Published in final edited form as:

J Cancer Educ. 2017 December ; 32(4): 721–727. doi:10.1007/s13187-016-1051-0.

Cultural competency training to increase minority enrollment into radiation therapy clinical trials - an NRG Oncology RTOG study

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Abstract

Background/Aims—Despite initiatives to increase the enrollment of racial and ethnic minorities into cancer clinical trials in the National Cancer Institute National Cancer Clinical Trials Network (NCCTN), participation by Latino and African American populations remains low. The primary aims of this pilot study are 1) To develop a Cultural Competency and Recruitment Training Program (CCRTP) for physician investigators and clinical research associates (CRAs); 2) To determine if the CCRTP increases cultural competency scores among physician investigators and CRAs; and 3) To determine the impact of the CCRTP on minority patient recruitment into NRG Oncology Radiation Therapy Oncology Group (RTOG) clinical trials.

Methods—67 CRAs and physicians participated in an in- person or online four hour CCRTP trainin.

Results—Five knowledge and attitude items showed significant improvements from pre to post training. A comparison between enrolling sites who did and did not participate in the CCRTP demonstrated a pre to one year post incremental increase in minority accrual to clinical trials of 1.2% among participating sites.

Conclusions—While not statistically significant, this increase translated into an additional 300 minority patients accrued to NCCTN clinical trials in the year following the training from those sites who participated in the training.

Keywords

Clinical trials; minority enrollment; cultural competency; radiation therapy

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Declaration of Conflicting Interests

Dr. Pugh and Ms. Boparai report grants from Pennsylvania Department of Health (CURE grant), during the conduct of the study. Dr. Yeager reports support for travel expenses for NRG Oncology meetings from NRG Oncology, outside the submitted work.

Introduction

An adequate representation of minority groups in clinical trials is necessary for the generalizability and applicability of findings to diverse populations. Despite national initiatives to increase the enrollment of racial and ethnic minorities into cancer clinical trials, participation by Latino and African American populations remain low relative to both their US population density and the disease burden they carry.

Clinical trials provide evidence that is formulated into recommendations for practice guidelines; however, without improvements in minority recruitment, patients enrolled in trials may not be similar to the general population treated in routine practice. There is evidence that clinical trials have a positive effect on patient outcomes and therefore, for reasons of social justice, all cancer patients should have access to the high-quality care, surveillance, and availability of the latest treatments put forth in clinical trials [1].

Considerable variation in cancer incidence rates occurs between race and ethnicity groups. African American men have the highest overall age-adjusted incidence rate (606.2) for cancer compared to whites (540.8) and Asian/Pacific Islanders, who has the lowest incidence of cancer (322.3) [2]. The largest disparity exist for stomach and prostate cancers where African American men carry the burden for these cancers. While clinical trials accrual for all adult cancer patients is small, at only about 5 to 8%, Caucasian patients make up the majority of trial participants at approximately 86% [3]. Latinos and African Americans constitute a much lower percentage of participants at only about 3.1% and 9.2%, respectively [3]. Lower enrollment rates persist after adjusting for age, sex, and cancer type, where African Americans are less likely to enroll in a clinical trial. Despite low accrual rates, research has shown that with equal access minorities generally appear to have similar clinical trials participation rates compared to Whites [4]. For example, while African American men have significantly lower enrollment rates for breast, lung, and colorectal clinical trials, representation of African Americans and whites in prostate cancer clinical trials have been shown to be comparable, thus demonstrating that equitable representation is possible [5]. While research on barriers to recruitment of underrepresented groups to cancer clinic trials is complex and multidimensional, evidence points to patient provider communication and the lack of culturally relevant education about clinic trials as areas in need of improvement [6]. Physician researchers and other research personnel play a major role in whether a person will enroll in a clinical trial. Cultural attitudes influence the ability to communicate effectively across racial/ethnic, cultural, and socioeconomic differences. With proper training and a multifaceted tool kit of tested strategies, it has been suggested that healthcare providers and research coordinators can help improve recruitment of minority patients into clinical trials [7]. Yet, there have been few studies that have empirically tested interventions to improve cultural competency among researchers and staff and link improvements to actual changes in minority clinical trial enrollment. Thus, the purpose of this study was to develop and empirically test methods to improve Latino and African American recruitment to clinical trials conducted through the National Cancer Instituted sponsored Radiation Therapy Oncology Group (RTOG; now NRG Oncology). NRG Oncology is a recent merger of the cooperative groups- RTOG, GOG (Gynecologic Oncology Group), and NSABP (National Surgical Adjuvant Breast and Bowel Project). A

Cultural Competency and Recruitment Training Program (CCRTP) was designed for physician investigators and clinical research associates (CRAs) participating in radiation therapy clinical trials in RTOG. The study also examined the extent the CCRTP had an impact on minority accrual into RTOG clinical trials among the sites which did and did not participate in the training.

Methods

Study cohort

The study received Institutional Review Board approval and the study population consisted of new and experienced clinical research associates (including clinical research nurses and clinical research coordinators) and physician investigators who were members of the approximately 750 full, affiliate, and satellite RTOG institutions.

Study Design

The CCRTP was advertised via the RTOG email list serve broadcast prior to a semi-annual RTOG meeting. The four hour in-person training program took place at the June 2011 RTOG semi-annual meeting in Philadelphia, PA, and was video-taped and posted on the RTOG website. Clinical research associates and physician investigators who attended the in-person CCRTP were informed of the study prior to the start of the program by the program leader. Participants were informed that filling out the requested demographic or pre/post-test questionnaire (either in person or via the web based survey) would indicate their consent to participate in the study.

A quasi experimental single group pretest posttest design was utilized for the survey portion of this study. Study participants were asked by the program leader to fill out a baseline Culture Competency Assessment (CCA) prior to the commencement of training and again at three months post training. The CCA was filled out on paper for those attending the in-person training and via a web-based survey system for video-assisted training and post training evaluations. In addition to the CCA, participants were asked to fill out demographic information and information on prior cultural competency training. Email reminders were sent to the participants at the three month post training assessment time point with a link to the web based survey.

Development of the Cultural Competency Recruitment Training Program

The development of the CCRTP drew on the work of Leininger [8] and utilized the Cultural Competency Model that suggests the importance of an interconnection between (a) cultural diversity, (b) cultural awareness, (c) cultural sensitivity, and (d) cultural competence behaviors among health care providers to promote culturally congruent patient care [9]. Guided by this model, a training program was developed that focused on the barriers, myths, beliefs, and norms within the Latino and African American culture that may impede clinical trial enrollment. Additionally, three to four RTOG clinical trials focusing on disease sites with high incidence in Latino and/or African American populations were chosen in order to develop study-specific recruitment and education materials.

The Cultural Competency Assessment (CCA) Tool

The CCA is a 26-item instrument designed to measure cultural diversity experience, awareness and sensitivity, and competence behaviors [9]. The cultural awareness (knowledge) and sensitivity (attitude) (CAS) subscale is based on a five point, Likert-like response set ranging from strongly agree to strongly disagree and scaled from one to seven, with seven indicating the answer demonstrating the highest cultural awareness or sensitivity and one indicating the answer demonstrating the least cultural awareness or sensitivity. If a respondent indicates “no opinion,” the item is not included. The subscale for cultural competence behavior (CCB) has response categories of “always, very often, somewhat often, often, sometimes, few times, and never”, which are scaled from one to seven. Items with a response of “not sure” are not scored. The items are summed for each subscale score; higher scores indicate higher levels of knowledge and more positive attitudes, and greater self-reported frequency of competence behaviors [9]. Psychometric properties have been examined among both an interdisciplinary group of hospice staff and an interdisciplinary healthcare providers in Canada and the U.S. Internal consistency reliability for the combined subscales of the CCA has ranged from .80 to .89, with a CAS and CCB subscale reliability of .76 and .93 respectively [9]. Construct, content, face validity and test-retest reliability have also been established [9]. For this study, the CCA was modified (with permission; S. Schim, personal communication, 20 March 2011) for use by clinical research associates and physician investigators as it relates to their interactions with Latino and African American cancer patients considering radiation therapy clinical trials. Instead of referring to clinical practice in general, the tool was adapted to apply specifically to the research setting. The revised tool was evaluated for face and content validity by five subject matter experts including two nurses, one physician and two clinical research associates.

Minority Accrual

Pre- and post-training minority accrual rates encompassed accrual to any RTOG study and any RTOG-endorsed study. Accrual for the year prior to the cultural competency training was used to determine pre-training accrual rates and accrual for the year post cultural competency training was used for the post-training accrual rates. Minorities in this context consisted of Hispanic/Latino, Black/African American and American Indian/Alaskan Native.

Statistical Analysis

Participant demographic information was analyzed using standard descriptive statistics. Pre- and post-training competency evaluation was assessed for significant changes in CCA item responses using the 2-sided Wilcoxon-Mann-Whitney test with an overall significance level of 0.05. A Wilcoxon Signed Rank test was performed to evaluate differences from pre to post evaluation CCA scores. Due to the large number of potential responses (five to eight depending on the item) and the moderate sample size, the analysis was performed after collapsing the survey responses into three or four responses per item. Table 1 depicts how survey items were collapsed.

Unadjusted (for number of open trials overall or by site) accrual rates were analyzed using standard descriptive statistics. To ensure that relative increase in minority enrollment was not

masked by overall declines in clinical trial enrollment, enrollment as a percentage of total RTOG enrollments were analyzed. Comparisons between minority accrual rates for pre- and post-training were performed via paired t-tests between sites who participated in training and those who did not participate in training. Sites with no total accrual were excluded from the analysis. Paired t-tests were used to compare minority accrual rates pre- and post-training with the subset of sites who participated in training and the subset that did not.

Pearson's correlation coefficient was used to determine correlations between baseline cultural competency scores and pre-training minority accrual, as well as post training cultural competency scores and post training minority accrual. Since total accrual may fluctuate, thus impacting minority accrual, the proportion of minorities accrued was used in the correlations.

Results

Despite a low response rate, the study enrolled 67 CRAs and physicians who participated in the in-person training and completed the baseline survey. Forty-one CRAs and physicians completed both the baseline and three month follow up surveys, while 25 completed the baseline survey only and one completed only the follow up survey. The median age of participants was 42 years with the majority being female (92.3%) and white (83.3%) as seen in Table 2. The majority of participants had a Bachelor's degree only (45.5%) or a graduate or professional degree (37.9%). Most of the CRA participants were research nurses (50.0%) or non-nurse research associates (43.9%) with a median of six years of experience. Physician investigators accounted for 3% of participants. Participants estimated that their patient population consisted of a median of 5% Hispanics/ Latinos and a median of 20% Blacks/African Americans.

Pre- and Post- Training Competency Evaluation

At baseline, 67.7% of participants had prior diversity training with the majority of training being from an employer sponsored program (59.1%). At the three month follow-up, 14.3% of participants had additional employer sponsored training since the CCRT program. Five items (considering culture for clinical trials participation ($p=.02$), seeking information on cultural needs ($p=.02$), access to resources on different cultures ($p=.004$), removing obstacles for clinical trials participation ($p=.007$), and assessing patient language preferences ($p=.01$)) demonstrated significant improvements from pre to post training.

Pre- and Post-Training Minority Accrual Rates

Pre- and post-training minority accrual broken down into those sites with training participants and those without is found in Table 3. Overall, there was a decrease in total accrual after the training for all groups. Sites with training participants did see a 1.5% increase (vs 0.7% increase in sites which did not participate) in the proportion of minorities accrued after the training, however these numbers did not reach statistical significance between pre training and one year post training nor between those sites which were and were not trained.

Table 4 provides the Pearson correlation coefficients and their corresponding p-values looking at the association between collapsed survey items and percent minority accrual. Three pre-training items (“if I know about a person’s culture, I don’t need to assess their personal preferences related to clinical trial participation; a person may identify with more than one cultural group; people from different cultures may define the concept of ‘research’ in different ways”) were found to be significantly correlated with pre-training percent minority accrual. No post-training survey items were found to be significantly correlated with post-training percent minority accrual.

Discussion

Much work has been done to train healthcare providers, including nurses and physicians, to give culturally competent care at the bedside. The effect of cultural competence training on clinical practice has been examined [10] but few have looked to see how such training can change recruitment activities and accrual to clinical trials [11]. This study is one of the first to design and empirically pilot test methods to improve CRA and physician culturally competent knowledge and attitudes and to assess the associations among those improvements and minority enrollment to radiation therapy clinical trials.

Five items showed significant improvement in knowledge and attitudes from pre to post training. Item 25, “I consider culture when I evaluate a patient for clinical trial participation,” response of often/always increased over 20% from about 49% to 71% from pre to post training. Item 26, “I seek information on cultural needs when I identify new patients that may be eligible for clinical trial participation,” response of often/always increased over 17% from 46.3% to 64.1% from pre to post training. Item 27, “I have access to a variety of resources that help me learn about people from different cultures,” response of often/always increased over 12% from 52.5% to 65% from pre to post training. Item 32, “I remove obstacles for people of different cultures when I identify barriers to clinical trial participation,” response of often/always increased over 15% from 61% to 76.4% from pre to post training. And item 36, “I assess patient language preferences for communication about clinical trials,” response of often/always increased over 14% from 75.6% to 89.8% from pre to post training.

Interestingly, none of these five items were correlated with minority recruitment pre- or post-training. The three items that correlated with minority recruitment were Item 20, “If I know about a person’s culture, I don’t need to assess their personal preferences related to clinical trial participation” which had negative correlation suggesting that agreement with this item is associated with lower minority accrual. Items 21, “A person may identify with more than one cultural group,” and 23, “People from different cultures may define the concept of ‘research’ in different ways” each had positive correlations suggesting that agreement with either item was associated with higher minority accrual.

Why the items that improved statistically were not the items that correlated with minority accrual needs to be addressed in future research. It may be a limitation of sample size in this pilot or it is possible that that there is synergy or overlap among the knowledge and attitude items.

As a percentage of total accrual one year prior to training, those who participated accrued 12.9% minorities compared to 12.3% for those sites who did not participate, leading us to conclude the study was not significantly biased in favor of only those institutions that accrued minorities well to begin with. Sites with training participants reported a 1.5% increase in the proportion of minorities accrued one year after the training compared to the year prior to training, versus a 0.3% increase in the sites which did not participate. While the difference was not statistically significant, this pilot study was not powered to assess differences in this outcome, and an incremental 1.2% increase in minority accrual to clinical trials after a one-time training is a finding of substantial importance. This alone translated into an additional 300 minority patients accrued to clinical trials in one year in the NCTN. However, the CCRTTP demonstrated only an incremental improvement in accrual. It was beyond the scope of this study to simultaneously address all components of the multi-factorial barriers to minority accrual such as insurance, travel burden, or available trials that do not exclude minorities with common pre-existing conditions. Future larger trials would benefit from testing multiple strategies in addition to CCRTTP training, as it was never anticipated that changes in attitudes and knowledge alone would be enough to reach the eventual goal of accruing minorities in proportion to their representation in the US population and their burden of cancer. Even with improved knowledge and attitudes, the best intentions of providers do not easily help them operationalize what they learn through the CCRTTP alone. Therefore additional resources are required. Potential *actionable recruitment plans and readily available tool kits* of resources should be companion materials for consideration in future research of the CCTRP.

Although further evaluation is needed, this study is a sound first step in the development of a theory based cultural competence program designed specifically for researchers and research staff. Implementation of this program as an in-person training program appears feasible for physician investigators and clinical research associates. However, as the program was voluntary, there was low participation relative to the entire RTOG membership, and in particular there was extremely low physician participation. As with most health organization led trainings, cultural competency would likely need to be mandatory for uptake by all, specifically including the physician investigators.

Limitations

Although findings of the study provide important information, due to the low participation rate from physician investigators, this study revealed very little about the impact on minority accrual from physician investigators. For the current study, only 64 percent of the participants that completed the baseline assessment also completed the follow up and this could have introduced some response bias. In addition, 14.3% of participants received additional training between the time of the baseline and follow up which could have affected the findings. Lastly, additional evaluation should include a more rigorous design for example to a randomized trial of CCPT vs a wait list control group and increasing the sample size. Future research can develop and test an online version of the CCRTTP broken up into time manageable modules to improve training and the evaluation of cultural competency trials on researcher and patient outcomes.

Conclusion

The RTOG NRG Oncology Cultural Competency and Recruitment Training Program for physician investigators and clinical research associates is the first to be developed based on sound theoretical underpinnings. The CCRTP demonstrated improvements in some key areas of provider knowledge and attitudes. The results of this study are also the first to suggest the importance of cultural competence training for researchers as one mechanism to improve minority enrollment in clinical trials.

Acknowledgments

Funding: This project was supported by RTOG grants U10 CA21661, CCOP grant U10 CA37422, UG1CA189867 and U10CA180868 from the National Cancer Institute (NCI). This project is funded, in part, under a grant with the Pennsylvania Department of Health. The Department specifically disclaims responsibility for any analyses, interpretations or conclusions.

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Table 1

Cultural Competency Assessment (CCA) Item Responses and Collapsed Items Used in Current Study Analysis

Original Item Response Options which Participants Completed	Collapsed Responses for Analysis
Very competent	Competent
Somewhat competent	
Neither competent nor incompetent	Neither competent nor incompetent
Somewhat incompetent	Incompetent
Very incompetent	
Very comfortable	Comfortable
Somewhat comfortable	
Neither comfortable nor uncomfortable	Neither comfortable nor uncomfortable
Somewhat uncomfortable	Uncomfortable
Very uncomfortable	
Strongly agree	Agree
Agree	
Somewhat agree	
Neutral	Neutral
Somewhat disagree	Disagree
Disagree	
Strongly disagree	
No opinion	No opinion
Always	Always
Very often	
Somewhat often	
Often	Often
Sometimes	Never
Few times	
Never	
Not sure/no response	Not sure/no response

Table 2**Baseline Characteristics All Participants**

Age (years)	(n=65)
Median	42
Min - Max	23 – 64
Gender	(n=65)
Female	60 (92.3%)
Male	5 (7.7%)
Race	(n=66)
Hispanic/Latino	1 (1.5%)
White	55 (83.3%)
Black	6 (9.1%)
Other	4 (6.0%)
Education	(n=66)
Associate degree	7 (10.6%)
Bachelor's degree	30 (45.5%)
Graduate or professional degree	25 (37.9%)
High school or above	4 (6.0%)
Current Role	(n=66)
Clinical Research Associate	29 (43.9%)
Clinical Research Nurse	33 (50.0%)
Other (Patient advocate or community health educator)	2 (3.0%)
Physician Investigator	2 (3.0%)
Years of Experience	(n=62)
Median	6
Min - Max	0.5 – 30
Percent Hispanic/Latino	(n=61)
Median	5
Min - Max	0 – 50
Percent Black/African America	(n=61)
Median	20
Min - Max	0 – 90

Table 3

Pre and Post Cultural Competency and Recruitment Training Program Minority Accrual among Sites that Did and Did Not Participate in the Program

	Pre-Training	Post-Training	P-value [†]
Institutions with RAs who participated in the training	(n=46)	(n=46)	
Mean percent minority accrual	12.9%	14.4%	0.64
Mean total accrual (std) 95% Confidence Interval	12.5 (14.6) (8.1, 16.8)	11.2 (11.7) (7.7, 14.6)	
Mean total minority accrual (std) 95% Confidence Interval	1.9 (2.7) (1.1, 2.7)	1.7 (2.2) (1.0, 2.3)	
Institutions with RAs who did not participate in the training	(n=401)	(n=401)	
Mean percent minority accrual	12.3%	12.6%	0.88
Mean total accrual 95% Confidence Interval	5.4 (8.4) (4.5, 6.2)	4.6 (6.8) (3.9, 5.3)	
Mean total minority accrual 95% Confidence Interval	0.9 (2.3) (0.6, 1.1)	0.8 (2.0) (0.6, 1.0)	

Minorities included: black/African American, Hispanic/Latino and American Indian/Alaskan Native

[†] Paired T-test

Table 4

Significant Correlations Between Collapsed Survey Item Responses and Percent Minority Accrual

	Pre-Training	Post-Training
20) If I know about a person's culture, I don't need to assess their personal preferences related to clinical trial participation.	(n=41)	(n=41)
Pearson Correlation Coefficient	−0.41 *	N/A
P-value	0.008	N/A
21) A person may identify with more than one cultural group.	(n=41)	(n=41)
Pearson Correlation Coefficient	0.41 *	N/A
P-value	0.008	N/A
23) People from different cultures may define the concept of "research" in different ways.	(n=41)	(n=41)
Pearson Correlation Coefficient	0.41 *	N/A
P-value	0.008	N/A

* These items have similar correlation coefficients and p-values because the distribution of the responses for each item are similar.