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Clinical paper

Application of digital engagement tools for exception from informed consent community consultation and public disclosure in the pediatric prehospital airway resuscitation trial *



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Abstract

Background: Emergency care trials may require compliance with federal Exception from Informed Consent (EFIC) regulations, including community consultation (CC) and public disclosure (PD). The reach of traditional CC and PD modalities is limited. We describe the application of novel digital engagement tools to enrich CC and PD in a pediatric emergency care trial.

Methods: In support of EFIC CC and PD efforts for the Pediatric Prehospital Airway Resuscitation Trial (Pedi-PART), a multicenter trial of paramedic airway management in critically ill children, we deployed two digital engagement tools: 1) social media advertisements, and 2) marketing research panels. We disseminated social media advertisements (Facebook and Instagram) describing the study to targeted users in 10 communities. We determined social media advertisement impressions and engagements (shares, reactions, saves, comments, likes and clicks). We also disseminated community surveys using a marketing research panel (Qualtrics Marketing Research Services), determining the number of completed surveys, time to achieve 200 surveys, demographics of survey respondents and percentage with supportive responses.

Results: There were 23.3 million social media advertisement impressions (range 1.8–2.7 million per community) reaching 3.4 million unique users (range 239,494–439,360 per community) and resulting in 13,873 engagements (range 828–1,656 per community). Distribution of the community survey through the marketing research panel resulted in 6,771 completed surveys (range 531–914 per community). Across communities, time to 200 completed surveys ranged from 5-28 days. Survey respondents were 61.9% female, 27.0% minority race and 40.8% household income <\$50,000. Most survey respondents (90.7%) supported the trial.

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Conclusions: Digital engagement tools efficiently reached a large and diverse population and yielded key community feedback to inform research trial deployment. Digital engagement tools offer valuable techniques to enrich EFIC CC and PD efforts.

Keywords: Emergency Medical Services, Airway management, Exception from informed consent, Clinical trials

Introduction

Clinical trials are essential for advancing knowledge of therapeutic interventions. Obtaining informed consent may be difficult or impossible for clinical trials of critical conditions such as cardiac arrest. major trauma and respiratory failure, where patients are unable to participate in research consent discussions and there is inadequate time to obtain informed consent from a legally authorized representatives. Federal Exception from Informed Consent (EFIC) regulations (US Department of Health and Human Services 45 CFR 46.101 and Food and Drug Administration 21 CFR 50.24) allow for clinical trial execution in emergent settings with an exception to the requirement for obtaining informed consent.² The application of EFIC entails additional challenges when applied to research with children. Compared with adults, children may experience different illnesses, parents or legally authorized representatives have a more prominent role in consent and decision making, and community stakeholders may exhibit different thresholds of support for the research.

Important requirements of EFIC are community consultation and public disclosure (CC and PD). The former refers to the bi-directional exchange of information between investigators and communities about the study, including obtaining community feedback. The latter refers to the process of informing the public about the study, its risks and benefits and the circumstances under which it will be conducted. Traditional approaches to CC and PD such as public meetings, community forums, newspaper, television advertisements, interviews, community group discussions, and manual and telephonic surveys have limited capacity to reach and penetrate communities. Modern digital engagement tools such as social media and marketing research panels offer novel tools for reaching and engaging communities on a scale not possible with traditional methods. While previously used in adult EFIC trials, these tools have not been applied in research involving children. 6–11

The Pediatric Prehospital Airway Resuscitation Trial (Pedi-PART) is a national multicenter trial comparing paramedic airway management strategies in critically ill children. In this report, we describe the centralized deployment of digital engagement tools to enhance CC and PD outreach efforts for the Pedi-PART trial.

Methods

Study design and setting

Pedi-PART (NCT 06364280) is a multicenter clinical trial comparing different strategies for paramedic prehospital advanced airway management. Conducted by the Pediatric Emergency Care Applied Research Network (PECARN) and supported by grants from the National Heart, Lung and Blood Institute, the trial is taking place in 10 US cities and surrounding metropolitan areas: Austin, TX; Charlotte, NC; Columbus, OH; Colorado (Denver, Aurora and Colorado Springs, CO); Indianapolis, IN; Los Angeles, CA; Milwaukee, WI; Sacramento, CA; Tucson, AZ and Washington, DC.

Inclusion criteria for Pedi-PART include children ages 1 day through 17 years requiring paramedic prehospital airway management due to cardiac arrest, traumatic injury, or other causes of respiratory failure. ¹² The trial interventions include strategies of: bag-valve-mask (BVM) only, BVM followed by supraglottic airway insertion (SGA), and BVM followed by endotracheal intubation (ETI). The primary outcome is 30-day intensive care unit (ICU)-free survival. The trial uses an adaptive strategy, with BVM-only compared to SGA in Stage I of the trial, and the winner of Stage I compared to ETI in Stage II. Pedi-PART will enroll 3,000 subjects, with division of subjects across the two stages of the trial based on Bayesian interim analyses conducted every 300 subjects.

Overview of community consultation and public disclosure activities

For Pedi-PART, CC and PD activities consisted of a combination of centrally and locally deployed engagement activities. Centrally deployed activities included social media and community survey campaigns coordinated by the Center for Injury Sciences of the University of Alabama at Birmingham. Locally coordinated activities included newsletters, posters, email, presentation at public meetings, and interviews with individual community members. The University of Utah Institutional Review Board (IRB) serves as the single IRB for Pedi-PART. The single IRB approved each community's CC and PD plan, including the centrally and locally coordinated elements, prior to their deployment.

Digital engagement tools

The digital engagement tools deployed in support of CC and PD efforts included 1) social media advertisements and 2) marketing research panels.

For the social media advertisements, we used the platforms Facebook and Instagram. (Appendix 1) The advertisements included emergency medical services (EMS)-related graphics and text related to prehospital airway management in children. We linked the advertisements to community specific websites providing information about the trial, including an overview of the study objectives, population, interventions, outcomes, and study contact information. (Appendix 2) The website allowed visitors to leave feedback and to access the community survey. The advertisements and study websites were built in both English and Spanish.

Deployment of the social media advertisements targeted select registered users using two strategies: 1) the geographic catchment area of each participating site, and 2) zip codes within the catchment area with high frequencies of pediatric EMS calls. While we enabled viewing of social media advertisements by users ages 18–65 years, we targeted users fitting the demographic profile of parents with children ages 3–17 years. The social media platforms do not allow targeting of individuals based on race/ethnicity or those under 18 years of age. We operated the social media campaign for a total of 61 days in each community.

For the marketing research panels, we devised a community survey encompassing questions related to the trial. (Appendix 3) The

survey included a one-page summary of the trial with the option to view a 1-minute video describing the study. Survey questions explored participant beliefs in the need for emergency medical research as well as receptiveness to the proposed trial. The survey also allowed for the provision of free-text comments. User demographics requested by the survey included age, sex, race, ethnicity, education, income, number of household residents, zip code and employment as a health care provider. The survey was available in both English and Spanish.

We deployed the community survey using Qualtrics Consumer Panel (Qualtrics International, Inc., Provo, UT), a commercial marketing research platform. ¹³ Qualtrics Consumer Panel is a service that provides clients access to a diverse and targeted group of respondents for survey-based research. While intended primarily for marketing research, the system has been leveraged for scientific purposes. ^{14–16} The service uses multiple recruitment tools, including website intercept recruitment, member referrals, targeted email lists, gaming sites, customer loyalty web portals, permission-based networks, and social media. The panel includes a broad and diverse range of participants representative of targeted communities. Panel members may be compensated for participation. Qualtrics applies multiple measures to ensure the quality of the surveys, including

Table 1 – Social media campaign results. Site level results provided in Appendix 4.	
Characteristic	Total
Total population in catchment area/geographic radius (persons) – n	31,985,140
Advertisement reach (users) – n	3,355,160
Advertisement impressions – n	23,291,572
Advertisement impressions per population – n per 1,000 persons	104.90
Advertisement impressions per users – n per user	6.70
Engagement (Clicks, emojis, shares, comments) - n	13,594
Engagement rate – n per 1,000 population	0.43

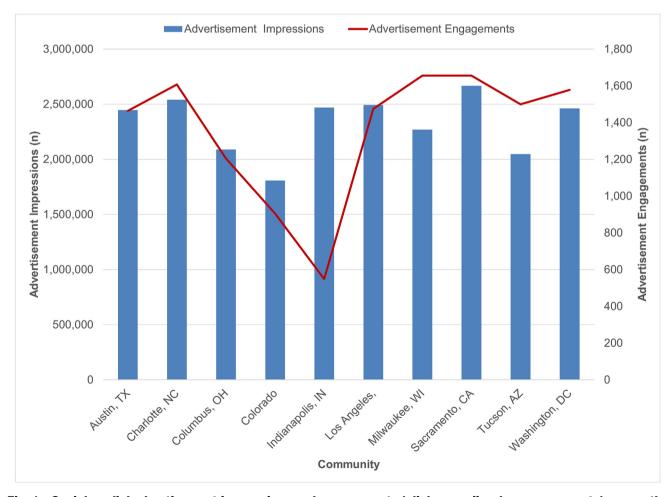


Fig. 1 – Social medial advertisement impressions and engagements (clicks, emojis, shares, comments) across the study communities. Total of 23,291,572 advertisement impressions and 13,594 total engagements across the communities. (Full site level details in Appendix 4).

screens for duplicate or fraudulent responses.¹⁷ For this study, we targeted individuals within the defined community catchment areas of the participating EMS agencies.

Users could also access the community survey through the marketing research panel, study websites, or quick response (QR) codes distributed by local research teams. Based upon our prior experience, we did not emphasize the latter modalities because these strategies typically result in few completed surveys.

Outcomes and data analysis

We determined the outcomes of the digital engagement tools using standard reports provided by social media and the marketing research panel. For each study community, we determined the population of the targeted community and number of registered social media users. For the social media advertisements, key outcomes included advertisement impressions (display of an advertisement on a user's social media feed) and advertisement engagements (user clicks, emoji annotations, sharing of content or posted comments). For each community, we determined the total advertisement impressions, the number of unique users exposed to an advertisement, advertisement impression rates (total advertisement displays per population, total advertisement exposures per user), and advertisement engagement rates.

For the marketing research panels, we determined the total number of surveys completed in each community and the time required to obtain 200 completed surveys (the IRB-approved minimum number of completed surveys for each community). We determined the overall survey response rate and the demographic characteristics of survey respondents. We determined the responses to the survey questions with focus on the percentage with positive or supportive views. We analyzed the data using Microsoft Excel.

Results

The study communities encompassed approximately 32 million persons (range 1.1–9.7 million per community). (Table 1, Appendix 4) The social media advertisements targeted approximately 3.4 million unique registered users (239–412 K per community) and resulted in 22.5 million advertisement impressions (range 1.8–2.7 M per community) and 13,594 advertisement engagements (range 549 to 1,656 per community). (Fig. 1).

The marketing research panel deployed 16,500 survey invitations. We received 6,771 completed community surveys (range 531–914 per community); 6,628 (97.9%) from the marketing panel and 143 from other sources. (Fig. 2) The response rate was approx-

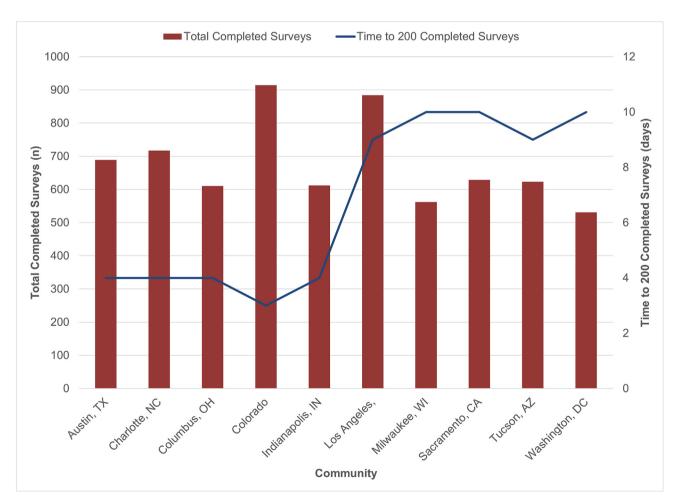


Fig. 2 – Total completed surveys and time to achieve 200 completed surveys in each community. Total of 6,771 completed surveys.

imately 40%. Across the communities, the elapsed time to 200 completed surveys ranged from 3-10 days. (Fig. 2).

Survey respondents were mostly < 45 years old and female. (Table 2, Appendix 5) A total of 20.8% identified as Black, Asian, Pacific Islander or American Indian race (range 17.5% to 38.6% per community). A total of 14.2% identified as Hispanic ethnicity (range 4.6 to 23.2 per community). Among survey respondents, 25.2% reported having a high school diploma or less than high school education (range 21.2% to 29.7% per community) and 39.3% reported an annual household income <\$50,000 (range 32.8% to 44.5% per community). Among respondents, 32.8% were parents of children <18 years old, and 12% were healthcare providers.

A total of 6,294 survey respondents (98.2%; range 97.8% to 98.8% per community) supported the need for emergency medical research. (Fig. 3) A total of 6,144 (91.0%; range 88.9% to 92.6% per community) supported Pedi-PART deployment in their communities. Among respondents, 76.8% (range 70.8% to 79.3% per commu-

nity) indicated that they would support inclusion of a child or young family member in the trial. A total of 82.3% (range 78.0% to 83.7% per community) indicated that they would support their own inclusion in an adult version of the trial.

Discussion

Our observations underscore the power of digital engagement tools for enriching CC and PD efforts. Traditional approaches to CC and PD such as posters, mailings, newspaper, television and radio advertisements, and discussion in public forums are arduous, expensive, and have limited reach and relevance in contemporary society. While the minimum thresholds for CC and PD engagement are not formally defined, our application of digital engagement tools efficiently reached over 3.3 million individuals and elicited over 6,600 completed surveys from 10 study communities, figures that eclipse those of traditional CC and PD efforts. 19

Table 2 – Demographics of survey respondents. Site level results provided in Appendix 5. *While the wording of the question referred to sex, the connotations of the question and response categories were based on gender. **Doctor, nurse, EMS provider (paramedic, emergency medical technician), fire fighter, law enforcement official, other healthcare provider.

Characteristic	Total
Age – years, median (IQR)	42 (30–59)
Sex* - n (%)	
Male – n (%)	2,499 (36.9)
Female – n (%)	4,194 (61.9)
Nonbinary/gender-nonconforming/other- n (%)	46 (0.7)
I don't want to answer	19 (0.3)
Race	, ,
White, n (%)	4,830 (71.3)
Black or African American, n (%)	855 (12.6)
Asian, n (%)	397 (5.9)
Native Hawaiian and Other Pacific Islander, n (%)	42 (0.6)
American Indian and Alaskan Native, n (%)	113 (1.7)
Other, n (%)	423 (6.2)
Decline to self-identify	102 (1.5)
Ethnicity	
Hispanic or Latino, n (%)	1,014 (15.0)
Not Hispanic or Latino, n (%)	5611 (82.9)
Decline to self-identify	121 (1.8)
Education	` ′
Less than high school, n (%)	167 (2.5)
High school diploma or GED, n (%)	1,540 (22.7)
Associate, Technical, or Vocational degree, n (%)	854 (12.6)
Some college, n (%)	1,507 (22.3)
Bachelor's degree, n (%)	1793 (26.5)
Post-graduate degree, n (%)	857 (12.7)
I don't want to answer, n (%)	44 (0.6)
Household Income	
Less than \$20,000	808 (11.9)
\$20,000 to less than \$35,000	942 (13.9)
\$35,000 to less than \$50,000	912 (13.5)
\$50,000 to less than \$65,000	823 (12.2)
\$65,000 to less than \$80,000	773 (11.4)
\$80,000 to less than \$100,000	751 (11.1)
\$100,000 or more	1458 (21.5)
I don't know, n (%)	107 (1.6)
I don't want to answer, n (%)	193 (2.9)
Parent of a child < 18y	2218 (32.8)
Healthcare provider**	845 (12.3)

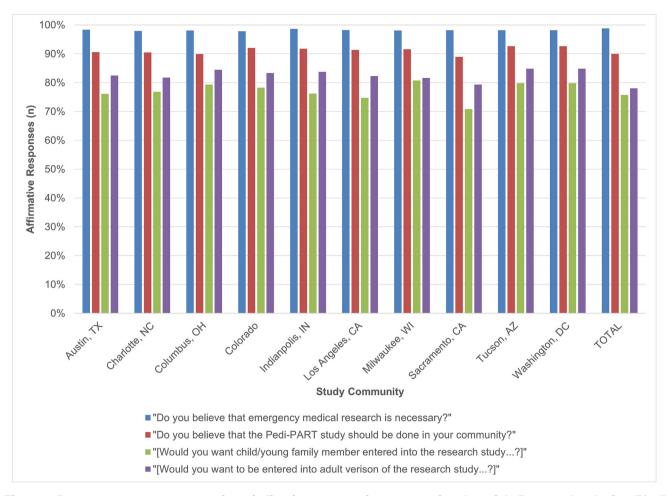


Fig. 3 – Responses to survey questions indicating community support for the trial. Bar graphs depict "Yes" responses only. Other potential responses included "No," "I don't know," and "I don't want to answer".

The methods were efficient; for example, we required less than 10 days to achieve 200 surveys from each community. The marketing research panel also elicited survey responses from a diverse population, including considerable numbers of under-represented minorities and individuals in lower education and income categories. Since digital media is a cornerstone of societal communication and often a foundation for social interactions and formation of communities, the use of digital engagement tools is highly relevant and appropriate in current society.²⁰

Prior applications of digital engagement tools for CC and PD have been limited to studies of trauma and cardiac arrest in adults. ^{6,7,9,21–25} Our observations support the utility of these strategies in an EFIC trial involving children. Children are considered a vulnerable population in medical research, and EFIC notification is usually facilitated through parents. In contrast with prior adult trials, in the current effort we targeted individuals who may be parents of children eligible enrollment for the trial. We also framed study information and survey questions from the perspective of a parent. With these modifications, we were able to achieve substantial community reach and engagement similar to prior adult trials. Of note, one-third of the survey responses were from parents of children <18 years. Federal research regulations require obtaining age-appropriate assent from children enrolled in clinical trials. ²⁶ In future efforts we plan to extend

upon these techniques to engage older children and adolescents in dialog about emergency care trials.

As expected, while almost 90% of adult survey respondents supported execution of Pedi-PART in their community, a smaller percentage (82.3%) indicated that they personally would be comfortable being included in the trial, and a smaller percentage (76.8%) indicated that they would be comfortable with their own young family members or children in the trial. While these levels of approval are consistent with those observed for other pediatric trials, our results are based upon a far larger number of survey respondents. Pediatric trials approved in a systematic review of 27 EFIC CC and PD efforts between 1996–2017, Feldman et al. found that while 81% of participants approved of the conduct of the EFIC trial in the community, only 73% would approve of family member inclusion and only 70% would approve of their own inclusion in the research study. PDA guidance and IRBs do not define specific thresholds of community support when approving EFIC trials.

We emphasize that the described digital engagement tools are not the only elements needed for successful CC and PD. For the Pedi-PART trial, study teams at each community complemented the broad digital engagement campaigns with additional local-level engagement activities, including group meetings/presentations and individual interviews. Study teams should exercise an individualized

approach to each trial, applying a range of current and relevant techniques to optimally engage and elicit feedback from targeted communities. 19,30

Limitations

The social media and community survey campaigns did not target all registered users nor non-users. We could not ascertain differences between those who did or did not engage with the digital tools nor the potential results of more extensive or repeated campaigns. Facebook and Instagram do not allow targeting by race, ethnicity, income or education categories. Other social media platforms such as X, TikTok and Snapchat do not currently allow advertisements targeting specific demographic groups. While a small number of community surveys originated from outside the marketing platform, it is unlikely that these responses would have altered the overall observations. We did not target adolescents, who are common users of social media and are likely to understand the general details of an emergency care trials. We did not perform a formal cost analysis, but local research teams believed that the overall costs were less than that typically needed for traditional CC and PD methods.

Conclusion

In EFIC CC and PD efforts for the Pedi-PART trial, digital engagement tools efficiently reached a large and diverse population and yielded key community feedback. Digital engagement tools offer valuable techniques to enrich EFIC CC and PD efforts.

CRediT authorship contribution statement

Henry E. Wang: Writing - review & editing, Writing - original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. Shannon W. Stephens: Writing - review & editing, Writing - original draft, Methodology, Formal analysis, Data curation, Conceptualization. Kammy Jacobsen: Writing - review & editing, Writing - original draft, Methodology, Conceptualization. Brittany Brown: Writing - review & editing, Methodology, Conceptualization. Cara Elsholz: Writing - review & editing, Methodology, Conceptualization. Jennifer A. Frey: Writing - review & editing, Methodology, Conceptualization. John M. VanBuren: Writing - review & editing, Methodology, Conceptualization. Marianne Gausche-Hill: Writing - review & editing, Methodology, Conceptualization. Manish I. Shah: Writing - review & editing, Methodology, Conceptualization. Nichole Bosson: Writing - review & editing, Methodology, Conceptualization. Julie C. Leonard: Writing - review & editing, Conceptualization. Nancy Glober: Writing - review & editing, Conceptualization. Caleb Ward: Writing - review & editing, Conceptualization. Daniel K. Nishijima: Writing - review & editing, Methodology, Conceptualization. Kathleen Adelgais: Writing - review & editing, Conceptualization. Katherine E. Remick: Writing - review & editing, Conceptualization. Joshua B. Gaither: Writing review & editing, Conceptualization. M. Riccardo Colella: Writing - review & editing, Conceptualization. Douglas Swanson: Writing - review & editing, Conceptualization. Sara F. Goldkind: Writing review & editing, Conceptualization. Alexander Keister: Writing -

review & editing, Methodology, Conceptualization. **Matthew Hansen:** Writing – review & editing, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.resplu.2025.100919.

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REFERENCES

- Dickert NW, Metz K, Fetters MD, et al. Meeting unique requirements: Community consultation and public disclosure for research in emergency setting using exception from informed consent. Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine 2021;28(10):1183–94. https://doi.org/10.1111/acem.14264.
- Food and Drug Administration, Department of Health and Human Services. 21 CFR 50.24 Exception from informed consent requirements for emergency research. (https://www.ecfr.gov/current/ title-21/chapter-l/subchapter-A/part-50/subpart-B/section-50.24).
- Tisherman SA. Defining "community" and "consultation" for emergency research that requires an exception from informed consent. AMA J Ethics 2018;20(5):467–74. https://doi.org/10.1001/journalofethics.2018.20.5.stas1-1805 (In eng).
- Lakshmi T, Tadiparty P. Leveraging social media platforms for community engagement and information dissemination. 2024: 297– 304.
- Porter COLH, Outlaw R, Gale JP, Cho TS. The use of online panel data in management research: a review and recommendations. J Manag 2019;45(1):319–44. https://doi.org/10.1177/0149206318811569.

- Stephens SW, Carroll-Ledbetter C, Duckert S, et al. Interactive media-based approach for an exception from informed consent trial involving patients with trauma. JAMA Surg 2024(1). https://doi.org/10.1001/jamasurg.2024.2147.
- 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(3):267–70. https://doi.org/10.1161/ CIRCULATIONAHA.113.002390.
- 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. https://doi.org/10.1016/j.jss.2018.09.007.
- Hsu CH, Fowler J, Cranford JA, Thomas MP, Neumar RW. Integration of social media with targeted emails and in-person outreach for exception from informed consent community consultation. Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine 2022;29(2):217–27. https://doi.org/10.1111/acem.14377 (In eng).
- Galbraith KL. Practical and ethical considerations for using social media in community consultation and public disclosure activities. Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine 2014;21(10):1151–7. https://doi.org/10.1111/acem.12483 (In eng).
- Farley P, Stephens SW, Crowley B, et al. Exception from informed consent trials: social-media-based community consultation campaigns are representative of target communities. Trauma Surg Acute Care Open 2021;6(1)e000830. https://doi.org/10.1136/tsaco-2021-000830.
- Bosson N, Hansen M, Gausche-Hill M, et al. Design of a novel clinical trial of prehospital pediatric airway management. Clin Trials 2022;19(1):62–70. https://doi.org/10.1177/17407745211059855 (In eng).
- Qualtrics. Market Research Services. (https://www.qualtrics.com/ research-services/).
- Johnson L. Exploring factors associated with pregnant women's experiences of material hardship during COVID-19: a cross-sectional Qualtrics survey in the United States. BMC Pregnancy Childbirth 2021;21(1):755. https://doi.org/10.1186/s12884-021-04234-1 (In eng).
- Miller CA, Guidry JPD, Dahman B, Thomson MD. A tale of two diverse qualtrics samples: information for online survey researchers. Cancer Epidemiol Biomarkers Prev 2020;29(4):731–5. https://doi.org/10.1158/1055-9965.Epi-19-0846 (In eng).
- Douglas BD, Ewell PJ, Brauer M. Data quality in online humansubjects research: comparisons between MTurk, prolific, cloud research, qualtrics, and SONA. PLoS One 2023;18(3)e0279720. https://doi.org/10.1371/journal.pone.0279720 (In eng).
- Qualtrics. Support. Security Survey Options. (https://www. qualtrics.com/support/survey-platform/survey-module/surveyoptions/survey-protection/#About).
- Vaslef SN, Cairns CB, Falletta JM. Ethical and regulatory challenges associated with the exception from informed consent requirements for emergency research: from experimental design to institutional review board approval. Arch Surg 2006;141(10):1019–23. https://doi.org/10.1001/archsurg.141.10.1019.

- Chisolm-Straker M, Nassisi D, Daya MR, et al. Exception From Informed Consent: How IRB Reviewers Assess Community Consultation and Public Disclosure. AJOB Empirical Bioethics 2021;12(1):24–32. https://doi.org/10.1080/23294515.2020.1818878.
- Datareportal. Digital 2024: Global Overview Report. (https://datareportal.com/reports/digital-2024-global-overview-report).
- Stephens SW, Farley P, Collins SP, et al. Multicenter social media community consultation for an exception from informed consent trial of the XStat device (PhoXStat trial). The Journal of Trauma and Acute Care Surgery 2022;92(2):442–6. https://doi.org/10.1097/TA.0000000000003425.
- 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. The Journal of Trauma and Acute Care Surgery 2016;80(6):1005–9. https://doi.org/10.1097/TA.00000000000001042.
- Jansen JO, Stephens SW, Crowley B, Inaba K, Goldkind SF, Holcomb JB. Interactive media-based community consultation for exception from informed consent trials: How representative should (and can) it be?. The Journal of Trauma and Acute Care Surgery 2022;92(3):e41–6. https://doi.org/10.1097/TA.0000000000003484.
- 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. https://doi.org/10.1016/i.resuscitation.2018.12.006.
- Matchett G, Ryan TJ, Sunna MC, Lee SC, Pepe PE. Measuring the cost and effect of current community consultation and public disclosure techniques in emergency care research. Resuscitation 2018;128:37–42. https://doi.org/10.1016/j.resuscitation.2018.04.033 (In eng).
- Shakhnovich V, Hornik CP, Kearns GL, Weigel J, Abdel-Rahman SM. How to conduct clinical trials in children: a tutorial. Clin Transl Sci 2019;12(3):218–30. https://doi.org/10.1111/cts.12615 (In eng).
- Ross CE, Lehmann S, Hayes MM, et al. Community consultation in the pediatric intensive care unit for an exception from informed consent Trial: a survey of patient caregivers. Resusc Plus 2023;13:100355. https://doi.org/10.1016/j.resplu.2022.100355 (In eng).
- Ward CE, Adelgais KM, Holsti M, et al. Public support for and concerns regarding pediatric dose optimization for seizures in emergency medical services: An exception from informed consent (EFIC) trial. Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine 2024;31(7):656–66. https://doi.org/10.1111/acem.14884 (In eng).
- 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(7)e197591. https://doi.org/10.1001/jamanetworkopen.2019.7591.
- 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 (1):67–76. https://doi.org/10.1177/1740774514555586.