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Barriers to Cancer Clinical Trial Participation Among American Indian and Alaska Native Tribal College Students

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Abstract

Purpose—American Indians and Alaska Natives (AIs/ANs) have some of the highest cancer-related mortality rates of all US racial and ethnic groups, but they are underrepresented in clinical trials. We sought to identify factors that influence willingness to participate in cancer clinical trials among AI/AN tribal college students, and to compare attitudes toward clinical trial participation among these students with attitudes among older AI/AN adults.

Methods—Questionnaire data from 489 AI/AN tribal college students were collected and analyzed along with previously collected data from 112 older AI/AN adults. We examined 10 factors that influenced participation in the tribal college sample, and using chi-square analysis and these 10 factors, we compared attitudes toward research participation among 3 groups defined by age: students younger than 40, students 40 and older, and nonstudent adults 40 and older.

Findings—About 80% of students were willing to participate if the study would lead to new treatments or help others with cancer in their community, the study doctor had experience treating AI/AN patients, and they received payment. Older nonstudent adults were less likely to participate on the basis of the doctor's expertise than were students (73% vs 84%, $P = .007$), or if the study was conducted 50 miles away (24% vs 41%, $P = .001$).

Conclusions—Finding high rates of willingness to participate is an important first step in increasing participation of AIs/ANs in clinical trials. More information is needed on whether these attitudes influence actual behavior when opportunities to participate become available.

Keywords

American Indian/Alaskan Native; barriers; clinical trials; survey; tribal college students

American Indians and Alaska Natives (AIs/ANs) have cancer-related mortality rates that are among the highest of all racial and ethnic groups in the US.[1,2] They are also more likely to be diagnosed with late-stage cancer and to have lower 5-year survival rates than other groups.[3] These pronounced disparities underscore the need for access to cancer clinical trials in this population. The National Institutes of Health recognize the importance of clinical

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trials for improving health care for racial and ethnic minorities, as they mandated in 1993 that all sponsored research must include women and minority groups.[4] However, fewer than 3% of US cancer patients are enrolled in trials funded by the National Cancer Institute, and AI/AN patients are conspicuously underrepresented in such trials, as are other racial and ethnic groups, rural populations, and older adults generally.[5–8] One study of participation in surgical oncology trials counted only 35 AI/AN participants (0.25%) out of a total sample of 13,991.[9]

Limited research has investigated barriers to participation in cancer clinical trials by AI/AN people. A review of articles reporting original data on recruiting barriers found that a scant 65 of 5,257 articles provided information on minority subgroups, and only 4 of these included AIs/ANs.[8] A few studies of barriers to general medical care and clinical trial participation for AI/AN people have identified medical mistrust and lack of transportation as issues.[10,11] In a survey of 112 AI/AN elders, we found that living far from the study site decreased willingness to participate in cancer clinical trials, as did a high risk that confidentiality would be broken. Several other factors also strongly increased willingness to participate in cancer clinical trials: research led by an investigator of AI/AN descent, research including a physician with experience treating AI/AN people, personal experience with the type of cancer studied, family support for participation, and hope that the research would provide new treatments.[12]

Building on these findings, we aimed to (1) identify factors that influence willingness to participate in cancer clinical trials among AI/AN students enrolled in tribal colleges, (2) develop a scale measuring willingness to participate, and (3) compare attitudes of AI/AN tribal college students to those of older AI/AN nonstudent adults. Because younger patients were over-represented in some studies of cancer clinical trials,[7–9] we hypothesized that younger tribal college students might demonstrate more willingness to participate in trials than would older nonstudent adults.

METHODS

Study Population and Design

Potential participants were AI/AN students enrolled at 3 tribal colleges west of the Mississippi River whose student populations were predominantly AI/AN. Two of the 3 colleges are located in rural areas in low population density states. Survey planning and administration were carried out in collaboration with on-site coordinators and student research assistants. All study procedures were approved by the Institutional Review Boards at each tribal college and at the University of Washington. Recruitment took place during 1-week periods of each academic quarter between January 2008 and February 2010. At each campus, recruitment flyers were posted the week preceding the survey dates, and tables were set up in locations predicted to have the most student traffic. Students who approached the recruiting table were informed that the study was about willingness to participate in research, and then asked to independently complete an anonymous written survey at nearby tables. Participants received a 12.5 megabyte jump drive after returning the survey.

In order to examine the effect of age on research participation, our analysis included results from an earlier survey of older AI/AN nonstudent adults, also called the elders' survey. The study population and design of the elders' survey have been described elsewhere.[12] Briefly, participants were AI/AN adults who attended a social event honoring AI/AN tribal elders in Seattle, Washington. As they arrived, potential respondents were offered a survey about factors that influence participation in research. Participants were entered into a gift raffle on completing the survey. Although the event took place in an urban setting, 29% of the 112

elders stated their current residence was on a reservation, and 16% stated their residence was rural, non-reservation.

Surveys

The tribal college survey was divided into 3 sections. Section 1 included 5 questions that we used to develop a 5-item scale to measure attitudes toward participation (the Research Participation Scale). Respondents were instructed to imagine that they had been diagnosed with cancer and were contemplating participation in a study that compared 2 treatments, both of which were suitable for their illness. They were first asked how likely they would be to take part in (1) this general scenario, then how likely they would be to take part if (2) the treatment was chosen randomly (with an explanation of randomization), (3) doctors didn't know which treatment was better, (4) they could leave the study at any time and receive another appropriate treatment, and (5) their doctor would fully explain both treatments before they were assigned to one or the other. Respondents rated their willingness to participate on a Likert scale with 5 possible answers: 1 = I definitely would not participate, 2 = I probably would not participate, 3 = I'm not sure, 4 = I probably would participate, and 5 = I definitely would participate.

Section 2 of the tribal college survey consisted of 4 items to ascertain experience with and attitudes toward medical research, as well as willingness to participate in research. Students were asked if (1) they had ever been in a research study or clinical trial (yes/no); (2) if they thought that patients should be asked to take part in medical research (yes/no/unsure). Then, given information from a hypothetical vignette, they were asked how willing they would be to participate in a research study testing (3) Prevention Plan R or (4) Prevention Plan K, using the Likert scale described above for their responses. In the hypothetical vignette, Prevention Plan R would reduce the chance that the participant would develop cancer by one-third, while Prevention Plan K would reduce the chance that the participant would develop cancer by one-sixth.

Section 3 of the tribal college survey included another brief vignette describing a hypothetical cancer trial, followed by items seeking students' attitudes on 10 factors that might influence participation. The 10 items were identical to a subset of items used in the elders' survey. The vignette and associated items for this survey and the elders' survey were based on materials used in an earlier study, which had previously been reviewed by AI/AN faculty and focus groups for cultural relevance and comprehensibility.[13,14] In the vignette, respondents were asked to imagine that they had cancer and were being invited to participate in a study testing an experimental drug designed to treat the cancer. The vignette stated that the experimental drug might be more effective than current standard treatments, that participants would be randomly assigned to the experimental drug or the standard treatment, that the study would require 10 study visits over a period of 6 months, and that the visits and treatments would be free.

The 10 survey items were as follows. Respondents were asked how likely they would be to participate in research if (1) the researcher was AI/AN, (2) the research was conducted at a facility located 50 miles away, (3) a family member or friend had the type of cancer being studied, (4) they thought that the study would help other people with cancer in their community, (5) they thought that the study would lead to new treatments for cancer, (6) they were paid for participation, (7) they thought that confidentiality might be broken, (8) they felt sure that all study procedures were clearly explained, (9) the doctor in the study was an expert in the type of cancer they had, (10) the doctor in the study had experience treating AI/AN people. For each item, tribal college students and elders used the Likert scale described above to rate their likelihood of participation.

Statistical Analysis

Surveys were offered to all tribal college students, but analysis was confined to students at least 18 years of age who responded "Yes" to the question, "Are you of American Indian or Alaska Native heritage?" First, we developed a short 5-item instrument (the Research Participation Scale) based on items from Section 1 of the college survey. We then evaluated the instrument. After generating descriptive statistics, we calculated Cronbach's alpha to ascertain the internal consistency reliability of the scale, and we used principal components factor analysis with a Varimax rotation to examine its unidimensionality. We employed multiple regression analysis to determine whether demographic variables were associated with scores on the Research Participation Scale. Age, gender, marital status, reservation residence, and educational level were entered into the regression model, with the Research Participation Scale score as the dependent variable.

We used analyses of co-variance (ANCOVAs) to examine the convergent or concurrent validity of the Research Participation Scale score by assessing its association with 3 validity items based on Section 2 of the college survey. The first 2 validity items were the yes/no responses from items 1 and 2 of Section 2. The third validity item was a composite of the responses to the third and fourth items on hypothetical Prevention Plans K and R. Responses were grouped into willingness to participate in (1) neither Prevention Plan K nor Prevention Plan R, (2) either Prevention Plan K or Prevention Plan R, but not both, or (3) both Prevention Plan K and Prevention Plan R. In each analysis, the Research Participation Scale score was the dependent variable, the validity items were the independent variables, and age was the covariate.

Finally, we used chi-square analyses to compare the tribal college sample and the elder sample in terms of the 10 factors that might influence research participation. Because we hypothesized that tribal college students' willingness to participate might decrease with age, we compared both the younger and older age groups represented by the college sample with the sample of elders. To simplify these analyses, we dichotomized the item responses into probable or definite participation versus uncertain participation or definite non-participation.

RESULTS

We collected 576 student surveys; 74 were excluded because respondents were not AI/AN, 10 because data on race were missing, and 3 because items on research participation were missing, leaving 489 surveys for analysis. Demographic and study participation variables are described in Table 1. Among tribal college students, the mean age was 28.3 years, 60% were women, and 84% had spent more than half of their lives living on a reservation. Overall, 7% had prior experience participating in research studies, and over 80% had a personal history of cancer or a family member or friend with cancer. Most students agreed with the statement that "patients should be asked to participate in research studies." Responses to the 2 hypothetical research studies were more or less evenly divided, with 35% refusing to participate in either Plan R or Plan K; 38% willing to participate in either Plan R or Plan K, but not both; and 27% willing to participate in both Plan R and Plan K.

Research Participation Scale

The Cronbach's alpha for the 5 items in our Research Participation Scale was .83. The principal component analysis of the 5 items resulted in a single factor with an eigenvalue of 3.0, which accounted for 59% of the item variance. All 5 items loaded on a single factor with factor loadings greater than .70. These results document the unidimensionality and internal consistency reliability of the scale. The Research Participation Scale was formed by summing the responses to the 5 items, which are scored from 1 (definitely would not

participate) to 5 (would definitely participate). Scores range from 5 (not willing to participate) to 25 (very willing to participate). In the regression model, age was the only demographic variable significantly associated with the Research Participation Scale score (t = 2.58, P = .02). Contrary to expectations, tribal college students aged 40 and older had higher scores, indicating greater willingness to participate in research (mean = 18.1, SD = 3.9) than students under 40 (mean = 16.8, SD = 3.8). Given this finding, we used age as a covariate to examine group differences with the Research Participation Scale.

Concurrent or Convergent Validity of the Research Participation Scale

First, in order to examine the concurrent or convergent validity of the Research Participation Scale, we hypothesized that students who had previously taken part in a clinical trial or research study would have significantly higher Research Participation Scale scores. Our results supported this hypothesis: Those who had taken part in a research study had higher Research Participation Scale scores (mean = 18.4, SD = 3.5) than students with no experience (mean = 16.9, SD = 3.8), after controlling for age (F(1,486) = 4.11, P = .04). Second, we hypothesized that students who would agree that *patients* should be asked to take part in medical research would be more likely to participate themselves. Students were asked, “Do you think that patients should be asked to take part in medical research?” (yes/no/unsure). Students who responded to these different options had significantly different Research Participation Scale scores (F(2,453) = 12.55, P < .0001). Their scores revealed a linear pattern of means, such that students who endorsed “yes” had the highest mean score on the Research Participation Scale (mean = 17.6, SD = 3.7), followed by students who endorsed “unsure” (mean = 16.2, SD = 3.2), and then by those who endorsed “no” (mean = 15.1, SD = 4.1). Third, as a final example of concurrent validity, we hypothesized that students with higher Research Participation Scale scores would be more willing to participate in research studies. As hypothesized, scores on the Research Participation Scale were significantly (F(2,485) = 59.34, P < .0001) related to willingness to participate in the hypothetical research studies. As the number of studies endorsed increased from 0 to 2, participation scores increased linearly, after controlling for age. Students who were unwilling to participate in either study had the lowest mean participation scores (mean = 15.0, SD = 3.8), followed by those endorsing 1 study (mean = 17.2, SD = 3.3), and those endorsing both (mean = 19.4, SD = 3.2).

Table 2 presents the responses of our 3 subsamples (older and younger tribal college students, AI/AN elders) to the 10 items on factors influencing research participation. All elders were at least 40 years old, with a mean age of 64.2 years (SD = 8.9). The younger college students had a mean age of 25 years (SD = 5.8), and the older students had a mean age of 48.6 years (SD = 6.2). The elder sample was less likely to participate on the basis of the study doctor’s expertise than either college sample. If the study was conducted 50 miles away, the elder sample would be only half as likely to participate as the 2 college samples. Interestingly, breaking confidentiality was significantly less important for the elder sample than for the 2 college samples. Notably, the 2 college samples did not differ significantly in their willingness to participate on the basis of any of the 10 items.

DISCUSSION

Few AIs/ANs enroll in clinical trials, and little research has investigated barriers that might prevent their participation. Studies of barriers to medical care and clinical trial participation among American Indians have identified medical mistrust as a significant barrier,[10,11,15] suggesting that this population might be hesitant to participate in clinical trials or medical research. In contrast, 64% of tribal college students thought that patients should be asked to participate in research, and 65% stated their willingness to participate in a hypothetical trial. The vast majority of students expressed willingness to participate in a research study if the

study doctor was an expert, if the study would lead to new treatments, if the study doctor had experience treating AI/AN patients, if the study would help other people with cancer in the community, or if a family member or friend had the type of cancer under study. Barriers to participation included distance from the study site and the possibility of broken confidentiality. Contrary to our hypothesis that younger people would be more willing than elders to participate in research, students and elders alike showed a strong willingness to participate except in cases involving long distances or potential loss of confidentiality.

These survey findings, although based on hypothetical vignettes, underscore the role of logistical rather than attitudinal barriers to research participation. Similar results were obtained from a study of a recruitment program involving clinical trials for AI/AN cancer patients in western South Dakota, where patients had to travel an average of 140 miles each way to the study site and lacked adequate resources for food, transportation, and lodging.[10] Many of the students and elders in our study also lived in rural areas that would require trips of 50 miles or more to reach a hospital or cancer treatment facility. Eighty-four percent of the students stated that they have spent more than 50% of their lives on reservations. Because most American Indian reservations are in rural areas, this statistic means that the majority of the students would have to travel significant distances to participate in a clinical trial. Larger research facilities, such as the National Cancer Institute's 59 Designated Cancer Centers, tend to be located in university settings in metropolitan areas. None exist in Montana, Idaho, Wyoming, North Dakota, South Dakota, or Oklahoma, where large numbers of AI/AN people live. Other studies have found that a disproportionate percentage of AI/AN patients present with late-stage disease and comorbidities, so that they do not meet guidelines for trial eligibility.[1,16,17]

Our brief Research Participation Scale had good internal consistency and validity in our student samples, as demonstrated by its significant association with the 10 items on factors influencing research participation. Age was the only demographic variable that was significantly associated with scores on this scale, whose utility should be replicated in other samples. We anticipated that younger people would be more likely than elders to express willingness to participate in research. For the most part, however, both younger and older people showed a strong willingness to participate, except in cases where long distances were involved or confidentiality might be broken. Elders were significantly less likely to participate than tribal college students of all ages if the study site was 50 miles away.

Our findings must be interpreted in light of certain limitations. First, our analyses were based on convenience samples of AI/AN students from 3 tribal colleges and AI/AN elders from 1 geographical area. As these participants do not represent all AI/AN adults, our findings cannot be generalized to tribal colleges in the aggregate, to individual tribes, or to other settings. Second, our analyses combined samples that were collected at different times and from different groups. This comparison of student populations and an elderly sample can only be considered very exploratory in nature. Third, our survey measured willingness to participate in hypothetical situations, not actual participation rates. A fourth limitation of the current report is that the Research Participation Scale did not contain items with negative content about participation. Future research might expand the scale with several negatively worded items to increase the range of the Research Participation Scale.

Nevertheless, our findings of high rates of willingness to participate are an important first step in increasing participation of AI/AN people in clinical trials. More information is needed on whether these attitudes influence actual behavior when AI/AN patients are offered an opportunity to participate. Continuation of efforts such as the National Cancer Institute's Cancer Disparities Research Partnership Program would enable AI/AN patients to enroll in clinical trials closer to their communities and provide information about actual

accrual rates.[18] Increased participation in clinical trials is vital to eliminating cancer-related health disparities in this underserved population.

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Table 1

Characteristics of Study Participants (N = 489)

Variable	
Age, mean (SD)	28.3 (10.1)
Age, % (N)	
18–39	86 (421)
≥40	14 (68)
Female, % (N)	61 (296)
Married, % (N)	27 (131)
Living on a reservation > 50% life, % (N)	84 (409)
Prior participation in research, % (N)	7 (33)
Experience with cancer, % (N)	81 (394)
Patients should be asked to participate in research, % (N)	64 (311)
Anticipated participation in prevention plans, % (N)	
Neither Prevention Plan R nor Prevention Plan K (0 plans)	35 (170)
Prevention Plan R or Plan K, but not both (1 plan)	38 (186)
Both Prevention Plan R and Prevention Plan K (2 plans)	27 (133)
Research Participation Score, mean (SD)[a]	17.0 (3.8)

[a] range 5–25

Table 2

Number and Percentage of Tribal College Students and Elders Who Would Probably or Definitely Participate in Research as a Function of 10 Factors Influencing Participation

Factors	Students < 40 years old N = 421	Students ≥ 40 years old N =68	Elders N = 112	Chi-square df = 2
Doctor in the study was an expert	84% (349)	84% (56)	73% (82)	7.20[a]
Study would lead to new treatments	80% (336)	81% (55)	76% (84)	1.05
Doctor in the study had experience treating American Indians/ Alaska Natives	79% (330)	84% (57)	74% (83)	2.40
Study would help other people with cancer in your community	79% (330)	84% (56)	72% (80)	2.99
Paid for your participation	77% (325)	75% (51)	69% (76)	3.10
Family member/friend had type of cancer being studied	73% (307)	84% (57)	74% (79)	3.45
All study procedures were clearly explained	70% (296)	81% (55)	69% (77)	3.46
Researcher was American Indian/Alaska Native	63% (265)	73% (50)	69% (75)	3.65
Conducted at health care facility located 50 miles away	40% (168)	49% (33)	24% (27)	12.72[b]
Confidentiality may be broken	16% (67)	22% (15)	29% (32)	9.82[a]

[a] $P < .01$;

[b] $P < .001$