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Educating Parents about Pediatric Research: *Children and Clinical Studies* Website Qualitative Evaluation

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Abstract

A gap in information about pediatric clinical trials exists, and parents remain uncertain about what is involved in research studies involving children. We aimed to understand parent perspectives about pediatric clinical research after viewing the online Children and Clinical Studies (CaCS) program. Using a qualitative descriptive study design, we conducted a focus groups with parents and phone interviews with physicians. Three themes emerged providing approaches to improve parent's understanding of clinical research by including strategies where parents: a) hear from parents like themselves to learn about pediatric research; b) receive general clinical research information to complement study-specific details; and c) are provided more information about the role of healthy child volunteers. Parents found the website a valuable tool that would help them become more educated about what it means to have their child participate in research. This tool can assist parents, providers, and researchers by connecting general information with study specific information.

Keywords

Children; education; patient; health information seeking; qualitative analysis; research; qualitative; technology; use in research

Improved healthcare for children demands that treatments be based on evidence from clinical research. Evidence for pediatric treatments has often been obtained from adult results. However, simply adjusting adult doses could be ineffective or harmful. Even different stages of growth in children require different doses, different sized devices, or different types of therapy (U.S. Food and Drug Administration, 2011). It is encouraging that from 2005–2010, ClinicalTrials.gov registered 5035 pediatric interventional trials (Pasquali, Lam, Chiswell, Kemper, & Li, 2012), yet the concept of children participating in research remains confusing and concerning to families and their healthcare providers (Brind'Amour, 2015; Woolfall et al., 2013). Most parents agree that clinical research is necessary to

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advance treatment of pediatric diseases (Caldwell, Butow, & Craig, 2003; Maayan-Metzger, Kedem-Friedrich, & Kuint, 2008; Morris, Besner, Vazquez, Nelson, & Fischbach, 2007; Singhal, Oberle, Burgess, & Huber-Okrainec, 2002), yet only 25% of U.S. adults said they would allow their child to participate in a research study (Harris Interactive, 2004). Pediatric nurses and physicians agree that research is important but express reservations about encouraging *their* patients to volunteer (Caldwell, Butow, & Craig, 2002; Mudd et al., 2008; Singhal, Oberle, Darwish, & Burgess, 2004). This disconnect between the need for pediatric research and actual willingness to participate could stem from cultural influences, a limited understanding of the way research is conducted, and confusion over basic study concepts such as randomization and blinding (Caldwell et al., 2003; Morris et al., 2007; Rajakumar, Thomas, Musa, Almario, & Garza, 2009; Singhal et al., 2002). Understanding parent and physician perceptions provides valuable information for researchers when preparing for pediatric recruitment.

Parents learn about research most typically from the internet, friends and family, popular press, clinics, through discussions with the research team and from the lengthy and complex consent forms that focus on specific study details rather than general research concepts. Although positive perceptions, and a better understanding of research concepts, can lead to increased willingness to participate (Hoberman et al., 2013; Maayan-Metzger et al., 2008; Miller, Drotar, Burant, & Kodish, 2005; Tait, Voepel-Lewis, & Malviya, 2004), few general, well-developed resources exist to provide this information.

Recognizing this gap, the Children and Clinical Studies (CaCS) program (<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>) was developed in 2008 by the New England Research Institutes with funding by the National Heart, Lung, and Blood Institute in collaboration with other National Institutes of Health Institutes and foundation partners. The goal has been to educate the public, and parents in particular, about children in research (Pemberton, Kaltman, & Pearson, 2009). This online program includes documentary videos featuring researchers, parents, and children sharing their clinical research experiences, children explaining general research concepts (including why clinical studies are important, difference between research and care, participant rights, common terms, saying no, and minority interests), didactic textual content (e.g., safety and ethical review), PDF resources, and other multimedia content.

Once developed and deployed, a qualitative assessment was conducted to understand whether the web-based tool helped parents become more fully informed about what pediatric clinical research was, why it is important, what approaches to educating parents were most informative, and the reasons behind these perceptions. Previous quantitative studies have primarily focused on the relationship between parental characteristics (e.g., race, ethnicity, socioeconomic status (SES), or perceptions such as fear or desire for safety) and decisions to participate in clinical research (Braunstein, Sherber, Schulman, Ding, & Powe, 2008; Eiser, Davies, Jenney, & Glaser, 2005; Lund et al., 2009; Zikmund-Fisher, Sarr, Fagerlin, & Ubel, 2006). Our study moves beyond the previous studies by capturing parent and provider perspectives after viewing the CaCS tool on what information was valuable or was missing, and what approach was appropriate to deliver the information for this audience.

Subjects and Methods

We conducted a qualitative descriptive study (Sandelowski, 2000) with parents and physicians (pediatricians and family physicians) using thematic analysis (Green & Thorogood, 2009). Physicians were interviewed because they are key in the communication pathway for parents as they either ask a parent to enroll a child in a clinical study or are asked about a study by a parent who has learned about it through other channels. We used the open-ended, flexible probing of a qualitative approach in focus groups with parents to understand complex views, to allow for unanticipated perspectives to emerge, and to provide opportunity for parents to share and build upon similar experiences from others (Green & Thorogood, 2009).

Participants

We recruited 65 parents of children under 18 years old who reported that they had not been involved in a pediatric clinical trial. Because we were interested in a broad range of perspectives about clinical research, parents were not excluded if they had a child with a health condition (i.e., some participants referenced during their focus group discussion having children with prior or existing health conditions). We did not survey participants specifically regarding their child's health. Recruitment occurred through advertisements posted electronically in local newspapers and through a community organization serving Hispanic residents. After screening for eligibility, parents were invited to participate in one of seven focus groups (FG) held over a six-month period. Eligibility criteria is described in Table 1.

Description of the parent focus group sample is described in Table 2a. Two focus groups were conducted with White participants, two with Black/African American participants, two with Hispanic participants (Spanish-speaking), and one with both Black/African American and Hispanic participants (English-speaking). Although parents were asked about prior participation in pediatric clinical research, having a child with a prior or existing health condition was not an exclusion criterion. A small number had participated in an adult clinical research study.

Physicians

We recruited our target goal of 15 practicing physicians to participate in English-language interviews. Description of the physician focus group sample is described in Table 2b. Physicians were recruited through regional lists of providers and pediatric clinics in Massachusetts and Rhode Island provided through professional contacts [listserves and other contact lists]. We recruited providers until we reached our target, and thus did not report a response rate for this group. Details of physician eligibility are described in Table 1.

Procedures

Each parent focus group was conducted in person and lasted one hour. The focus group moderator's guide was designed by a doctoral-trained qualitative expert, Lisa C. Welch, Ph.D., to provide a consistent set of core questions across the groups. The moderator's guide covered knowledge about pediatric clinical studies, information parents would want if

considering whether to enroll a child, and an assessment of the website. Physicians participated in half-hour, semi structured telephone interviews, intended to augment the primary goal of parent feedback. The interview guide was developed by the same qualitative researcher, Lisa C. Welch, Ph.D., and elicited information about physicians' knowledge specific to pediatric clinical studies and perspectives on the website. For consistency, all focus groups and interviews were conducted by the same moderators and interviewer who were trained in qualitative data collection and on the discussion guides for this study (Table 3).

Physicians were paid \$75 for the 30-minute interview, and parents were paid \$50 for participating in the one-hour focus groups. The study was approved by the New England Research Institutes' Institutional Review Board and written informed consent was obtained from each participant. Parents and physicians were sent a link to the website upon determination of study eligibility and asked to review it prior to participation in the focus group or interview. Moderators projected the website for reference during each focus group, and physicians could access it during interviews. During data collection, the moderators and interviewer directed participants to specific parts of the website.

Data Analysis

Parent Focus Groups—Focus groups were digitally recorded and transcribed verbatim by a professional transcription service. Transcripts were imported into Atlas.ti qualitative analysis software (www.atlasti.com) to facilitate data organization and coding. To establish systematic and consistent coding, two analysts followed a consensus-based process for each set of transcripts (focus groups and interviews) separately. First, two analysts independently developed an initial list of codes (or “tags” for categorization) based on the content of the transcripts (Lofland & Lofland, 1995). Next, analysts individually coded two transcripts, met to discuss their coding, and resolved differences through discussion and consensus. A codebook with the initial codes and their definitions was then created and stored in Atlas.ti, for secondary review by the analysts.

Following coding, thematic analysis was conducted independently for each set of transcripts to develop themes (Green & Thorogood, 2009). For the focus groups, two analysts conducted thematic analysis by focusing on codes that appeared frequently and thoroughly examining corresponding quotations to understand how respondents connected their ideas. Codes and the attached quotations were examined across all transcripts and then by race/ethnic group. Thematic analysis was conducted to reduce the likelihood that the opinion of one person is given more credence than the perspective of the larger group, therefore responses endorsed by only one person are not presented in this manuscript. Codes and the attached quotations were examined across all transcripts and then by race/ethnic group.

Physician Interviews—Interview transcripts were also digitally recorded and transcribed, and coding was conducted consistent with the focus group methodology described above. Both analysts conducted a second round of coding with an additional meeting to resolve discrepancies through consensus. After the codebook was established and confirmed, analysts individually coded the remaining transcripts and met as needed to resolve questions.

Because the research question focused on whether the CaCS program educated parents, physician interviews were a second data source that was analyzed in relation to the themes that parents identified as important, providing triangulation of sources. Other themes specific to technical elements of the CaCS website are not reported here.

After analysis of the seven focus groups and 15 physician interviews, themes were recurring without substantial new information, suggesting sufficient data saturation. In some cases we provide results by focus group composition, but the paper primarily considers the larger themes across all focus groups, rather than relying on the conclusions about differences between these groups.

Results

The data from these analyses identified three key areas that could educate parents about clinical trials in pediatric populations. First, parents expressed an interest in hearing from parents similar to them. Second, parents considered the importance of a bridge between general information and study specific information. Lastly, parents expressed concerns around the concept of healthy volunteers.

Hearing from People “Like Me” Creates a Personal Connection

Parent participants said that hearing information presented in the video by other parents who had already been through the process of learning about clinical studies and deciding whether to enroll their child provided a level of credibility and comfort beyond what a researcher or didactic materials could offer. One participant said she could relate to the parents in the videos because “...it seems like their children were the same age as mine, and also because of...the questions and the explanations that...they were giving” [Hispanic-speaking FG]. Physicians agreed that parents need to hear the experiences of others who had been “in their shoes.” As one physician said, “The people who are accessing this website can’t identify with the doctor or the ethicist; they can identify with other people going through the same process.” About half of the physicians (7/15, 47%) also commented that hearing stories from actual participants provides a concrete context for parents to better understand the unfamiliar, abstract concepts that underpin clinical research.

Along with providing credibility, using a “like me” approach was considered effective by parents because they felt that it created a personal connection that engaged them in the topic of clinical studies. A parent explained, “And then the teenage girl...who was talking about the kidney problem—that kind of touched my heart...That website is really showing parents [who have] only healthy kids...about clinical studies, [and] that these things can help” [African American FG]. In contrast, when parents believed or were unsure if the children in the videos were actors (as some were), this emotional connection was missing.

One aspect parents suggested would benefit from further development was related to cultural likeness. For example, a Hispanic participant said, “If Latino families are in it [the video] ... you might feel more comfortable because you share more of the same culture and are interested in finding out what those people think in terms of culture” [Hispanic-speaking FG]. The CaCS website includes a Spanish language version of the text, with video subtitles;

however, Hispanic participants commented that hearing the videos in their first language (versus subtitles) would help them make more of a connection.

A Link Between General and Study-Specific Information

When asked if the website would help in making a decision about a child participating, parents in most of the focus groups agreed that it would be helpful, describing the website as “a good resource” and “a place to start.” Notably, participants in one of the African American (AA) focus groups specifically expressed concern about enrolling a child in a clinical study. Overall, parents reported that they valued the general information on the CaCS site regarding what clinical studies are, how they work, and why it is important to conduct clinical studies with children. They thought it important to know that one can withdraw from a study at any time or say “no” to participation. Parents found one section, “Good Questions to Ask”, particularly helpful and appreciated that the list could be printed and used in a conversation with their doctor or research team.

Parents across all groups emphasized that they would also need study-specific information to make a truly informed decision about joining a study. For example, a parent commented that linking the general information on the CaCS site to information about a specific study “would be excellent” for facilitating a decision about whether to enroll a child in a study. This general research information helped parents understand the *idea* of clinical research with children and provided examples of what one should consider when deciding to participate in a *specific* study, which would necessarily require additional study-specific information.

A majority of physicians (11/15, 73%) echoed the importance of general information, identifying three reasons: to provide a rationale for conducting clinical studies with children, to educate about how clinical studies work, and to offer information that applies regardless of the specific protocol. About half of the physicians (8/15, 53%) also identified the need for details of a particular study protocol, either through online links with general resources like the CaCS or from researchers or clinicians. As a physician said, “I think [the website] would be a great resource for anyone doing clinical trials to include that as an opportunity when... [trying] to enroll patients. I think that easily could be made as kind of part and parcel of that consent process. I think that would be fabulous.”

Parental Concerns about Healthy Children as Research Participants

Despite an overall acceptance of the need for clinical studies for sick children, parents conveyed concern about including healthy children as volunteers in studies. Participant concerns pertained to placing a healthy child at risk from any potential hazards involved in clinical research. A subset of parents (particularly those in one of the focus groups with African American participants) referred to clinical studies as “experimenting” on children (especially if medications were involved). More generally across the groups, understanding the need for pediatric research did not lead to increased willingness to enroll a child as a healthy volunteer. This is illustrated in one parent’s explanation, “...I’m *not* getting the feeling that...’this is going to motivate me to want to put my kids at risk to help the other kids,’ even though I know how much they need it” [Caucasian FG].

Parents had specific questions about the conditions under which healthy children are asked to volunteer and the effects of participation on healthy children. For example, one parent found the idea of healthy volunteers confusing, indicating that it was unclear how studying a disease would benefit from involving healthy kids: “They’re doing the studies on healthy individual[s], but how do they know if the medication is really going to work ... for her child who has autism, but her child is not in the study, my healthy kid is?” [African American/Hispanic English speaking FG]. This suggests that further clarity and education about healthy volunteers is important for improving recruitment in this population. Parents across all groups stressed their need for assurance that they were being given a balanced presentation, including all the risks and downsides of a particular study, to consider enrolling a healthy child into research.

Discussion

Based on the themes described in the results, we identified key strategies that researchers and clinicians could adopt to improve parental understanding of pediatric clinical research. As noted above, previous studies have identified parental characteristics associated with increased fears and anxieties about clinical research (Braunstein et al., 2008; Eiser et al., 2005; Lund et al., 2009; Zikmund-Fisher et al., 2006) but do not provide an understanding of what could improve parents’ understanding of and potential comfort with clinical studies for their children. Our study is unique in that it explores in detail the types of information that parents who are not familiar with pediatric research would prefer to learn about, and which may improve their familiarity with pediatric clinical studies. These findings are particularly relevant for researchers as they develop recruitment strategies for pediatric trials, and clinicians who are often involved in enrollment.

Use a “Like Me” Approach

Parents and physicians in our study confirm prior research showing that parents want to learn from other parents’ experiences when considering participating in research (Caldwell et al., 2003; Iredale, Mundy, & Hilgart, 2011). Parents have reported that this communication can result in increased engagement in clinical research (Eder, Yamokoski, Wittmann, & Kodish, 2007; Harris Interactive, 2004). Providing opportunities to link parents together in virtual ways, via the CaCS program or other creative mechanisms, might be an effective addition to current recruitment strategies.

In addition to peer-to-peer homophily, culturally-appropriate research materials and research teams composed of individuals with similar racial and ethnic backgrounds as study subjects can promote trust and enhance pediatric research acceptance (Rajakumar et al., 2009). Hispanic and African American parents in this study desired a connection from those who were culturally and linguistically similar to them, making them more receptive to the information being conveyed. Although it is sometimes difficult for research teams to reflect the diversity of the population, considering ways to improve homogeneity between delivery of information and study population (i.e., videos in multiple languages, patient advocates, connecting parents with interpreters long before the consent process) can be a productive recruitment approach.

Link General and Study-Specific Information

Parents know little about pediatric clinical research and have suggested that other literature, pamphlets and internet websites could help increase public knowledge about pediatric research methods and processes (Caldwell et al., 2003; Eder et al., 2007). For specific studies, parents want to understand who is conducting the research; how their child regards participation; the time commitment and impact on family life; risks and safety, particularly if a medication is involved; and benefits to the child or family (Blake, Lemay, Kearney, & Mazor, 2011; Caldwell et al., 2003; Fisher, McKevitt, & Boaz, 2011; Singhal et al., 2002). They also expressed a desire to understand basic research concepts (randomization, blinding, placebo, care vs. research, study withdrawal) to enhance effective communication with pediatric researchers (Tait, Voepel-Lewis, & Malviya, 2003). Parents and physicians found the *general* research information provided by the CaCS website to be a useful and necessary complement to study-specific information. Research teams, doctors' offices and children's hospitals should consider the best way to deliver general information as a complement to study-specific consent forms and brochures. When parents have study-specific information coupled with a general understanding about how and why clinical studies are conducted, results from this study imply that they believe they can make a more informed decision about participation. Providers also felt having more general information to share with parents would be valuable.

Educate about the Role of Healthy Child Volunteers

Little is known about parental perceptions of research with healthy children, except for limited research suggesting they are less likely to participate than parents of sick children (Chantler et al., 2007). Studies with parents of children with diseases and conditions consistently find that altruism, i.e., helping others without expectation of results for themselves, is an important motivator for participation in clinical studies (Hoehn et al., 2005; Morley, Lau, Davis, & Morse, 2005; Singhal et al., 2002; Zupancic, Gillie, Streiner, Watts, & Schmidt, 1997). Our results show that the concern to maintain a healthy child's safety may outweigh the suggestion of altruism, or may suggest that there is less information available to parents of healthy children about the role of a healthy child volunteer and the importance of this population to successful clinical research. Participants reported misperceptions about the role of healthy children in clinical studies. This suggests that researchers and providers should be mindful that there is considerable confusion and concern about this issue. To improve access to pediatric healthy volunteers, our research indicates that researchers should incorporate a "like me" approach, provide more emphasis on general study procedures related to healthy subjects, the importance of involving healthy volunteers to understand clinical outcomes, and address safety concerns.

Limitations

Sample size in qualitative research is often raised as a limitation. Our goal was to gain knowledge about level of understanding about clinical trials after viewing the CaCS web tool, to ultimately address perceived hurdles to pediatric clinical trials participation and improve public awareness of the importance of pediatric clinical research. While population based surveys make important contributions, qualitative research methods were more

appropriate for gaining in depth parent and physician perspectives. Thus the sample size for both parents and physicians was necessarily smaller than would be expected for a population based survey. Qualitative methods provided clear benefits because they allowed for an open-ended, flexible approach and the ability to probe for detailed feedback. Second, we focused on learning what misperceptions exist about clinical trials generally (including perspectives from racial/ethnic minority parents). It is possible that recruitment through advertising accessed a convenient population who may have been more aware of or willing to be involved with clinical research. Third, the insights we present provide an important starting point but are based on an assessment of only one toolset. A randomized or pre-post design is needed for a rigorous test of knowledge gained from viewing the website and to address any potential effects of variation in the timing of website review relative to data collection. Additionally, further research is needed to test whether use of the website actually impacts enrollment decisions in future clinical research.

Conclusions

The CaCS program was developed to provide general research information on clinical studies with children. Our qualitative assessment revealed several important implications for researchers conducting pediatric clinical studies: parents want to hear from other parents who have participated in clinical research; it is important for researchers to connect study-specific details with general clinical research information; and further work is required to improve parental understanding of the role, safety and importance of healthy volunteers to engage participants in this area of research. Assessments of additional approaches and updates to the existing Children and Clinical Studies website (for instance focusing on healthy volunteers) can build on the results presented here. Future studies can also benefit from these findings by informing studies investigating knowledge or behavior change. Providing valuable and user friendly tools about the goals, approaches, safety and importance of children in research can address the gap between participation in adult versus pediatric clinical research studies.

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Table 1

Eligibility Criteria

Parents	
1	Has at least one child under the age of 18
2	Reports that they had not had a child in a clinical study
3	Self-identifies as Black or African American, White, and/or of Hispanic origin.
4	Speaks English or Spanish
5	Able to travel to the location of the focus group during a scheduled time
Physicians	
1	Practicing as a pediatrician or a family/general practitioner who sees children
2	Provides clinical care at least half time during an average week
3	Speaks English

Table 2a

Sample Description for Parents

Parents	
Gender	<i>n=65</i>
Men	20 (31%)
Women	45 (69%)
Race/ethnicity	<i>n=65</i>
Black/African American	17 (26%)
Hispanic	26 (40%)
White	22 (34%)
Asian Indian	0

Table 2b

Sample Description for Physicians

Physicians	
Gender	<i>n=15</i>
Men	6 (40%)
Women	9 (60%)
Race/ethnicity	<i>n=15</i>
Black/African American	0
Hispanic	0
White	14 (93%)
Asian Indian	1 (7%)
Age	<i>n=13*</i>
30–39 years	3 (23%)
40–49 years	4 (31%)
50–59 years	3 (23%)
60–69 years	3 (23%)

*
2 respondents did not provide an age

Table 3**Key Discussion Guide Items***

Parents' Focus Group Guide
<i>Knowledge of pediatric clinical studies</i>
1. Think back to before you looked at the website we're going to talk about today. Had anyone ever heard of a clinical study or a clinical trial? For those of you who had heard of clinical studies, what did you know about them?
2. Now that you've seen the website, do you have a better understanding of what clinical studies are and how they work? How so?
<i>Information parents would want if considering whether to enroll a child</i>
3. As a parent, imagine that you were asked to decide whether or not one of your children—let's say your youngest child—could participate in a clinical study. What would be your initial reaction?
4. What kinds of concerns would you have?
5. What kinds of things would you need in order to make that decision?
6. Are there certain types of clinical studies or activities that would be out of the question for you to agree to? Why?
<i>Assessment of website</i>
7. Thinking about the website you looked at for this focus group, did the website address any of the concerns or questions that you might have as a parent?
8. The website talks about why it is important to have kids in clinical trials. Did this section affect your opinion about whether you think that kids should be part of clinical trials?
9. The website talks about the effect on the family of a child being in a clinical study. What effects on the family in particular stood out to you as important to consider? Did you want more or different kinds of information about effects on the family?
10. The website talks about the rights of study participants—including a child and his/her family. Was what the website showed enough, or did you want to know more about this? What would be your biggest concerns about safety and rights of a participant?
11. When you were going through the website, did you read the written text below the videos? Did you look through the page about resources, news, and updates?
12. What other types of information or topics do you think the website could address?
13. Do you think the website was easy to understand and use? Why or why not?
14. Were you able to relate to the parents in the video? Why or why not?
15. Again, imagine that you've been asked to decide whether your youngest child can be in a clinical study. Would this website help you in making your decision?
16. What would be the best way to advertise this website so that you as a parent would go to the site to be informed about clinical trials?
<i>Physicians' Interview Guide</i>
<i>Knowledge about clinical studies with children</i>
1. How familiar are you with clinical studies being conducted with children?
2. As a physician, what would be your view about sending one of your patients—a child—to participate in a clinical study? Would you have any concerns or reservations?
3. If the parents of one of your patients were considering enrolling their child in a clinical study, how would you advise them?
4. What types of information about clinical studies with children would be helpful to you as a physician?
5. Do you think a typical physician in a practice like yours has enough information about what a clinical study with children involves? Do you have sufficient information on how to find a clinical study for a child who is a patient of yours?
6. What do you think a physician in a practice like yours should know about clinical studies with children?
<i>Assessment of website</i>
7. What parts of the website stood out to you? Do you think that part would be helpful for parents? Do you think that part would help you as a physician explain clinical studies with children to parents?
8. Are the videos on target in your view?
9. Did you see the list of questions that parents could ask the doctor or researchers? If yes, Would you add anything to that list?
10. What other types of information or topics do you think the website could address?
11. We are thinking about adding some information to the site that would be directed toward children. Do you think this would be helpful?

* Open-ended, non-leading probes were used as needed to elicit rich responses.

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