

Cancer Clinical Trials in Hawai'i: Who's Being Represented

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Abstract

Background: Representation of diverse ethnic/racial groups is critically important in the development of cancer prevention and treatment strategies. However, representation of diverse ethnic/racial groups has yet to be fully realized, especially among historically disadvantaged minority groups. Ethnic minority groups account for about 75% of Hawai'i's population; approximately 55% of the state's population self-identify as Asian (with the most predominant ethnic/racial groups being Japanese, Filipino, Chinese, and Korean) and approximately 24% as Native Hawaiian/Pacific Islander. Such diversity provided researchers a unique opportunity to characterize the demographic profile of cancer prevention and treatment trials conducted in Hawai'i.

Methods: In the current study, the gender and ethnic/racial distribution of four national cancer prevention trials and 178 treatment trials conducted in Hawai'i from 1992 to 2004 were characterized.

Results: Native Hawaiian men were significantly less likely to participate in both cancer prevention and treatment trials than Native Hawaiian women. In addition, Native Hawaiian men and women had the lowest proportion of participation in cancer clinical trials in comparison to White and Asian American men and women.

Conclusions: Our findings identify gender and ethnic/racial differences in the participation of cancer clinical trial participants in the state of Hawai'i. This serves as an important indicator for the need of future research to specifically investigate the relationship of culture and other factors on participation. Such research may inform promotional strategies that increase trial participation, with the hopeful prospect of decreasing cancer incidence and increasing quality of life for those diagnosed with cancer.

Keywords: Clinical trials; Disparities; Cancer; Cancer prevention trials

Introduction

Minority populations, which can be defined as those who experience disadvantage in resource access and/or experience persistent social marginalization [1] tend to be burdened by disproportionately high cancer incidence and mortality rates. The creation of the Minority Based Clinical Oncology Program (MBCCOP) was designed to enhance participation of minorities in clinical trials for cancer [2], as well as to accrue samples representative of persons from diverse ethnic backgrounds. Identification of accrual differences by ethnicity and gender may inform the development of more effective and culturally appropriate recruitment strategies for those groups most under representative.

Historically, clinical trial participants have been predominately white males [2,3]. Despite the mandate of the 1993 National Institutes of Health Revitalization Act that minority groups must be included as subjects in all federally funded clinical research, ethnic minorities consistently are underrepresented in cancer clinical trials [3-6].

Importantly, minority participation in these trials is disproportionate to the overall burden of cancer experienced by these groups [7,8]. In Hawai'i, Native Hawaiians have experienced the lowest rates of participation in clinical trials [9]. Improved representation in clinical trial research across ethnic/racial groups may lead to the development of prevention efforts and therapies that are more beneficial for all [10,11].

Cancer-related disparities exist among Hawai'i's multiethnic populations. Overall cancer mortality rates are highest among Native Hawaiians despite this group's relatively low cancer incidence rates compared to other ethnic groups in the state [12]. Native Hawaiian women are diagnosed at later stages of breast cancer than other ethnic/racial groups, and in 2010 their mortality rates were 52% above the state average [12]. In Hawai'i, Filipino and Native Hawaiian men experience the highest and second highest ratio of prostate cancer incidence to mortality (IMR), respectively [11,12]. In comparison to men of non-Hawaiian ethnicities, Native Hawaiian men present at diagnosis with the highest prevalence of advanced prostate cancer [12].

The University of Hawai'i (UH) MBCCOP has been in existence since 1993. It has participated in four large cancer prevention trials: two breast cancer trials, the Breast Cancer Prevention Trial (BCPT)

and Study of Tamoxifen and Raloxifene (STAR) and two prostate cancer studies, the Prostate Cancer Prevention Trial (PCPT), and the Selenium and Vitamin E Cancer prevention Trial (SELECT) [13-17]. The goal of the BCPT trial was to determine whether 20 mg of daily tamoxifen would lead to the prevention of breast cancer in high-risk women 14. Recruitment for the BCPT was conducted from June 1992 through May 1994 [14]. A total of 11,064 women ages 35-59 with a high-risk of breast cancer were recruited 14. The nationwide distribution by race/ethnicity of the BCPT's 11,064 participants was 95.5% Whites, 1.0% Hispanic, 1.65% African American, 0.65% Asian American, and 0.78% other [14]. The PCPT trial's overall goal was to determine if finasteride reduced the risk of prostate cancer [15]. 18,882 men ages 55 and older were recruited from January 1994 through May 1997 [15]. The nationwide distribution by race/ethnicity of this trial was 92.1% Whites, 3.8% African American, 2.6% Hispanic, and 1.5% other [15]. The STAR trial compared the effect of raloxifene and tamoxifen in reducing the risk of breast cancer in postmenopausal women [16]. The study recruited 19,747 women from July 1999 through November 2004, who were in general good health, postmenopausal (minimum age of 35), and at high risk for breast cancer based on the Gail risk model [16]. The nationwide distribution by race/ethnicity of the STAR's 19,747 participants was 93.4% White, 2.5% African American, 2.0% Hispanic/Latino, and 2.1% other minorities [16]. The goal of the SELECT trial was to determine whether selenium, vitamin E, or both could prevent prostate cancer and other diseases with little or no toxicity in men who were relatively healthy. Nationally, 35,533 men including African-American men 50 years and older, 55 years or older for all other men, and with no prior prostate cancer diagnosis were recruited to the study [17]. The nationwide distribution by race/ethnicity for this trial consisted of 35,533 participants, 77.6% Whites, 12.1% African American, 5.4% Hispanic, and 2.0% other [17].

The UH MBCCOP has conducted multiple treatment trials as well, with 83 treatment trials conducted during the same time period as the span of all four prevention trials (1992-2004). Varying recruitment strategies were employed in these studies, such as direct physician referral, print and radio media, health fairs and targeted direct mailing of a physician-signed recruitment letter. In order to understand 'who' participates in clinical trials within the State of Hawai'i, we sought to: (a) identify the distribution of ethnic/racial groups participating in clinical cancer prevention and treatment prevention trials and (b) assess if there were significant gender differences.

Methods

Data extraction

As part of the UH MBCCOP, demographic data (age, gender, and ethnicity) was collected on individuals recruited as a part of BCPT, PCPT, STAR, and SELECT studies. We abstracted demographic data, including type of cancer, way in which the participant was referred, and year of recruitment and participation, for the four cancer prevention trials described above as well as the cancer treatment trials conducted in Hawai'i from 1992 through 2004. Chi-square tests were conducted to compare gender and ethnic/racial distributions across cancer prevention and treatment trials. The current study received approval from the Institutional Review Board (IRB) of the University of Hawai'i.

Results

Cancer prevention trials

For the BCPT and STAR breast cancer prevention trials conducted in Hawai'i from 1992 through 2004 (Table 1), Native Hawaiians participated at the lowest rates (9% in the BCPT trial and 11% in the STAR trial), followed by Whites (38% and 27%, respectively), with Asian Americans (53% in the BCPT trial; Japanese 43%, Chinese 7%, Filipino 4%, and Korean 2% and 60% in the STAR trial; Japanese 47%, Chinese 7%, Filipino 6%, and Korean 3%), representing the largest ethnic/racial group. For the PCPT and SELECT prostate cancer prevention trials in Hawai'i (Table 1), Native Hawaiians participated at lower rates than other ethnic groups (6.9% in the PCPT trial and 4.3% in the SELECT trial). Asian Americans were the largest racial/ethnic group for the PCPT trial (44.4%) while Whites were the largest group for the SELECT trial (53.3%). In comparing the ethnic/racial distribution by gender across the four prevention trials (Table 2), an overall significant difference was observed ($p < 1.0 \times 10^{-4}$). Notably, analysis of participation in prevention trials indicated a significant gender difference between Native Hawaiian and White participants ($p = 0.005$).

	BCPT (%) (n=113)	STAR (%) (n=161)	PCPT (%) (n=116)	SELECT (%) (n=98)
Native Hawaiian	8.8	11.2	6.9	4.3
Asian American	53.1	60.2	43.1	39.1
White	38.1	27.3	48.3	53.3
Other	--	1.2	1.7	3.3

Table 1: Ethnic/Racial-specific participation proportions in HI cancer prevention trials.

	Females (n=272)	Males (n=213)
Native Hawaiian	10.2%	5.5%
Asian American	57.3%	41.3%
White	31.8%	50.5%
Other	0.7%	2.4%
*P=1.0 x 10 ⁻⁴		

Table 2: Ethnic/Racial-specific participation proportions in HI cancer prevention trials by sex*.

Cancer Treatment Trials

From 1992 through 2004, there were a total of 178 cancer treatment trials conducted at the University of Hawai'i Cancer Center. Of these trials, females participated in 108 of the trials and males participated in 70 trials. During this time period, a total of 870 women participated in treatment trials (Table 3) with Native Hawaiians participating at the lowest rates (13.3%), followed by Whites (22.3%). As consistent with the other prevention trials and the demographics in Hawai'i, Asian Americans represented the largest racial/ethnic group (62.9%). Of those participating, 65% of the sample participated in breast cancer trials, 5% lung cancer trials, and 4% ovarian cancer trials. A smaller

number of men participated in treatment trials during this period (n=313) with 8.7% of the total sample identifying as Native Hawaiian, 30.1% identifying as White, and 58.7% (Table 3). Of the men who participated, 25% participated in prostate cancer trials, followed by 18% for colon cancer, and 15% lung cancer. The gender difference across the racial/ethnic groups for treatment trials in Hawai'i was modestly significant (p=0.048) with the strongest difference seen between Native Hawaiians and Whites (p=0.018).

	Females (n=631)	Males (n=196)
Native Hawaiian	13.3%	8.7%
Asian American	62.9%	58.7%
White	22.3%	30.1%
Other	1.4%	2.5%
*P=0.048		

Table 3: Ethnic/Racial-specific participation proportions in HI cancer treatment trials by sex*.

Discussion

A primary goal of the MBCCOP [18-23] is to evaluate the most beneficial prevention and treatment options. Adequate representation of persons from all ethnic backgrounds is crucial to advancing this goal. In the current research on minority recruitment, study results indicate that trial participants were recruited primarily through MBCCOP efforts (i.e., physician referral and media campaigns). Efforts yielded some success in recruitment of Native Hawaiians and other ethnic/racial minorities. However, between-group differences in level of participation were revealed, especially in comparisons of Caucasian and Native Hawaiian participants. Closer examination of within-group differences revealed gender variation namely; in comparison to Native Hawaiian men, Native Hawaiian women tended to participate more actively in cancer prevention and treatment trials. In examining more recent treatment trial data (2005-2012) participation rates are nearly identical. Identifying reasons for such differences currently are not known. Results of our analysis strongly suggest that future research is needed to: (1) collect and document more comprehensive information on recruitment, with an emphasis on approaches used to successfully recruit Native Hawaiian men and other ethnic/gender minorities, (2) describe proximal influences to participation such as geographic and other access factors, type of trial (prevention or treatment), promotional medium (physician referral, media campaign), and culturally-based health beliefs, with specific attention to ethnic and gender variation, and (3) describe other more distal influences to participation, including history of collective trauma and inter-generational marginalization.

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Disclaimer

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