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"There was No Opportunity to Express Good or Bad": Perspectives From Patient Focus Groups on Patient Experience in Clinical Trials

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Abstract

To understand how patients perceive their experiences leading up to, during, and after a clinical trial, and the relationship these experiences had with future willingness to participate, we conducted 3 focus groups with patients who had prior clinical trial involvement (n = 25). Discussion topics included clinical trial discovery, enrollment, communication, trust, patient-centricity, and future enrollment. Patient focus groups revealed a variety of motivations for enrolling in clinical trials (eg, altruism, efficacious treatment, curiosity, desperation, etc.). Patients learned about clinical trials through trusted sources (eg, primary care physicians, patient advocacy groups) and social media. Access and uncertainty about clinical trials were barriers to enrollment. Patient-centric communication and attention given to disease states and symptom severity were valued and made patients feel genuinely cared about. Post-trial follow up and being informed of trial results were inconsistently reported by patients. Critically, patients described frustration with an overall lack of patient experience measurement. Patients identified a need to measure experiences before, during, and after clinical trials and emphasized that doing so would facilitate patient trust and overall experience.

Keywords

clinician-patient relationship, communication, patient feedback, patient satisfaction, trust

Key Points

- Patient centricity is critical in facilitating trust and patient engagement during clinical trials.
- Patients enrolled in clinical trials want to be asked about their experience.
- Regular and frequent communication with patients should occur, even after trial completion.
- Patient-centric resources, for example, user-friendly technology, transportation, and on-site support, can impact patient experience.

Introduction

Trust is a central component of patient-provider relationships at large,[1] and notably, a critical component of patient willingness to enroll in and remain in a clinical trial.[2-4] Uncertainties about the risks and benefits of participating in clinical trials, and the motives of care providers and organizations conducting the trials can undermine trust.[5] As such, there is a need to understand how patients experience trust throughout clinical trials, because clinical trials are in and of themselves, uncertain. Doing so may bolster enrollment and retention across all phases of clinical trials, which has been a longstanding issue.[6,7] Unfortunately, measurement of patient experience and perceptions of clinical trial research is heavily under-researched.[8] As such, standardized measurement tools are needed to determine where site and sponsor quality improvement efforts should be focused.

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The first step in understanding patient experience in clinical trials is identifying how it is currently measured and how potentially burdensome it may be for patients to have their experiences measured during a clinical trial. The goal of this research was to qualitatively examine how patient experience has been measured in previous clinical trials with a diverse set of patients who have been involved in clinical trial research (eg, sought to enroll, enrolled, participated in, or completed a trial). To do this, we conducted focus groups with former clinical trial patients and asked them if and how patient experience was measured, and about common facilitators and barriers to positive patient experience.

Method

Recruitment and Sample

Patient focus group participants were recruited by Savvy Cooperative® participant pool using prespecified inclusion/exclusion criteria. If participants answered "yes" to "Do you have any clinical trial experience?", they were further screened. Participants having comorbid conditions were also included in the sample. Purposive sampling using patient demographics was employed to identify and ensure diversity of focus groups. Savvy Cooperative® then confirmed participant availability and scheduled focus groups with patients.

Data Collection

The research team created patient focus group discussion guides with topics derived from peer-reviewed literature and internal and external stakeholder input. Topics included the experience of clinical trial discovery and enrollment, communication across a trial, patient trust, patient centricity, patient needs, patient burden, and reasons for potentially participating in a clinical trial in the future.

Data Analysis

Focus groups were conducted over the course of 3 sessions, using the Forsta InterVu platform within Forsta Foundations. Average length of focus groups was 81.04 min (range: 78.58-85.27 min).

Results

Twenty-five clinical trial patients participated in one of the focus groups depending on condition type (eg, oncology, neurological, and other chronic). Seventeen identified as women (68%), 5 as men (20%), 1 as transgender male, and 2 as gender nonbinary. The mean age was 44.0. Most participants reported their general health as "good" (44%), however, none rated it as "excellent" (see Table 1).

Table 1. Patient Characteristics.

Characteristic	Total (%)
Total	25
Age	
18-39	9 (36.0)
40-64	14 (56.0)
65 +	2 (8.0)
Education	
High school/GED or lower	1 (4.0)
Post high school training (vocational/technical)	5 (20.0)
College graduate (Associate's degree)	3 (12.0)
College graduate (Bachelor's degree)	9 (36.0)
College graduate (Grad degree)	7 (28.0)
Gender	
Male	5 (20.0)
Female	17 (68.0)
Transgender male	1 (4.0)
Transgender female	0 (0.0)
Nonbinary	2 (8.0)
General health	
Excellent	0 (0.0)
Very good	7 (28.0)
Good	11 (44.0)
Fair	5 (20.0)
Poor	2 (8.0)
Household income	
<$50k	8 (32.0)
$50k-$100k	12 (48.0)
>$100k	3 (12.0)
Prefer not to Answer/Don't Know	2 (8.0)
Race/ethnicity	
Asian	3 (12.0)
Black/African American	4 (16.0)
Hispanic/Latino	2 (8.0)
White/Caucasian	13 (52.0)
Other/Multiple	3 (12.0)
Health insurance	
Medicare	10 (40.0)
Medicaid	1 (4.0)
Employer-sponsored	11 (44.0)
Private insurance	1 (4.0)
Health insurance marketplace (eg, Obamacare)	1 (4.0)
I do not have health insurance	1 (4.0)
Health insurance	
Urban	10 (40.0)
Suburban	12 (48.0)
Rural	3 (12.0)

Abbreviation: GED, tests of general education development.

Learning About Clinical Trials

Patients described numerous barriers and facilitators related to clinical trial discovery and learning about the specifics of a clinical trial they were considering. Common methods for patients to learn about clinical trials were through patient advocacy groups and newsletters, primary care providers, and social media. Patients voiced frustrations and uncertainty about requirements of clinical trial enrollment and participation due to complexity of language about the clinical trial itself as well as information contained within the informed consent.

Table 2. Patient Quotes.

Theme	Quotes
Learning about Clinical Trials	I first heard about this research clinical trial on social media. And I just like helping people and I also look for relief in different alternative methods. And I think like the only barrier with like signing up was that they didn't list a way for you to say your pronouns and like what you identify as.—Patient 2182 (27)
	I've seen some trials that I've considered enrolling in, and then they're not clear about things like how often I'll need to come in, or how big a time commitment it'll be in the long term, and I'm less likely to pursue enrolling in those if they're not upfront about that from the beginning.—Patient 2208 (20)
	I almost feel like they should have a "this is for the patient" and "this is what the patient's doctor should go and read," and make sure it's not going to interfere with what their treatment is or what's happening…there's gotta be an easier way to communicate what we're doing.—Patient 2185 (55)
Reasons for Enrollment	African American individuals are enrolled at a lower percentage and we have the highest mortality rate of death. So I wanted to be the voice for the voiceless.—Patient 2246 (39)
	I mean, there's definitely a stigma associated with clinical trials. You know, of being a lab-rat.—Patient 2261 (50)
	This condition that I now have for life, I could get something out of it to help me and help others.—Patient 2299 (67)
Patient Experience Measurement	I'm going to say flat out no. I think other than the nurse asking how I'm feeling and what's going on, and the survey asking me specifically what I was taking and how I felt physically, there was no pre survey, during survey, or after survey that talked about my experience…So there was no opportunity to express good or bad.—Patient 2185 (55)
	I haven't experienced any follow up surveys anywhere to give positive or negative feedback. I do get a call, just to make sure I'm not experiencing any side effects, but nothing to really say like how the study was, or how I experienced it.—Patient 2315 (25)
	I was not asked any questions related to patient experience before, during, or after the clinical trial. In fact, I wanted to learn about the patient experience from other folks who had already gone through CAR-T. And obviously I wasn't given that information.—Patient 2261 (50)
Positive Patient Experience	My whole team will even call me and be like, hey, we're just touching base to see how you're doing. They're constantly, I feel like, checking in to make sure that I'm ok and that makes this experience so much better. I think, I get the feeling that they're all concerned about how I'm doing. And I really, really like that.—Patient 2255 (45)
	I just felt like they really cared about my experience. They were constantly asking me about my experience. I even ran into an issue with the device not working right. And they were able to swap it out. They believed me that the device wasn't working right.—Patient 2386 (47)
	So I had a complete, satisfied experience. Everybody was always concerned. I would get frequent calls of how I was doing. And I had the personal emails and phone numbers for my oncologist, the clinical trial nurse, and other people that were associated with the trial. So, I always had a direct line if I needed to get ahold of somebody, they were all very responsive.—Patient 2368 (66)
Negative Patient Experience	One thing that didn't like was sometimes I had to sit around for four hours waiting for something to thaw out, so they could give me an IV drip.—Patient 2185 (55)
	They put me responsible for gathering a lot of the medical records. And I had 12 different institutions or physicians that they wanted medical records from. And I felt like I was on an archaeology dig, trying to get all of those records sent to them. And that put a lot of responsibility on me…But then when I told them I was having problems, they were kinda like, oh, we'll take over from here.—Patient 2267 (46)
	I have like a family and I have kids, so to be like to be able to drive five hours, round trip, drop everything and, and spend all day, two hours from here is not ideal. And so I asked that they would schedule me like six months in advance and they haven't been able to do that, which has been really annoying.—Patient 2250 (33)
	I kind of felt like a number, and I felt like when I started having adverse side effects, I didn't feel like they believed me and it was really frustrating for me.—Patient 2386 (47)
Patient-Centric Resources	I would say that one of the most difficult things has been scheduling with driving a long distance because a lot of us don't live close to our clinics or the clinics that do research. So, I think that the biggest thing that would be most important would be an ability for us to schedule our appointments, like out.—Patient 2250 (33)
	I have a rare disease that, it makes travel really, really hard. And it's a very rare condition…So they were looking at hiring a firm that has like traveling nurses. So that we can have, so that if we participate in the clinical trial, we wouldn't have to go to a site, but basically the site would come to us, via a traveling nurse…I really think this is where clinical trials need to go. Because to get patients to be able to participate, it's got to become easier for the patience to participate.—Patient 2386 (47)
	All of the technology that I've dealt with, like trial diaries and like websites and like interfaces that they have given us are not user friendly and very difficult and clunky. Like I don't understand why it's not so easy when you're dealing with like medical things for people that require these medical treatments. Like why is it just not easier?"—Patient 2250 (33)

(continued)

Table 2. (continued)

Theme	Quotes
Follow up and Clinical Trial Results	I think again, the more we can create environments that are showing that trials and indeed are not trying to make people lab rats, but in fact, are trying to build communities. And to do so, it requires to think differently about how we disseminate information that we don't simply say "it's in the journal," but rather have opportunities for patients to describe what the outcomes were and how it affected them.—Patient 2274 (57)
	The one thing that I felt could have been done better was that I, patients are made aware of what the results were of the clinical trial.—Patient 2368 (66)

Reasons for Enrollment

Patients described a variety of reasons for enrolling in trials including reducing stigma, desperation and wanting to live longer, assisting patient communities, curiosity, and other altruistic purposes.

Patient Experience Measurement in Clinical Trials

Patients described if and how patient experience was measured in clinical trials, and how often. Patients described frustration over the lack of patient experience measurement. Clinical trial teams with a patient-centric focus that put the unique needs of each patient first was valued by patients. Regular communication, responsiveness, multiple contact methods, and genuine feelings of care increased trust and overall patient experience. Negative experiences during clinical trials centered around participant burden and not feeling genuinely cared about. Patients often voiced frustration with the time commitment required for participation, transportation obstacles, waiting around, and infrequent or impersonal communication with clinical trial teams. Gathering of requisite health history to participate in a trial was also a burden for patients.

Patient-Centric Resources

Patients described numerous ways that clinical trials could become more patient-centric to decrease patient burden. Common patient-centric solutions included being able to schedule appointments as opposed to being given appointment times, the ability to schedule appointments far in advance, more user-friendly communication tools, and decentralized trials for more severe disease states that made travel difficult.

Follow Up and Trial Results

Patients described frustration with communication about clinical trial results as well as follow up about results after the conclusion of a clinical trial. They also described how the lack of communication about trials results and follow up by clinical trial teams made them feel like they were "datapoints" as opposed to individuals (Table 2).

Discussion

We conducted focus groups with patients possessing various disease states (eg, oncological, neurological, and other chronic) to examine if and how patient experience had been measured in clinical trials they had participated in. Overall, patient experience measurement was viewed positively by patients when conducted frequently, consistently, and importantly, in a genuine manner. In fact, many patients expressed frustration that patient experience was not being measured more. Although sponsors of clinical trials have begun to distribute patient experience surveys at the conclusion of trials, this lends credence to the fact that it should be measured more consistently *throughout* a trial, because doing so only at the end can lead to bias.[9]

Patients discussed different ways of learning about clinical trials such as through social media, primary care providers, and patient advocacy groups and newsletters. The desire to help others and give back to patient communities were primary reasons for clinical trial participation, and for some, the ability to give a voice to historically marginalized communities. Patients voiced concerns over stigma associated with clinical trial participation, being another "datapoint." Patients also cited the ability to attain care that was superior to standard care, desperation, compensation, and curiosity as reasons for participating.

Many patients identified multiple barriers to enrolling in a clinical trial, including uncertainty about clinical trial requirements, preexisting symptom severity, long distances required for travel, time commitment, family obligations, and gathering of extensive requisite health information. Prior research supports these findings, demonstrating how extended screening processes and symptom severity undermine enrollment.[10] Patients also described wanting more "plain language," prior to enrollment, about what the trial would entail, and during the informed consent process, corroborating research describing how information about a trial can be overwhelming.[11] Our research supports how informed consent processes and understanding of risks involved in participating in clinical trial research continues to be an issue,[12] and that ultimately, trial participation and remaining in a trial is driven by patient/provider trust.[11,13,14]

High symptom severity made travel difficult for some patients and they recommended more support services to

compensate for such burdens. Past studies have found that symptom severity is a strong predictor of patient drop-out,[15] and identifying ways to compensate for this can decrease attrition (ie, providing transportation and/or decentralized trials). Recent research has attempted to decrease the burden of in-person visits through digital solutions that can replace such visits,[16] however, more work in this area still needs to be done. Patients also expressed a desire to communicate with clinical trial research teams via means that catered to their unique needs and preferences, and frustrations with usability of communication platforms. Sensitivity to patient sociodemographics (eg, urban/rural divide and education) should also be used to inform patient-centered approaches to care to decrease burden.

At the conclusion of a clinical trial, patients described a need for more follow up and information about the results of their clinical trial, which has been described in previous research.[17] However, some patients described wanting to learn more about research findings beyond it "being in the journal."

Limitations

Many clinical trials exclude patients with chronic or comorbid conditions (eg, vaccination trials), however, these focus groups did not. Additionally, a minority of focus group participants were only exposed to clinical trial participation through enrollment, having no on trial experience. We view these potential limitations as strengths, as these participants aided in understanding the clinical trial enrollment experience and inclusivity of trial design. Caregivers were excluded from participating so that focus group discussion was more fluid, but caregiver experience should be examined in future studies.

Conclusion

Frequent and consistent patient experience measurement was identified as facilitating trust between patients and clinical trial care teams during a clinical trial. Patients valued being asked about their experience, but only when it was done in a genuine manner. Patients described a willingness to answer patient experience measures and expressed deep frustration that they had not been asked about their experiences more. Efforts should be made to develop and validate a standardized clinical trial patient experience instruments across a variety of clinical trials. Doing so will facilitate patient-centric quality improvement efforts to decrease patient burden and increase patient retention.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval

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Statement of Human and Animal Rights

All procedures in this study were conducted in accordance with Savvy Cooperative®.

Statement of Informed Consent

Written informed consent was obtained from the patient(s) by Savvy Cooperative® for their anonymized information to be published in this article.

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