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CLINICAL TRIALS

Message Factors Affecting the Recruitment of Black Caribbean and African American Participants for Clinical Trials

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Abstract

The need for effective and ethical recruitment of Black Caribbean and African American individuals for participation in research studies and clinical trials is urgent; without adequate representation, findings cannot be generalized to these populations. The factors affecting recruitment are complex, including many systems-based issues. However, communication issues have received relatively little attention. To advance knowledge of communication behaviors that impact recruitment of research participants from Black communities, we describe the findings from a study of 48 participants in 9 focus groups. Participants included 31 African American and Black Caribbean individuals who described their experiences being recruited for research studies and clinical trials as well as 17 (primarily Hispanic and African American) clinical research coordinators who described how message factors impacted recruitment and retention of Black Caribbean and African American participants. Using the lens of the Elaboration Likelihood Model (ELM), which describes the communication factors that help motivate the cognitive processing of information, we describe how the amount of information provided, the accessibility of information, and the complexity of information all impact study recruitment. Participants offered insights about the adequacy (and excess) of information provided, tensions related to deviation from consent form language when simplifying complex terminology, preemptively addressing common conspiracy theories during recruitment, the importance of using metaphors and analogies, and communicating complex information using multiple communication modalities.

Introduction

Clinical trials require the enrollment of proportionate numbers of individuals from all racial and ethnic populations in order to reach valid conclusions about the safety and efficacy of new treatments and approaches to disease management [1]. Unfortunately, while the proportion of Black and African American individuals who are approached to join clinical trials has risen to approximately 16% [2-4], this has not translated into minority representation in study participation [3]. There are many factors that impact the willingness of members of minoritized populations to join clinical trials, including lack of knowledge about clinical trials and low awareness of their availability, medical mistrust, lack of medical insurance, concerns about the risks associated with research participation, and lack of clear and/or culturally appropriate communication behaviors during

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recruitment [5-9] but relatively few researchers have investigated the impact of communication factors on the willingness of Caribbean Black and African Americans to enroll in studies, particularly when part of interactions during the recruitment process. While researchers have examined communication factors such as linguistic framing, the use of metaphors and analogies, the encouragement of question-asking, and "translating" technical language into lay terms, and simplifying information in order to provide clarity [10-25], few researchers have examined the communication preferences of African Americans and none apart from Morgan and Wright and colleagues [23-24,26]have investigated communication with Black Caribbeans. The significant size of this population (half of all Black immigrants are from the Caribbean [27]), the rapid growth of the Black population (30% over two decades [28]), and the urgent need to diversify participants in clinical trials and in precision medicine initiatives in order to improve medical science [22] make it imperative to conduct greater formative research to support interventions that have the potential to increase accrual among Black populations.

Comprehension of study information is no guarantee that a patient will enroll in a clinical trial, but it is a prerequisite for informed consent. The ultimate goal for researchers focusing on the recruitment process is not to increase study enrollment but rather to increase informed consent or refusal. Meaningful consent (or refusal) requires prospective participants to be motivated to fully consider information which they can easily understand. While some patients are likely to be overwhelmed with the details of a new diagnosis or the reality of their everyday lives and cannot afford the cognitive energy to think about the prospect of joining a research study or clinical trial, many individuals are simply not presented with adequate information in a manner that patients find effective. It is the goal of this study to explore factors related to in-person messaging about clinical trials during the recruitment process; this information may guide the development of more effective communication protocols, particularly for members of minoritized communities. The elaboration likelihood model provides a theoretical framework for this investigation.

The elaboration likelihood model

The Elaboration Likelihood Model (ELM) has been widely applied to contexts related to attitude change. This theoretical framework posits that meaningful attitude change is largely a function of cognitive elaboration, i.e. effortful thinking about an issue, via central route processing [29]. Such careful thinking about an issue is likely when an issue is important to a person and when a person has the cognitive capacity to process the information. Individuals who are already motivated to consider joining a clinical trial include those for whom standard treatments have failed or those who are highly altruistic and want to contribute to medical knowledge. Conversely, individuals who mistrust the medical system and believe they may be harmed if they enroll in a research study are considerably less motivated to think about information related to clinical trial participation.

Qualities of the actual messages that are conveyed to patients also play a significant role in whether receivers are motivated to elaborate on (i.e. think about) the message. Message factors that are associated with elaboration include argument quality and quantity; argument quality addresses the "perceived desirability of the outcomes associated with the advocated view" [30], while argument quantity simply refers to the number of reasons provided for engaging in the recommended behavior. While providing many reasons to participate in a clinical trial can produce a shift in attitudes, this can be expected to be effective only when an individual believes that the issue is not particularly important to think carefully about. For this reason, a messaging strategy that only presents a large number of arguments without consideration of the importance of the issue or desirability of outcomes is unlikely to produce enduring attitude change. In the context of clinical trial recruitment, clinical research staff might be able to persuade someone to enroll, but they would be unlikely to be retained in a study.

Work that is grounded in the elaboration likelihood model has argued that other specific message features are also important. These include the length (i.e. amount of information), complexity (i.e. clarity of information), and accessibility of a message (i.e. comprehensibility of information) [31]. While these message features may not play as profound a role as an individuals' level of issue involvement [32,33], they are important for encouraging deeper processing of information [28]. Researchers using this framework have explored how message variables like format and message credibility impact the motivation to process information. Within a health communication context, Trivedi and colleagues [34] contrasted health

messages using a narrative (versus non-narrative) format as well as those which varied in degree of veracity (i.e. evidence versus nonevidence-based messages). Evidence from eye-tracking methodology demonstrated that evidence-based messages received greater cognitive attention from individuals with higher levels of health literacy.

However, other evidence from studies on clinical trial communication indicate that in-depth cognitive processing by patients may be associated with strong positive affect. Patients who were provided with information about study participation were more likely to engage in effortful cognitive processing and indicate a desire to join a trial if they had optimistic feelings [35-37]. Similarly, Curbow B, et al. [38] found that positive feelings about clinical trial participation were highly influential on behavioral intentions as long as individuals believed that they had received sufficient information. Yang and colleagues argue that "communication about clinical trials is a balance act between providing sufficient information about the potential risks and benefits" of a clinical trial and managing patients' emotional responses [35]. Effortful cognitive processing is clearly associated with a greater likelihood of clinical trial enrollment but positive affect provides some measure of motivation for this effort [39]. Thus, ELM is a theoretical framework that can support the development of broad message strategies that can are more easily understood and perhaps more importantly, help motivate effortful cognitive processing of unfamiliar information.

In the current study, we are focusing on elements of the ELM framework that are associated with what is actually said during the recruitment process as well as the characteristics of the information that is conveyed. We seek to answer the following research question:

RQ: How do Clinical Research Coordinators (CRCs) and African American and Black Caribbean patients characterize effective and ineffective messages about research participation?

Methods

Participants

Following IRB approval (University of Miami approval #20210606), staff members employed by the Behavioral and Community-Based Shared Resource (BCSR) and the Clinical Translational Science Institute (CTSI) of an academic medical center in a major metropolitan area recruited 48 individuals who participated in 9 focus groups. Focus groups were conducted separately with African American patients (k = 3), Black Caribbean patients (k = 3), and clinical research coordinators (CRCs; k = 3). Data were collected in the fall of 2021. Table 1 presents demographic information for both the patient and CRC groups. None of the authors have competing financial interests to declare.

Eligibility and compensation

Participants in the patient focus groups were required to have experience being recruited for at least one study prior to the current study. Additionally, they had to be over 18 years of age, self-identify as African American or Black Caribbean and speak either English or Haitian Creole. Clinical research coordinators were required to self-identify as someone who had

Table 1: Participant demographic information.

Demographic Category		Patient groups (*n* = 31)	CRC groups (*n* = 17)
Race			
	Black or African American	13	3
	Black Caribbean	18	0
	White	0	12
	Asian	0	1
	Other	0	1
Ethnicity			
	Non-Hispanic	31	3
	Hispanic	0	14
Age		18 - 68 (M = 54.29)	23 - 75 (M = 43.65)
Gender			
	Female	19	14
	Male	11	3
	Transgender	1	0
Education			
	Some high school	8	0
	High school diploma	9	0
	Some college	5	1
	College degree, Associates	1	2
	College degree, Baccalaureate	3	5
	Some post-graduate education	2	2
	Graduate degree, Masters	2	5
	Doctoral degree, PhD/MD/JD	1	2

significant experience recruiting African American and/or Black Caribbean patients for research studies. All participants received a $40 gift card in exchange for their time; focus groups lasted 50 to 113 minutes.

Procedures

A team of two individuals co-facilitated each focus group; each team included at least one Black Caribbean facilitator. Co-facilitation approaches can bring added insight in cross cultural research studies [40]. After being consented to the study by one of the study authors or a facilitator from the BCSR, participants were asked five questions about the experiences of being recruited for a research study (patient groups) or the process of recruiting Black Caribbean/African American participants for research studies (see **Appendix A and Appendix B**). Focus groups were audio and/or video recorded to facilitate the transcription process. English-language focus groups were transcribed by three of the authors, while the Haitian Creole-language focus group was transcribed and translated by certified medical translators. All names used in the manuscript are pseudonyms.

Data Coding and Analysis

After all members of the research team familiarized themselves with the transcripts and made detailed observations of emerging themes and offered recommendations for the development of coding categories, NVivo (2020 release) was used to code the data by the first two authors using a modified constant comparative method [41]. Both authors coded all data, resolving any disagreements through discussion. After the data were coded, the authors identified patterns in the data that related to the research question on message factors. These patterns were discussed by the research team and additional input resulted in modifications to the analysis and subsequent results.

Results

Our research question centers on how messages about research participation are characterized by both Black Caribbean/African American patients and clinical research coordinators. Major categories of findings include the amount of information that is given/received, and the clarity and accessibility of the information that is provided.

Amount of information

There was general agreement among both patients and CRCs that all relevant study information needed to be shared. Maria, a research coordinator, linked a failure to provide complete information to distrust: "I think that you have to go above, you leave nothing, like unsaid. Yes. Nothing, even the most minimal things because if something becomes a surprise, then that triggers distrust."

However, the amount of information considered to be sufficient was not always completely clear. Some patients found information presented during the consent process to be excessive, while others indicated that because of the anxiety and uncertainty involved with clinical trial participation, no amount of information could make them feel confident about the decision to participate in research. Research study staff are required to fully present all available information about a study in order to secure meaningful informed consent. However, this information can be boring or difficult to understand, which sometimes frustrates patients. Vicky characterized these exchanges as being "dragged out."

> Vicky: Don't drag it out.
>
> Facilitator: Don't drag what out? ...The information?
>
> Vicky: The information... For instance, explaining the drug, don't drag it out. Don't go through all these all these steps when they're not necessary. It's not necessary for you to have me do this. Do that, do that. What does that mean? ... No, don't make me wonder and have anticipation anxiety.

However, while patients may sometimes dislike listening to lengthy and detailed explanations of studies, they nonetheless want to receive enough of the "right" information to assess risks.

> Liliane: They just told me they had to do something, and they told me the risks. Plain and simple. But certain things, they don't tell you. They brush it off, they tell you the surface, icing on the cake. They not really go deep inside and tell you "Listen, this is what may happen. This is a percentage of this and percentage of that." So, some people are not going to do it. ...Even if you're in medicine, you're scared. This [treatment] is something new. [Maybe] you're not telling me everything.

This sense of uncertainty may point to the importance of partnering with patient stakeholder groups to adjust the consent process to include the kind of specific information that is important to patients themselves, not just what is deemed important by the medical institution. Alexandra, a CRC, describes an adaptive approach, where a greater amount of information is provided only when the patient indicates interest in the study.

> [I use] general language when [I] initially approach everyone, and then kind of getting a gauge. Like, for instance, you can tell when someone's really interested in this study, like they are personally very interested in learning more about their [health issue] ... And I think it's really important, you know, to take the time to talk to them and elaborate when someone is really interested in and to share that excitement with them.

For patients who are not particularly interested in a study, additional information about the protocol or drug being tested simply will not make a difference. The assumption that "more (information) is better" may be misplaced when prospective participants rely on information from their social network to make decisions about research participation.

> [I]n that consent [form], by law, we have to provide every information. Sometimes... your Mom tells you to take this aspirin, and you take it, the neighbor across the street will tell you to take this aspirin, and I'm the doctor, especially giving you all the information. Here is a 20 page [document] of the things that could and could not happen. I'm telling you, you can take this pill, and you're telling me no. And did you ask your neighbor from across the street? Your mother, like, you know, if you take a Tylenol, it's more risky than taking some other drugs. But nobody reads the label. And it's a Tylenol, everybody takes Tylenol. ...I put it sometimes that way, like, because it's our culture, you know, we usually rely on more on the people we know than the people we don't know.

Clearly, the amount of information provided about a study alone is not persuasive to many patients who are being recruited for study participation. In fact, providing too much information may be regarded as ineffective persuasion when familiar, trusted sources provide opposing opinions. To boost their credibility, research study staff try to address conspiracy theories and other forms of misinformation even when they are not confronted with it by patients directly, according to Angela, a CRC with 15 years of experience with study recruitment.

> [There are] conspiracy theories tapped into ... everything we're trying to roll out. [W]hen you do a web search, it's one of the first things that pop up, all of the conspiracy theories tied to it rather than the correct information or the scientifically proven information. Making sure that we can tackle the misinformation or dismiss the conspiracy theories and stuff like that is super important. So not fumbling, right, like making sure you flow, or you have all the tools and being comfortable with saying "You know what, I'm happy to go get more information about that." Like, "Let me come back to you, I definitely want to give you the right information." And so making sure all of that [is] in your script ...is super important, because more than likely, they definitely got some misinformation along the lines.

Thus, in addition to being well-versed in all information about a research study, it may also be helpful for study staff to review the type of misinformation available on the internet about similar types of studies and create effective scripts that counterargue false information.

Message complexity and accessibility

While the amount of information plays an important role in successful research study recruitment, it is not the only message-based variable to play a role in motivating cognitive elaboration by prospective research participants. Messages about clinical trial participation can involve complex concepts, which CRCs must work to make more accessible to ordinary lay individuals. Some patient participants describe their angst in receiving incomprehensible messages. At the same time, CRCs describe several strategies to reduce the cognitive demand required for patients to fully consider information about research participation, including simplification, creating redundancies, and the use of metaphors and analogies.

Patient participants noted their frustration with the use of complex information or medical jargon about research studies:

> Facilitator: Did the person explain the study to you in ways that you could understand? What kind of words did they use? Scientific terms? Did they give

you some examples in ways that you could actually understand what the study was about?

Jack: Actually, scientific words.

Facilitator: Scientific words. Not layman terms that...

Multiple participants: Big words.

Claude: They try to [sound smart to] you just to get you [to participate].

In contrast, patient participants felt comfortable when they were explained the details clearly. For example, Eric said, "I felt comfortable because I was able to, you know, comprehend, the way they were doing it and the way they were trying to explain it to me."

In demanding simpler messaging, patient participants also gave insights into how they felt when they were confounded by the information they received. Charles suggested, "It should be in laymen's terms cause everybody else don't understand big scientifics and all that... don't agitate them, don't have them confused." Participants further reinforced this suggestion by noting that explanations of study participation should provide "clear cut, straight to the bone [information]"; when the participants can "explain it [the study] back to you" constitutes evidence of non-complex, accessible communication. Patients, like Alisha, also expressed satisfaction when the information presented was clear: "he was talking to me, like, not as a doctor, [or] like an expert would presenting all this jargon. He was actually explaining to me everything in a way that I can understand it and told me the aftermath [of the procedure]."

Perhaps the most obvious communication strategy that CRCs use involves simplifying complex messages. Jenifer described the way she explains the use of a placebo in a randomized trial and the effect that simplification has on patients:

When I explain to the patient I say, you will get the real medication or not the real medication so they know. ...the people respond very nice when you treat it simple, with respect and very nice, very simple words, and try to avoid [terms like] "the PI of this research", the "CT scan", because they will not understand that.

Moreover, simplifying complex concepts is critical not just for recruitment but for study retention, as Sheila indicates.

I make sure I'm extremely familiar with the concept, so if I have to paraphrase some things for their understanding I will. And then I ask them if they understand; if not, if I have to go even down to 5th grade level, I will until I get to the point that they understand completely. So that means taking out the extra time, [going] the extra mile. Some people may not have the patience to do that, or the willingness to do that. But if we want people in our study to stay in our study, this is what we have to do.

Interestingly, not all CRCs agree that simplifying or "translating" complex information for patients is desirable. To deviate from official information presented in the consent form, for example, may be misunderstood as an inconsistency. Sharon, a relatively new CRC, said that she avoids changing terms as a way of fostering trust with prospective participants.

I don't try to simplify any terms, I just say the terms, I define it for them if they don't know, and then I just, I like repetition. That way, it lets them know that if you hear the same thing, it's nothing being switched up or changed and that way I'm consistent, that builds the trust. And if they want me to repeat something, or you know, get more clarity, I just tell them a definition of a specific term.

CRCs also report using word substitutions, verbal reframing, and metaphors to make core concepts related to clinical trial participation more accessible to prospective research participants. Angela provided this description of how using a variety of linguistic strategies can boost comprehension:

We typically try not to assume educational background, regardless of who we're approaching or who screens into our study. ...[W]e like to tap into all types of metaphors and similes that can really paint the picture of what [data] we're trying to collect and what their participation will look like. So whether that involves a video, whether that involves a little PDF [document].

Other CRCs offer specific word substitutions for terminology that might trigger negative associations in patients' minds.

> Kelly: I think that instead of like, "study" and "research", where it's like experimental, and they're just [afraid it will be] causing you harm and using [you] as a guinea pig, maybe using words like, "learn" and "knowledge" and "benefiting people in the future" so [patients feel that they] can contribute, like, in an altruistic way.

CRCs offered a number of examples of other metaphors that they use to improve the accessibility of information. Juan indicated that, along with metaphors, he creates redundancies when presenting study information.

> Well, randomization is... you just flip a coin, you know? It's kind of like a 50/50...you're explaining it [like you would] to a kid. ... And if they still don't get it up to that point, [you try to] break it down even more... try to use your imagination to... make them understand. Sometimes you have to be graphic so you know you can get the coin actual coin and flip it... or, you know, usually when you're consenting someone you have a pen and paper, you draw it. Some people are more visual than others, so if you if you put it on a piece of paper [you can] then just hand it over.

Like Juan, Angela also indicated that she uses metaphors to explain important biological mechanisms that would help research participants understand the medications used in a study.

> I typically kept it at one grade level [for verbal explanations], and I would draw out a picture of what [HIV] resistance looks like. [I would show them] if you don't have a medication level in your system, then your gate is lowered, so what happens is the virus is hopping the fence. Every time it hops the fence, it builds resistance; it already knows how to hop the fence. ...I don't assume you are like this grade level. I'm going to give you the metaphor and simile. I'm going to give you the proper terminology and then I'm going to paint the picture in a different way, so you grasp it in both ways.

Thus, the message strategies used by CRCs can involve not just simplification but the careful construction mental images through visualization techniques in addition to the use of metaphors and analogies to support comprehension of important study information.

Discussion

This study was designed to investigate the types of messages sent and received in interpersonal encounters between clinical research coordinators (or other staff who recruit for research studies) and Black Caribbean or African American patients. Several message factors that are described in the framework of the Elaboration Likelihood model emerged from the analysis of our data. First, comprehension is essential to the process of providing informed consent; the clarity of messages is linked to whether messages can be understood by prospective participants. CRCs indicated that clarity can be increased by simplifying the words used or by providing a variety of alternate explanations. Similarly, our clinical research coordinator groups told us about the importance of using linguistic messaging strategies such as using metaphors and analogies, creating visual depictions of key study concepts or adapting complex information to the educational level of a prospective participant, which is consistent with ELM. Our findings are consistent with previously published literature on clinical trial communication with predominantly White [16-18,42-44] and Hispanic [45] prospective research study participants.

The amount of information provided is another core message feature linked to motivated cognitive processing that is described in the ELM framework. While some patients were concerned that information might be left out of explanations of clinical trials, others seemed exhausted by what they perceived as an excessive level of detail, which in this context can be viewed as a lack of communication competence. Our data indicate that when the amount of information is (subjectively) "just right" and when CRCs work to provide information that can be easily understood by prospective participants, mistrust can be reduced. While being responsive to patients' preferences for the quantity of information being presented may prove helpful in study recruitment, it should be acknowledged that this recommendation may conflict with the demands of institutional IRBs. The irony, of course, is that while IRBs are ostensibly working to support patients' best interests, which interests are addressed are dictated by the institution rather than patients.

A closer collaboration between CRCs (who are more familiar with the communication needs of patients) and IRBs may lead to the development of more patient-centered consent forms. Based on

our findings, Principal Investigators and IRBs may want to incorporate the use of participant-centered graphic visuals to support meaningful informed consent; this type of information redundancy may prove to be welcome. Additionally, reworking information contained in scripts and consent forms to reflect a more tiered initial approach may be more patient-friendly, as would the incorporation of (IRB-approved) tools that incorporate visual communication, animations, and other information aids. Further, leading with a more general overview of the topic of study, followed by potential positive outcomes for research participants could motivate patients to exert the cognitive effort required to learn about the remaining details of the study, including obligations, risks, and benefits.

In our study, CRCs discussed message characteristics far more often and in much greater detail than patients do. This may be linked to the nature of CRCs' work. CRCs frequently use scripts to guide their initial approach of patients and make careful mental notes about what seems to "work" best with patients in order to refine their future approach. This requires a great deal of professional attention to what to say and how to say it. Patients, on the other hand, are likely to be approached to participate in a trial rather infrequently so it is not surprising that they remember only the general outline of what was said. Instead, patients seem to remember how they were made to feel during the encounter and tended to speak in terms of whether they believed that the recruiter was respectful and seemed trustworthy (Authors, under review). The positive affect that may result from interactions with CRCs who are attentive to these message factors should lead to more motivated cognitive processing of information related to clinical trial communication [34-35].

While scholars focusing on clinical trial communication frequently make recommendations based on empirical qualitative and quantitative research, applying theoretical frameworks is less common. This is unfortunate because such frameworks hold the potential to serve as the foundation of more effective interventions to improve communication practice in the context of recruitment. Based on our findings, for example, we would recommend the design of training programs that emphasize the importance of patient-centered messages about clinical trials that are succinct, address possible sources of misinformation, emphasize potentially desirable outcomes associated with research participation, and to use techniques known to help clarify complex information, including the use of metaphors and analogies.

While this study is notable for its inclusion of Black Caribbean and African American patients as well as CRCs from diverse backgrounds to address the ways in which message factors influence the recruitment of participants for research studies and clinical trials, there are nonetheless limitations that future researchers should keep in mind when designing subsequent studies. First, because our eligibility criteria did not specify a timeframe for when participants were recruited to join a clinical trial or research study, participants' recall of the recruitment encounter may be compromised by the passage of time. Second, while our participants came from broadly diverse ethnic and educational backgrounds, we believe we would have benefitted from a more stratified approach, particularly with patient focus groups. In other words, our findings may have been even more useful if we had concentrated on communication strategies that are the most helpful with less-educated, low-literacy individuals. Similarly, it is nearly impossible to generalize our findings to diverse Black Caribbean and African American communities even across our region, much less to other regions. Additional research is needed to develop protocols for effective communication with members of these communities.

Conclusion

What gets said during interactions between a clinical research coordinator and a prospective research participant matters to the success of efforts related to recruitment, consent, and study retention. While this study is relatively small, its focus on the communication needs of Black Caribbean and African American patients and the strategies used by racially and ethnically diverse clinical research coordinators to meet those needs provides important insights; these findings can be used to help establish a set of communication best practices which can be incorporated into future training programs for research study staff. Without this type of formative research, training interventions would be built on a foundation of findings from research done on White patient populations.

It is important to emphasize that the while the elaboration likelihood model is a theoretical framework that helps advance the understanding

of processes of attitude change, the variable that best explains favorable attitude shifts is cognitive elaboration. In other words, the goal of this study (and other studies of clinical trial communication using an ELM framework) is to identify factors that are associated with patients' willingness to think carefully about information related to clinical trial participation. While message factors are only one point in a complex constellation of factors impacting clinical trial accrual, they are well worth attending to not least because they hold the promise of effective intervention to increase rates of informed consent or refusal.

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