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Collaborative Development of Clinical Trials Education Programs for African American Community-Based Organizations

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Abstract

This paper describes the use of a unique "Learning and Feedback" approach to tailor cancer clinical trials education programs for Community Bridges, a peer training intervention designed for African American communities in North Carolina. Generic community education modules were demonstrated with key community leaders who were designated as trainers. Quantitative and qualitative assessments were provided on understanding of content, comfort with material and cultural relevance. The generic materials were adapted into three revised modules, all featuring key messages about cancer clinical trials, discussion regarding distrust of medical research, common misconceptions about trials, patient protections, and a call to action to prompt increased inquiry about locally available trials. The revised modules were then used as part of a train-the-

Conflict of Interest Among the nine authors of this paper, one has a conflict of interest. The first author served as an independent contractor for ENACCT and owns a health and wellness service.

Ethical Standards The Community Bridges project described in this paper was approved by an appropriate ethics committee and was performed in accordance with the ethical standards as outlined in the 1964 Declaration of Helsinki and its later amendments.

trainer program with 12 African American community leaders. ENACCT's use of the Learning and Feedback process is an innovative method for culturally adapting clinical trials education.

Keywords

Clinical trials recruitment; Clinical trials as topic/utilization; Community-based participatory research; Consumer advocacy; Neoplasms/prevention & control; Patient education as topic; Patient participation; Research design

Introduction

Overall, the rate of adult participation in cancer clinical trials is less than 3% nationally, and participation is even lower in communities of color [1, 2]. African-Americans experience an unequal burden of cancer mortality and yet remain underrepresented in adult cancer clinical trials (CCTs). A number of barriers that negatively affect CCT participation have been cited in the literature [3]. These include barriers related to lack of knowledge and as well as public attitudes and beliefs about research [4–6] Several studies have suggested minorities may be more likely than Whites to have mistrust or distrust in research [7–9]. Yet some have suggested that distrust does not necessarily impact interest in learning about research participation or willingness to participate [10–13]. Despite willingness, however, minorities are less likely to be asked [10].

Increasing access to clinical trials is important but not sufficient. Reversing this trend requires increasing minority groups' awareness of clinical trials [8]. Numerous experts have suggested that improving general cancer clinical trial awareness, access, and acceptability as well as addressing distrust may potentially help overcome barriers to [3,8,14–17]. Key education messages in particular should be targeted to address unique interests and concerns African- Americans have regarding research participation. Further, community members should be directly engaged in collaborating on the development of message content in order to increase the impact of education activities and acceptance of clinical trials. Use of group targeted messaging has been identified in the literature as an important form of customization along the continuum of tailored health communications [18].

Community-based organizations, due to their strong local connections and regard as trusted sources of social and informational support, can play an important role in articulating community challenges regarding trial participation and identifying methods of intervention to address these concerns. Interventions designed to influence social norms through key opinion leaders can effectively prompt individuals' behavior changes in the community [19].

Community Bridges to Cancer Clinical Trials, an intervention led by Project Connect and the Carolina Community Network, was designed with the goal of raising community awareness and supporting informed decision-making about participation in cancer research. The Community Bridges to Cancer Clinical Trials, an intervention led by Project Connect and the Carolina Community Network, was designed with the goal of raising community awareness and supporting informed decision-making about participation in cancer research. The Community Bridges team collaborated with the Education Network to Advance Cancer

Clinical Trials (ENACCT) to adapt ENACCT's generic cancer clinical trials education modules as part of the Community Bridges project. In this paper, we describe the collaborative process among academic and community partners involved in customizing cancer clinical trials education for African- American communities in North Carolina.

Methods

In March 2009, 12 community trainers were recruited from among four community-based organizations serving African-American communities in North Carolina. Each organization selected for participation in the project had significant experience with community outreach in breast or prostate cancer education in the African-American community. Six organizations responded to a public call for community partners to develop and pilot cancer clinical trial materials. Applications elicited the organization's perceptions of minority participation in cancer research, cancer-related outreach activities and experiences, and organizational capacity to serve as community partners over the period of the initiative. Following an independent review of applications, four non-profit organizations were selected based on the aforementioned characteristics:

- Black Men's Health Initiative conducts prostate cancer outreach and education within barbershops and collaborated on the development of a summer health theater production on prostate cancer.
- Community Health Coalition, Inc. provides screenings and outreach to local churches using monthly health tip newsletters.
- Crossworks, Inc. conducts breast cancer lay health advisor training for community members and cosmetologists to encourage screening and breast exams.
- North Carolina Institute for Minority Economic Development provides prostate cancer ambassador training for lay health leaders and coordinates annual prostate cancer screening events and educational conferences.

A stepwise process of curriculum development was used to adapt and implement ENACCT's train-the-trainer workshop. Between March and May 2009, ENACCT conducted three 4-h Learning and Feedback sessions with Community Bridges project staff and community organization representatives. At each session, ENACCT demonstrated one of its education modules, previously shown as effective in the community setting [16]. Each was 1.5h and contained similar components: an introduction, didactic slide presentation, one follow-up small group exercise, a role-play activity, and closing featuring a call to action of talking to others about cancer clinical trials in the community. Each module included trial risks and benefits, patient protections, reasons for low rates of participation, and ways of accessing information about locally available trails. Grounded in Rogers' diffusion of innovations theory, the modules focused on providing community leaders with information about trials to encourage them and their peers to actively discuss cancer clinical trials with patients and others as a high quality treatment option [20]. The modules also drew upon Bandura's social cognitive theory, promoting individually focused activities in knowledge acquisition and self-efficacy to change behavior (i.e., trainers training peers) [21, 22]. Immediately following each demonstration, the featured module was discussed by all

session participants using a quantitative ranking questionnaire to identify areas of consensus on the most needed changes to the module (see Table 1). Qualitative feedback was also solicited regarding the module's cultural relevance to African-American communities assessing language, length, imagery, key messages, and the calls to action.

After each session, ENACCT staff used feedback to make revisions to text and visual content. Follow-up conference calls facilitated by Community Bridges and ENACCT staff occurred 2–3 weeks following each session to preview the revised module content among participating community representatives for final refinement (see Table 2).

Results

Through facilitated large group discussion, participants prioritized content features most in need of adaptation. The most significant aspect of cancer clinical trials messaging which community representatives identified included the following: 1) increased flexibility in delivery format and length of training, 2) acknowledgment of community members' concerns and questions about trial participation, 3) use of specific and personal examples to illustrate the connection between advances in cancer care and cancer clinical trials, and 4) development of brief, easy-to-remember call to action message. Table 3 details specific adaptations made for each main category of changes.

Increased Flexibility in Delivery Format and Length of Training

Community leaders expressed concerns regarding the duration of the training, the use of jargon to explain how trials work, and the need to foster trust with communities participating in workshops. Using these priority areas, ENACCT adapted the demonstrated modules into three revised formats, including "What Are Cancer Clinical Trials and What Do They Mean for My Community?," a revised 90-minute workshop including a presentation with slides "Why Our Community Needs to Know about Cancer Clinical Trials," a flexible "call and response" format, approximately 1 h in length, addressing myths and facts about clinical trials, and "Mr. Wilson" and Mrs. Woods," two versions of a 40-minute narrated role-play featuring the personal story of a cancer patient in the form of a "photonovel" discussing their treatment options, followed by guided discussion.

Acknowledgement of Community Members' Concerns and Questions about Trial Participation

The Call and Response module, patterned after a tradition found among many Black churches where congregants speak back to persons in the pulpit to acknowledge agreement, was formatted to initiate group discussion, allowing participants to brainstorm questions and reservations regarding clinical trials prior to delivery of the presentation. Based on participant feedback, trainers had the flexibility to focus on the sections of presentation that were most relevant to the group. Additionally, within the role-play formats, family members and patients were featured as characters expressing uncertainty and exploring myths surrounding trial participation. Providers featured in the role-play offered information about cancer clinical trials to the characters to address concerns while reinforcing the patient's autonomy in treatment decision-making. The trainers' guide for all formats prompted

trainers to disclose their role as community volunteers and indicate that training did not promote any particular trial or drug company.

Further changes to address community concerns included insertion of salient imagery featuring African- Americans to support the slide presentation and expanded discussion regarding the impact of limited minority participation in trials. Specifically, group discussion was incorporated into the standard workshop and call and response formats to allow time for participants to explore how low rates of participation among communities of color impact trial outcomes and the effectiveness of new treatments resulting from cancer research. The exercise allowed audience members to articulate the consequences of limited minority involvement in their own words and realize the need for taking action. Complex wording throughout the modules was substituted with simpler terms to describe concepts like randomization, standard of care, and informed consent. Clinical trials were highlighted consistently as a quality treatment option for cancer care. Costs and coverage concerns were addressed by including resources to address needs of patients who may be uninsured or underinsured.

Specific Examples Illustrate the Connection between Advances in Cancer Care and Cancer Clinical Trials

Community members indicated that exercises in the modules highlighting the benefits of clinical trials to society were helpful and should be expanded. In response, each revised format was designed to convey how clinical trials contribute to progress in patient care, with the standard workshop format specifically detailing ways in which treatment modalities for cancer and other health conditions have been improved as a result of medical research. This included a revised icebreaker exercise to share examples of medicines that resulted from past clinical trials. To further personalize examples, role-play was adopted as one of the revised module formats to convey the experiences of a male and female cancer patient as they considered cancer clinical trials as a treatment option. For other formats, inclusion of personal testimony from past clinical trial participants was encouraged.

Development of Brief and Easy-to-Remember Call to Action Messages

During the Learning and Feedback sessions, community leaders expressed uncertainty regarding the main call to action that the curriculum sought to communicate. Each module was revised to include core key messages about the local cancer burden and cancer clinical trials, African Americans' distrust of medical research, common misconceptions about trials, and patient protections. A set of revised call to action messages was then developed by the entire group in order to prompt increased inquiry about locally available trails as well as join a local research registry. All modules also included language prompting trainers to clearly state the call to action messages of the workshop at the beginning of the session. Messages were formatted into a succinct, easy-to-recall acronym "Why CARE about Cancer Clinical Trials?" and were prominently featured in curriculum materials (see Figure 1). The four key messages linked to the acronym included the following:

- Cancer clinical trials are on option in quality treatment.
- African –Americans should ask their doctor about cancer clinical trials.

- Rights are protected of everyone who participates in research.
- Everyone in North Carolina is affected by cancer.

Community Leader Training on Revised Modules

In August 2009, community leaders who participated in the Learning and Feedback sessions attended a 16-h train-the-trainer program facilitated by ENACCT to launch use of the revised modules. Trainers reviewed essential concepts regarding clinical trials including randomization, trial phases, and their purpose, as well as use of placebo. Participants became familiar with techniques for teaching adult learners, how to use the training evaluation instruments, and trainers practiced delivery of module content. At the end of each practice delivery, presenters received immediate feedback on the presentation style and the accuracy of their answers in response to question from the audience

Qualitative feedback on the Learning and Feedback process among community trainers, such as the comment from a trainer below, suggests the experience was instrumental in positively influencing attitudes regarding cancer research and their willingness to talk with peers about clinical trials.

[Community Bridges] approached programs that had extensive outreach in hard to reach communities and had an established track record of success and they chose those entities to introduce the clinical trials training and they listened. So although they came in with models of approaches, we spent a lot of time and a lot of hours, incorporating the input of those organizations that were selected to participate. There are a lot of people and a lot of institutions that don't do that and the end product was something that we thought would have a chance to work because we had buy-in through the process. We were engaged throughout the process and in the end, we were allowed to introduce it to the community in our own way that's already been established by our years of work and our outreach.

Discussion

Few examples exist in the literature regarding best practices to overcome barriers to awareness, opportunity, and acceptance of clinical trial participation [3]. While other interventions have included a focus on community-based cancer clinical trials education, the evidence in the literature is limited regarding effective approaches to cultural adaptation of cancer clinical trials education [17, 23–25]. ENACCT's use of Learning and Feedback sessions in the Community Bridges project is an innovative, collaborative method for culturally adapting cancer clinical trials education messaging, resulting in the development of multiple, flexible, interactive training formats and greater community ownership of training content. Specifically, ENACCT's use of this technique is unique in the extensive cocreation of key education messages with community leaders, its rigorous training in fundamental clinical trial concepts for trainers, and its expectation of significant practice among trainers prior to delivery in the community. This method of stakeholder engagement is a promising approach for adapting educational messaging for other diverse populations. Empowering community members with the knowledge and skills to advocate for greater access to cancer care choices is a significant step forward in changing awareness and social

acceptability of cancer research participation. It also improves individuals' ability to make more informed decisions about selecting a cancer clinical trial as a high quality treatment option. Further study is warranted to assess the relative effectiveness of this approach across different populations and identify the most salient call to action messages that work best for each group, recognizing that these messages may vary accordingly.

One important limitation of this approach to note is the time-intensive nature of the process, which requires commitment from community members to provide substantive input on recommended improvements and then complete several rounds of follow-up review. Institutions or organizations seeking to replicate this approach should therefore take this into account when considering a timeline for curriculum development and implementation.

Finally, efforts to enhance community awareness and engagement in clinical trials cannot effectively be done independently. Without corresponding changes occurring within the cancer care systems serving the community, the likelihood of success will be minimal. In community settings as well, interventions are needed to improve the quality of communication between patients and providers to ensure a two-way dialogue regarding the availability, acceptability, and appropriateness of cancer clinical trials as a quality treatment option.

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Figure 1.
Curriculum Logo

- o **Cancer clinical trials are an option in quality treatment**
- o **African Americans should ask their doctor about cancer clinical trials**
- o **Rights are protected of everyone who participates in research**
- o **Everyone in North Carolina is affected by cancer**

Table 1

Learning and Feedback Session Assessment Form

Yes; it should stay the same	Yes, but needs improvement	No, must change	COMMENTS (HOW)	
				1. The purpose of the project is clear and would help people in my community understand the context for this training
				2. The <i>icebreaker</i> would be meaningful for the community members to whom I would be presenting
				3. The <i>video clip discussion</i> would be meaningful for the community members to whom I would be presenting
Yes/No/Comments				a. <i>I would be comfortable presenting these video clips and running a discussion on them Y/N</i>
				4. The <u>content</u> presented is relevant to the community members to whom I would be presenting
				5. The content allows participants to relate the content to their own experiences
				6. The content adequately addresses the concerns of my community when it comes to cancer clinical trials.
				7. The key messages of the training are clear
				8. The key messages of the training are easy to remember
				9. The “call to action” of the training is clear
				10. The “call to action” of the training would be easy for people in my community to do
				11. The language used would be easy for the community members to understand
				12. The language used is meaningful to the community members to whom I would be presenting
				13. The images used are relevant to the community members to whom I would be presenting
				14. The <i>group activity (small group)</i> helps reinforce the content of the training and it is realistic for people in my community to take part in.
Yes/No/Comments				a. <i>I would be comfortable presenting this small group activity Y/N</i>
				15. The group activity (role play) would be helpful for people in my community to practice and it’s realistic that people would participate
Yes/No/Comments				a. <i>I would be comfortable running this role-play Y/N</i>
				16. The delivery of the material allows for active discussion between trainer and participants
				17. The delivery of the material keeps participants engaged by using different techniques to illustrate key points (<i>combining activities of listening, watching, reading, and speaking</i>)
				18. The pace of each segment (<i>Intro, icebreaker, video clips, slide presentation, group activity, role play, closing</i>) is appropriate.
19. As a whole, how would people in your community respond to this workshop?				
20. Other suggestions for improvement				

Table 2

Timeline

Date	Community Bridges Activity
March 2, 2009	Kickoff Meeting with Community Leaders
March 26, 2009	Learning and Feedback Session # 1
April 8, 2009	Review and Editing Meeting with Community Leaders
April 21, 2009	Learning and Feedback Session # 2
May 11, 2009	Learning and Feedback Session # 3
May 21, 2009	Review and Editing Meeting with Community Leaders
June 2, 2009	Review and Editing Meeting with Community Leaders
June 17, 2009	Review and Editing Meeting with Community Leaders
July 15, 2009	Review and Editing Meeting with Community Leaders
August 12, 2009	Review and Editing Meeting with Community Leaders
August 26–27, 2009	Training of Training Program Featuring Revised Modules

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Table 3

Intervention Changes

Tailoring in Response to Learning and Feedback Sessions	Module 1	Module 2	Module 3
Increased flexibility in delivery format and length of training content	<ul style="list-style-type: none"> Revised to 90 minute Workshop format “What Are Cancer Clinical Trials and What Do They Mean for My Community?” 	<ul style="list-style-type: none"> Revised to two role-play Photo-novels “Ms. Woods” (breast cancer patient) and “Mr. Wilson” (prostate cancer patient) 	<ul style="list-style-type: none"> Revised to “Call and Response” session “Why Our Community Needs to Know About Cancer Clinical Trials”, a participant-guided question and answer format
Acknowledgement of community members’ potential concerns about trial participation	<ul style="list-style-type: none"> Included trainer disclaimer indicating trainers are not promoting any particular trial for enrollment Highlighted clinical trials as a quality treatment option for care Addressed guinea pig fears, standard vs. experimental care and myths regarding participation (e.g. clinical trials as a “last resort”) Explored role of low rates of participation among communities of color on trial outcomes and the effectiveness of new treatments resulting from cancer research Substituted simpler terms to describe randomization, standard of care, informed consent, etc. Added images of African Americans to represent “the faces of cancer clinical trials” Included optional video clips featuring African American doctors and trial participants to supplement slide presentation Added resources for identifying locally available trials Highlighted clinical trials as a quality treatment option for care Included resources included to address needs of patients who may be uninsured or underinsured 		
Specific and personal examples to make the connection of advances in cancer care to cancer clinical trials	<ul style="list-style-type: none"> Revised icebreaker to share examples of medicines that resulted from past clinical trials Encouraged discussion of personal experiences with cancer diagnosis and treatment decision-making (through testimony of past trial participants or as illustrated in role play) 		
Development of brief, easy to remember call to action messages	<ul style="list-style-type: none"> Added language for trainers to clearly state the intention and call to action messages of the workshop at the beginning of the session Created “Why CARE” tagline featuring 4 key cancer clinical trials awareness and action messages 		