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Utilizing Focus Groups with Potential Participants and Their Parents: An Approach to Inform Study Design in a Large Clinical Trial

Sandeep Kadimpati, B.D.S., MPH,
Mayo Clinic

Jennifer B McCormick, PhD, MPP [Assistant Professor],
Biomedical Ethics Program College of Medicine Mayo Clinic 200 1st ST SW Rochester, MN 55905

Yichen Chiu, MA,
Mayo Clinic

Ashley B. Parker,
Davidson College

Aliya Z. Iftikhar,
University of Wisconsin Madison

Randall P. Flick, M.D., and
Mayo Clinic

David O. Warner, M.D.
Mayo Clinic

Abstract

Background—In the recent literature, there has been some evidence that exposure of children to anesthetic procedures during the first two years of life may impair cognitive function and learning in later life. We planned a clinical study to quantify this risk, a study involving testing 1,000 children for neurodevelopmental deficits. As a part of this planning, we conducted focus groups involving potential participants and their parents to elicit information regarding three issues: communications with the community and potential participants, recruitment and consent processes, and the return of neurodevelopmental testing results.

(corresponding author) mccormick.jb@mayo.edu.

AUTHOR CONTRIBUTIONS
JBM, SK, DOW, and RPF conceived the idea and the study design and were involved in drafting and editing the manuscript. JBM and SK conducted the focus groups. SK, YC, AI, and ABP, led by JBM, did the data analysis and contributed to writing the first draft. All authors approved the final version of the manuscript.

COMPETING INTERESTS
None declared.

ETHICAL APPROVAL
This study was approved by the Mayo Clinic Institutional Review Board.

Methods—Three focus groups were conducted with the parents of potential participants and one focus group was conducted with an 18-19 year old group; each group consisted of 6-10 participants. The moderated discussions had questions about recruitment, consenting issues, and expectations from the study about return of both overall trial findings and individual research test results.

Results—The focus group data gave us an insight on potential participants' views on recruitment, consenting, communications about the study, and expectations about return of both overall trial findings and individual research test results. The concerns expressed were largely addressable. In addition, the concern we had about some parents enrolling their children in the study solely for the sake of getting their child's cognitive function results was dispelled.

Conclusions—We found that the individuals participating in our focus groups were generally enthusiastic about the large clinical study and could see the value in answering the study question. The data from the focus groups were used to inform changes to the recruitment and consent process. Focus group input was also instrumental in affirming the study design regarding return of results. Our experience suggests that the approach we used may serve as a model for other investigators to help inform the various elements of clinical study design, in particular the recruitment and consenting processes and expectations of potential participants regarding the return of individual research findings.

Keywords

Anesthesia; Learning disability; Focus groups; Research trial participation; Return of test results

INTRODUCTION

Increasingly, researchers are turning to potential research participants to seek input on the research they do using a variety of approaches, including, for example, deliberative community engagement, community based participatory research, or community advisory boards. In some instances, the goal is to identify the needs of the community, and in others it is to better understand the hopes and concerns the community may have about a particular study. Many institutions with bio-banks have established community advisory boards, and investigators turn to the members of these boards for input on a variety of ethical, social, and policy issues (e.g., particular studies requesting samples, return of genetic research results, and data sharing policies).

We report here the use of focus groups to obtain feedback on certain elements of a clinical research study we were planning. We received a National Institutes of Health (NIH) multi-year award to conduct a clinical study that aims to define a detailed phenotype of anesthesia-associated neurotoxicity (if this injury in fact exists). The study is based on data from prior animal model and observational investigations done by our research team and others (Boscolo et al. 2013; Brambrink et al. 2013; Bruins et al. 2012; Eriksson et al. 2006; Flick et al. 2011; Fredriksson et al. 2007; Friedman et al. 2003; Lehohla, Kellaway, and Russell 2004; McFie et al. 2012; Sprung et al. 2012; Wilder et al. 2009; Yu and Liu 2013).

The central hypothesis of the study is that exposure to multiple anesthetics prior to three years of age will impair later performance of children on detailed tests of neurodevelopmental performance. To evaluate this hypothesis, we plan to identify a cohort of children born in Olmsted County, Minnesota between 1994 and 2007 and currently residing in the area. From this cohort, children exposed to anesthesia prior to age 3 will be propensity-matched to children never exposed to anesthesia. Children from both groups will be invited to participate in a single four-hour session of detailed neuropsychological testing, and the results will be analyzed according to anesthesia exposure history. Testing will be performed at ages 8-12 years and ages 15-19 years in separate groups of children.

At the outset of planning, we identified several potential ethical and social implications that might challenge the successful implementation of the study. These can be broadly divided into issues related to recruitment and consent processes and issues related to return of both individual and aggregate research results. Most individuals are not aware that exposure to anesthesia at an early age may have detrimental effects, and we wanted to minimize any distress that our hypothesis might raise during recruitment. The latter set of issues were also of concern as neurodevelopmental testing could reveal otherwise undetected learning impairments. In addition, because the testing regimen will involve a battery of research assessments, rather than a defined battery of tests used in clinical practice, the clinical significance of any identified impairment may not be apparent without further testing, which could complicate the full reporting of results to the participants or their parents. Since these issues raise important ethical issues, and since high rates of consent will be crucial to the successful completion of the study, we sought feedback from potential participants using focus groups as a part of the study planning process.

Using focus groups allowed us to better understand the perceptions of potential study participants and their parents regarding three domains pertinent to the planned study: (1) communications, both with the larger community regarding plans for the study and with individual potential participants and their families; (2) the recruitment and informed consent processes; and (3) whether and how to return neurodevelopmental testing results for individuals. Our experience using focus groups to obtain input from potential study participants suggests that the approach we used may serve as a model for other investigators to help inform the various elements of clinical study design, in particular the recruitment and consenting processes and expectations of potential participants regarding the return of individual research findings.

METHODS

We employed focus group methods to collect qualitative data that could not be gleaned from a survey using forced-choice methodologies. In addition, participant interactions can facilitate exploring questions or themes not originally conceived in the research design.

Two distinct populations participated: parents with school-age children and adults who were 18 to 19 years of age. The former population represents parents of potential study participants, who would be giving consent for their children to participate in the study, while the latter represents potential study participants who themselves would provide consent.

Participants were recruited through local city-wide newspaper advertisements, internal institutional "classified ads," and flyers distributed to local businesses (e.g., notice boards in coffee shops, the local mall, and bookstores).

Individuals who were interested in participating in this study were instructed to contact a study coordinator. Inclusion criteria included being able to speak English (a requirement for participation in the planned clinical study). In this initial conversation, we explained the study procedures. Those who were still interested were sent an invitation letter and invited to attend a scheduled focus group, at which time oral informed consent was obtained. The only information the participants had about the parent study was the brief description provided in the advertisement and classified ad.

Four focus groups were conducted in May and June of 2012 at the Mayo Clinic in Rochester, Minnesota after approval by the Mayo Clinic Institutional Review Board (IRB). Three groups consisted of parents of school age children, while the remaining group consisted of 18-year-olds. Two co-moderators conducted each group using a semi-structured moderator guide covering the domains of interest.[1] The guide for the parents' groups was slightly modified between sessions based on prior focus group deliberations. To summarize the approach, the moderators briefly described the parent study and then asked the participants to share their hopes, concerns, and expectations about the study. Moderators then explored issues regarding communications, the logistics of testing, and the return of individual and aggregate neurodevelopmental testing results. Each focus group was approximately 90 minutes in length. Participants were served refreshments during the focus groups and received compensation for their participation.

Data Analysis

All focus group discussions were audio-recorded, transcribed, de-identified and then analyzed using the following approach. Initially SK, JBM, ABP, and AI (the analysis group) each read the transcripts carefully, making notes and identifying possible themes that would lend themselves to codes. The analysis group met to devise an initial coding scheme that was iteratively modified over time while it was simultaneously(?) piloted by two team members independently coding the same transcript and comparing their results. We agreed upon a final scheme after several iterations of this piloting process and this final scheme was used for complete coding and analysis. ABP and AI, using the final coding scheme, independently coded each transcript in QSR Nvivo8, a qualitative data analysis software application. The analysis group came together to arrive at a consensus when differences arose. JBM and SK moderated differences as needed. The development of these themes and subsequent coding was based on the principles of grounded theory and inductive qualitative analysis to look for themes that were not anticipated by the study team members (Corbin and Strauss 2000).

All data were stored on a secure server and only accessible to study team members. Audio and any materials with identifiers were accessible to only SK and JBM.

[1]The focus group moderator guide is available upon request from the corresponding author.

RESULTS

This section presents the major themes identified within each domain explored in the focus group discussions. A total of 24 individuals participated in the four focus groups. Eighteen individuals participated in our three "parent" focus groups, and 6 participated in the single 18-19 year old focus group. All parents participating in the focus groups had at least one school age child who could potentially be eligible and recruited to participate in the parent study. It was not necessary for parents to have a child with a learning disability or to have a child who had been exposed to general anesthesia prior to 3 years of age, and we did not specifically ask for this information. However, some participants did voluntarily disclose that they had a child with a learning disability or had a child exposed to anesthesia before age 3. All individuals in the 18-19 year old focus group were 18 years of age and had just graduated from high school. There were not major thematic differences between the 18-19 year olds and the three parent groups.

Recruitment and Informed Consent

A consistent theme was the need during recruitment and consenting to be explicit about the tasks the child would perform during testing, how long the child would be in the testing room, where the testing would occur, and who would supervise. Participants told us that parents would want to know exactly what types of tests would be performed during this time, and that the explanation be in lay language so that their children would not be intimidated or embarrassed:

> "I would want to know or see what the child has to go through, if they are individual or if they are in a group setting. So the child doesn't feel intimidated or embarrassed or anything like that. So, and then, you know, I think that is the main thing in how the studies would be done." (FG2, Parent Participant)

In this vein they also suggested that supplemental materials be available during the consent process for parents and potential participants to take home after the initial consent discussion. As this parent noted,

> "I want to know what kind of tests you are going to do, more specifically. I want you to tell me there's IQ tests, there's motor skills tests, there is – whatever the tests are going to be. I want a good idea of what you are going to be doing." (FG1, Parent Participant)

They also assigned a high priority to the safety and comfort of their children, and established that researchers needed to meet children on their level:

> "I would suggest to allow the time of getting to know for the younger age group, getting to know the investigators so that way they – like my child, he would stay back in the corner and would not talk to you for a good hour just until he felt comfortable. Just allowing that possibility." (FG3, Parent Participant)

Regarding scheduling of testing, parents recommended that the research team consider offering testing slots on weekend days rather than weekdays. For many, the concern over weekday scheduling had to do with not wanting their child to miss school. They indicated

that evenings or after school hours might be difficult for the child being tested since such testing might impinge on after school activities or be “too tiring” for the child to undergo a four-hour test after a full school day and therefore more testing slots should be available on school holidays or breaks. Most agreed with this participant who said, “Yeah, I think either a weekend, possibly, or during the summer” (FG2, Parent Participant).

Finally, participants said it would be more beneficial to have the informed consent process face-to-face, rather than for them to simply receive consenting materials in the material to read, sign, and return, or to provide consent over the phone. This, they said would allow time for the spouses and the children to fully discuss the study and consider questions amongst themselves before enrolling. Here is how one female participant envisions the consent process happening:

> “It could be a one-on-one lunch hour kind of a thing. I would probably go get it (consent documents) ask my questions and have to take it home and kind of debrief my husband.” (FG2, Parent Participant)

Participants in all focus groups were in agreement that when recruiting and consenting potential participants for the parent study, it would be critical for the investigators to spend time and effort providing as much information as possible about the study process and procedures.

Communications

Community

To enhance recruitment, a community-wide communications plan was contemplated before the study was launched, with the goal of increasing community awareness of the study and making those potential subjects and their families contacted more likely to consider participating. This could also have the benefit of providing community benefits by educating community members about the issue of anesthetic exposure of children and potential neurodevelopmental effects. However, many focus group participants voiced concerns about this plan, fearing that it would cause unnecessary fears, especially for parents of young children who might need surgery as their concerns may cause them to postpone necessary surgery. For example, one parent stated that by publicizing the concerns about anesthesia and surgery,

> “I think you'd get more people, but I just would fear that you'd get a lot of parents who won't do surgery on their little kids.” (FG1, Parent Participant)

Another participant echoed a similar concern saying,

> “If you can't back it up, then you shouldn't be scaring that many people.” (FG1, Parent Participant)

The sentiment was that the potential link between anesthesia and neurodevelopmental delays should not be publicized in the absence of firm supporting evidence. One individual said this quite clearly:

> "Why would you tell people that we are doing this because they came out and we don't know if it is true or not...and then what happens when all these people say I want in the study and you have already identified these folks that you want in there? I just think that will cause more upheaval." (FG2, Parent Participant)

Some participants also felt that publicizing the study could initiate the spread of misinformation similar to the purported but discredited link between vaccines and autism.

Contact materials

The language used in contact and other study materials was commented on by some parents, specifically the negative connotation of "disability" and the possibility of substituting the term "ability". Some thought that parents of potential participants might be dissuaded because of fear. For example, one parent said

> "...I guess people would be scared to find out that they have a learning disorder or something because it would just sort of bring your self-esteem down." (FG4, 18-year-old participant)

Another parent explored this issue further by saying that the mere labeling of a child with a "learning disability" can have a negative impact on the child's educational outlook. This parent, speaking largely in the context of her own daughter who recently had been diagnosed with attention deficit disorder (ADD), noted that she would rather hear about her child being tested for her *"learning ability ... but not learning disability"* (FG2, Parent Participant).

One participant made the observation that perhaps a simple change in terms might help with recruitment efforts, saying,

> "What if you used the word learning ability in this study? Is there a possibility that you could get more people interested because people like to know how their kids learn? That doesn't set it up in such a negative way." (FG1, Parent Participant)

Another participant indicated how such a simple change would change his perception of the study goal, stating:

> "Boy, that changes the whole paragraph for me if I said it's to test learning ability, and you can include the tests of memory, reading and intelligence. That's fine, but that's different than saying I'm testing for disabilities. Then, ... I'm much more comfortable with that as a parent." (FG1, Parent participant)

In contrast, others felt that perhaps it would be an incentive to actually enroll their child into the study since this would be something actionable:

> "I think what would make my ears as a parent perk to do it would say, she could potentially have a learning disability, but, maybe as a parent of a child who hasn't had anesthesia, like my other child, and you said I want to test his learning ability, then I would be like, oh, yah! I would like to know where he falls in the category, but I think it depends on which part of the study you are approaching or how you phrase it." (FG2, Parent participant)

Another parent participant echoed this sentiment stating,

> "It [study participation] would be a definite benefit then because I'm looking at one of my children going through a battery of tests and it's going to – I don't know what you are thinking test-wise, but it's a thousand dollars for us to take this test. So, if I were to be able to get even just a test – one or an hour's worth of whatever, just an insight into what the performance is..." (FG1, Parent Participant)

And still others were slightly ambivalent about the change in terminology, stating that seeing a study on learning disability would not necessarily scare them away nor necessarily entice them to enroll their child into the study saying, *"I don't know if the term makes a difference..."*(FG2, Parent Participant).

Return of Results

Participants consistently supported a final summary of the aggregate study findings being sent to all study subjects. Initially, however, there was a diversity of opinion regarding the return of individual test results, expressed through deliberative, thoughtful discussion among the participants that later resolved into group consensus. Some observed that research participation is not a means to obtain clinical care and people should not enroll in any study expecting diagnostic results. This participant shared a previous experience as an example:

> "I had my son in one [study] where he had to give his blood ... and we didn't find the results out... Because ...people shouldn't be in it to find out if their child may have something that's not diagnosed already..." (FG1, Parent Participant)

In addition, most participants were comfortable with researchers not sharing individual test findings in cases where the child scores within the "normal" range, with one saying, *"...no news is good news"* (FG1, Parent Participant).

However, most parents also wanted to know if some previously undetected abnormality in their child's performance was noted. For example, one parent observed that

> "These people are contributing their time, if there's some big red flag or... that they should know that their child is way below level [abnormal testing range]..." (FG1, Parent Participant)

These views align with the earlier comments from parents in all the focus groups who said the nature of the study itself, namely examining cognitive and behavioral performance, is a motivator for participating in the study. Nevertheless, allowing for personal choice and setting expectations up front during the consenting process was very important to most of the focus group participants. One individual said that learning any kind of result – individual or aggregate – should not be a requirement but that "*...they should be available to them"* (FG3, Parent Participant).

By the conclusion of the focus groups, agreement centered on the view that if there is a problem then it would be

> "...irresponsible of the study [investigators] to not share that." (FG3, Parent Participant)

and that parent should be notified

> "If they're testing way below and they could use some help with dyslexia, [for example]..." (FG1, Parent Participant)

Participants were also queried about how individual test findings should be returned if they were indicative of a possible problem. There was a range of opinions, with some saying that they would prefer to have the findings communicated to them by their primary care physician and others proposing that the research team facilitate setting up a plan of action. However, most had no expectations that the research team provide follow-up care, with one individual saying

> "Understanding this is a study, I would just expect that when they have the follow-up appointment to go in and have a plan of action you could take the plans of action that are available to take, but like recognize that this would be kind of on your own." (FG4, 18-year-old participant)

Some felt that a letter would be sufficient, although they also recommended that within the letter there should be some information for parents to use for follow-up if they so desired. Wording of such a communication would be critical, as this participate notes:

> "You really want to look at the wording and how gently you offer that information..." (FG1, Parent participant)

Another expanded on this notion saying,

> "... getting results back in terms of someone who has a learning disability, it's [letter wording] more along the lines of please come in and, introduce the whole topic of a learning disability – especially for parents who...may have no idea, and so, really, introducing it tenderly or easing them into it..." (FG4, Parent participant)

DISCUSSION

Using focus groups, we were able to understand the expectations and concerns of potential participants in the domains of recruitment and consenting processes, communications, and return of individual and aggregate results. What we learned from the focus group participants, who were also potential participants in the parent study, has allowed us to optimally meet the needs of study participants in the context of recruitment and consenting processes. Our focus group data particularly informed what kinds of supplemental recruitment and consenting materials would help the individuals we approached to be in the parent study in their decision-making processes about whether or not to enroll.

At the outset of the parent study, we had significant concerns about how to handle the issues surrounding returning individual research findings. Our focus group data helped us create a study participant-centric process for returning any research finding that rose to the level of having potential clinical utility to the individual. In addition, the input we obtained during the focus group discussions helped us better understand what would need to be communicated to individuals consenting to the parent study about the possibility of learning about such findings as well as when no individual research findings would be returned. Finally, the focus groups findings have helped us to implement and conduct the parent study

in a manner that is research participant-centric while still working within the constraints of resources and regulatory oversight.

Recruitment and Informed Consent

The consent process is a seminal part of the recruitment process and provides information that can affect the decision to participate in the trial (Erwin et al. 2013; Fernandez 2003; Fernandez et al. 2003; Knoppers and Dam 2011). The focus groups provided several actionable themes that could be incorporated into the conduct of the study. For example, parents of potential participants suggested that the informed consent process should be face-to-face and should allow ample time for parents (and children) to ask questions. Participants also desired supplemental materials for the parents to take home with them after the initial consent discussion (Wendler 2006), including a description of the assessments and sample questions so that they can prep their kids on what type of questions to expect. Focus group participants were very helpful with suggestions about the logistics of conducting the testing. For example, a suggestion about scheduling more slots on the weekends and summer breaks so as not to impinge on the child's school day led the study team to modify testing schedules. These and other suggestions were incorporated into the design of study procedures.

Communications

Focus group participants supported the goals of the parent study and expressed appreciation of its value. However, several expressed concerns that general dissemination of information about the study prior to its launch for the purposes of community awareness could have negative consequences. They feared that parents might jump to the conclusion that exposure to anesthesia causes developmental abnormalities and might prevent or delay their child's needed surgery on this basis. After careful consideration of these concerns, the study team decided to proceed with a general communications plan, but made sure to carefully communicate that any risk of anesthesia has not been proven, and that needed surgery should not be postponed or delayed.

Participants suggested using the term learning “ability” instead of the term learning disability in all consenting and explanatory materials. Previous research shows how a simple change in such terminology has the risk of creating labeling and a potential to impact societal views (Remen 2001). What was interesting about this conversation is that some of our participants expressed a more general desire to unlabel people in the context of ability vs. disability. While we liked this concept and appreciated the underlying rationale, given that the standard language in the psychological and educational research communities is learning disability, we opted to retain that terminology. We were also concerned that in the context of professional and research domains, stating that we tested and analyzed learning ability would confound comparisons with other studies and perhaps make our findings appear not as rigorously collected and analyzed. Our concern is that the context of this study may not be the appropriate venue to make a sudden shift in terminology.

Return of Individual and Aggregate Test Results

Although the procedures used to analyze scientific data obtained in human studies may be clear, the return of results, especially those with clinical implications, to the child

participants and their parents may be much less straightforward and is extensively debated in the literature (Fernandez et al. 2009; Fernandez et al. 2003; Kozanczyn, Collins, and Fernandez 2007; Miller et al. 2008; Wallace 2011). Extreme caution must be exercised in cases where the return of results involves children because of the tripartite relationship between researcher, child, and parent(s), which may give rise to conflicting priorities as to whether results should be returned and to whom (Avard et al. 2011; Fernandez 2003). For example, the Canadian Pediatric Society has issued guidelines that indicate, irrespective of the unfavorableness of the results, they should be offered to the individuals after going through reliability and validity checks (Avard et al. 2011).

We recognized that the testing conducted during the research study might identify a subset of participants who may have a previously undetected learning impairment. In addition, we also anticipated that some of the parents of our participants would want to obtain the full report from the testing of their child, regardless of any clinical significance. For instance, some parents may be influenced solely by the idea of getting a free cognitive test report of their child, while some others might only allow their child to participate if they were to obtain this report. This issue of individuals participating in research studies motivated by the hope that they may receive some clinical benefit is not new and has been discussed by numerous commentators, largely in the context of phase I oncology trials (Appelbaum et al. 1987). The parent study presents a scenario akin in some ways to the early days of the BRCA1/2 research – women with familial histories of breast cancer enrolled in these studies in part to receive “free” genetic testing (Lerman et al. 1994; Struewing et al. 1995).

Our findings suggest that there was no specific expectation that actual scores or numbers would be consistently returned to participants. However, there was a clear consensus that if there were abnormal test scores potentially indicative of problems that the researchers would contact the parents, with no contact implying that their child was normal. These findings reflect current literature in the context of genetic research findings (Beskow and Burke 2010; Fabsitz et al. 2010; Knoppers and Dam 2011; Wolfe et al. 2012). As with this literature, one challenge is that experimental results are rarely clear-cut in terms of diagnosis or prognosis. In this case, the battery of neurodevelopmental tests is not identical to those tests used to make a clinical diagnosis of learning or behavioral abnormalities. Thus, the clinical implications of any suspicious pattern of experimental test results are not definitive, and require follow-up with additional clinical testing to provide a diagnosis and potential treatment plan – testing that is beyond the scope of study procedures.

Based on the results of the focus groups, the study team planned a method to return individual results to parents or participants (in the case of subjects ≥ 18 years of age). This method will be fully described in the future report of the study results. To summarize, if experimental testing identifies a pattern of results that is of potential concern to the study psychologists, the parents or participant will be invited to a session with the psychologist. At this time, the psychologist will review the experimental findings, explain their limitations in terms of making a clinical diagnosis, and provide recommendations for further clinical evaluation.

Regarding aggregate results, other authors suggest making a timely disclosure based on actionability but have cautioned against disclosing invalidated work, balancing the desire to let the participant know the results as soon as possible with ensuring the accuracy of results (Beskow et al. 2012; Fernandez, Skedgel, and Weijer 2004). Taking into account that the participant's desire to get answers to the study question is very high, the study team plans to make aggregate results available as a newsletter after the results are known and “validated,” including estimates of when these results may be available.

Limitations

An important strength of our study is that the same person (JBM) moderated all four focus groups, and one of the investigators for the parent study (SK) was the comoderator for all groups. This ensured some uniformity in how questions were posed. In addition, our findings were consistent across all four focus group discussions, and we view this as strong support for our conclusions.

This study does have several limitations. Although we strived to recruit individuals from under-represented racial and ethnic groups, participants were largely of European descent. These factors limit the generalizability of our findings, as does our mode of data collection. While we did not collect demographic data from our participants, for example, age, marital status, education, occupation, number of children (for parent participants), we were able to elicit basic information about whether the parents in our focus groups had a child with a learning disability or not, as well as whether any of their children had been exposed to anesthesia prior to three years of age. Indeed, in each of the three parent focus groups, at least one parent had a child with a learning disability and at least one parent had a child who had been exposed to anesthesia prior to age 3. Although we recognize the limits of focus group methodology, we chose this approach because it does enable the emergence of topics and themes that may not otherwise emerge.

Conclusion

Parents (and clinicians) have long assumed that there are no lasting consequences of anesthesia administered to children, and the potential of anesthesia and surgery to cause long-term neurodevelopmental changes is of significant public health and personal concern. Given the research question under study, the potential socially sensitive nature of some of the individual research results we might find, and significant number of minors (< 18 years old) who would be enrolled, we thought it important to engage potential study participants in a discussion of several study-related issues that could both minimize parental concerns and maximize study participation. Our experience using focus groups comprised of potential participants allowed us to optimize our approaches for both recruitment and consenting to best meet the needs of individuals we approached to be in the parent study. The perspectives of the focus group participants on the issue of returning individual research findings alleviated our concerns and have helped us think through processes for returning findings if the need arises. Overall, what we learned from the four focus group discussions has facilitated the implementation and conduct of a large clinical study in a manner that is research participant-centric while still working within the resource and compliance constraints.

Our experiences also suggest that the approach we describe here could serve as a model for other studies in which a community advisory board may not be available or where limited resources and time prevent full deliberative community discussions.

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