Social Media and Community Engagement in Trials Using Exception From Informed Consent

Katherine C. Chretien, MD

The field of emergency research has come a long way. Once stymied by the difficulties in obtaining informed consent from patients with catastrophic injury or illness, the Food and Drug Administration (FDA) and the Department of Health and Human Services published regulations 21 CFR 50.24 in 1996 to guide the ethical and legal conduct of emergency research using exception from informed consent.¹ For studies to qualify, subjects must have a life-threatening condition, available treatments are unproven or unsatisfactory, valid scientific evidence is needed to determine the safety and efficacy of the intervention, and obtaining informed consent is not feasible.² Because these critically ill patients are quintessential vulnerable subjects, 21 CFR 50.24 incurred extra responsibilities for parties involved in such research including consultation with communities from which subjects would be drawn and public disclosure of information before study commencement and after study completion (Table).¹ These guidelines are used in studies evaluating FDA-approved therapies and devices and other interventions not under the direct purview of FDA, as well. Local institutional review boards (IRBs) have the responsibility to review a study’s plans for community consultation and public disclosure (CC/PD) and to ensure their adequacy. The FDA recommends that IRB members attend community consultation activities to hear community views and inform their decision as to a study’s disposition.²

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Traditional approaches to CC/PD have not been particularly successful in eliciting community attitudes toward research or informing communities of planned research. Commonly used methods include community meetings (town halls), random-digit telephone dialing, traditional media (print, television, radio), and Web sites. Among emergency department patients, awareness of an ongoing study involving the exception from informed consent that had used 5 community meetings, local newspaper, television, and radio spots, and brochures distributed at a community health fair was low at 8% of those surveyed.³ Acceptance of the study differed between certain demographic groups and was much lower than a previous study that surveyed subjects who had attended a CC/PD community meeting, pointing to a possible selection bias of who chooses to attend such meetings.³ Town hall–style community meetings often yield few questions and discussion.⁴ Furthermore, traditional methods are often expensive and time-consuming.

Noting the guidance ambiguities resulting in delays in IRB approval and heterogeneity in practice, in 2007, Halperin et al⁵ proposed different levels of CC/PD based on the degree of incremental risk involved in a study, while taking into account a community’s potential sensitivities. Yet, existing guidance remains broad, and there are no specified metrics of community engagement or understanding.¹² New low-cost, effective, and efficient methods of community engagement are needed to improve this critical process. Social media, with their qualities of rapid dissemination, message amplification, broad reach, and appealing price tag (most are free) would seem, on the surface, to be a promising solution. But like social media’s emerging role in clinical care,⁶ careful consideration of the ethical implications and outcomes may bring important issues to light.

In this issue of Circulation, Stephens et al⁷ describe their preliminary experience using the widely popular social networking site Facebook to mediate community consultation and public disclosure (CC/PD) in 2 studies involving emergency research. Their study represents the first known report in the literature that uses a social networking site for CC/PD. In their study, Stephens et al used Facebook advertisements to target visitors to the study Web site for 2 separate clinical trials: one studying standard cardiopulmonary resuscitation versus continuous compressions in out-of-hospital cardiac arrests, and one comparing standard versus limited volume crystalloid resuscitation in hemorrhagic shock.⁷ Clicking on the ≈110-character-long advertisements took Facebook members to the study Web site where the study was explained in layman’s terms, information given on how to opt out of the study, and contact information given for the investigators and the governing IRB. The authors report overall Web site traffic data (number of visitors to the Web site) and Facebook-supplied advertisement-related analytics (the age and sex of those who clicked on the ad); they note a substantial cost savings by using social media in comparison with the traditional town hall meeting sometimes used for CC/PD, based on a per person or per Web site visitor estimate. They conclude that social media can serve as an additional option for facilitating the CC/PD process. There was no mention of alternate methods of CC/PD used for these 2 studies.

From this study, 2 major questions arise: (1) Should social media ever serve as the sole method for CC/PD? (2) How should social media ideally be used to facilitate CC/
that have a Cardiac Arrest survive. University of Alabama is conducting a Cardiac Arrest Study. Click here for more information.” Community interest and response might have differed if the advertisement read, “Learn about a Cardiac Arrest Study that could enroll you or a loved one if you live near Birmingham. Click here for more information or to opt out.” There should be transparency; regardless of the incremental risks involved, communities that will participate must be informed and be able to express any concerns, especially given the mistrust rampant in certain communities toward medical research.

For these reasons, it is difficult to imagine a scenario where social media could be used as a sole method for CC/PD without further attention to the populations missed, better methods to engage, and further study to determine the understanding, engagement, and active participation of the community.

How Should Social Media Ideally Be Used to Facilitate CC/PD in Emergency Research That Uses Exception From Informed Consent?

As an adjunct, social media could complement other traditional approaches to CC/PD. To be effective for community consultation, features that encourage active discussion such as chats (video or text-only) and forums could be used, with IRBs able to review transcripts or chat recordings or to observe in real time. Additional demographic data should be collected to ensure that all subgroups, particularly the most vulnerable – lower socioeconomic status, the elderly – are properly represented by the end of all CC/PD activities, both online and offline. Truth in advertising must be sought to encourage important discussions about the acceptability of studies within a particular community with inherent sensitivities. Social media can play an important role in CC/PD if done thoughtfully and designed to maximize engagement and document understanding. More studies are needed to determine how this is best done.

More broadly, the emerging role of social media in medical research has generated new questions for human subject protection spanning issues such as privacy (Are IP addresses identifiable?), data ownership (Do data ultimately belong to third-party Web sites?), informed consent (Is informed consent necessary when performing studies on public Web site content and postings, and, if so, how should researchers obtain it?), and access (Who has access and what groups are being excluded?). Guidance from the FDA and other research regulatory bodies on social media use in medical research is lagging, leaving individual IRBs trying to negotiate the power of social media to facilitate research while ensuring human subject protection in a rapidly changing world. This guidance is a pressing need.

In sum, social media bring promise as a tool for CC/PD, as in medical research in general, but more work and thought are required to produce desired outcomes and to ensure that the use of social media is ethical and just. Clearly, emergency research is an important societal need: we need to advance medical science for individual patients and for the good of all. Yet, we also have a duty as investigators, as IRBs, as members of the medical profession, to fully inform, even if consent is not the goal. The methods by which we do this need to stand

Table. Key Elements of the Community Consultation and Public Disclosure Process

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<th>Element</th>
<th>Description</th>
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<tr>
<td>Community consultation involves the people who are more likely to be affected by the research.</td>
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<tr>
<td>Community consultation invites discussion from a broad sample of community members and representatives to inform IRB deliberations of whether and how a study should go forward (ie, 2-way communication).</td>
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<tr>
<td>Community consultation should make communities aware of any opt-out mechanisms (although opt-out mechanisms are not required by the FDA).</td>
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<tr>
<td>Public disclosure before the study begins disseminates information about the study to the community, including study procedures, risks, and expected benefits, and states that informed consent will not be sought for most participants.</td>
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<tr>
<td>Public disclosure after the study is completed informs communities, the public, and researchers of the study results.</td>
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<tr>
<td>Public disclosure materials should be easily understandable and disseminated widely (multiple forums and media sources recommended).</td>
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FDA indicates US Food and Drug Administration; and IRB, institutional review board.

PD in emergency research that uses exception from informed consent?

Should Social Media Ever Serve as the Sole Method for CC/PD?

A major barrier to social media’s use as a sole method of CC/PD is, as Stephens et al rightfully note, that certain subgroups are not using it. Approximately 20% of Americans do not access the Internet, and these people are generally older and poorer and have lower levels of education. Americans living with disabilities are also less likely to use the Internet than those without a disability (54% versus 81%). Of those Americans who use the Internet, only half access social networking sites such as Facebook. Full CC/PD simply cannot occur when certain subpopulations, vulnerable populations who are more likely to require emergency medical services, are not invited to the discussion.

Stephens et al created 2 Facebook advertisements that were targeted to different age groups to match the most likely age groups that would be involved as study participants. The cardiac arrest trial was shown to Facebook users >40 years of age in a 50-mile radius of Birmingham; respondents were predominantly female and in the age groups 35 to 44 and 45 to 54. The trauma trial advertisement was shown to users 15 to 44 years of age in the same geographic area; respondents were predominantly female and in the 13 to 17 age group. For both advertisement referrals, the majority of respondents spent <10 seconds on the study Web site (75% and 79%, respectively), indicating a preponderance of fleeting visits. There were no questions or comments from respondents noted. Although there are no established metrics of adequate community engagement, this would not seem to meet the requirement of community consultation. Demographic data for race and socioeconomic status of respondents were not available.

The limited-character advertisements themselves may not adequately convey why potential visitors should learn about the study and be involved in the discussion with investigators. For instance, for the cardiac arrest trial, the advertisement read: “Cardiac Arrest Research. Less than 5% of people
up not only to published regulations, but also to an even higher standard of what is right.

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Disclosures
None.

References

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