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Impact of Social Media on Community Consultation in Exception from Informed Consent Clinical Trials

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ABSTRACT

Background: Exception from informed consent (EFIC) allows clinician scientists to perform much needed emergency research. Obtaining this exception, however, requires many meetings with community groups for consultation, which can make the process time-consuming and expensive. We aim to determine the impact of using social media in lieu of some community meetings in an effort to obtain an EFIC.

Materials and methods: An economic analysis of four randomized clinical trials was performed. Costs were conservatively estimated using personnel costs, social media costs, and adjusted to 2016 US dollars. People were considered reached if they attended a community meeting or were directed to the study website by social media and spent ≥1 min.

Results: The Early Whole Blood study required 14 meetings, reached 272 people, and cost $8260 ($30/person reached). The Pragmatic, Randomized Optimal Platelet and Plasma Ratios study required 14 meetings, reached 260 people, and cost $7479 overall ($29/person reached). The Prehospital Tranexamic Acid Use for Traumatic Brain Injury study required 12 meetings, reached 198 people, and cost $6340 ($32/person reached). Only the damage control laparotomy trial utilized social media in lieu of some community meetings. The damage control laparotomy trial required six meetings at which 137 people were reached. The $1000 social media campaign reached 229 people. The cost was $3977 overall and $11/person reached.

Conclusions: Including a social media campaign during the EFIC process increased the number of potential patients reached and reduced total and per person costs reached costs. Obtaining an EFIC for future emergency clinical trials may be facilitated by the inclusion of a social media campaign.

Introduction

A recent call to action to achieve zero preventable trauma deaths has identified the need to address regulatory barriers to performing high-quality research for emergency interventions in injured patients.[1] A major ethical and regulatory burden to performing research on emergency interventions is the inability to obtain individual informed

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consent, often due to altered mental status, distracting injury, and/or the need to provide time-sensitive interventions. To address this burden, the federal government provides a mechanism to allow for Exception from Informed Consent (EFIC) if the trial meets certain criteria.[2] The specific mechanisms by which institutions grant EFIC are varied and poorly reported, leading to wide variation in institutional perceptions regarding EFIC across the United States.[3] At our institution, the process to obtain EFIC, including the specification of the number of community meetings required, was developed by our institutional review board (IRB) decades ago without significant changes since. That process traditionally involved 12-15 consultative meetings with community groups and public notification via advertisements and other traditional media. This process is time-consuming, expensive, and constitutes a significant barrier to research involving emergency interventions.

In an effort to address this burden, the investigative team and university IRB developed a pilot hybrid EFIC model by combining traditional community consultation meetings with modern means of communication—social media.[4,5] This hybrid model was created with the dual goals of increasing the ability to reach more potential patients than community meetings allow and decreasing the cost of obtaining EFIC. This hybrid model was then used to obtain EFIC for an ongoing, comparative effectiveness clinical trial on damage control laparotomy (ClinicalTrials.gov NCT02706041).[6]

The purpose of this study was to evaluate the reach and cost of this hybrid model compared with traditional EFIC models used at our institution. We hypothesized that the hybrid model would increase the number of potential patients reached and reduce costs. We also aim to report the potential barriers faced using social media for EFIC and future strategies to address these challenges.

Materials and methods

According to guidance published by the IRB, the present project was not regulated human research.[7]

Trauma surgeons and research personnel from UT Health have obtained EFIC for four randomized clinical trials performed at the Red Duke Trauma Center at Memorial Hermann Hospital-Texas Medical Center in the last decade. The four trials included in this analysis were as follows: 1) the Early Whole Blood study (EWB; ClinicalTrials.gov NCT01227005),[8] 2) the Pragmatic, Randomized Optimal Platelet and Plasma Ratios study (PROPPR; ClinicalTrials.gov NCT01545232),[9] 3) the Prehospital Tranexamic Acid Use for Traumatic Brain Injury study (TXA; ClinicalTrials.gov NCT01990768), and 4) the DCL Trial (ClinicalTrials.gov NCT02706041).

The traditional EFIC model developed locally at our institution included 12-15 community meetings, advertisements in local media, and interviews on local radio/television programs. There is no predefined minimum number of people needed to be in attendance at these meetings in order for the IRB to approve the EFIC effort. This traditional model was used for the EWB, PROPPR, and TXA trials.

In collaboration with the IRB, investigators created a hybrid model of EFIC combining six planned community meetings in addition to a social media campaign. The results of the two activities would then be presented to the IRB to either recommend additional community meetings or allow the trial to begin enrollment. An advertising campaign was developed using Facebook, targeting people ≥16 y within 150 miles of Houston, Texas (the catchment area of the Red Duke Trauma Center). When a user on Facebook clicked on the ad, they were taken to the clinical trial's website (https://www.uth.edu/cetir/research/dcltrial/), which had information on emergency research and EFIC, frequently asked questions, a description of the study and study personnel, a mechanism to opt out of the study, and an email address where questions could be sent. The DCL Trial was the only study to utilize social media in the hybrid EFIC model.

Personnel costs were conservatively calculated using standardized estimates of personnel hours and salaries. Involved personnel include the research coordinator, an IRB representative, and the principle investigator.

Personnel hours

The number of hours required by the research coordinator to arrange community meetings was known for all four trials. To adjust for increased efficiency of arranging these meetings as personnel accumulated experience with each trial, the average number of hours required to coordinate a single community meeting for all four trials was used to estimate the required time to arrange a single meeting in the economic analysis. The hours required to perform the community meetings were estimated to be 1.5 h for the three individuals who attended each meeting: the research coordinator, the representative of the IRB, and the principle investigator.

Personnel salaries

The personnel salaries were estimated to be $70,000 for the research coordinator, $70,000 for the IRB representative, and $300,000 (assistant professor of surgery salary) for the principle investigator.

Overall costs were then calculated by adding the estimated personnel costs to arrange the community meetings (research coordinator hours arranging meetings multiplied by salary), the personnel costs to perform the meetings (1.5 h for each the research coordinator, IRB representative, and principle investigator multiplied by respective salary), and the social media cost (a known amount). Costs were then inflated to 2016 US dollars.

Costs not included in this estimate include opportunity costs, traditional media costs, and website development costs. Opportunity costs were not included as they could not be accurately estimated. Traditional media advertisements were also not included as these are not heavily used methods of community consultation at our institution, and the actual cost of these in each trial was more reflective of temporal factors and not a required, prespecified amount of money that must be spent or specific media that must be used. Website cost information was not included as there was not enough information regarding the cost of each website, if one was created. The TXA website was created by a national coordinating center but not used by our institution. Cost information