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Assessing Communication Practice during Clinical Trial Recruitment and Consent: The Clinical Trial Communication Inventory (CTCI)

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Abstract

The development and evaluation of training programs with the potential to improve informed consent and accrual to clinical trials depend heavily on the ability to measure outcomes of these trainings. In this chapter, we present the development of an instrument, the clinical trial communication inventory (CTCI). Data were collected from 87 clinical research professionals at three academic medical centers, which were analyzed using factor analytic methods and reliability testing procedures. This testing resulted in eight subscales representing verbal, nonverbal, and privacy protection behaviors. While the final CTCI instrument would benefit from further validity testing, it represents a resource that can be used to evaluate future trainings of research professionals.

Keywords: clinical trial communication, accrual, verbal & nonverbal communication, informed consent, measures

1. Introduction

The abysmal rate of accrual to clinical trials, particularly among members of minority and underserved populations, has impeded medical and scientific progress [1]. Ironically, when members of marginalized populations do not participate in numbers that allow the medical community to draw conclusions about the efficacy of new treatments for members of

these communities, health disparities are deepened further [2]. This makes the participation of members of marginalized communities in clinical trials and research studies increasingly urgent.

There is growing evidence that the communication behaviors exhibited by medical and nonmedical professionals tasked with approaching and consenting patients impacts eventual enrollment [3–6]. Most research on clinical trial communication has focused on general guidelines for communication practice. These guidelines include making sure that the type and amount of information are appropriate for the patient [7], using plain language to explain a trial [5, 8, 9] and being open to answering potential participants' questions [3, 8, 10]. Additionally, recruiters are exhorted to be “warm” and respectful with patients [8, 11].

It is important, however, to examine the specific communication behaviors that lead to more effective recruitment, consent, and retention. A study of 63 medical professionals in two diverse U.S. cities indicates that both verbal and nonverbal communication practices support effective recruitment and consent processes [12–15]. Specific verbal communication behaviors that are associated with effective patient recruitment and consent include translating and simplifying information through the use of lay language and examples; reframing information through the use of metaphors, analogies, and storytelling; balancing discussions of risks with benefits; and encouraging potential participants to ask questions [12].

Nonverbal communication behaviors may be even more important, given the central role of nonverbal communication in the process of meaning generation [16]. However, this topic has received little attention by researchers studying factors that impact clinical trial accrual. In the recruitment and consent process, nonverbal communication behaviors that appear to be particularly important include the ability to “read” patients' state of mind before approaching them to participate in a study; the willingness to adapt to a patients' mood and communication preferences; mirroring patients' body posture, tone, and rate of speech; using eye contact, touch, and smiling in situationally and culturally appropriate ways; and being conscious of the impact of physical appearance [13]. Importantly, both verbal and nonverbal communication function to create a sense of relational connection which, in turn, creates both trust and the motivation required for patients to process often-complicated study information [14].

It should be noted that while these verbal and nonverbal communication behaviors are necessary (but not sufficient) for increasing enrollment in clinical trials, the goal of clinical trial communication interventions should not simply focus on accrual but rather improve informed decision making by potential participants. Thus, whether patients consent or do not consent is beside the point. All patients, we believe, should be (1) offered the opportunity to contribute to medical knowledge through study participation and (2) provided study information in language (and a format) that they understand so they can make an informed decision about whether to participate.

Contrary to popular belief, good communication skills come naturally to very few people. Just as public speaking abilities can be developed through professional training, the specific interpersonal verbal and nonverbal practices that foster positive interactions with

patients in a clinical trial recruitment context can be taught [17]. The content of clinical trial communication training programs varies considerably (as do outcomes), but most programs appear to be successful in improving the confidence of those who recruit for studies [18].

While clinical trial communication training programs are not yet widely available, there are some laudable examples that warrant discussion. Fallowfield and colleagues [19–21] have been among the first to develop communication training programs specifically focused on clinical trial recruitment and consent issues. Their training programs provided information on common communication issues and ethical concerns and were primarily directed toward physicians and nurses with clinical trial management roles. The main outcomes from these trainings were improved knowledge of clinical trials and increased confidence in their ability to recruit and consent patients. Similarly, Wells and colleagues [22] developed a training program to improve professionals' communication abilities but focused largely on developing increased cultural competency by focusing on barriers and beliefs of African Americans and Latinos. The program focused on outcomes related to knowledge and attitudes of minority patients' cultural needs. Another communication training program, developed and piloted at the University of Miami, focused on educating research coordinators on specific verbal and nonverbal communication skills to improve clinical trial recruitment and informed consent discussions. This communication training program consisted of five modules and adopted several educational strategies including a didactic presentation, in-group discussions, live demos, and role play activities [17].

One issue that has troubled virtually all existing clinical trial communication programs is the actual assessment of training outcomes. This may be a symptom of a larger problem in that there seems to be little consensus about what the goal should be for communication trainings. We assert that there should be two central goals: (1) increasing the willingness and ability of recruiters to use "best practices" in communication about clinical trial participation, with the ultimate goal of (2) increasing informed decision making among potential participants. Whether patients and other potential participants provide informed consent to enroll in a study or make an informed decision to decline the opportunity to participate, we believe that all patients should be presented with the choice to advance knowledge relevant to their health conditions wherever such opportunities exist. The burden is on us to communicate well in order to maximize the patients' comprehension of all factors that are relevant to their decisions.

Current assessments of the quality of communication practice as an outcome of clinical trial communication training has focused on several tools: (1) surveys of training participants' knowledge, attitudes, and perceived self-efficacy; (2) role-plays to practice skills; (3) video-taping participants to provide individualized feedback, and (4) the use of check lists to assess recruiters' behaviors when interacting with potential participants [18]. While all of these assessment strategies are valuable, none of these approaches has been validated, including the self-report survey, which is the most commonly used tool [18]. The development and evaluation of more effective training programs depend heavily on the use of validated and, preferably, triangulated outcome measures.

Toward this end, we have developed a self-report questionnaire that focuses on communication behaviors that are critical for effective clinical trial recruitment and consent. The measure is grounded in the empirical literature on clinical trial communication, particularly the work of Morgan and colleagues, who identified verbal and nonverbal communication behaviors that recruiters themselves associate with effective recruitment and consent processes [12–15]. We created an initial pool of 138* items which corresponded to a wide variety of communication behaviors including eye contact; conversational style; protection of patient privacy; tone of voice; ability to “read” patients; ability to adapt to patient communication preferences; mirroring patient communication behaviors; smiling and friendliness; body positioning; the use of touch; physical appearance; simplifying/“translating” medical and technical information into lay language; reframing or using metaphors and analogies to explain difficult concepts; encouraging question asking; balancing the presentation of risks and benefits of study participation; describing the benefits to self and society of study participation; and other communication behaviors that ensure that potential participants comprehend information that is relevant to the decision to participate in a research study or clinical trial.

2. Methods

2.1. Procedures

All survey items were entered into online formats including REDCap and Qualtrics for dissemination. Following institutional review board (IRB) approval, the survey was distributed to research professionals at three academic medical centers: University of Miami, University of Florida, and University of Texas Health Science Center. Because of a technical error, data from the University of Texas Health Science Center ($n = 16$ surveys) could not be retained for the study.

The eligibility criteria for participation were broad: Any employee whose job duties regularly involved recruiting and/or consenting patients for clinical trials or research studies could participate in the study. The survey was distributed via email link by managers within each academic medical center. No compensation for participation was offered. A total of 71 people who completed the survey were included in the analyses. Respondents had an average of 6 years of experience ($M = 5.93$, $SD = 4.20$). The demographic and professional characteristics of our sample appear in **Table 1**.

2.2. Measures

In addition to the items assessing communication behaviors in clinical trial contexts, demographic questions, the nature of their work, and their level of experience, we asked research professionals about how they feel about their jobs, their motivation levels, and their self-assessment of their competence in recruiting for clinical trials and research studies. These items were used to explore the relationship between responses to these questions and self-reported communication behaviors as a way to test the capacity of the clinical trial communication inventory (CTCI) to discriminate different audience characteristics.

Variable	n	(%)
Gender		
Male	14	(19.7)
Female	54	(76.1)
Not reported	3	(4.2)
Race		
American Indian	0	(0)
Asian	4	(5.6)
Pacific Islander	0	(0)
Black or African American	4	(5.6)
Middle Eastern	0	(0)
White or Caucasian	60	(84.5)
Not reported	3	(4.2)
Ethnicity		
Hispanic	32	(45.1)
Education		
High school-less than bachelors	8	(11.3)
Bachelor	23	(32.4)
Master	23	(32.4)
PhD	6	(8.5)
MD	11	(15.5)
Institution		
University of Miami	40	(57.1)
University of Florida	28	(40)
Both UM and UF	1	(1.4)
Other	1	(1.4)
Not reported	1	(1.4)
Type of trial*		
Drug	44	(62)
Device	11	(15.5)
Behavioral/social	30	(42.3)
Medical intervention/procedure	16	(22.5)

*Some individuals reported recruiting for more than one type of trial.

Table 1. Characteristics of the sample.

3. Results

Because of the high ratio of survey items to number of participants, an exploratory factor analysis that included all survey items did not yield meaningful results. Breaking the survey down into smaller groups of conceptually linked items proved to be a more useful strategy. All reported exploratory factor analyses used an oblimin rotation because items representing, for example, different dimensions of nonverbal communication necessarily have a strong relationship with each other. An item was considered to be an indicator of a factor if it had a loading of .5 and a loading of no more than .4 on any other factor. The results of the exploratory factor analyses for four sets of items appear in **Table 2** (nonverbal communication), **Table 3** (translation, simplification, and lay language), **Table 4** (reframing medical information), and **Table 5** (fostering understanding of medical research). Appendix A contains the items retained for each scale.

The results of the factor analyses (where viable results were obtained) were used to construct final versions of the scales. Descriptive statistics for each of the final subscales and Cronbach's alpha appear as **Table 6**. Pearson correlations between all of the CTCI subscales appear in **Table 7**.

The relationships between the final CTCI subscales and other variables in the survey were examined. Specifically, we sought to look for possible difference in responses by gender, race/

Item	1	2	3
I usually mirror a patient's body posture when I'm discussing a study with them.	.85	-.14	.25
I try to adjust my facial expressions to reflect the current situation they are in.	.75	.12	.13
When I am discussing study participation, if a patient appears relaxed, I relax my body too.	.74	-.23	.06
I often mimic a patient's mannerisms when I talk about a study.	.74	-.07	.18
Based on my first impressions of a patient, I adapt how I talk about a study.	.69	.00	.07
Whether a person talks loud and fast or softly and slowly, I adjust the way I speak about a study to how they talk.	.69	-.05	.18
I slip into the same style and manner of speech as the person I am talking to about a study.	.68	-.13	.20
I think it's more important to be warm and friendly with patients than to maintain professional distance	.67	.02	-.45
When I walk into the exam room (or waiting area) with patients, I try to figure out what kind of mood they are in.	.46	.36	-.54
I am very good at 'reading' a patient before I start talking about study details.	.42	.38	-.6
I always maintain a highly professional tone and demeanor when I talk to a patient.	.06	.77	.32
I act the same way with every patient regardless of their mood.	-.03	.67	.40

Table 2. Nonverbal communication (reading, adapting, mirroring) factor loadings for exploratory factor analysis with oblimin rotation.

Item	1	2	3	4
I 'translate' information about a study to help patients	.69	.00	.38	-.18
I find ways of using lay language	.67	-.08	.31	-.21
I believe that members of some minority/ethnic populations have specific preferences for words or research-related terminology	.68	.10	-.45	.18
I try to avoid certain words or medical terms when talking with members of certain cultural groups	.73	.30	-.44	.06
I try to use language that I think would be received well by members of the cultural group to which they belong	.78	.01	-.42	-.02
When going through a consent form with a patient, I often say something like, 'so this means...' followed by a lay explanation	.70	.03	-.02	-.38
Based on what I know about the educational level of the patient, I adapt my explanation of a study	.75	-.16	-.04	-.24
I break down the study protocol into smaller steps to make the prospect of participating in the study less intimidating	.59	-.15	.41	-.22
I simplify the language of the consent form	.58	-.25	.28	.56
I substitute simple words for complicated medical terminology	.54	-.38	.11	.58
I make sure that all of my explanations of a study can be found directly on the consent form	.15	.71	.50	.18
Because the consent form must be approved by the IRB, I keep to the language that is specified in the consent form	.08	.84	.12	.04
I do not diverge from the information and explanations offered in the consent form even when I understand a study well	.16	.82	-.11	.11

Table 3. Translation, simplification, and lay language use item factor loadings for exploratory factor analysis with oblimin rotation.

ethnicity, and type of trial recruited for. We also looked for correlations between responses to the CTCTI subscales and job satisfaction and years of experience. None of these analyses produced a significant pattern of results except for years of experience. The number of years of experience as a research professional correlated significantly with use of eye contact ($r(62) = .45, p < .001$); efforts to preserve patient privacy ($r(61) = .47, p < .001$); translation of medical and research terminology into lay language ($r(56) = .55, p < .001$); the use of reframing to explain research ($r(51) = .52, p < .001$); fostering understanding of research concepts ($r(49) = .43, p = .002$); and attitudes toward answering patient questions ($r(54) = .67, p < .001$). The correlation between years of experience and fostering understanding of medical research was nearly significant, $r(52) = .27, p = .06$. However, correlations between years of experience and the measure of mirroring and adapting to patients' nonverbal communication was non-significant, $r(54) = -.05, p = n.s.$

Item	1	2	3
I frame unfamiliar or potentially scary concepts in terms that are more familiar or acceptable to patients	.84	-.04	-.02
I frequently use examples as a way to explain technical information about a study	.78	.30	.19
I often use metaphors and analogies to explain randomization or other study concepts	.76	-.29	-.24
I use analogies to explain potentially scary tests or concepts	.76	-.41	-.31
If it's a complex study, I often reframe information in medical terms that are more familiar to them	.71	-.32	.30
I often give specific examples of what will happen to a patient if they join a study	.69	.09	.37
I find that I often use analogies (that aren't part of the consent form) when explaining a study	.66	.14	-.21
Patients like to hear stories about other patient's experiences with research participation	.51	.51	-.10
I make sure that patients know that the consent form is not a contract	.42	.42	-.30
I often use predetermined and rehearsed stories to clarify difficult concepts	.44	.32	.60
I find it difficult to explain how randomization works in the context of the trial being offered	.31	-.57	.54

Table 4. Reframing medical information factor loadings for exploratory factor analysis with oblimin rotation.

Item	1	2
I always begin a discussion with a patient by explaining the purpose of our conversation	.51	-.24
Before getting a patient's signature on a consent form, I always check their understanding of the study information	.69	-.44
I ask patients to 'teach back' (or summarize for me) the key points of a study to me before they consent to being in a study	.68	-.26
I offer patients the option of delaying their decision about study participation	.59	.19
I explain to patients that the research study is being conducted to improve scientific knowledge about a particular disease, condition, or treatment	.75	-.15
I explain the general rationale for a randomized clinical trial (when appropriate)	.60	-.50
When offering patients the opportunity to participate in a research study, I explain the researchers' motivations for conducting the study	.70	-.38
When offering patients the opportunity to participate in a research study, I tell them that all trials have to receive approval from ethics committees	.75	-.08
When offering patients the opportunity to participate in a research study, I acknowledge the uncertainty of treatment benefits	.73	.16
I explain the concept of equipoise (trials are conducted only when there is collective uncertainty that the benefit of an experimental treatment is better than the current best practice standard treatment)	.62	.49
I explain the concept of beneficence (trials are conducted to determine whether there is a significant additional benefit from the experimental treatment)	.58	.60
I explain the concept of non-maleficence (there is evidence to suggest that being involved in a clinical trial will in no way worsen the patient's chances)	.68	.71

Table 5. Fostering understanding of medical research factor loadings for exploratory factor analysis with oblimin rotation.

	Mean	SD	Cronbach's alpha
Eye contact (3 items)	4.10	.55	.69
Maintaining patient privacy (4 items)	3.34	.72	.76
Translation of medical and technical information (7 items)	3.55	.60	.86
Reframing medical and technical information (7 items)	3.50	.71	.86
Fostering understanding of research (9 items)	4.29	.59	.86
Explaining specific research concepts (3 items)	3.96	1.13	.88
Nonverbal communication (reading, adapting, mirroring) (8 items)	3.12	.57	.90
Question answering (3 items)	3.25	.54	.83

Table 6. Means, standard deviations, and reliabilities of Clinical Trial Communication Inventory subscales.

	1	2	3	4	5	6	7
1. Eye contact	–						
2. Privacy	.53*** (70)	–					
3. Translation	.51*** (64)	.60*** (64)	–				
4. Reframing	.53*** (59)	.41** (59)	.70*** (58)	–			
5. Understanding	.11 (50)	.13 (57)	.23 (56)	.23 (54)	–		
6. Explaining	.19 (60)	.01 (60)	.14 (58)	.26 (55)	.46*** (56)	–	
7. Nonverbal	.59*** (61)	.56*** (61)	.56*** (59)	.41** (54)	.04 (52)	.13 (54)	–
8. Questions	.37** (62)	.41** (62)	.53*** (61)	.50*** (.59)	.36** (56)	.08 (58)	.17 (57)

*p = .05.

**p = .01.

***p < .001.

Table 7. Pearson correlations of Clinical Trial Communication Inventory subscales.

4. Discussion

This chapter presents the development and analysis of an instrument designed to evaluate the communication behaviors of professionals who recruit for clinical trials and research studies. Of the original 133 items, 44 items were retained in 8 subscales. These subscales include maintaining patient privacy; translation of medical and technical information; reframing medical and technical information; fostering understanding of research; explaining specific research concepts; question answering; nonverbal communication, including reading patients, adapting to patients' communication, their state of mind, and preferences, mirroring behaviors; and eye contact.

The results of supplemental analyses demonstrate that there are statistically significant relationships between all but one of the subscales of the instrument (including all of the verbal communication measures) and years of experience. This may indicate that as research professionals gain experience, they acquire knowledge about effective strategies to communicate about complex medical and scientific concepts. In fact, the fact that the measure of nonverbal communication (behaviors which are often described as something akin to “instinctual” or innate in the published studies of Morgan and colleagues) has a correlation of nearly zero may indicate that many individuals who are drawn to this type of research position may naturally be “people-people” who may nonetheless benefit from training programs with an emphasis on verbal communication techniques when recruiting and consenting potential research participants. Tentative validity testing of several items and subscales of the instrument described here was performed in early 2017. The results of this early pilot testing demonstrated that items contained in the Clinical Trial Communication Inventory can be used to assess the pre- to post-test impact of a clinical trial communication training (see Ref. [17] for full results of the evaluation).

While the CTCI is likely to prove useful to evaluate efforts in clinical trial communication training, it should be noted that with a relatively small sample, the validity of factor analytic strategies used to construct some of the initial scales may be limited, although the scales we created based on these results showed strong reliability. Future research should further develop this instrument by testing its robustness with a larger sample of research coordinators and validate it with other types of medical professionals who recruit for clinical trials, including physicians and study nurses. Additionally, it is vitally important for this instrument to be evaluated through convergent validity testing. The question remains whether the Clinical Trial Communication Inventory reflects real-world communication practice and indeed, whether these communication behaviors predict increased informed decision making or improved rates of clinical trial accrual. Convergent validity can be established through a variety of strategies, including checklists of exhibited communication behaviors during role plays and video recordings of actual recruitment and consent behaviors with patients. Predictive validity could be established by demonstrating that communication training results in changed scores on the CTCI from pre- to post-test, and more importantly, that scores post-training reflect improvements to informed consent with patients, which can be evaluated through patient “teach-backs” and an increased number of accurate responses to a set of study-related knowledge questions.

5. Conclusion

Improvement of low accrual to clinical trials and research studies is urgently needed, particularly for members of minority populations. Research has demonstrated that communication behaviors play an important role in the recruitment and consent processes. While communication behaviors can (and should) be developed through professional seminars and workshops, there are few available instruments to conduct evaluations of the outcomes of those trainings. In this chapter, we outline the development and testing of a measure of communication in clinical trial contexts: the Clinical Trial Communication Inventory. While additional

testing needs to be conducted to more thoroughly establish convergent and predictive validity with multiple professional groups, we believe that this instrument will help advance the development of clinical trial communication training programs.

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Appendix A: Subscales of the Clinical Trial Communication Inventory

Use of eye contact

I use eye contact to try to figure out whether a patient understands a study through eye contact.

I use eye contact to assess a patient's state of mind while I talk with them about a study.

I find that most patients do not want to make eye contact when discussing study participation.

Maintaining patient privacy

If the patient is comfortable discussing a study in an area where privacy cannot be secured, I will still consent the patient.

Most patients don't care about being consented in a private location.

It is not practical to always consent patients in a private location.

If a private location is unavailable, I talk in a quiet voice to enhance a sense of privacy when discussing a study.

Translation of medical and technical information

I 'translate' information about a study to help patients.

I find ways of using lay language.

I believe that members of some minority/ethnic populations have specific preferences for words or research-related terminology.

I try to avoid certain words or medical terms when talking with members of certain cultural groups.

I try to use language that I think would be received well by members of the cultural group to which they belong.

When going through a consent form with a patient, I often say something like, 'so this means...' followed by a lay explanation.

Based on what I know about the educational level of the patient, I adapt my explanation of a study.

Reframing medical and technical information

If it's a complex study, I often reframe information in medical terms that are more familiar to them.

I find that I often use analogies (that aren't part of the consent form) when explaining a study.

I frequently use examples as a way to explain technical information about a study.

I often give specific examples of what will happen to a patient if they join a study.

I frame unfamiliar or potentially scary concepts in terms that are more familiar or acceptable to patients.

I often use metaphors and analogies to explain randomization or other study concepts.

I use analogies to explain potentially scary tests or concepts.

Fostering understanding of research

I always begin a discussion with a patient by explaining the purpose of our conversation.

Before getting a patient's signature on a consent form, I always check their understanding of the study information.

I ask patients to 'teach back' (or summarize for me) the key points of a study to me before they consent to being in a study.

I offer patients the option of delaying their decision about study participation.

I explain to patients that the research study is being conducted to improve scientific knowledge about a particular disease, condition, or treatment.

I explain the general rationale for a randomized clinical trial (when appropriate).

When offering patients the opportunity to participate in a research study, I explain the researchers' motivations for conducting the study.

When offering patients the opportunity to participate in a research study, I tell them that all trials have to receive approval from ethics committees.

When offering patients the opportunity to participate in a research study, I acknowledge the uncertainty of treatment benefits.

Explaining specific research concepts

I explain the concept of equipoise (trials are conducted only when there is collective uncertainty that the benefit of an experimental treatment is better than the current best practice standard treatment).

I explain the concept of beneficence (trials are conducted to determine whether there is a significant additional benefit from the experimental treatment).

I explain the concept of non-maleficence (there is evidence to suggest that being involved in a clinical trial will in no way worsen the patient's chances).

Nonverbal communication (reading, adapting, mirroring)

I think it is more important to be warm and friendly with patients than to maintain a professional distance.

I slip into the same style and manner of speech as the person I am talking to about a study.

Whether a person talks loud and fast or softly and slowly, I adjust the way I speak about a study to how they talk.

I usually mirror a patient's body posture when I'm discussing a study with them.

When I am discussing a study participation, if a patient appears relaxed, I relax my body, too.

I often mimic a patient's mannerisms when I talk about a study.

Based on my first impressions of a patient, I adapt how I talk about a study.

I try to adjust my facial expressions to reflect the current situation they are in.

Question answering

I enjoy answering a patient's questions about a study.

I always invite patients to ask questions about a study.

I make sure to give a patient the names of who to contact if they have additional questions about the trial

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