ORIGINAL RESEARCH

Determinants of Patient and Surrogate Experiences With Acute Care Research Consent: A Key Informant Interview Study

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***Background*—**Informed consent for acute myocardial infarction and stroke research is challenging. Time for enrollment decisions is limited, patients and family are usually stressed, and being asked to participate in research is often unexpected. Despite these barriers, patients and surrogates have reported a preference for prospective involvement in research decisions and generally positive views of the consent process. It is unknown what drives positive or negative consent experiences. These data are crucial to making consent processes more context appropriate.

***Methods and Results*—**We conducted a qualitative interview study with 27 patients and surrogates enrolled in acute myocardial infarction and stroke trials in the past 5 years. Purposive sampling from the P-CARE (Patient-Centered Approaches to Research Enrollment) study was based on participant characteristics and responses to initial patient-centered interviews. In-depth interviews used open-ended questions to explore factors influencing consent experiences. Qualitative descriptive analysis was performed utilizing a multilevel coding strategy. Participants identified specific researcher behaviors as important, including expressions of respect, professionalism, and nonpressuring communication. Participants preferred consent conversations focused on risks/benefits and the trial protocol. They had varying views of consent forms and communicated several reasons the form was valuable unrelated to informational content. Participants also valued postenrollment interactions as opportunities to ask questions and learn about the study.

***Conclusions*—**Barriers to consent in acute myocardial infarction and stroke trials are unavoidable, but participants identified productive ways to demonstrate respect for patients during enrollment conversations. These include key researcher behaviors, concentrating consent discussions on what participants find most important, and structured postenrollment follow-up. **(*J Am Heart Assoc*. 2019;8:e012599. DOI: 10.1161/JAHA.119.012599.)**

Key Words: acute myocardial infarction • acute stroke • informed consent • research ethics

> I had just arrived in the operating room and was just told that I was having a heart attack. . . I was being told [about both my heart attack and research] at the same time, or roughly about the same time. It's a little much to take in. . ..I understand there's very limited time, and I get that. It's just all of that at once is very overwhelming—very difficult to deal with.

Informed consent for clinical trials in emergency situations such as acute myocardial infarction (MI) and stroke poses a fundamental challenge: there is a clear disconnect between clinical reality and the typical regulatory and ethical expectations for research consent and decision making. Patients with acute MI, such as the one quoted above, being rushed to the catheterization laboratory for emergent percutaneous coronary intervention, are in physical and emotional distress, are not expecting to be asked to participate in a clinical trial, and almost certainly do not know what to do with the long consent forms that have become the norm in research. Similar challenges exist in acute stroke trials, although the decision maker is most often a surrogate rather than the patient.

There has been a long-standing debate about whether and how informed consent should be sought in these acute conditions.[1-7] Some have argued that it is cruel to involve patients and families in consent discussions at this time and that doing so may delay treatment or skew enrollment.[1,7] Moreover, available empirical data suggest that reaching traditional expectations regarding understanding of a trial is difficult in these settings. Patients and surrogates who have agreed to participate in acute MI and stroke

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An accompanying Table S1 is available at https://www.ahajournals.org/doi/suppl/10.1161/JAHA.119.012599

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Clinical Perspective

What Is New?

- Informed consent for acute myocardial infarction and stroke research presents unique challenges.
- Participants and surrogates in acute myocardial infarction and stroke research advocate optimizing researcher behaviors, concentrating discussions on the most meaningful information, and providing postenrollment follow-up.

What Are the Clinical Implications?

- Professional and respectful action on the part of researchers enhances participant experiences with informed consent for research in stressful, acute situations.
- Participants in acute care trials seem to have a preference for more focused consent conversations.
- Structured consent processes including postenrollment follow-up may enhance perceived respect but require empirical evaluation.

studies often have very poor recall of even basic trial details.[7-13] Patients especially may be experiencing physical symptoms and may have more difficulty reading the forms provided.[14] However, both patients and surrogates have consistently expressed the view that they can and should be involved in making these enrollment decisions.[9,14] They have also generally reported positive experiences with consent.[14] Together, these findings suggest that consent processes in these situations may have value for patients and surrogates, even when enrollment decisions are less than fully informed. The consent process may function to express respect to patients by giving them the ability to control whether enrollment occurs, helping them to feel they are treated "like a person," or enhancing trust through transparency.[15]

Consent processes should be designed around patients' and surrogates' needs in a way that bolsters the value gained from the process. In order to develop optimal approaches that are sensitive to these contexts and that are maximally patient-centered, it is important to understand in greater depth the drivers of positive and negative consent experiences of those who have been enrolled. We designed this qualitative key informant study to provide these data.

Methods

Study Population

This qualitative interview study was nested within the P-CARE (Patient-Centered Approaches to Research Enrollment) interview study. The P-CARE interview study, which has been previously published, included 176 English-speaking, adult patients (or surrogates if they provided initial consent for trial participation) who had been enrolled in an acute MI or acute stroke trial within the last 5 years at 6 participating sites.[14] Initial P-CARE interviews were highly structured and quantitatively focused. Key domains included recall of the trial, perceptions of the consent process, and preferences regarding involvement in the enrollment decision.

The primary objective of this follow-up qualitative interview study was to explore in greater depth the experiences of participants—specifically drivers of positive and negative experiences—and thoughts on alternative strategies for enrollment including an exception from informed consent (EFIC) and, for stroke research, a prearrival research discussion.

Recruitment

All P-CARE participants were eligible for key informant interviews. A purposive sampling strategy was employed in order to ensure representation of a range of characteristics and types of experiences of analytic relevance. After review of initial P-CARE interviews by A.M., C.S., N.D., and V.S., participants, who varied in both in their objective characteristics and in their views, were discussed and selected for interview. The objective characteristics included presenting condition (acute MI or stroke), patient/surrogate status, sex, race, prior research participation, and trial type (Table 1). Participant views included overall attitude toward the trial experience (very positive, very negative, or neutral), general attitudes toward research, initial reactions to being asked to participate in research, and attitudes toward the consent form. A matrix of participants was developed to display these characteristics and views, and sampling continued until all cells in the matrix were represented and informational redundancy was achieved (Table S1).

Interview Conduct

An interview consisting of a set of open-ended questions was prepared for each key informant interview individually based on the participant's initial P-CARE responses. Interviews were designed to explore the factors that made the consent process positive or negative, to probe interesting aspects of that participant's initial interview, and to solicit suggestions for improvement. Most interviews explicitly explored domains of general attitudes toward the consent process, researcher behaviors, content of consent discussions, attitudes toward the form, and alternative approaches to consent (including conducting the trial without prospective consent and prearrival research discussions). Participants were interviewed via telephone by trained interviewers (N.D., A.M., V.S., C.S.). Interviews generally lasted 20 to 30 minutes and were audio recorded and transcribed verbatim.

Table 1. Participant Demographics

	Number of Participants (N=27)
Myocardial infarction, n (%)	
Patients	12 (44)
Surrogates	0 (0)
Stroke, n (%)	
Patients	2 (7)
Surrogates	13 (48)
Stroke surrogates by relation, n (%)	
Child	6 (22)
Spouse	5 (19)
Sibling	2 (7)
Age (range, y)	34 to 85
Sex, n (%)	
Female	10 (37)
Patient race, n (%)	
White	19 (70)
Black	6 (22)
Asian	2 (7)
Prior research participation, n (%)	7 (26)
Trial types, n (%)	
Procedural interventions	14 (52)
Novel devices	6 (22)
Medications	4 (15)
Medical management strategies	3 (11)

Informed consent for participation in initial P-CARE interviews and key informant interviews was obtained verbally over the phone. Participants were paid with a $20 gift card for each interview. The P-CARE interview study was reviewed and approved by the Emory University School of Medicine Institutional Review Board and by other participating sites' institutional review boards.

Analysis

Interviews were transcribed verbatim, corrected for errors, and imported into MAXQDA (VERBI GmbH, Berlin, Germany) for analysis. Interviews were analyzed using a multilevel coding strategy.[16] First, all transcripts were reviewed, and simple codes of main domains were applied to allow sorting (how researchers interacted with participants, content of the consent discussion, and enrollment processes). These segments were then categorized further as positive, neutral, negative, and areas for change. Within each of these categories, inductive subcodes of salient emerging themes were developed collaboratively by the research team (see Tables 2 through 4 for examples of subcodes under each main domain). Once the codebook was finalized, all interviews were reviewed using the completed codebook.

Data were primarily coded by 1 author (V.S.). Multiple rounds of verification were performed to ensure trustworthiness of the analysis. First, 5 interviews were double-coded (N.D., C.S.). All discrepancies were discussed, and the codebook was revised as needed. All interviews were then reviewed based on changes to the codebook. Finally, instances of all major codes were reviewed by all authors to ensure that coded segments represented a coherent theme. Instances of uncertainty or conflict were resolved by consensus. The data that support the findings of this study are available from the corresponding author on reasonable request.

Results

Population

In total, 27 interviews were conducted, with a response rate of 73%. Twelve participants were acute MI patients, 2 were stroke patients, and 13 were surrogates for stroke patients (Table 1). Stroke surrogates included 6 adult children, 5 spouses, and 2 siblings. The sample was balanced in terms of sex. Ages ranged from 34 to 85. Most participants identified as white (19), 6 as black, and 2 as Asian. Eight had previous research experience before enrollment in their respective trials. Participants were enrolled in 12 different acute MI and stroke trials. In total, 14 interviewees had been included in trials of procedural interventions, 6 in trials of novel devices, 4 in trials of medications, and 3 in trials testing medical management strategies. Average time from trial enrollment to initial P-CARE interview in the overall P-CARE population as compared with follow-up interview was 1.9 versus 1.5 years for stroke, and 2.8 versus 3.4 years for acute MI participants.[14] Average time from initial P-CARE interview to follow-up interview was 157 days or about 5 months.

Key Domains

How Researchers Interacted With Participants

The most common theme raised by participants as a driver of their consent experiences was the quality of their interaction with researchers. Participants' experiences were influenced by whether they perceived that researchers focused on them, treated them in a dignified way, and made them feel like more than just a number. They appreciated when, as one participant stated, "[Researchers] took the time to let you know that they knew you were very—you weren't just something that they were learning from, you know? You were somebody to them." Specific behaviors that accomplished these

Table 2. Quotes by Subcode About Researcher Interactions With Participants

Focusing on the participant as a person
Positive
"They took the time to let you know that they knew you were very—you weren't just something that they were learning from, you know? You were somebody to them."
"He showed enough concern for me and understanding of where my thought process was coming from, and that made me more willing to help him with what he was doing, you know what I mean?" "So respect to me at that time is understanding our feeling and talk at the same level, if they would be in our position." "If you talk to me like I'm an adult and I'm a human, and don't try to use too big of words, but also don't try to use baby words. And, you know, treat me like I'm one of your friends, but don't get too comfortable. . .. That's good bedside manner—I think it's pretty obvious." "Just realize that people are people, and even though everybody is different, when it comes to being nice to someone and communicating with them at a level that they can understand, I think that's important."
Negative
"They weren't disrespectful, but everything was in a rush, doctor, quite honestly, and it was a—and this is the best term I can give you, and again, it was like an 'oh by the way.'"
Professionalism
Positive
"Well, it was—it was the way he talked and the way I could tell that he was doing what he needed to do to get me the help I needed. It was—well, his tone of voice, for one thing. I mean, he was professional, yet, you know, compassionate. He was—like I said, when I say professional, I mean very professional."
"That 30 seconds or whatever it took to sign off on those papers and explain the paperwork—you know, and it wasn't so bad because everybody was prepping me at the time that I was signing stuff, so it's not like it hindered my process, or you know, my procedure. I mean, they're—those people were amazing. I mean, good Lord, they were like, the best of the best, and so it's not like they weren't doing anything when I was signing it; they were working."
". . .and the team approach; everybody knew what each person in the team was going to do before it happened. You know, you have assignments and you're going to record, the other guy is going to do this, the other guy is going to do that. And that gives the patients [confidence], saying, well, they know what they're doing. Instead of everybody asking questions in front of each other while you're laying [sic] there."
Negative
"The surgeon, he came in and did surgery, and I said, 'Well, what's my 5-year survival rate?' And he got irritated and walked off. . .. Anyway, you know, you don't question the doc. He's a good guy. He knows what he's doing. . .. He won't answer my question, and I just smiled, because I know some of these guys are very confident in what they do, and so who talked to me mainly was his intern. . .."
"Like, I heard one say, 'Do you think she'll make it through the night?' You know, and then I think, 'What? Is there any chance I won't?' So it—maybe they just need—maybe you just need to give a little help and instruction to those doctors [who] are participating in it as to how to approach the patient, reassure them in every way."
Nonpressuring
Positive
"I think the reassurance and they didn't really pressure me. I knew there was a time limit, but they didn't tell me, you got to do it right now, you got to sign right here, without me reading. I think they gave me something to read. I can't remember. I just don't feel—I just wasn't pressured to make the decision."
Negative
"I remember just saying, 'Just go away. Please leave me alone,' and then he said, 'If you just sign here we can proceed and I won't bother you anymore.' And I tried to sign my name and I couldn't, so he said, 'Well, just make an X.' That's all—that's all I remember about it. But at the time I felt already, you know, beleaguered, and so that just added to my stress at the time."

objectives included actively listening to the participant, speaking directly to the participant, spending time to explain the research, and responding to participants' emotional needs (Table 2).

Additionally, participants cited how the presence or absence of pressuring speech and behavior affected their perception of being asked to participate in the research study (Table 2). As expected, participants appreciated an approach that did not make them feel forced or rushed into a decision despite the obvious time limitations of acute MI and stroke research. Those participants who did feel pressured spoke negatively about that experience; as one MI patient stated, ". . .I felt already, you know, beleaguered, and so that just added to my stress at the time."

Table 3. Quotes by Subcode About Content of the Consent Discussion

Risks and Benefits
"You know, just the description of something they can do and they're doing and how the outcomes are—you know, the percentages of outcomes. And the way I understood it, she wouldn't be gaining or losing [any]thing. You know, she'd be gaining more than she would be losing. That's when I told him to go do something."
"The benefits of having surgery and not having surgery, the risks—they did tell me the risk of complication, but it should have been detailed more by telling me—by explaining it more, that it doesn't make sure if she gets surgery or not, it's just a study, you know? I think that's the 2 things, the benefits and the risks, in completely more details."
What to Expect as Part of the Study
". . .and when he explained they were not going to open up his head or anything, you know, that made me feel a lot better. He told me what they were going to do and how they were going to do it, so we agreed for them to do that." "I guess the most important part was the fact that somebody was going to come and actually check on her and those areas daily, where she didn't have to worry about what her sugar was doing,. . ." "I'm sure it wouldn't have changed my decision at all, but I would have known that I was going to get woke up [sic] quite often. But you don't know, and people just coming in, and you're trying to get some rest, and they keep coming in and keep coming in—it gets very frustrating and annoying. But if I had known that prior to, I would have known it's just part of [the study]."
Should Researchers Spend Time Explaining Randomization?
Include
"No one ever really let us know that there was a randomization part of it. I don't know that we would have made any different decisions, but it was a little bit—from a consumer standpoint, it was a little bit of a letdown. Like, okay, you have to go through this and make these decisions and all this pressure, pressure, pressure. I got my siblings to talk about the pluses and the minuses, and you know, it could cause damage, it could do this, it could cause more damage. So we have to make that assessment and then make the decision to say, 'Okay, let's do it,' and then say, 'Just kidding, we're not going to do it.' That was the part that was a little—I mean, I know there's a bigger plan than all of us, but it was a little—that was the part that, if I was just a little bit more clear, at least we would have understood."
Do not Include
"No. I think true randomization is actually kind of a difficult thing to explain, so I don't think it's worth going through that discussion. I think it would be better to just tell the person, you know, there's 2 ways that we're going to do this, you'll get one or the other. . .. I think if you try to explain it beforehand, you're giving them too much to think about." "No, because if they. . . . If they tell me we're going to randomize it, we don't know which one you're going to get. At that point though, well do I want to be a loser or do I want to be a winner? No one wants to know that stuff. . .. I think it'd scare them to death. You just don't have time to talk or visit."

Finally, professional conduct was brought up by participants as an important driver of their consent experiences (Table 2). As indications of professionalism, respondents mentioned confident tone of voice, being polite, appearing knowledgeable, working well as a team to execute care seamlessly, and projecting that the patient was going to receive the best care. It is worth noting that some of these behaviors were more directly related to clinical care, but they influenced the research enrollment experience.

Content of the Consent Discussion

In general, participants did not spontaneously raise the disclosure of specific information as a determinant of their experience. As noted in the initial P-CARE report, participants often had relatively poor recall of trial details.[14] When asked to articulate what information they thought was important to communicate as part of the consent process, most participants gave responses that centered on study risks and benefits. A few participants also would have wanted to know why the research was being done and what would be required of them for participation (Table 3). The latter was specifically raised in the context of trials in which the research protocol lasted beyond the acute intervention period.

One of the distinctive features of most clinical trials is random treatment assignment, a concept known to be difficult to understand even in nonacute settings.[17,18] Some participants were unable to demonstrate good comprehension of randomization even after repeated attempts at education during the interview. Participants who were able to understand the concept were asked whether researchers should spend time explaining randomization to potential participants in the acute context. One surrogate for a patient enrolled in a trial of procedural versus medical management for acute stroke felt strongly that randomization should be explained upfront; this view was heavily driven by the experience of his family member being randomized to the control group (medical therapy), which was a "letdown." Other participants felt that randomization should not be a focus of the conversation because it was too complicated and the explanation itself might "scare them to death," leading to more anxiety and distress. As one participant in a trial of a commonly used medication stated, "I think true randomization is actually kind of a difficult thing to explain, so I don't think it's worth going through that discussion.. . . I think if you try to explain it beforehand, you're giving them too much to think about."

Table 4. Quotes by Subcode About Enrollment Processes

The Consent Form
Form proves study legitimacy
"Well, to me [the consent form is] a very important thing. Like I said, I'm military, very detail-oriented. You know, for action there needs to be something signed to say it happened or why it happened. So to me that's the norm."
Signing form made participant feel like part of the research
"I'm giving consent for this to take place, you know. Made me feel like I was a part of what was actually going on."
Form serves a legal function
"I mean, the consent form is important. I mean, you need the—people make mistakes, things can happen, and family members may or may not misconstrue that it's the doctor's fault or the hospital's fault, and maybe it wasn't; it was just—you know, it just happened. But it might have been my time, you know what I'm saying? I mean, they need that protection. They all do, the doctors and the hospital." "You have a piece of paper showing that you are legally allowed to do that because I gave permission. I think you'd open yourself up for legal ramifications if you just used verbal, is my opinion." "This may sound weird, but I think medicine has gotten to the point to where doctors and nurses and the researchers and everything, they have to protect themselves, as well, so I think they need something that says, you know, yes, I did talk to this person and they did sign."
Form is good resource to refer to later
"Well, I think it's more than that. It's not even the reading. I mean, sometimes it's just the tangibleness of it, you know what I mean? So that if in 5 years I start to wonder, is this causing—I can pull this piece of paper out and take it to the doctor and say, hey, is this causing me a problem?. . .. So that's what the paperwork means to me."
Signing form caused aggravation
"'You have to sign this, otherwise we're not going to fix you.' And so, you know, it is kind of a moot point to have a signature, and it was distressing at the time because I couldn't see, you know, I couldn't read what it said, and I certainly wasn't listening to what it said. All I heard was, 'Sign here and sign here and sign here.'"
Prearrival and postenrollment interactions
Prearrival research discussion
Positive
"Well, that way I could have been aware of it, and it could have saved a little time. But I know driving and talking on the phone, especially in a situation like that, would be kind of dangerous, too, but it could have been something to think about. You could have—if somebody's riding with you, they could have been looking it up or something—whatever, something to that effect."
Negative
"I wouldn't have paid attention to it, and I would have—honestly, I wouldn't understand it while I was driving, if they would have talked to me. . .. So I'm glad that they didn't tell us over the phone, otherwise I wouldn't have paid attention. I would have been causing an accident by listening to all of that."
Postenrollment interactions
"[The postenrollment conversation] helped because I knew I had done the right thing. Prior to, it just—everything was kind of in a haze, and you don't really know why did I do this, but then when the follow-up comes in, you figure out, okay, so I did make the right choice, it was important to do, we're getting good research, so you kind of feel better about the reason or the decision you made." "Someone could've come back there within the week, you know, when things are all calmed down, and the doctor could've come back and, you know, brought me some information and given it to me. Because I did have to call and get someone to mail me out some information. You know, I just felt kind of dumped."
Exception from informed consent
Positive
"If you're that overwhelmed, I think having someone else take that pressure off you and enroll that—you know, the person, knowing that they fit the criteria, that's great. . .." "I guess me, personally, that would have been fine [with doctors deciding to enroll me]. Yeah, I don't see anything wrong with that, I mean, because you can always just—you know, when you're aware of what's going on or whatever, you can always just say no, I don't want to do this."
Negative
"I think it would have been better if someone would have just asked as they did. . .. If the person was [sic] in a situation where they were not able to answer for themselves, you know, that—I guess that would anger some people if they did something." "I think maybe I would have turned them down [if they had enrolled without prospective consent], because that seems a little secretive to me. I'd rather them be out in the open."

Enrollment Processes

The Consent Form. Participants generally reported being given what they considered to be long consent forms to read and sign (Table 4). Participants who had negative experiences with the form described not knowing what they were signing, not being able to see in order to read the form, and feeling distress and aggravation from the act of signing the form. As one MI patient stated, "[Signing the form] was distressing at the time because I couldn't see, you know, I couldn't read what it said, and I certainly wasn't listening to what it said. All I heard was, 'Sign here and sign here and sign here.'" In contrast, some participants explicitly valued the consent form. Interestingly, most reasons for valuing the consent form were not related to improving understanding of the study. Instead, some felt that having a form to sign provided legitimacy to the study. Others expressed that the act of signing the form, "Made me feel like I was a part of what was actually going on." Related to its legal function, some felt that the form was important in order to protect patients from unwanted treatment or researchers from legal action. One participant even mentioned that the signed form might help to avoid future familial conflict if any complications were to arise from study participation. Finally, some participants felt that the form and the other written materials were a good resource for later reference.

Alternatives to Traditional Consent: EFIC Approach. In initial interviews, participants were asked whether they would prefer an approach to enrollment in which the doctor makes the initial enrollment decision for them, and they are told about the study later and have an opportunity to decide whether to continue participation. This is the process in studies using the EFIC for research in emergency settings. When asked about this approach, some participants had difficulty understanding it and thought, incorrectly, that withdrawing later from the study meant that they would not have been affected by initial enrollment. Others felt that doctors could be trusted to make research decisions for them. One participant stated that an EFIC approach was appropriate given that the clinical situation was too stressful for patients to understand information about the study in a meaningful way. However, 2 participants in this study who were not supportive of EFIC in their prior interview simply stated a preference for being included up front and felt that people enrolled without being asked would be angry about it.

Prearrival Research Discussions. In stroke trials, it is often the case that patients are identified as eligible trial participants at community hospitals before transfer to tertiary-care centers, or patients may arrive at a treating hospital well before a surrogate.[19] In some of these instances researchers will provide study information over the phone. This study included 1 stroke surrogate who had this experience and 3 stroke surrogates who had clear opportunities for such an interaction. Of those 3, 1 surrogate felt it would have been hard to concentrate on the conversation and the road at the same time, putting her at risk for a car accident. However, the other 2 felt that prearrival telephone conversations would have given them and their family members time to process the idea of research participation, to look up information, and to prepare themselves for what to expect when they arrived at the hospital (Table 4). They did recommend, however, that the description of the study at the time be very brief.

Postenrollment Interactions. One potential area for improvement identified in the initial P-CARE study was postenrollment contact. In exploring this domain further in this study, participants almost universally either appreciated or wanted more postenrollment contact from research teams (Table 4). They felt that this time with researchers was an important opportunity for them to receive more information about the study and to ask any remaining questions. "Prior to [the postenrollment conversation], it just—everything was kind of in a haze, and you don't really know why did I do this, but then, when the follow-up comes in, you figure out, okay, so I did make the right choice, it was important to do, we're getting good research, so you kind of feel better about the reason or the decision you made." Those who did not recall substantial postenrollment contact sometimes had lingering confusion, questions about the research itself, and, in the strongest reactions, a resultant feeling of abandonment.

Discussion

This follow-up key informant study was designed to explore factors influencing positive and negative experiences with research enrollment in the setting of acute MI and stroke and to further contextualize results of the initial P-CARE interview study.

One of the most important findings is that some of the principal drivers of patients' and surrogates' experiences are aspects of informed consent that have often been ignored in the literature. Because the primary ethical goal of informed consent is typically considered to be allowing participants to exercise their autonomy, informed consent research has focused on improvement of trial recall or understanding as a means of enabling autonomous enrollment decisions. In acute settings, time and situational constraints predictably lead to imperfect trial understanding and recall.[7–13] These and other data, however, suggest that consent processes have value through functions that do not rely on understanding.[1] Consent conversations provide opportunities for researchers to express respect for patients by treating participants as more than just a number, by not pressuring them, and by exhibiting

professionalism. Therefore, in order to maximize value gained by consent processes, efforts should be made to systematically incorporate these behaviors into study design, review, and conduct.

Participants' perspectives on consent forms were heterogeneous and sometimes unexpected; these forms were felt by some to be valuable for reasons entirely unrelated to their content. Despite data from initial interviews suggesting that participants often do not read consent forms, those in support of the form felt that it was an avenue for showing their involvement in the research decision, proved study legitimacy, and provided legal protection for the patient and the hospital. These findings suggest that doing away with consent forms completely may not be optimal or necessary. On the other hand, there are those who were bothered by being asked to sign extensive forms. Acute MI participants in particular sometimes expressed being limited in their ability to engage with a consent form due to physical limitations such as pain, stress, and inability to read the form in the moment.[14] Simplifying and shortening consent forms in a way that is consistent with the clinical context seems important, and consent forms may have more of a meaningful role in surrogate consent for stroke trials than in acute MI trials.

Focusing on key elements identified by participants as important to decision making may be a way to decrease length and increase the value of consent discussions. Participants in this study advocated primarily for discussing risks and benefits, why they were being asked to participate, and what would be required of them if they participated. Conflicting data exist regarding the optimal level of detail about randomization, a topic known to be complex for patients to understand.[17,18] From a regulatory perspective, focusing on participants' aforementioned suggestions would be consistent with the requirement from the new common rule for an upfront "concise and focused" presentation of the key elements of research.[20] However, the role or value of the rest of the form remains uncertain.

Another process-related factor that was important to participants' experiences was postenrollment contact. In initial P-CARE interviews, little less than half of acute MI and stroke participants did not remember having any postenrollment interactions with researchers.[14] Participants who did not remember having postenrollment contact conveyed lingering confusion, unanswered questions, and, in the worst cases, a feeling of being, as one participant stated, "dumped." Although it has not been tested, it seems likely that enhanced postenrollment contact has the potential to convey appreciation, gratitude, and respect for research participants as well as to provide an opportunity to improve participants' understanding of the study. This is especially important given that limited information is retained from the acute setting. The participants who proposed specific timing for postenrollment contact advocated waiting 1 to 2 days after enrollment to ensure the patient or surrogate would be more alert and, ideally, in a more stable state.

One interesting tension within the research community that was explored during interviews was prearrival research discussions. Stroke surrogates who had the potential to be involved in prearrival research conversations over the phone had mixed feelings. Some felt it would be beneficial in affording extra time to consider study participation, look up information, and prepare mentally for what would happen on arrival at the hospital. Others were concerned about important issues such as whether such a discussion would distract them while driving. Logistical considerations make prearrival communication strategies difficult to implement. In addition to challenges related to driving, it is also important to ensure that adequate communication has taken place with the clinical team so that family members are aware of the clinical situation prior to engaging in a research consent conversation. Researchers may also be reluctant to begin a conversation over the phone if they believe it would cause misunderstanding and premature rejection of the study.[21] However, it is an important practical issue for acute stroke trials that should be considered in future research.

Limitations

Several limitations warrant mention. This study was designed as a qualitative supplement to initial P-CARE interviews. Its objective was to provide in-depth insights into the drivers of different viewpoints and experiences rather than information on the frequency of views. Although sampling occurred until investigators believed that informational redundancy had been achieved, it is possible that the full breadth of views was not represented. It is important to note that the response rate was high for these key informant interviews. However, our sample was limited to participants in the initial P-CARE interview study, and we only had access to data collected within that study. For example, people who declined the initial P-CARE study were not represented, and we did not have access to patients' medical history, including trial-related medical outcomes. There was also a potential for recall bias, as these interviews were sometimes conducted years after initial enrollment in the clinical trial. This did not appear to affect recall significantly in the initial P-CARE study; however, the follow-up interviews focused more on trial-related experiences than on knowledge of the trial-related details. Finally, these data represent participants' preferences for informed consent processes, but in the future, it would be useful to study particular approaches prospectively to examine any impact on outcomes related to both enrollment rates and the extent to which participants feel respected by the process.

Conclusions

Because meeting the goal of fully informing patients in order to facilitate autonomous decisions may not be feasible in acute MI and stroke research, it is important to maximize what opportunities exist to express respect for these patients and their surrogates. These data identify several key ways to enhance respect: exhibiting a caring, nonpressuring, and professional demeanor; focusing discussion on features identified by participants as important; and ensuring postenrollment communication. Future research is warranted on how best to operationalize these goals.

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SUPPLEMENTAL MATERIAL

Table S1. Examples of Open-Ended Interview Questions by Domain.

General attitudes toward the consent process

- You were in the *** study which is about ***. Can you tell me a bit more about how the study team asked to participate in that study?
- Can you walk me through what happened during the time that you were asked to participate in the research study?
- What was your thought process during the conversation when you were first told about the study?

Researcher behaviors

- Describe your interaction with the person who told you about the study.
- Are there ways that you can think of that he/she could have approached that situation differently that might have been more effective for you?

Content of consent discussions

- What information about the study do you remember being important to you at the time you were deciding about whether to be in the study?
- Was there anything that was confusing to you at the time about the study?

Attitudes towards the form

- How did you feel about being asked to sign a written consent form?
- Was there anything that stuck out to you about the form itself?
- Did you feel it was important to have a form to sign? In what ways was it important?

Alternative approaches to consent

- EFIC-like approach: How would you have felt if the doctor had enrolled you in the study at their discretion and then told you about the study and asked if you would continue to be part of the study later?
- Pre-arrival research discussions: Did anyone call you while you were on the way to the hospital? Would you have wanted somebody from the study team to talk to you over the phone?