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Public Deliberation as a Novel Method for an Exception from Informed Consent Community Consultation

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Abstract

Objectives—Community consultation is required for clinical trials considering federal exception from informed consent (EFIC) procedures. Questions remain about the value of the community

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Author contributions:

Activity	Author initials
Study concept and design	PEP, KKS, SP, DR, NK, DKN
Acquisition of the data	PEP, KKS, SP,DR, JFH, LST, HS, DKN
Analysis and interpretation of the data	PEP, KKS, SP
Drafting of the manuscript	PEP, KKS, SP,DR, DKN
Critical revision of the manuscript for important intellectual content	PEP, KKS, SP, DR, NK, JFH, LST, HS, DKN
Statistical expertise	KKS
Acquisition of funding	PEP, NK, DKN

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consult process and whether it adds intended protections to study subjects. Public deliberation methods that provide baseline participant education and elicit values and opinions about consent options is a novel approach for community consultation. This study evaluated the use of structured public deliberation methods to assess a community's values and opinions about informed consent procedures for a pediatric trauma trial.

Methods—This was a mixed-methods descriptive study of public deliberation sessions assessing participants' opinions about informed consent procedures for a pediatric trauma randomized controlled trial (RCT). Participants from communities with high rates of pediatric trauma were recruited via community-based organizations and social media. Deliberation focused on three consent options for a proposed RCT: 1) enrollment using EFIC procedures with no attempt to obtain informed consent; 2) enrollment using EFIC procedures after attempting to reach a parent; or 3) enrollment only with informed consent. Participant demographic data and their opinions about the proposed study and deliberative session were also collected.

Results—There were 102 participants across eight sessions (range of 9 to 15/session, average of 13). Most participants were female (n=78, 76%) and a plurality black (n=48, 47%). The majority of participants preferred enrollment using EFIC procedures only after an attempt was made to reach a parent and informed consent was not possible (n=56, 55%), followed by enrollment using EFIC procedures with no attempt to obtain informed consent (n=32, 32%), and enrollment only with written informed consent (n=13, 13%). One participant declined all options. 84 participants (82%) agreed or strongly agreed that the RCT was important to do, and 79 participants (77%) said the sessions provided enough information to make an informed decision about the proposed RCT.

Conclusions—Structured public deliberation is an effective approach when consulting communities for trials considering EFIC procedures. Future studies are needed to evaluate whether public deliberation methods provide participants with enhanced understanding of clinical trials compared to other community consultation methods.

INTRODUCTION

Patients with life-threatening injuries are frequently unable to consent to research that may inform improved care delivery and health outcomes. This presents emergency care researchers with the ethical challenge of balancing patient autonomy with the need for evidence-based investigations to identify the most effective treatments. The uncommon, but essential, use of the federal exception from informed consent (EFIC) in emergency care research helps achieve a balance between these two important perspectives. Research using EFIC judiciously has provided valuable evidence for improving patient care and health outcomes over the last 20 years.[1–3]

EFIC regulations, promulgated by the FDA in 1996, permit research in populations unable to give prospective, informed consent due to life-threatening and time-sensitive illness and injuries. However, EFIC regulations do not standardize guidelines or methods for obtaining community input, a key component to the EFIC approval process.[4–6] The requirement to conduct community consultation as part of an EFIC application provides an added level of protection for potential study subjects by soliciting community input on the research. This

patient proxy input demonstrates respect for community concerns through a bi-directional communication path between researcher/institution and community/study subject.[6]

Questions remain about the value of the EFIC community consult process and whether it adds intended protections to study subjects.[7–9] The evidence of effectiveness of community consultation is ambiguous. Some studies note the community consultation process is resource-intensive and costly with questionable value.[4,10,11] Others report participants' high satisfaction and acceptance of EFIC through the community consultation process.[12–14]

One validated method that appears to be unexplored, but well-matched to the goals of the EFIC process, is public deliberation.[15] This qualitative methodology elicits informed public opinion and understanding of ethical and social values. Public deliberation can be especially inclusive of underrepresented groups, bringing the public's views to decision-makers regarding complex social issues. Three primary characteristics differentiate public deliberation from other research methods: 1) the topic is an ethical or value-based dilemma requiring an active exchange of reasons and justifications for preferences, opinions, or values; 2) participants are members of the public who are encouraged to take a societal viewpoint rather than a personal viewpoint, not people with a vested interest or expertise in the topic; 3) participants are presented with unbiased evidence to inform discussion and positions. [15] A bioethics researcher explains that it is a unique method that facilitates the opportunity for community members to "develop, examine, and challenge their own views."[16] The methodology may use a variety of techniques (e.g., case studies, surveys, focus groups); however, all use educational materials and content experts, and all encourage participants to cross-examine experts and peers.

Although public deliberation is used in bioethics research, its use lags in health services research, including emergency care research. This case study employing public deliberation methods aims to demonstrate its application to the community consultation process when informed consent is infeasible. Public deliberation may strengthen the community consultation process as well as the enrollment protocol for a clinical trial.

METHODS

Study design

We conducted a mixed methods study that included 1) surveys, and 2) public deliberative sessions with community members living within the geographic area served by a Level I trauma center where a pediatric randomized clinical trial (RCT) seeking EFIC is being conducted. Participant demographics were collected. Quantitative methods included surveys with questions about emergency department (ED) use, whether the RCT was important to do, whether the participants would be willing to have his/her child included in the study without parental/legal guardian consent, whether they had enough information to give an opinion about the study proceeding, and whether they thought researchers would seriously consider community input. The qualitative component consisted of participants deliberating about different approaches related to parental informed consent for a blood-clotting drug that may help pediatric patients after a physical traumatic injury; the drug must be administered within a three-hour time frame to be effective. Participants were asked to respond as

decision-makers representing their communities and ultimately voted on the acceptability of three pre-determined resolutions to the problem. The study was approved by the university's institutional review board (IRB).

Study setting, recruitment, and population

We used community-based organizations and social media to recruit 102 participants in communities that historically experienced relatively high pediatric ED use at a local Level I trauma center. Target geographies were identified by reviewing historical data on pediatric trauma use of the tertiary center's ED by zip code.

Because many of the target geographic areas are lower income, community-based organizations (CBOs) within these areas that are viewed as trusted sources were enlisted to assist with recruitment. CBOs deployed a variety of methods to recruit eligible participants, including emails, phone calls, flyers, and face to face invitations. Sessions were held on site at the CBOs.

To ensure patient confidentiality CBOs are not named here; however, they included: a nonprofit for sustainable housing; two youth organizations in different communities that counsel and provide services to underserved youth; an advocacy organization based in a low-income community that manages multiple programs, including the Centers for Disease Control and Prevention REACH program – Racial and Ethnic Approaches to Community Health; a family resource center; and a counseling center with programs and resources primarily serving an Hispanic community.

Three groups were recruited through social media using targeted Facebook groups (e.g., Good Neighbors of [name of city]) and the Nextdoor social media application. Although there was a slightly higher "no response rate" when we circled back to confirm participation with social media recruits, we compensated for that by accepting additional people for those sessions to reach our goal of 12–15 participants per two hour session. Sessions with social media recruited participants were held in community spaces (e.g., a community center, university conference room). All of the recruitment methods were low cost.

Eight deliberative sessions were conducted: six groups of adults at least 25 years old who had a child under 18 years of age; two groups of youth aged 16 to 18 years (because teens are at higher risk for traumatic injury than younger children and are close to study consent age). An average of 13 people attended each two-hour session (range 9–15 participants), and each participant received a $50 gift card.

Study Protocol

We started each session with an explanation of EFIC community consultation and the participants' role as representing the perspectives of their communities. Facilitators (authors Powers, Shore, Perez, Ritley), trained in qualitative research, including public deliberation methods, reviewed and discussed an educational handout defining medical research, the purpose of research, RCTs (including placebo and intervention arms), and informed consent. We developed the handout with input from emergency care physicians and health services

researchers. Participants discussed the educational materials in small groups as well as collectively with facilitators.

Facilitators read a description of the study requiring the community consultation. The facilitators provided information on pediatric traumatic injury, including the current standard of care, the current evidence on the efficacy of the study drug to facilitate blood clotting in adults experiencing trauma, and the potential yet unknown benefits and risks of using this drug to treat pediatric traumatic injury. Similar to the development of the educational materials, emergency care physicians and health services researchers provided input to ensure clinical accuracy and clarity of the of the study description.

Participants were encouraged to ask questions of the emergency care physician (attending 5 of 8 sessions); in the absence of a physician, facilitators read factual information written by an emergency care physician that addressed questions raised in prior deliberative sessions.

Participants were presented with three potential options if a study-eligible child arrives at the ED: 1) the physicians immediately enroll the child in the study without seeking parental consent; 2) the physicians attempt to contact the parents for up to three hours, which is the window of effectiveness for the drug to be administered. If the physicians are unsuccessful in reaching a parent, enroll the child in the study using EFIC; and 3) the physicians must obtain consent before enrolling the child, which means the child will not be enrolled if the parent cannot be reached. For options 1 and 2, once the patient is stabilized and the parent available, the physicians would initiate the informed consent process. Parents would be able to disenroll their child from the study at that time. Although the child may have already received the study drug, disenrolling the child would mean the child would not participate in any follow-up specific to the study.

After the facilitators read the options aloud, participants were asked to choose the most acceptable option. On a visible flipchart, the co-facilitator recorded each participant's selection. Participants then discussed and deliberated the choices; some people changed their minds or proposed alternatives or modifications to the options. During the initial pre-EFIC trial period of the RCT, researchers learned that many parents of eligible children were driving long distances to reach the ED after they learned of the injury; discussion of this issue was incorporated into subsequent deliberative sessions.

Quantitative and Qualitative Analyses

Quantitative survey analysis consisted of descriptive statistics (means and frequency distributions). The number and percent of participants who favored the various options were central to assessing results. Initial votes at each session were tallied across the three options after the educational portion of the session, followed by a tally of final votes at the close of deliberation. The purpose of the second vote was to see whether any participant(s) changed their mind following the group discussion where elaboration of alternative viewpoints often occurred.

With participant permission, session discussions were audio-recorded and detailed written notes taken at each session. All of these were analyzed using inductive, grounded theory

methods. Three project team members experienced in reviewing and coding qualitative data conducted a theme analysis. The theme analysis focuses on the reasons and values given by participants for why certain options were more or less desirable and how others' comments influenced their perspectives. By the last session, no new themes were emerging.

RESULTS

Demographics and survey analysis

Of the 102 individuals who participated in one of eight deliberative sessions, about one-quarter were under age 18 (two discussion groups were composed only of youth ages 16–18 years), with most of the remainder over age 25 (Table 1). Participants were predominantly female, non-Hispanic (black and white), with an education level at some college or more.

Survey Results—Most participants (72%) knew someone who had a severe life-threatening injury and had to go to the ED – either for themselves, a child, or other family members or friends. Among those participants, 75% reported knowing two or more such people.

Participants agreed that the pediatric trauma RCT is important to do, with 82% agreeing or strongly agreeing. Parental desire for inclusion of their child into the study without consent is shown in Table 2 with over half agreeing. Consistent with this, 65% indicated they would not want their child excluded from the study.

More than three-quarters (77%) responded that they had enough information to give an informed opinion about researchers conducting the RCT. Among those who responded that they did not have enough information, several said they would like to see more specifics on prior research in this area (e.g., patients who were involved in studies in other countries, potential side effects and long-term effects of the drug, dosing for children versus adults), more detail about the ingredients in the drug and how it is administered, and samples of the RCT notifications that would be sent to the community. Several respondents also asked what ED physicians thought about the study and whether they would want one of their family members to participate. About 70% of participants responded that researchers would seriously consider community input into the study design.

Each participant in the deliberative groups was asked to select one of three options that best aligned with how they thought children should be enrolled in a future RCT to assess the effectiveness of a blood clotting drug for traumatic injury. Most participants (55%, N=56) supported Option #2 requiring physicians to *attempt* to obtain consent; this was true both within and across sessions except for group #2 (Table 3). Option #1 ranked second with 32% (N=32) supporting immediate enrollment of eligible children in the study. This result is consistent with the survey response of 32% (N=33) agreeing that they would be okay with researchers enrolling the participant's own child without obtaining their consent ahead of time. Option 3 mandating that parental consent be obtained ranked third (13%, N=13). This is also consistent with the survey responses of 8% of parents strongly disagreeing and 10% disagreeing that it was acceptable for researchers to enroll their child without obtaining their consent. (One participant declined all three options.)

Twelve participants changed their votes after discussion. Ten changed from Option 2 to Option 1, thus option 1 increased by 9 percentage points after the discussion.

Key reasons and values that arose during the deliberative session for each option are listed in Table 4 and described in detail below. Specific themes shown in the table were discussed by four or more groups; other themes discussed by a smaller number of groups are described in the narrative sections following the table.

Participants supporting Option #1: Immediately enroll the child in the study without consent

Participants in favor of Option 1 frequently cited "time is of the essence" and that the child should be saved at all possible costs. Several participants shared personal relevant direct experiences about loved ones, relaying the importance of quick action in life-or-death situations. In one youth group, a participant stated, "*My home boy [friend who was shot] died this year from bleeding out - this medicine could have helped him. Bled out as soon as soon he got into the ambulance - if this drug exists and could help, don't wait. Just do it. Don't waste time at the scene asking questions*."

Participants in seven of eight groups were recorded as valuing saving the child at all possible costs, with a person in one group noting that "*In a perfect situation, you want to weigh the possibilities, but if there is something to save that child's life, then we would do it. We would go with immediate enrollment because it is in the best interest of that child."* A number of participants supporting this option deferred to the physicians as the experts and, as one person said, they did not want to *"get in the way of you saving my child's life."*

Another reason raised by two individuals supporting this option was that the drug had already been tested in adults and was safe for use in that population. One participant noted this while adding, "*children are generally healthier*."

Participants supporting Option #2: Enroll the child into the study if contact with parent cannot be made within three hours (the window of effectiveness for the study drug)

There were several reasons why supporters of this popular option favored it, with the most common being the need to balance patient choice with the potential to save lives. Some participants stated that they simply wanted to be presented with the choice of enrolling their child. One person said, "*At first I was going to pick Option 1, but I thought that I would at least want to know the hospital tried to contact me before giving an experimental drug*."

In two groups, participants mentioned that they trust the doctors to determine what is best. While they wanted some attempt to be reached, they felt that if for some reason they could not be contacted, "*if this is going to help my child, try it*." One participant stated that most community members are familiar with the oath, 'Do no harm' and therefore, should trust that physicians will do the right thing.

In half of the sessions, participants mentioned the importance of respecting others' religious beliefs and values that may conflict with the first option to administer the drug without informed consent. Participants also noted that some parents oppose medical interventions in

general, citing the anti-vaccine movement as an example. Option 2 provided a balance to respecting the beliefs of those groups by giving them a chance to decide, but also protecting (in their view) the injured child's interest if the parent was unreachable.

Conflicting emotions or opinions were evident among some participants who selected Option 2 based on comments like "*It's worth noting that it's still research, under study, and not proven yet. Telling parents after the fact, [it] seems like you could have a lot of angry parents*." One participant observed that it was in the hospital's interest to ask for consent to protect the facility for liability reasons, stating "*People like to sue for stupid things*." Another key reason expressed by supporters of Option 2 from half of the sessions is that study doctors may not know important medical history that could lead to adverse effects to the child upon administration of the experimental drug. For example, one woman mentioned an experience with a grandchild being given an experimental medication in the ED that triggered an allergic reaction.

Option 2 Modification: Participants proposed shortening length of time to contact parents from 3 hours to 30 minutes—Participants in early sessions who supported Option 2 suggested a modification that was then presented in subsequent sessions. Participants suggested considerably shortening the three-hour contact window because the drug is most effective the sooner it is administered. This shorter length of time was consistently supported by participants who favored Option 2. Participant comments overall were similar to one person who said, "*If you are not going to reach them in one hour you are not going to reach them in two hours*." In general, participants supported reducing the contact window to 30 minutes.

In several sessions, participants suggested that the doctors may determine how much time can be spared for parental outreach based on the patient's stability. Ideas for gauging stability included measuring the patient's blood pressure or blood loss; for example, "*If [their blood pressure] is really bad, then give them the drug; if not, try to wait for the parents*."

One group of participants engaged in a robust discussion about alternative approaches to contacting parents. This ranged from calling them on the way to the hospital, or at the scene where the child was injured, to sending a police officer to the parents' home to try to obtain consent. Others suggested that study physicians should try to reach the parents for a specified number of times (e.g., 1 to 3), and if parents cannot be reached, then "*take matters into your own [doctors'] hands*."

Participants expressed mixed views on calling parents who are driving a long distance to the ED—As stated above, during the initial pre-EFIC trial period of the RCT, researchers learned that many parents of eligible children were driving long distances to reach the ED after they learned of their injury. The researchers thought that it was inappropriate to reach out to distraught parents while they were driving to explain the study. Because this information was revealed after five of the eight deliberative sessions were already completed, only three groups of participants (about 35 people) were asked how they would feel if they were contacted about the study while driving to meet their child at the ED.

Opinions on this were strong and mixed, with some participants wanting the option of being informed of the study while they were driving and others stating that most parents would not be able to process clearly or react appropriately over the phone.

Participants supporting Option 3: Do not enroll without consent - provide standard of care if consent cannot be obtained

In all but one session, at least one person selected Option 3. In five of the eight sessions, participants who selected this option felt strongly that parental choice and personal values must be respected by the medical system. Some participants questioned why parents would not always be asked for consent: "*I am questioning the whole concept and process. Why is this up for discussion? Shouldn't everybody have a say in giving consent*?"

Others cited the unknown risks: "*I don't want to be a guinea pig, including a new drug. I just want the standard of care,"* and *"If I had to choose between transfusions and this drug, I would go with transfusions because I know the risks*." In two groups, participants mentioned concerns regarding unknown long-term risks of the drug: "*The long-term effects of a drug may not be known on a child, such as reproductive organ or brain development. The follow-up is only for 6 months – what if other effects happen as a child ages? Children are still developing until age 25*." Consistent with these comments and expressing this uncertainty, one participant stated on the survey, "*I think the medicine can be a good, life-saving thing but can also be a risk that kills children*."

A few participants expressed fatalistic views: "*If it's their time to go, it's their time to go – I don't know if the drug would kill the kid, or something else [would]. I would not have any closure and it [not knowing whether the child died from the drug or injury] would bother me a lot."*

In addition to wanting parents to retain the choice of study enrollment, skepticism of the medical system overall was raised in half of the sessions. Some participants pointedly mentioned or alluded to the Tuskegee Syphilis Study. This well-known study is held up as an example of unethical behavior by scientists and led to changes in future research protocols. A representative comment referencing this study from African American participants in the deliberative sessions included, "*Now I am thinking about the Tuskegee study, and I feel like I am putting my children on something like that, and I am giving consent to something I don't even know about. You're asking a medical idiot to decide if doctors should use this drug on my child when they're not even sure it's going to help. These are our children we're talking about!*"

Several other comments that arose in one or two sessions by participants who supported Option 3 noted that it is easy to contact people so there is no excuse not to try: "*We live in an era when you have access to so many people and creative ways to reach out to those people [referring to potential study enrollee parents]*." One participant who supported mandatory consent stated, "*As much as I'd like the study to get as many patients enrolled as possible, if any adverse reaction happens as a result of the medication, the parents would attack the hospital and whoever was in charge*."

Proposed alternatives to the three options

In the educational portion of the session, prior to deliberation, participants learned the definition of a placebo. Many people were surprised to learn that a placebo group is commonly used in clinical trials and asked many questions (e.g., what was in the placebo, how it was administered, what is meant by blinded). A handful of participants did not want to vote for any of the three proposed options, with one stating they would only place their child in the study if there was no placebo. Another person proposed that if a parent decides that they want to participate in the study but don't want their child to be given the drug, they may be given the placebo.

When a youth group was asked about other ideas for this study, one participant proposed conducting a retrospective study of children in other countries rather than *"go to the trouble of creating a new clinical trial."*

Key reasons for changing votes post deliberation

Most people who switched their vote post-deliberation moved from Option 2 to Option 1. Youth (5/26, 19%, 95% CI 6.6, 39%)were more likely to switch votes than adults (7/76, 7.9%, 3.0, 16%). Overall, reasons for switching included the fact that the drug has been deemed safe for adults with trauma in the US and is also used to treat children with traumatic injuries in other countries. Others were influenced by a fellow adolescent participant in one session stating that "*If I don't have any ID and I am about to bleed out or die and you don't know who to contact, I want someone to try to help me*." Following the group discussion, a couple of participants noted that they could not handle the stressful situation and would want the doctors to do whatever is needed.

Study notifications and options for opting in/out of study

EFIC requires community notification of the protocol, and the FDA website suggests several public notification options, including local newspapers. Participants nearly unanimously viewed this option as antiquated. Many people immediately commented, "*Who reads the newspaper?!*" A variety of alternatives for notification were suggested, such as posting on social media and including on TV news; asking pediatricians, schools, or insurance companies to inform parents; or registering through the DMV because many traumatic injuries occur through car accidents. Signaling an interest in learning about the study, one participant stated on the survey, "*if [the study drug] can save lives or improve our health in any way, sure! I'm all for it. Advertise, promote, educate us more to want to support or consider options that can really save lives*."

An IRB option of opting out by placing a medical bracelet on a child was largely discounted as infeasible. Participants noted that their children would not wear a medical bracelet "*just in case*," especially over the five-year duration of the study. Others noted that a parent may initially want to opt out, but when faced with an actual emergency situation, their views may change. A minority of participants did find medical bracelets acceptable, pointing to people with diabetes or members of specific religions who wear bracelets currently.

Some participants supported opting out in advance, particularly at the pediatrician's office, noting it could save time during an emergency situation. Others felt that opting in was more respectful of parents' choices than opting out. Participants suggested having parents sign papers to opt in or out of research at every physician visit or through schools.

DISCUSSION

Benefits to the use of public deliberation methods for a community consultation

To our knowledge, the published literature yields no EFIC-related studies that employed the public deliberation method in the community consultation process. Kasner et al appear to have used very similar tools; however, participants' input was primarily based on their personal perspective rather than being asked to represent their communities.[14] Often traditional community consultations are conducted by principal investigators (PIs) of the research seeking an EFIC who present their study and respond to questions from several local community groups. This study created a neutral, third party environment where the research PIs served as clinical experts and neutral facilitators presented options and elicited participants' values and opinions.

Another key aim of the study was to conduct the consultations in areas that historically experienced high rates of childhood physical trauma. Consistent with the inclusive nature of public deliberation, participants disproportionately represented areas whose residents are of lower socio-economic status who are racially and ethnically diverse. Seeking out these members of the community through trusted sources ensured that their opinions would be heard and expressed in a safe community space. This approach may be used to solicit views of any historically underrepresented group(s) for a community consultation.

Public deliberation may be used for both pediatric and adult EFIC studies. Recruitment will vary; with parents/guardians serving as proxies for children. We also found it valuable to include two youth groups of participants aged 16–18 since teens are more likely to experience physical trauma than younger children and are close to the age of consent. Depending upon the nature of the pediatric study for which an EFIC is being conducted, including youth may be valuable. Youth participants will need to obtain written parental permission.

This study included all three primary characteristics of public deliberation. Participants reflected the community in the hospital catchment including teens and adult parents from different socioeconomic backgrounds. Additionally, participants were educated about how research is conducted, about the particular intervention option, and were asked to represent their community while discussing and negotiating about the value-laden options. Many participants naturally spoke to direct experiences with the ED on behalf of loved ones, and some of them had friends or family members who passed away in the ED. However, they took their role as a community representative seriously; while they may have noted a personal viewpoint, they generally noted the importance of factoring into their vote considerations of other community members.

Second, the methods used here included unbiased education and discussion materials written in lay language at a high school reading level and explained in multiple ways - through reading together as a group, reading individually, and through small group and then a full group discussion. Participants were afforded the opportunity to ask questions of the facilitators and clinical expert throughout the session, as well as ask each other why they supported a particular perspective. Third, public deliberation fosters exchange among participants and allows for exploration of value-based decisions, with facilitators probing to elicit and clarify values, while assuring participants that there is no right or wrong answer.

Finally, as evidenced by this study, through the deliberative process, participants may come up with modified or alternative options that were not contemplated by study investigators. In this study, for example, rather than use the full three-hour window of time to attempt to reach a parent under option 2, participants suggested reducing the time frame to 30 minutes. Further, when discussing how community members would be notified about the study and the methods for opting out, participants pointed out that these methods are unrealistic and outdated. New approaches, including advertising through social media and schools, along with opting out through pediatrician visits, were some of the suggested alternate ideas. Biros et al note that challenges remain in optimizing the EFIC flexibility permitted by the FDA regulations.[8]

Public deliberation may make community consultations more meaningful

The meaningfulness of a community consultation may be enhanced by requiring researchers to factor in at least some of the results where there is clear participant consensus. For example, in this study, many participants desired a researcher to attempt to contact the parent for at least 30 minutes if their child was injured. This was true for parents who were not driving a long distance. Participant views were mixed, however, on whether they wanted to be contacted if they were driving a long distance to get to the ED as it may be challenging to process the information while also driving safely. If researchers knew that parents were driving a short distance, the IRB could require them to attempt parental contact for at least 30 minutes. If researchers knew that parents were driving a long distance, researchers could be permitted to enroll the child directly into the study and notify the parents when they arrived.

LIMITATIONS

Our study should be interpreted in the context of several limitations. First, the study was conducted in a single region in the US. Participants from other regions in the US or from other countries may have differing opinions. Second, participant opinions are in response to a specific pediatric clinical trial. Other clinical trials with different patient populations, interventions, and study procedures may have different responses. Third, we did not compare public deliberation methods to other community engagement methods. Fourth, different recruitment methods may have yielded different findings. Also, while the sample size was sufficient to achieve theme saturation and general consensus, it was relatively small and not sufficient to explore subgroup analyses of demographic characteristics (age, gender, race, education). It is possible that opinions may differ greatly between demographic

subgroups. Finally, we presented three different consent options that broadly reflected general consent options to participants. However, there are many variations to each of these consent options (e.g., timing, use of family objections) that we did not evaluate due to the complexity of including multiple options.

CONCLUSIONS

Public deliberation is a novel community consultation method that produces robust information for informing researcher and IRB EFIC decisions and ensuring rigorous study protocols that are responsive to the community. Researchers have called for improvements to community consultation guidelines (Eubank et al., 2018; Biros, 2015), and public deliberation may serve as a valuable tool for insight into community needs, concerns, and interests. Future studies need to evaluate whether public deliberation methods provide participants with enhanced understanding of clinical trials compared to other community consultation methods.

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Table 1.

Demographic Characteristics of Participants (n=102)

Age	**N (%)**
16–18	23 (23)
18–25	4 (4)
26–35	24 (24)
36–45	23 (23)
46–55	18 (18)
>55	10 (10)
Gender	
Female	78 (76)
Male	24 (24)
Race	
Black	43 (42)
White	24 (24)
Other	17 (17)
More than one race	7 (7)
Missing	11 (11)
Ethnicity (Hispanic/Latino)	
Hispanic/Latino	32 (31)
Not Hispanic/Latino	68 (67)
Blank/Don’t know	2 (2)
Highest level of school completed	
Still in high school	21 (21)
Didn’t finish high school	4 (4)
High school	9 (9)
Some college or associate’s degree	41 (40)
Bachelor’s degree	18 (18)
Master’s degree or doctorate/professional degree	9 (9)

Table 2.

Post-deliberation Survey Questions about the Pediatric Trauma Randomized Controlled Trial (n=102)

If you are/were a parent and your child had a severe life-threatening injury, you would be okay with him/her being included in the RCT without giving your consent ahead of time.	**N (%)**
Strongly agree	32 (31)
Agree	26 (25)
Neutral	22 (22)
Disagree	10 (10)
Strongly disagree	8 (8)
Depends	1 (1)
Missing	3 (3)
Would you like to tell doctors that you do not want your child to participate in the RCT?	
Yes	33 (32)
No	66 (65)
Neutral	1 (1)
Missing	2 (2)
Do you feel that you have been given enough information to give your informed opinion about whether you think it is OK for researchers to do the RCT?	
Yes	79 (77)
No	22 (22)
Missing	1 (1)
Do you think that the RCT researchers will seriously consider what community members like you have to say about this study before starting it?	
Yes	71 (70)
Don’t know	28 (27)
Yes/don’t know	1 (1)
Hope so	1 (1)
Missing	1 (1)

Table 3.

Participant Choice of Consent Options at Completion of Public Deliberation Process

Group	Option #1: Immediate enrollment	Option #2: Attempt to get consent	Option #3: Must obtain consent	TOTAL
1	2	10	1	**13**
2	6	3	4	**13**
3	4	6	1	**11**
4	2	11	2	**15**
5	3	7	0	**10**
6	6	8	1	**15**
7	7	5	3	**15**
8	2	6	1	**9**
TOTAL	**32**	**56**	**13**	**101**
Percent	**32%**	**55%**	**13%**	**100%**

Table 4.

Key Themes from Group Discussions about Consent Options

Consent Option	Theme	Quotes	Group Number								Total # of Groups mentioned theme (n=8; min. 4)
			1	2	3	4	5	6	7	8	
#1: Immediate enrollment	Time is of the essence	"*My home boy [friend who was shot] died this year from bleeding out - this medicine could have helped him. Bled out as soon as soon he got into the ambulance - if this drug exists and could help, don't wait. Just do it. Don't waste time at the scene asking questions.*" (Youth Participant)	x	x	x	x	x	x	x	x	8
	Save child at all possible costs	"*In a perfect situation, you want to weigh the possibilities, but if there is something to save that child's life, then we would do it. We would go with immediate enrollment because it is in the best interest of that child."* (Adult Participant)		x	x	x	x	x	x	x	7
#2: Attempt to get consent	Importance of patient choice balanced with potential to save life	"*At first I was going to pick Option 1, but I thought that I would at least want to know the hospital tried to contact me before giving an experimental drug.*" (Adult Participant)		x	x	x	x	x	x	x	7
	Doctors may not know important medical history information that may affect drug administration	*"I would also want to know the information because my son does have a long medical history. When I take him to the emergency room, I have to give a high level history and doctors don't see that because it's so far back in his medical history. I worry them not knowing everything about his medical history."* (Adult Participant)	x		x	x	x				4
	Religious beliefs/ values need to be respected	"*There are a lot of people that have different religions and what if they [doctors] gave the medications and they [parents] didn't want them. That would be a huge dilemma. I've been through it."* (Youth Participant)	x		x	x	x				4
#2a amended	Time is of the essence, but at least try to make contact	*"If you are not going to reach them in one hour, you are not going to reach them in two hours."* (Adult Participant)	x	x	x	x					4
#3: Must obtain consent	People must be given a choice so that personal values will be respected	*"Anytime you are changing a treatment, that consent it important to me. When you go into a hospital and you can decide for yourself you can feel confident in the outcome. If someone makes the choice for you, then you are not as confident about that outcome. What if they don't get the drug, or what if they have a reaction to a high dose. Ethically, it's unsettling to me because you don't have a choice. It sounds like a positive treatment and I might choose it for my daughter."* (Adult Participant)	x	x		x			x	x	5
	Skeptical of the medical establishment/There is a history of unethical research studies particularly with African American participants	"*Now I am thinking about the Tuskegee study, and I feel like I am putting my children on something like that, and I am giving consent to something I don't even know about. You're asking a medical idiot to decide if doctors should use this drug on my child when they're not even sure it's going to help. These are our children we're talking about!*" (Adult Participant)		x		x		x	x		4