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ORIGINAL ARTICLE

Measuring the efficacy of community consultation in a pediatric exception from informed consent trial

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Abstract

Background: Community consultation activities are required by the Food and Drug Administration prior to conducting research using exception from informed consent (EFIC) for emergency research and aim to provide additional participant protections. However, it is difficult for institutional review boards (IRBs) to assess the efficacy of such activities. In this study, our primary aim was to evaluate the efficacy of the PediDOSE trial's consultation activities by answering key questions about whether consultation efforts reached a relevant community and if the perspectives of the consulted community coincided with those of parents actually enrolled in the study.

Methods: Qualitative findings of semistructured interview data collected during community consultation efforts were compared with interview responses from parents of children enrolled in the PediDOSE trial to identify common themes.

Results: Most themes were identified in both groups, but additional themes emerged with parents of enrolled participants that may be important for future study teams and IRBs to consider. Even with an overrepresentation of White and non-Hispanic/Latino participants in the community consultations compared to those who were enrolled in the EFIC study there was common overlap of themes.

Conclusions: Parent interviews added to our understanding beyond the themes identified in the consultation interviews. The theme of therapeutic misconception was not found in the consultation interviews, possibly due to the child's emergency medical care being theoretical. With modest accommodations, collection of additional demographic and follow-up interview data can successfully assess key elements of community consultation efficacy for EFIC trials.

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INTRODUCTION

The practice of informed consent is an accepted standard for respecting the autonomy of participants in clinical trials; however, foregoing prospective informed consent in research during medical emergencies is often necessary to test and evaluate new interventions. The regulatory provisions for an exception from informed consent (EFIC) study allow institutional review boards (IRBs) to approve clinical trials for life-threatening conditions that will begin study interventions without first obtaining consent from the participant or proxy consent from a legally authorized representative.[1] The regulations require that EFIC studies must meet strict criteria for an acceptable risk–benefit ratio and require engagement in community consultation and public disclosure processes to create public awareness and generate feedback from the communities where the study will take place.[1,2] It is up to IRBs to evaluate these elements of an EFIC study and determine if requirements have been satisfied.

Publications and guidance describe methods to conduct community consultation in ways that may be considered suitable, including community forums and meetings, social media, surveys, and discussions with patient advocacy groups.[2–10] However, the current literature shows limited evidence to demonstrate how an IRB can or should evaluate the efficacy of the community consultation once these activities have been performed.[11]

Attempts to define and report on elements of community consultation efficacy have been described. Elements consistently discussed are whether the consultation include a relevant community[12–14] and if the consulted community: (a) understood the concept of EFIC and/or the study design and procedures[4,15,16]; (b) provided meaningful feedback about the study to the researchers and if feedback was incorporated by the researchers[13,17]; and (c) accepted or rejected the proposed study.[4,13,16–19] Venue location for consultation and information dissemination is also described.[4,16,20] These elements of efficacy and quality are likely valid and appropriate based on the overarching purposes of community consultation. They are not necessarily straightforward to define and measure; however, as they are complicated by the difficulty in defining "community" and indications of discordance with community responses, making it difficult for an IRB to know if the consultation was truly efficacious.[14,15,17,19]

An aspect of community consultation efficacy missing from the literature is whether the community of potentially affected persons participating in the consultation aligns with the population of persons enrolled in the emergency research. This alignment can certainly be viewed with a demographic lens, and while comparing the demographics of a clinical trial's enrolled population to the general population is common, we have yet to identify a comparison in the literature of an enrolled EFIC population to those specifically included in the community consultation activities. This alignment can be further assessed based on the perspectives and understanding of the enrolled EFIC population to those who provided feedback during the consultation phase. The EFIC regulations only require that community consultation activities be conducted prior to enrollment; however, without further evaluation in comparison to the new information that can be learned from enrolled participants, IRBs are missing a key component in evaluating efficacy.

The purpose of this study was to evaluate the efficacy of community consultation in a pediatric EFIC study by answering the following questions: (a) Did the consultation include a relevant community that was demographically representative in comparison to both the general population and the enrolled pediatric participants? and (b) Did the perspectives and understanding of the consulted community coincide with that of the parents of enrolled pediatric participants? We partnered with the Pediatric Dose Optimization for Seizures in Emergency Medical Services (PediDOSE) clinical trial, whose aim is to compare the efficacy and safety of using a seizure treatment protocol with standardized, age-based midazolam dosing compared to conventional protocols with weight-based dosing when treating children transported to an emergency department (ED) for a paramedic-witnessed seizure. PediDOSE is a 20-site trial with a stepped-wedge design, enrolling children between 6 months and 13 years old in the Pediatric Emergency Care Applied Research Network (PECARN). Prior to enrollment, each site conducted community consultation and public disclosure procedures including at least 100 surveys from families seen in the ED, 10 parent interviews, hand-outs and/or posters displayed in high-risk patient areas, emails to the EMS and medical communities, and development of a website. Sites selected additional activities from a list of options including social media advertisements, targeted mailings, or distribution of newsletters to community representatives. PediDOSE received approval as an EFIC study from both the Food and Drug Administration (FDA) and a central IRB and began enrollment in 2022.

METHODS

The present efficacy study of community consultation was approved by the central IRB and the local human research protection programs prior to initiation.

Demographics comparison

Demographics from the general population and the study site geographic areas were collected from the 2020 U.S. Census. Demographic information about PediDOSE consultation participants were used as previously collected from the PediDOSE study. We collected demographic data directly from parent interview participants during the interviews. Demographics included age, gender, race, and ethnicity. We note that race and ethnicity are social constructs without biologic meaning; however, these variables can be valuable for understanding disparities and inequities in health care and related research.[21]

Perspectives comparison

We interviewed parents of children enrolled in the PediDOSE study during the first 14 months of enrollment who provided consent for ongoing participation. PediDOSE participants were informed of the opportunity to be interviewed after their child was enrolled, as a part of the study's notification process. Parents were able to indicate their preference about being contacted in the future for a follow-up interview. During the recruitment period, 101 parents agreed to future contact; all 101 parents were contacted via phone or email by a member of the study team not involved in the conduct of the PediDOSE trial. Research staff obtained verbal consent and scheduled the interviews ($n = 18$). Parents of enrolled children who participated in the follow-up interview were at least 18 years of age and preferred English or Spanish. Parents from six out of 20 sites were included, as we conducted most of our interviews before all 20 sites were activated to begin enrollment. At the time of the interviews, none of the contacted parents had made a formal complaint through the PediDOSE trial.

Interview questions were developed to align with the PediDOSE community consultation interview guide and online survey to ensure consistency in the topics discussed[20]; a semistructured interview guide with standardized questions was used (interview guide is available as supplemental material accompanying the online article). Interviews were conducted by a trained researcher (NR) and transcribed.

We obtained deidentified data and analysis results from the PediDOSE community consultation semistructured interviews for comparative analysis. For the PediDOSE community consultation interviews, seven different investigators independently analyzed a subset of interview transcripts, applying grounded theory and using constant comparison to develop codes and themes. The PediDOSE investigators jointly discussed their independent analyses, agreed that thematic saturation had been achieved, and then developed a cohesive framework based on the codes and themes they identified from their independent analysis. Eight major themes emerged from interviewee comments (Table 1).

Content analysis was used to evaluate our parent interview transcripts, comparing the content with the themes of the PediDOSE community consultation interviews.[22] Thematic codes for the parent interviews were developed by two independent coders (AJ and NR). The Spanish-speaking research associate (AC) who conducted the Spanish-language interviews reviewed the English translations of the transcripts as well as the thematic codes to ensure accuracy for Spanish-speaking interviewees. Any discrepancies in coding were discussed until consensus was reached. Quotes represented under

TABLE 1 Comparison of community consultation and parent interview themes.

Community consultation themes	Theme description	Parent interview themes	Theme description
Beneficence	The potential the research had in ensuring delivery of evidence-based, high-quality patient care that would benefit the greater good.	Benefits and importance (veracity)	The potential the research had to find truth that could benefit those experiencing a seizure disorder.
Maleficence	The need to prevent unsafe care that could result in patient harm.	Consent, autonomy, and respect	The value of providing high-quality information in a timely way, even when parent decision-making opportunities are limited by the emergency situation.
Autonomy	The desire to have agency to make decisions for their children in an emergency while acknowledging that people may not have the capacity to do so in a stressful situation.	Consultation and communication	How to effectively disseminate study information to the parents of potentially enrolled children.
Concerns and fears	Related to potential medication dosing errors, allergic reactions, or adverse events.	Trust and distrust	Trustworthiness of health care professional and the systems in which they work in contrast to the distrust some had in an untested treatment.
Trust and distrust	Trustworthiness of health care professionals and the systems in which they work in contrast to the distrust some had in allowing non–family members to make decisions for their child.	Fear and relief	Related to the fear of experiencing their child have a seizure and the relief that comes when a treatment starts to take effect.
Veracity	The desire to find truth through studying life-threatening conditions to know what can save lives and improve treatment.	Therapeutic misconception	Confusion about the distinction between the child's medical treatment and the study procedures.
Respect	The need for investigators to establish trust with people and letting them ask questions about the study as soon as possible.		
Research challenges	Awareness of challenges in doing pediatric prehospital research.		

Results may have been edited for understandability or conciseness, without changing the meaning or sentiment of the quote.

RESULTS

Demographic comparison of those engaged in PediDOSE community consultation surveys and interviews after 14 months of trial enrollment and the general population of the United States is presented in Table 2. Those who identified as White (61% and 70%) and/or not Hispanic or Latino (77% and 79%) made up the majority of community consultation survey and interview participants, respectively. This contrasts with the enrolled participant and general population data, which show individuals identifying as White accounting for 29% and 55% of the populations, respectively, and non-Hispanic or Latino individuals accounting for 58% and 81%, respectively. This phenomenon was further assessed at the site level (Figure 1), directly comparing the percentage of White respondents in the PediDOSE community consultation activities with the percentage of White participants enrolled in the PediDOSE study. The proportion of White participants was normalized among participants where race was known. For most sites, the percentage of White respondents in the PediDOSE community consultation was greater than the percentage of White subjects enrolled in the PediDOSE study. A large majority of community consultation survey and interview participants identified as female (71% and 79%) and as a parent of a child (77% and 77%). After 14 months of PediDOSE trial enrollment, 140 parents, representing 7% of all eligible children, elected to have their child withdrawn from the study after intervention and notification processes occurred.

Eighteen follow-up interviews of parents whose children were enrolled in the PediDOSE study were completed, with key demographics described in Table 3. Most parents also identified as White (62%), non-Hispanic or Latino (72%), and female (72%). Fifteen of those interviews were conducted in English and three

TABLE 2 Demographic characteristics summarized by population for the PediDOSE community consultation and trial.

Variables	U.S. population	Community consultation surveys ($n = 2451$)	Community consultations interviews ($n = 206$)	Enrolled subject data ($n = 1425$)[a]
Race				
White	54.7%	1483 (60.5%)	144 (69.9%)	418 (29.3%)
Black or African American	21.7%	374 (15.3%)	24 (11.7%)	461 (32.4%)
Asian	8.7%	137 (5.6%)	5 (2.4%)	87 (6.1%)
Other	7.6%	314 (12.8%)	22 (10.7%)	19 (1.3%)
Two or more races	7.4%	62 (2.5%)	9 (4.4%)	35 (2.5%)
Unknown	—	81 (3.3%)	2 (1.0%)	405 (28.4%)
Ethnicity				
Not Hispanic or Latino	80.8%	1890 (77.1%)	163 (79.1%)	825 (57.9%)
Hispanic or Latino	19.2%	523 (21.3%)	43 (20.9%)	347 (24.4%)
Unknown	—	38 (1.6%)	0 (0%)	253 (17.8%)
Sex				
Female	50.7%	1730 (70.6%)	163 (79.1%)	651 (45.7%)
Male	49.3%	661 (27.0%)	43 (20.9%)	768 (53.9%)
Unknown	—	60 (2.4%)	0 (0%)	6 (0.4%)
Age (years)	—	37.0 [30.0, 44.0]	39.0 [34.0, 47.0]	3.6 [1.9, 7.0]
Age (years)				
<5	5.9%	0 (0%)	0 (0%)	—
5–17	14.1%	18 (0.7%)	0 (0%)	—
18–65	67.6%	2300 (93.8%)	200 (97.1%)	—
≥65	12.4%	41 (1.7%)	4 (1.9%)	—
Unknown	—	110 (4.5%)	2 (1.0%)	—
Parent of a child				
Yes	—	1886 (76.9%)	159 (77.2%)	—
No	—	502 (20.5%)	45 (21.8%)	—
Unknown	—	63 (2.6%)	2 (1.0%)	—

[a]Data shown here are for subjects enrolled in the PediDOSE trial up until the time when data analysis was conducted for this ancillary study, not subjects enrolled in the entire trial.

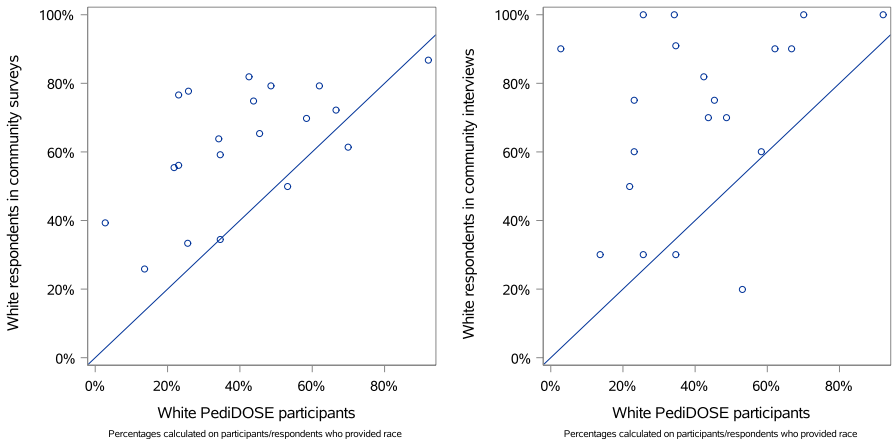

FIGURE 1 Percentages calculated on participants/respondents who provided race.

TABLE 3 Demographic characteristics for parents of enrolled children who participated in a follow-up interview.

Demographic variable		*n* (%)
Mean age 36 years		
Gender		
	Female	13 (72%)
	Male	4 (2%)
	Missing	1 (6%)
Ethnicity		
	Non-Hispanic/Latino	13 (72%)
	Hispanic/Latino	5 (28%)
Race		
	Black/African American	4 (2%)
	White	11 (62%)
	Decline to answer	3 (17%)

were conducted in Spanish. The average interview lasted 15 min, ranging from 5 to 35 min. The six themes identified from the follow-up interviews were (1) benefits and importance (veracity); (2) consent, autonomy, and respect; (3) consultation and communication; (4) trust and distrust; (5) fear and relief; and (6) therapeutic misconception.

Benefits and importance (veracity)

Several parents shared what they believed were the benefits of an EFIC study, who would benefit, and their motivation to participate. One potential benefit was that the medication might be administered more quickly, which could improve outcomes; "It lessens the time of delivery, right? We were talking a matter of seconds and minutes that could really make a big difference. That's a benefit." Many parents acknowledged that studies like this benefit a community of people who experience seizure disorders, as noted by this parent: "we'd be willing to participate, especially if we felt like it would be beneficial, not only to us, but to help others in the future." Many parents also expressed their support for research because of the benefit of improving our understanding of the treatment and the outcomes of patients with this condition. Several examples of this are included as follows:

> I think it should be conducted because I'm all for data. If we don't get the data that we need in the medical field, we will not be able to improve on treatment for patients. This has to continue. More data has to be gathered, and then if there are certain improvements to be made or changes or anything, then it can be effective.

> ... epilepsy is kind of something that's not really been figured out and just something that needs to be researched before—because it can easily, quickly become a deadly situation. ... Within the moment for epilepsy is when the person is seizing where you find out the most information. I would definitely be willing to do it, and I would hope other people would too, because you can't really find out that much if you're not seizing.

> ... I think you get a broader picture how people are gonna react, and you get a broader picture of the medication itself .... You can see, okay, we did X, Y, and Z, and this worked, but this didn't, and now we can streamline it so in a full-on setting where we're using this every day, we can do this and make it work better.

Consent, autonomy, and respect

A notification process for informing parents that their child had been enrolled in the PediDOSE study occurs at the earliest feasible opportunity after their child had been stabilized, which could be hours to days after ED arrival. When asked about the concerns parents had about their child being enrolled in a study without their consent, parents generally understood the limitations for consent in an

emergency situation. However, some expressed that they wished consent could have happened before the treatment started. A few quotes highlight this feeling:

> To find out afterwards that it was a study was a little concerning, but to be honest with you, it was the least of my concerns … I guess, possibly if the paramedics would have let me know at the time that, hey, this dosing for this age group or something like that … —I would have appreciated knowing that as opposed to participating in a study without realizing that it was a study and just assuming that it's accepted general practice.

> I think consent is very important, but then, also, it depends on each situation. In this case, it was an emergency. For an emergency situation, consent is okay, but then also you're also thinking about, "Oh, my God, what's going to happen to my child?" In that situation, whatever is given is going to be okay for a parent.

When asked if there had been time to gain informed consent prior to the study treatment, most parents said that they would still want their child enrolled, with only one parent stating that they were undecided. No one said they would not have participated.

Parents were asked how researchers could promote more respect for patients when doing emergency research on children. Many parents expressed an understanding that emergencies are unique and therefore consenting after the intervention was necessary, voiced well by a parent stating, "As long as you just get the permission that you need as soon as you can, it was fine, which was—in our case—what happened."

The most common recommendation parents gave to promote more respect during emergency research was concerning the timing of research notification, with a desirable time being after the child was stabilized but before discharge. For example, "I think maybe if they could time it slightly closer to the urgent activity that maybe that would feel a little more appropriate … Obviously, not in the middle of it, but maybe prior to release from the hospital or within 12–24 h or something like that."

One parent expressed that they felt informed about what was happening to their child throughout the process of treatment, despite the research notification process not having occurred:

> I guess it didn't necessarily feel like it was without my consent that they were treating her. They figured out what the dose was, and they gave it to her. I felt like I was kept in the loop, and I appreciated that because, as a parent, I want to make sure I'm understanding what's happening to my kids and why they're given—being given particular dosages of whatever. In that case, it was a lot going on, but I did feel like I was kept informed, and I appreciated that.

Additionally, some parents expressed understanding for not being given all the information about what was happening to their child during treatment, noting that it is helpful for the care team to keep the parent informed in pieces along the path of treatment until the child was stable. For example, one parent said the following:

> As a nurse myself, I realize that sometimes—there's always gonna be a guy in the room that knows more than me, and sometimes you just have to go with it because there's probably—as long as they're explaining to me what's going on or let me semi know what's going on, I might go for it because I'd rather my child have the best chance at not having brain damage or getting sick or progressing and then waiting for the other stuff because that's why I brought him into the emergency room, was for emergency care, and that does not always mean that there's time to ask me.

Consultation and communication

Parents gave suggestions for who should be involved in disseminating the study details and the best mode to communicate with the community. Many parents wanted the information to come from their child's physician in a face-to-face conversation or over the phone, so they could be present and ask questions. Other suggested modes for the dissemination of study information included email, social media (e.g., Facebook, Twitter), or support groups or foundation websites (e.g., Dravet Syndrome online support group, Epilepsy Foundation); using banners/billboards or booths at a community events; or through one's primary care physician, letters sent to those with children known to have seizures, patient portals (e.g., MyChart), a phone call, advertising within the ED with flyers on the wall, or a letter sent home with discharge papers. Many parents were basing these recommendations on places and venues to which they regularly pay attention. For example, "I tend to like emails. I check my emails 24-7. I probably check my emails every hour. For me, emails is easier" and "Maybe putting it on the news … Billboard … My husband usually tells me. He listens to talk radio."

Trust and distrust

The next theme identified from the interviews was about trust. Many parents expressed their trust that the medical team had the expertise to provide the best care possible, even if the treatment was part of research. This is represented by the following quotes:

> I felt like I trust the professionals to do their job like they're trained to do that, and I'm not an expert.

> It's almost like not knowing that it was experimental allowed the medical professionals to make the best judgment at the time, so relying on their expertise to control the situation.

The expressions of distrust manifested largely as fear of an untested treatment, as is seen in the following quotes:

> When they were trying to figure out the dosage, that's when a red flag came up and was like, okay, do these guys know what they're doing? Because in the moment, they're basically guessing. I didn't know that it was, "experimental," just that they were trying to figure out the right dosage, if that makes sense.

> —if someone's going to do something that's a deviation from the standard of care, or they're not doing standard of care in lieu of doing this other study thing, that's in the study, then I think that's where it could get risky.

> They are like mixed feelings. It's like, my son, a child, I don't know what's going on, but at the same time, I'm trusting them, but at the same time, I'm worried that they're going to use a medication that's dangerous and they won't ask me.

Fear and relief

Parents shared their feelings about witnessing their child seizing. For those who had one or more children with a history of seizures, their views were often more pragmatic in the way they described their child's seizure episode, as opposed to parents who experienced the seizure of a child for the first time when enrolled in PediDOSE. However, during the emergency circumstance, parents expressed a fear of the unknown, as they related their experiences of the seizure as "terrifying" no matter how often the parent had experienced them in the past and a sense of relief when their child was no longer in danger. For example:

> We're on this seizure med, so this isn't supposed to be happening. We have nothing on hand to treat this, and we're just kinda makin' it up, so we're just terrified, just sittin' here holding him. … the 10 min between the—when [EMS] got there—and the seizure started was just the most horrifying experience ever. All you could think about was how I'm gonna lose my child or he's gonna have brain damage because I've seen this before, and I'm like—what else could I do more? Just so powerless too.

Therapeutic misconception

Some parents communicated confusion about their child's medical treatment versus the study procedures. Additionally, some participants did not understand that their child had been enrolled in a study or did not remember being enrolled. This may have come from misunderstanding some of the language used to differentiate the study from clinical care. For example, when asked about the benefits of doing research in an emergency, one parent responded with, "That they might already have results by the time they need … Because, in our situation, all the other tests that we have done have all came back normal. We didn't really have too many answers in the beginning of our journey …" This parent had confused the term "research" with laboratory testing done for their child's care.

Some parents also expressed a lack of understanding between research staff and clinical staff responsibilities for informing participants about research. One woman shared, "It's okay. [The ED staff] help the best they can or the best they can do it because I cannot able to tell you nothing about the benefits, ma'am, because it's—… I know they have some other babies that they need to take care of." When asked how to improve the study's procedure, one participant suggested, "if there was any sort of suggestion that I would have, it would most likely be that doctors and nurses try to explain it to the average person," again confusing clinic personnel with research staff. One parent, when asked if they had heard of the PediDOSE trial prior to enrollment, answered "No. When you say '*enroll*,' what do you mean by that? Like my child is enrolled in that program and maybe they are going to do further studies or something," indicating limited understanding of how participants are enrolled into research studies. Fortunately, there were also parents who were able to recall and share the details of the study.

DISCUSSION AND LIMITATIONS

Demographics comparison

The demographic comparison shows a difference between those who participated in the community consultation activities and those who were enrolled in the PediDOSE study. Those who identified their race/ethnicity as White and/or non-Hispanic or Latino appear to be overrepresented in the consultation activities and underrepresented as enrolled participants, in comparison to the general population. In contrast, those who identified their race/ethnicity as Black or African American and/or Hispanic or Latino appear to be underrepresented in the consultation activities, but overrepresented as the enrolled participants. This conclusion is limited by the fact that for enrolled participants, race is unknown for 28% of the group and ethnicity is unknown for 18%. One reason race and/or ethnicity is missing in 18%–28% of enrolled participants is that a subset of enrolled participants were transported to a hospital from which race/ethnicity data could only be acquired from the EMS record. Many

EMS records attribute Latino ethnicity without a race classification and classify race classifications without an ethnicity classification. However, the trend toward higher representation of White perspectives was also observed with the parents who agreed to participate in follow-up interviews. Demographics alone do not necessarily lead to a difference in perceptions toward research and the use of EFIC procedures; however, the existing concerns over social injustices in the United States are perpetuated when we over- or underrepresent groups of people.

Perspectives comparison

The themes from the parent interviews were largely in common with those from the community consultation interviews. This supports a conclusion that the consultation was efficacious in understanding the views and perceptions of parents of enrolled children. There are a few limitations in making this conclusion. First, parents who participated in interviews were self-selected and may not necessarily represent the views of all participant parents. Although all interviewed parents indicated they would likely have participated in the study had they been given the opportunity to consent in advance of the study intervention, there have been two parents who complained about the PediDOSE trial to site personnel and 140 who asked that their child's data not be used in the trial. The possible self-selection bias for parents in the interviews was not able to capture these perceptions. Second, the comparison of participants with English versus Spanish language preference does not account for the depth of cultural perspectives that may differ; this study was not designed to capture and understand these differences. Lastly, the study could have benefitted from inclusion of parents from all 20 sites.

The parent interviews did add to our understanding that went beyond the themes identified in the consultation interviews. The parent interviews identified the theme of therapeutic misconception, one that was understandably not found in the consultation interviews as the need for a child's emergency medical care was only theoretical and did not have the same urgency or emotion as the actual experiences of parents of enrolled children. It is unsurprising that this theme arose for the parents, given the pervasiveness of therapeutic misconception in clinical trials,[23–25] the nuanced difference between PediDOSE's intervention versus the standard of care, and the higher stress of emergency situations possibly leading to reduced memory recall.[26,27] This may suggest the need for study personnel to emphasize the difference between the intervention and normal care in the postintervention notification process. However, fully overcoming the barrier of therapeutic misconception in a trial such as this may not be realized.

The idea that informed consent can happen in parts over time—as identified in the theme of consent, autonomy, and respect—is one for IRBs to consider more deeply. There are valid and important criteria that must be met for informed consent to be obtained compliantly in a research setting,[28–30] though IRBs should evaluate areas of flexibility that would allow the informed consent process to be more natural to lay persons. The parent interviews showed instances where parents felt informed and respected because caring health care professionals and research staff were providing them with information as care was delivered and time passed. Though regulatory vigor would not consider the process these parents experienced to constitute a complete research consent process, it did offer the necessary respect and feedback that parents valued in those moments. It would be unfortunate for IRBs not to give credence to what this process accomplishes and the meaning it provides to participants.

A final point that we observed is that the use of social media for consultation and public disclosure is expected from participants' parents in the current era. As social media has become a central forum for information receipt for many segments of the population, its responsible use in research continues to be explored with published recommendations that provide IRBs with a framework for reviewing and approving this method of communication in general and in EFIC research.[5,6,31,32]

Methodologic feasibility for standard use in EFIC trials

The demographic assessment was valuable in showing that greater effort is needed to seek the perspectives of minoritized populations during the community consultation phase. The collection of these demographic data required minimal effort and cost; census data are available to the public and clinical trials are routinely designed to collect demographics, including age, sex, race, and ethnicity. To further streamline the process, study personnel should ensure that data capture systems support ease in collection and reporting of such data.

The follow-up interview experience was valuable by providing actionable feedback from the parents of enrolled participants on issues that were not mentioned during the community consultation. Conducting follow-up interviews requires additional time and money. Such costs could be accounted for in a study's budget, were the study team to take on this responsibility. It could also be performed by an institution's human research protection program or IRB, were the necessary infrastructure in place, perhaps as part of the program's postapproval monitoring and quality assurance activities. There may be value in having a party independent of the study team conduct these follow-up interviews, were there to be concerns that the participants would not be forthright about their feelings if study personnel were to ask. In trying to ascertain perspectives from participants who withdrew from or complained about the study, independence may be more imperative.

CONCLUSIONS

Though there were differing race and ethnicity demographics for those who participated in PediDOSE community consultation

activities, those who enrolled in the PediDOSE trial, and the parents of enrolled children who participated in follow-up interviews, there was a concurrence of interview themes between community consultation participants and interviewed parents. Participants in both sets of interviews acknowledged the benefits of research using exception from informed consent procedures, while understanding the limitation to consent and autonomy. The themes also showed the participants' competing feelings of their trust in medical professionals and their distrust due to the loss of autonomy when an untested treatment is used. Therapeutic misconception continues to be a concern for these types of clinical trials, as shown in the parent interview themes.

With modest accommodations for collecting additional demographic and follow-up interview data, we believe our methodology for assessing two key elements of community consultation efficacy was successful and can be applied to other exception from informed consent trials. Additional use and evaluation of this methodology are needed, across a wide variety of exception from informed consent studies, to understand its true benefits, costs, and limitations.

AUTHOR CONTRIBUTIONS

Ann R. Johnson contributed to the study concept and design, analysis and interpretation of data, drafting and critical revision of the manuscript, and acquisition of funding. Naomi O. Riches contributed to the acquisition of data, analysis and interpterion of data, and drafting and critical revision of the manuscript. John VanBuren contributed to the study concept and design, drafting of the manuscript, statistical expertise, and acquisition of funding. Ana E. Corona contributed to the acquisition of data, analysis and interpterion of data, and drafting of the manuscript. Kammy Jacobsen contributed to the acquisition of data, analysis and interpterion of data, and drafting of the manuscript. Shu Yang contributed to the drafting of the manuscript. Manish I. Shah contributed to the study concept and design, analysis and interpretation of data, drafting and critical revision of the manuscript, and acquisition of funding.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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