical trials utilizing EFIC.

Methods

The activities for this study, including the use of social media for CC/PD, were approved by the IRB of the University of Alabama at Birmingham (UAB). Both trauma resuscitation trials were conducted by the Resuscitation Outcomes Consortium (ROC). ROC is a collaboration of 10 sites in the United States and Canada dedicated to the study of out-of-hospital cardiac arrests (OHCA) and severe traumatic injury. The ROC catchment area includes a population of 20.5 million persons over a coverage area of 35,500 square miles and treats approximately 7,100 Emergency Medical Services (EMS) treated serious traumatic injuries per year.^{5, 6} The Alabama ROC site includes 10 EMS agencies in the

greater Birmingham, Alabama community, encompassing a population of 650,000 persons over 1,300 square miles, and served by over 1,400 EMS personnel.

The Pragmatic, Randomized Optimal Platelets and Plasma Ratios (PROPPR) trial was a multicenter, prospective, randomized trial which compared different ratios of blood products given to trauma patients who were predicted to require massive transfusions (greater than 10 units of PRBCs within the first 24 hours).⁷ Prehospital Tranexamic Acid Use for Traumatic Brain Injury (ROC-TXA) is a multi-center, Phase II trial designed to determine if Tranexamic Acid (TXA) initiated in the prehospital setting, improves long-term neurologic outcome compared to placebo in patients with moderate to severe TBI who are not in shock.⁸

We created advertisements using the social media website Facebook (www.facebook.com), a leading social networking website (Figure 1). Each advertisement was approximately 110 characters long, appeared on the right-side bar of the Facebook website. When Facebook users clicked on the advertisement, it forwarded the users to the website for the University of Alabama at Birmingham (UAB) Alabama Resuscitation Center (ARC) (www.uab.edu/arc). The ARC website provided information about both trials, frequently asked questions about each study, methods for opting-out of the studies, and contact information for the investigators and the Institutional Review Board. We posted the advertisement for the PROPPR clinical trial from October 01, 2012 through November 31, 2012, and for the ROC-TXA clinical trial from August 01, 2014 through September 30, 2014.

Facebook allows advertisers to target ads to specific user demographics, & specific geographic areas. We targeted our ads to individuals over the age of 15, and people who lived within a 50-mile radius of Birmingham Alabama, our primary trauma population.

We evaluated the social media interface by examining user statistics provided by Facebook and website traffic on the ARC website. User statistics provided by Facebook included the number of advertisement exposures (actual views of the ad), the number of exposures resulting in redirection to the Alabama Resuscitation Center website (the number of individuals who clicked on the advertisement and were redirected to the ARC website), and the listed age and gender of the Facebook user. Information on the race and ethnicity of viewers was not available. We similarly determined user access statistics to the Alabama Resuscitation Center website using Google Analytics (Google, Inc., Mountain View, California, United States). Google Analytics generates descriptive statistics about the usage of a website, including the number of unique visitors to a website, the individual pages visited, and the time spent viewing each page. We analyzed the data using descriptive statistics and comparing the web access characteristics between the PROPPR clinical trial and the ROC-TXA clinical trial advertisements.

Results

From October 01, 2012 - November 31, 2012 the PROPPR Facebook advertisement was displayed 5,001,520 times (12 displays per target population) with 374 individuals selecting the advertisement and redirected to the Alabama Resuscitation Center website. From August

01, 2014 – September 30, 2014 the Facebook ROC-TXA advertisement was displayed 3,806,448 times (8 per target population) with 790 individuals selecting the advertisement and redirected to the Alabama Resuscitation Center website.

Respondents to both Facebook advertisements were mostly male (52.6%), with the highest proportion between the ages 15-24 (28.2%) [Table 1]. For both trauma trials, ARC website engagement was brief (0-10 seconds) for most respondents (PROPPR 29.9%, ROC-TXA 30.4%) [Table 2]. The most commonly accessed web pages on the ARC website were “Faculty & Staff” (PROPPR 15.2%, ROC-TXA 18.2%), “Q&A about trauma research” (PROPPR 7.3%, ROC-TXA 10.8%), “Contact Us” (PROPPR 5.5%, TXA 7.7%), “Training” (PROPPR 5.2%, ROC-TXA 6.2%), “Study-specific FAQs” (PROPPR 2.4%), ROC-TXA 6.7%) and “Opt-Out of Research” (PROPPR 2.5%, ROC-TXA 3.8%). Of 51 total individuals viewing the opt-out of research information (PROPPR 19, ROC-TXA 32), time spent on that specific page was modest (PROPPR 62 seconds, ROC-TXA 55 seconds), with no individuals requesting to opt-out of either study participation.

Discussion

Social media has emerged as a powerful tool for international communications. Since its inception in February 2004, Facebook has acquired more than 1.49 billion active users worldwide.⁹ Of the 310 million residents in the US, 156 million (50.3%) have a Facebook account. American internet users devote more time to Facebook than any other website, spending a total of 53.5 billion minutes a month, or 39 minutes per user, each day on Facebook.⁹ Social media is arguably a favored means of social interaction and has influenced interactions between individuals and their local communities and communities around the world.¹⁰⁻¹³ Our observations illustrate a novel approach using social media to facilitate the CC/PD process in EFIC trials. Through the use of social media, we were able to efficiently reach a large audience.

One of the most important barriers to conducting acute care research is the limited ability to obtain informed consent from critically ill patients. Many of these individuals are unconscious or in an immediately life-threatening state, precluding the ability to obtain formal written or verbal informed consent. The federal EFIC rules were developed in 1996 to allow for waiver of obtaining and documenting informed consent for a strictly limited class of research. This waiver outlines specific research activities that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained. This action was in response to growing concerns that regulations requiring informed consent were making high quality acute care research activities difficult or impossible to conduct, especially immediately after a subject exhibits physiological symptoms and when enrolled, could maximize the potential benefit of the investigational intervention. This therapeutic window, as defined by the FDA, is the time-period during which administration of the intervention might have reasonable changes of producing a positive clinical effect.

Among the salient components of EFIC research rules are the requirements for Community Consultation and Public Disclosure. Encompassing the bidirectional flow of study information between investigators and at-risk community members, Community Consultation contains three primary objectives: 1) to explain the nature, possible risks and benefits of the research intervention, 2) to inform the community that informed consent will not be obtained before study enrollment, and 3) to explain the process by which potential subjects can refuse to participate. Involving the unidirectional flow of information from investigators to the general public, Public Disclosure includes: 1) prior to study initiation, explanation of the study plan, including the risks and benefits of participation, 2) after study completion, disclosure of the results and subject demographics.

There is substantial variation in how Institutional Review Boards interpret the federal regulations for community consultation and public disclosure.¹⁴⁻¹⁶ Methods of community consultation included in the 1996 guidance 21CFR50.24 - Code of Federal Regulations, Protection of Human Subjects,³ involved the use of town hall meetings with community members, focus groups, and random digit dialing phone surveys. In 1996 when these consultation methods were outlined by the FDA, just 20 million American had access to the internet in their homes, compared to 90 million homes today.¹⁷

While varying in scope, a traditional community-meeting format includes a brief presentation of the study in non-technical language followed by a question-and-answer session. Prior studies suggest that community meetings are often logistically complex, inefficient, and expensive. Additionally, community meetings access a limited audience and typically yield few questions.¹⁸⁻²⁰ In the Control of Major Bleeding after Trauma (COMBAT) trial, the investigators presented study material at 16 community forums over four months at an expense of \$84,000.²¹ In the ROC trial of hypertonic saline for major trauma, in the Birmingham, Alabama region we conducted 39 community meetings, costing \$18,000 and garnering a total attendance of only 465 participants (\$38.70 per person). In contrast, the social media campaign described in this report cost \$1,000, resulting in 5.1 million views of the Facebook advertisement (\$0.0002 per view) and 374 visits to the study website (\$2.67 per visitor). Similarly, the ROC-TXA social media campaign cost \$1,000, resulting in 3.8 million views of the Facebook advertisement (\$0.0003 per view) and 790 visits to the study website (\$1.27 per visitor). While there are no existing measures or standards to determine the adequacy of CC/PD, compared with traditional approaches, our social media strategy clearly reached a larger audience. This is consistent with other attempts to utilize Facebook to disseminate information related to resuscitation research.²²

Some studies have used “random-digit-dialing” telephone surveys to augment the CC/PD process, but this strategy is expensive and laborious, and may become obsolete as fewer people elect to maintain home telephones. Many also view uninvited phone calls as intrusive.

There are clearly tradeoffs between social media and traditional methods of CC/PD. While the advertisement was exposed to a large number of persons, we observed relatively modest rates of study website access. Respondent characteristics were also skewed, with primarily younger males and females responding to the advertisements. We were unable to ascertain

the quality of information uptake or retention by users who viewed the research website, which may be modest in light of the relatively short time durations spent on study web pages. The research website utilized relatively static content with no multimedia content; the latter may have increased or improved user engagement.

Prior reports suggest that up to one-third of the US population does not use social media. Efforts to leverage social media for CC/PD must account for these demographic gaps. For example, men are less likely to use social media than women (62% vs 71%). Non-Hispanic whites, individuals over the age of 65, and rural residents are less likely to use social media. Ironically, social media use is lowest in the highest annual household income group (> \$75,000).⁹ CC/PD efforts must include alternate strategies to target these gap populations.

Prior studies have used social media to facilitate medical research but focused on subject recruitment and follow-up.¹⁰⁻¹² We believe that our efforts are among the first to use social media for CC/PD activities.²² These examples, as well as our current effort illustrate novel ways to leverage social media to facilitate medical research.

The scale, breadth, and reach of social media are clearly appealing. Social media is arguably a patient-centered approach to CC/PD, as it capitalizes upon a favored communication modality in the US and allows individuals to choose if and how they will respond to solicitations. Further research must elucidate how to optimally leverage this modality for medical research while safeguarding protected health information as well as the rights of individuals as research subjects. As society's communication practices migrate to social media and computer-based networks, social media may one day emerge as one of the best ways to interface with research subjects.

Conclusion

In clinical trials using exception from informed consent, social media may provide an additional option for facilitating the community consultation/public disclosure process.

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Trauma Research Study

Trauma is a leading cause of death in the US. UAB is conducting a research study to improve trauma care. [Click here for more information.](#)

Figure 1. Examples of social media advertisements

Demographics of individuals accessing information through the PROPPR & ROC TXA research study advertisement

Table 1

Sex Group	Age Group	Number of Respondents Accessing PROPPR Study Advertisement (n=374) (N=%)	Sex Group	Age Group	Number of Respondents Accessing TXA Study Advertisement (n=790) (N=%)
Female	13-17	48	Female	15-17	153
Female	18-24	33	Female	18-24	51
Female	25-34	31	Female	25-34	30
Female	35-45	21	Female	35-44	22
Female	45-54	17	Female	45-54	25
Female	55-64	15	Female	55-64	76
Female	65-100	10	Female	65-100	23
TOTAL		175	TOTAL		380
		46.8%			48.2%
Male	13-17	38	Male	15-17	106
Male	18-24	36	Male	18-24	61
Male	25-34	35	Male	25-34	58
Male	35-44	33	Male	35-44	53
Male	45-54	28	Male	45-54	70
Male	55-64	22	Male	55-64	47
Male	65-100	7	Male	65-100	15
TOTAL		199	TOTAL		410
		53.2%			52.0%

Table 2
Duration of visits to the study website

Visit Duration	PROPPR Page Views (n=710) (N=%)		ROC TXA Page Views (n=807) (N=%)	
0-10 seconds	212	29.9%	245	30.4%
11-30 seconds	71	10.0%	69	8.6%
31-60 seconds	82	11.5%	105	13.0%
1 minute - 3 minutes	154	21.7%	143	17.7%
3 minutes - 10 minutes	87	12.3%	96	11.9%
10 minutes - 30 minutes	71	10.0%	85	10.5%
Greater than 30 minutes	33	4.6%	64	7.9%

Table 3
Web pages visited by those accessing the Alabama Resuscitation Center web site

UAB Webpages visited	PROPPR Pages visited (n=751) (N=%)	Avg. Time on Page	ROC TXA Pages visited (n=839) (N=%)	Avg. Time on Page
ARC home page	371	49.4%	202	24.1%
ARC faculty	114	15.2%	153	18.2%
Q & A = trauma research	55	7.3%	91	10.8%
Contact-us	41	5.5%	65	7.7%
Training	39	5.2%	52	6.2%
Stats	27	3.6%	44	5.2%
Training/critical care	25	3.3%	61	7.3%
Questions & answers = ROC	23	3.1%	49	5.8%
Participating EMS agencies	19	2.5%	34	4.1%
Study-specific FAQ	18	2.4%	56	6.7%
Opt-Out of ROC Research	19	2.5%	32	3.8%