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Asian Americans and Cancer Clinical Trials: A Mixed-Methods Approach to Understanding Awareness and Experience

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Abstract

Cancer clinical trials have been based on low accrual rates. Barriers to recruitment of minority populations affect the generalizability and impact of trial findings for those populations. The authors undertook a mixed-methods approach to understanding levels of awareness and experiences with cancer clinical trials. A survey was administered to new cancer patients and their caretakers (family, close friends, or other social support) at outpatient oncology clinics. Field observations of the trial accrual process also were conducted by employing the grounded theory approach in qualitative methods. Comparison of survey results for Asian-American respondents and non-Asian respondents indicated that Asians were less likely to have heard the term "clinical trial" and were more likely to define a clinical trial as "an experiment" or "a test procedure in a clinic" than non-Asians. Asians were more likely to have employer-based insurance and to report understanding issues related to cost reimbursement. Asians were less likely to have been involved in or to know someone in a trial and reported less willingness than white respondents to consider trial participation. Qualitative observations suggested that Asians who presented for a potential trial were interested in the availability of a novel cancer therapy but were not eligible for available trials. Multiple strategies will be necessary to enhance awareness of and experience with accrual to cancer clinical trials for Asians, including richer understanding and increased involvement of Asians in cancer clinical trials and greater attention to the location and diversity of the Asian population in structuring study centers and evaluating trial results.

Keywords

accrual; clinical trials; Asian Americans; mixed-methods research

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Clinical trials are designed to evaluate the safety, efficacy, and effectiveness of novel anticancer agents or approaches. Unfortunately, patient accrual into all phases clinical of trials has been low, accounting for only about 2.5% of all new cancer patients.[1] It has been suggested that the relative proportions of Latinos, African Americans, and Asians may be even lower than the national averages,[2,3] particularly for older patients and for specific types of clinical trials.[1] Barriers to recruitment of minority populations affect the generalizability, impact, and use of cancer clinical trial findings.[2,4–6] When a population of potential participants is excluded from research or is involved only in small numbers, scientists and clinicians find it necessary to extrapolate the results of research from other populations—a risky enterprise— or to forego treatment of these individuals and populations altogether.[7] To provide state-of-the-art therapy for all patients, attention to differential group access and participation in research is warranted.[1,2,8,9]

A history of research[10,11] and clinical atrocities[12–16] reflects a time of virtually unchecked experimentation on certain groups, either 1) without even the most basic attempts to inform individuals about what would be done to them and to obtain their consent or 2) by achieving consent through active deception of individuals.[10] General disparities in access to and delivery of healthcare further increase the gap in patients' willingness to participate in and their overall understanding of clinical trials research. However, even in situations that controlled for access to care, delivery of care, and severity of illness, disparities have been documented in the use of available services between whites and non-whites.[17,18] The history of both research atrocities and clinical atrocities, as well as general disparities in healthcare for nonwhite populations, suggest that there is a need for direct attention to areas in which differences in levels of awareness, types of experiences, and potential understanding and communications may impact the accrual of underrepresented populations.[3]

Adding to the variation in perceptions, it has been shown that patient concerns about insurance denial are a primary barrier to trial participation.[19,20] To our knowledge, only 14 states to date, including California, have responded to public concerns about cost reimbursement for clinical trial participation. A 2002 California law (SB37) mandated that Californians with cancer who are accepted onto any phase of a federally approved clinical trial of an investigational drug, device, or procedure can rely on reimbursement from their third-party insurers for services they would have received for standard cancer treatment.[21] Although efforts requiring third-party payers to assume costs related to clinical trials are encouraging, it remains unclear whether awareness of clinical trials and the new California law will enhance accrual to early-phase clinical trials and will help to reduce disparities in access to novel cancer therapies.

We have undertaken a mixed-methods, descriptive approach to understanding both the level of awareness and the experience of recruitment for Asian Americans in the University of California–Davis Cancer Center (UCDCC) greater Sacramento area. In this report, we compare our findings for Asian Americans with those for whites and other ethnic groups and discuss differences in levels of awareness and potential experiences with cancer clinical trials.

MATERIALS AND METHODS

The current study involved both macro-level survey and micro-observational level approaches to understanding awareness and the experience of recruitment to cancer clinical trials. All phases of this study were approved by the UCD Institutional Review Board (IRB).

Data Collection

Survey design and methods—To begin to understand the overall level of awareness of cancer clinical trials, we developed a self-administered survey for cancer patients and their

caretakers (family, close friends, or other social support) in the UCDCC Sacramento catchment area. The UCDCC catchment area has a population of > 4.5 million individuals in a 9-county area (Amador, El Dorado, Placer, Sacramento, San Joaquin, Solano, Sutter, Yolo, and Yuba Counties).

The first phase of our project involved gaining a better understanding of cancer patients and/or their social supporters/caretakers' understanding of cancer clinical trials and trial reimbursement, including awareness of the new California law on reimbursement. In an effort to advance diverse patient participation, UCD investigators created partnerships with the Association of Northern California Oncologists (ANCO), the Veterans' Administration of Northern California, and the Cancer Information Service. The group held monthly steering committee meetings to direct the course of survey design and distribution as well as to give direction regarding the face validity and feasibility of the instrument.

Our "awareness survey" targeted English-speaking cancer patients and their caretakers who were seen for the first time in an oncology-based clinic within the UCDCC catchment area. The survey instrument was assessed for face validity and was pilot-tested for readability and comprehension by 10 cancer patients who were seen at the UCDCC and at the Sutter Cancer Center, an ANCO affiliate. Feedback from the pilot test demonstrated the operational feasibility of the self-administered instrument. Survey data collection was conducted through our partnership network, which was organized to gather baseline data on clinical trial and SB37 awareness by way of convenience sampling. Our objective was to obtain 1000 completed surveys during our data collection period (October 2003 through April 2004).

Surveys were distributed and collected by designated site coordinators during patients' visits to oncology clinics and were mailed by coordinators to UCDCC every four weeks for data entry. Data sets were prepared by the programmer and were transmitted with codebooks for each data set to the Division of Biostatistics through a secure file transfer protocol. Each respondent was assigned a unique study identification number, and data sets contained no personal identifiers.

Field observation methods—Our investigation also included microlevel data collection on the processes involved in trial accrual and participation in those processes. Methods of qualitative investigation were used to "observe" the process of patient recruitment to clinical trials at the UCDCC by immersion in the recruitment process and detailed notes, which described elements and individuals important to the conduct of specific behaviors associated with the process.[22,23] Observations of clinical trial accrual were made with the approval of the UCD IRB and permission of the principal investigators and clinical coordinators for UCDCC cancer clinical trials. Ethnic identity and other personal identifiers, such as gender, age, and occupation, were collected based on patient or physician reports, not from patient medical records.

All cancer patients who potentially were eligible for a cancer clinical trial and their caretakers were sampled purposefully for observation. Purposive sampling included specific selection of situations and elements for study[24] based on general hypotheses about situations (e.g., the Phase I consent process will differ from Phase III; situations that involve family members differ from situations that do not involve family members; treatment regimens and dosing schedules vary widely among protocols) and variation in the population (e.g., differences in demographics and tumor type). The objective of purposive sampling was to obtain representation from the diversity of recruitment processes and potential clinical trial participants. All individuals involved in the situations that were selected for observation provided verbal consent to have the visit observed.

The lead author (D.A.P.) described each clinical encounter, which was observed in detail, and dictated descriptions of each encounter into an audiotape recorder immediately after the observation. Dictated field observations were transcribed immediately for qualitative analysis. All transcripts were reviewed for accuracy by the lead author. The method of "grounded theory" emphasized review of data as soon as the first observations were made and the use of knowledge from each prior observation to inform questions that are brought to subsequent observations.[23] Transcribed documents were entered by two research assistants (N.H. and L.S.) into a qualitative software program for consistent analytic comparison and systematic analysis.[25]

Data Analysis

Survey analysis—Analyses of the survey data were carried out by faculty and staff of the Division of Biostatistics using SAS, S-Plus, and SUDAAN software. Cancer patient and caregiver responses were pooled, and frequencies were calculated to represent levels of awareness. Herein, we summarize the results from the "Awareness Survey," including descriptive differences between white respondents, Asian respondents, and respondents from other racial/ethnic groups.

Qualitative analyses—Data analysis consisted of review of complete transcripts for all dictated field observations (initial coding), development of a list of redundant themes and thematic categories (thematic identification and organization), and systematic assignment of coding categories across all transcripts (focused coding).[26,27] The lead author (D.A.P.) and research assistants (N.H. and L.S.) met on several occasions to discuss emergent themes and patterns and to reach consensus on their categorization. The team performed a systematic content analysis of the transcripts to ensure abstraction of all data indicative of each theme. The review included assessment of positive and negative examples of the same phenomena (where evidenced in the data) and critical discussion with the entire project team until consensus was reached on the salient and clinically relevant processes of the accrual experience. Emergent coding categories were assigned consistently to each transcript using a qualitative software program.[25] The lead author used the software program not only to index but also to search across categories for recurring patterns and themes in the data using the method of constant comparison between categories.[28]

RESULTS

Table 1 shows the representation of newly diagnosed patients with cancer and patient enrollment in clinical trials by patient race/ethnicity. Similar to their representation in the nine-county catchment area, patients with newly diagnosed cancer who were seen at UCDCC were more likely to be white than non-white. Asians (5.3%) had the lowest proportion of patients who presented with newly diagnosed cancer compared with whites (81.9%) or individuals of other ethnicities (12.8%) (detailed data for African Americans, Latinos, or other ethnic groups were aggregated and are not displayed in Table 1). With the exception of Asian patients, who showed a 2.2% gap in accrual to trials compared with new patients, whites and patients of other ethnicities showed proportional increases of 1.1% and 0.7%, respectively, in the number of patients entered into clinical trials.

Survey Responses

Participant demographics—In total, 1187 respondents from the UCDCC catchment area completed the survey. Approximately 6% of the respondents described their race/ethnicity as Asian; 74.6% were white, and 17.1% described themselves as another racial/ethnic category. Demographic characteristics of the survey respondents are presented in Table 2.

Most respondents reported some college or a college degree, and nearly 25% reported a high school diploma or its equivalent, and 8% reported only some high school. Just greater than 20% of those who completed the survey reported earning < $25,000 annually. Nearly 25% of the sample claimed to have earned between $25,000 and $49,999 yearly, and 14% reported annual earnings ≥ $100,000. All survey respondents were asked to specify their insurance source. Forty-five percent claimed that their employer or their spouse's employer was their insurance payer. One-third of all respondents specified Medicare or Medi-Cal as their insurance payer. Fourteen percent reported that they paid out-of-pocket for medical care, whereas 3% claimed to have no insurance payer.

Asian respondents showed a greater frequency of college degrees (34%) and employer-sponsored insurance (59%) than whites (19% and 47%, respectively) or other ethnic groups (15% and 33%, respectively). Furthermore, Asians reported that they were enrolled on Medicare or Medi-Cal (19%) with less frequency than whites (33%) or responders of other ethnicities (41%). Members of ethnic groups other than white or Asian more frequently had only some high school education (18%), earning < $25,000 annually (45%), and more frequently reported being uninsured compared with whites (5% and 16%, respectively) or Asian Americans (6% and 19%, respectively). Asian Americans also described themselves as a "family member or other support person" with greater frequency (61%) compared with whites (45%) or respondents from other ethnic groups (51%).

Awareness survey—Responses to the Awareness Survey are summarized in Table 3. A general overview of the survey results and relevant comparisons will be provided in a separate report. Our current investigation of clinical trial awareness involved two components: 1) understanding of what a clinical trial is, and 2) understanding of how clinical trials may be reimbursed. Fifty-eight percent of Asian respondents reported that they had heard the term "clinical trial," compared with 75% of whites and 49% of survey respondents who reported other racial/ethnic identities. A greater proportion of Asian respondents (34%) and respondents of other ethnicities (39%) than white respondents (20%) stated that they had never heard the term "clinical trial." Furthermore, respondents who were not white or Asian more frequently had uncertainty about the term "clinical trial" (11%) compared with whites (5%) or Asians (8%). When they were asked to define a clinical trial, Asian Americans were most likely to describe a clinical trial as "an experiment" or "test or procedure in clinic" (73%) compared with whites (57%) or respondents of other ethnicities (51%).

To examine knowledge of reimbursement for clinical trial costs, survey participants were asked to express their overall level of agreement with a statement about payers and, then, about the existence of a new California law, SB37. Asian Americans agreed the most frequently (i.e., correct responses) with the statement, "in a clinical trial, the sponsor pays for the new drug being tested; all other costs are billed to your insurance company." Knowledge of the new California law was nearly equivalent for white and Asian survey respondents, with greater than one-half of all respondents (62% overall; 65% of whites, 61% of Asians, and 54% of other ethnicities) reporting uncertainty about the law's existence.

A greater proportion of white respondents described having been in a trial or having known someone who has been in a trial (21%) compared with Asians (10%) and respondents of other ethnicities (11%). Asian respondents were more likely to say that they did not know anyone in a trial or had not been in a clinical trial (75%) compared with whites (63%) or respondents of other ethnicities (67%). Overall, Asians reported less willingness to consider participation in a trial (i.e., "very likely to consider a trial"; 15%) compared with respondents who were identified as white (39%) or other race/ethnicities (28%). Overall, non-white respondents stated with greater frequency that they were "not likely" to participate in a clinical trial (21% of Asians and 24% of others) compared with white respondents (13%).

Field Observations

In total, 56 hours of observational field research over a 9-month period were conducted at the UCDCC Out-patient Oncology Clinic. In accordance with IRB approval, all patients and family members gave their verbal consent for the visit to be observed immediately prior to the visit. Observations included 59 unique patients with 9 different types of cancer (lung cancer was the most common type). Patients ranged in age from 19–85 years (mean age, approximately 63 yrs), and 75% of the patients observed were male. Racial/ethnic identification was announced by patients or physicians during the interaction and (in accordance with human subjects review) was not obtained through medical records. Fifty-nine percent of the patients observed were white; 5% were Asian; 14% were African American, Latino, or Native American; and 22% were not identified for race/ethnicity.

Visit interactions were sampled purposively, according to visit characteristics that we hypothesized were elements in clinical trial accrual (e.g., patient demographics, cancer type and stage, family member present). Systematic content analysis of the content of 76 unique observations of interactions between physicians, clinical research associates, cancer patients, and patients' family members resulted in identification of 5 stages in the trial accrual process: 1) presenting of potential participants, 2) informing participants about trial and therapies, 3) identifying criteria for participation, 4) specifying parameters for the trial, and 5) administering therapies and monitoring. Our observations included potential recruitment to clinical trials of four Asian Americans. Excerpts of field notes from these observations are provided below to illustrate the experience of potential trial accrual for Asians. Specific patient names and institutional identifiers (with the exception of UCDCC) have been omitted or changed to protect the confidentiality of the individuals and institutions involved in the interactions.

Presentation of potential participants—The presentation of potential participants involved the process by which patients were recommended or elected to establish a relationship with the cancer center. The following excerpts from field notes describe the context in which two characteristic patients presented for trial consideration.

> One of the medical residents described a Korean male in his mid-30s who presented with AJCC Stage IV cancer. The man was completing a doctoral program at a nearby university. Although he recently enrolled in a hospice, he decided that he wanted to pursue "more aggressive therapies and treatments," according to the resident's report (Field Observation 1).

Asian patients who presented for trial consideration made direct requests to be considered for trial participation; some even identified a particular trial for which they wanted to be considered, as evidenced in the following example.

> When we entered the examination room, we met a Filipino man—a local physician in his late-40s. He was with his wife, who claimed that she had been "doing all of the driving," because symptoms from the metastases in his brain produced sudden dizziness. During the early stages of his lung cancer, the man received care at another university cancer center in the area. When they no longer had anything to help him, he did his own research. The reason for his visit was clear: "[Texas] Cancer Center told me they have a protocol for me, but I would like to stay in this area if you have something here" (Field Observation 7).

Three of the four observations of Asian patients who presented for consideration were patients who were diagnosed with late-stage, metastatic cancers. On average, the age of Asian patients was younger (late 40s to early 50s) than the mean age of other participants we observed (approximately 63 yrs).

Information about trial and therapies—Frequently, patient self-referral was coupled with direct requests for information about trials and therapies. Because the Filipino physician who was a patient (described above; Field Observation 7) was not eligible for trials like the Texas Center-sponsored trial due to his advanced disease, his direct quest for what might be available prompted the attending oncologist to inform him about potential UCDCC trials.

In another observation, a Chinese woman presented to the oncology clinic seeking clarity about a trial in which she currently was enrolled at another site. The following provides an excerpt of the oncologists' consideration of her query about trial participation at the non-UCDCC site:

> The attending oncologist counseled a resident on how to discuss trial participation with a middle-aged Chinese woman who had asymptomatic nonsmall cell lung cancer: "There is a lot of evidence in the literature that [what is involved in the trial described by the patient] is not effective in lung cancer patients… It is not always good to treat patients just for the sake of treating them. Saying 'no' is a lot harder than saying 'yes'" (Field Observation 9).

In each of the four observations that involved clinical trial participation and Asian patients, physicians discussed the specific trials available at UCDCC and those for which the patient reasonably may have been eligible.

Identifying criteria for participation—After information about potential trials and therapies was presented to the patient, oncologists worked with the patient to characterize parameters of the illness that would allow them to assess adequately his potential eligibility. Discussions of reasonable eligibility typically occurred in consultation with another physician and, later, with the patient and family member.

> (Interaction continued from Field Observation 7: the Filipino physician.) The attending oncologist asked the resident about the status of the man's central nervous system. The resident noted that there were still "multiple metastases" but that "he actually performed relatively well on some of the function tests." Because he was still a "practicing physician," "still ambulatory," and "not confused," both the attending oncologist and the resident agreed to rate his performance status (an indicator frequently used as a parameter for trial eligibility) relatively high.***
>
> In the examination room, the attending oncologist described in detail some of the protocols that may be available for the patient's lung cancer, providing there was no interference from the brain metastases (Field Observation 7).

Due to the advanced disease in the Asian patients we observed, identifying adequate markers of eligibility for a trial was problematic. If patients, such as the Filipino physician who was a patient, met the functional criteria for trial accrual, then their disease stage or progression often was too advanced for trial consideration. The instance of the physician patient provides further exemplification of this point:

> (Interaction continued from Field Observation 7.) The attending oncologist explained to the resident that most protocols exclude patients with brain metastases. "Most people with brain met[astase]s actually die of the brain met[astase]s, so we don't get to see [the effect of the therapeutic agent being tested in the trial]" (Field Observation 7).

Specifying parameters for the trial—Separate from but also linked to broader trial eligibility criteria, such as the absence of brain metastases, were those criteria to be considered for recommendation of a particular patient to a specific trial. Further examination of the observation of the Filipino physician is instructive.

> (Interaction continued from Field Observation 7.) The patient recently had a magnetic resonance image and inquired whether its results, in addition to his good functional status, would make him eligible for one of the trials the attending oncologist had described. The oncologist explained that "it was difficult to read the recent scan… perhaps there was still some swelling in the brain from the most recent radiation treatments." The attending oncologist explained that, if another magnetic resonance image showed there were no brain lesions, "we may, in fact, be able to find some available protocol. Right now, we don't have any protocols for people with brain metastases" (Field Observation 7).

Each clinical trial required special attention to parameters that defined both patient eligibility status (identifying criteria for participation) and tumor-related or experimental factors that permitted the conduct of a successful trial (specifying parameters of the trial). Because the patient recently had been treated with radiation for his brain lesions, the attending oncologist considered the patient's plea for further consideration by having the extent of his disease reassessed.

Despite the detailed character of trial discussion, three of the four Asian patients we observed were ineligible for trial participation due to their advanced disease. In contrast to the 55 other patients we observed, the mean age of Asian patients was younger at presentation for trial consideration. None of the four Asian patients we observed were eligible for a UCDCC trial; thus, no Asian patients were witnessed in the fifth stage of *administering therapies and monitoring*.

DISCUSSION

We undertook a mixed-methods approach to understanding levels of awareness and experiences with cancer clinical trials. We assessed Asian-American knowledge of clinical trials and their purpose as well as understandings of cost reimbursement for participation in cancer clinical trials through a brief survey of new cancer patients who presented in outpatient oncology clinics in a nine-county area around Sacramento. In addition, we conducted field observations of our local process of recruitment to clinical trials in the UCDCC Outpatient Oncology Clinic over a 9-month period to better understand the Asian-American experience of trial accrual.

The results of our survey indicated that Asian respondents were less likely to know the term "clinical trial" or know someone in a trial, a finding also presented by others who have studied Asian Americans' understandings of clinical trials.[29,30] Asian respondents in our study, however, were more likely to have an understanding of clinical trial participation reimbursement factors than other individuals we surveyed. Reimbursement issues have been described previously as major barriers to clinical trial enrollment.[19,20] Although Asian Americans in our study showed a higher frequency of understanding reimbursement-related issues, they were less likely than other respondents to have participated in or to know someone who had participated in a clinical trial. Furthermore, our survey found that Asian respondents were less willing to consider participation in a cancer clinical trial than other respondents. Our qualitative observations suggested that Asian patients who presented for cancer clinical trials presented at a younger age, on average, than other patients who presented for trials; made direct requests about participation in a clinical trial; and were unlikely to meet the parameters for trial participation due to advanced disease.

A metaanalysis of Asian accrual to National Cancer Institute (NCI)-sponsored clinical trials found that, when they do participate in trials, on average, Asians are younger than the mean age of participants.[1] In large part, age differences may be linked with acculturation, including linguistic and education-based factors. Perspectives about cancer are framed by factors linked

to culture, including acculturation (e.g., language, folk beliefs),[31–34] family relationships,[35–37] and perspectives about uncertainty.[29,32,33,37] Normative understandings given by cultural values establish a set of organized rules for making and expressing choices that reduce uncertainty.[33,38,39] Cultural factors also affect beliefs about who should make medical decisions.[34,35]

To our knowledge, the current study is the first of its kind to employ a mixed-methods approach to understanding awareness of cancer clinical trials, trial reimbursement issues, and the qualitative experiences of recruitment processes for Asian Americans. However, this study has several limitations. First, our survey findings were derived from a sample of respondents who were not selected randomly; therefore, our data suffer from biases of convenience sampling and participant self-selection. Second, our observations and survey results reflect a single institution and its catchment area. Although ours is a large, NCI-designated institution in an area with great ethnic diversity, our findings can be generalized only to institutions and geographic areas similar to UCD and Sacramento.[40] Third, our survey was conducted in English, and we did not disaggregate results for individuals of various Asian ethnicities. Asian respondents for our study were likely to be highly educated and to have employer-sponsored insurance. Other researchers have discussed the significance of a bimodal distribution in socioeconomic resources in the Asian population based principally on levels of acculturation.[1] Because our aggregated data do not allow us to account for the range of educational, linguistic, and socioeconomic diversity that exists in the Asian population more generally, it is unlikely that our findings reflect or are highly generalizable to the greater Asian community in the Sacramento area or elsewhere.

A recent study of awareness among Asians showed that general awareness of cancer information services was low, with an increased level of awareness among those with higher levels of education and health insurance.[30] Our findings on familiarity with “clinical trials” mirrored those from other studies,[29,30] showing that Asian Americans have a limited understanding of and experience with cancer clinical trials. Our comparative results for Asian Americans versus non-Asians regarding trial reimbursement may be overestimated due to the level of education and insurance status reported by Asians who completed our survey. It is noteworthy that our study included only individuals who had access to care and individuals with linkages to oncologists and cancer centers, which means that we likely underestimated the range of individuals with disease who may be eligible for trial participation. Overestimation of awareness and underestimation of eligibility are problems suffered by studies that are unable to capture populations with limited access or no access to care. Although the number of qualitative observations for Asian patient recruitment was small, the Asian patients observed were proportional to the Asians who participated in clinical trials at our center.

Multiple strategies are necessary to enhance awareness of and experience with accrual to cancer clinical trials for Asians. First, greater description of the content of awareness and its specific contexts among the Asian population is warranted, particularly among Asians with less access to care who may be not only less acculturated but also more distrustful of Western medicine and clinical research.[41] Informational and educational campaigns at the community level directed by members of the community, in fact, may be a necessary starting point for clarifying misconceptions and for heightening awareness among Asians who lack information about cancer treatment and trials. Second, researchers have noted a critical need for facilitating avenues for healthcare professionals to interact with patients in a culturally acceptable manner, so that they can optimize the roles of patients in evaluation, diagnosis, and treatment.[3,32,42] Optimizing the role of Asian-American patients in clinical trials requires the inclusion of family members in the decision-making processes[43] and the involvement of Asian-American physicians in the design and conduct of clinical trials.[1,44] Third, suggestions to ensure clinically relevant trial findings in addition to more comprehensive recruitment of diverse

Asian populations in the accrual process include locating trial study centers in areas with high Asian-American population density[3] and disaggregating trials and their results for ethnically diverse groups, such as Asians, to garner more meaningful trial effects.[1,35,43,44] Finally, it will be necessary to elicit greater information regarding attitudes toward accurate knowledge about clinical trials and participation in cancer clinical trials for more effective outreach and education among Asian Americans.

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TABLE 1

New Cancer Diagnoses and Participation in Clinical Trials, 1999–2003

Demographic characteristics	No. of patients (%)		
	New cancer diagnoses, 1999–2003	Entry into trials, 1999–2003	Catchment area demographics 2000[a]
Race/ethnicity			
White	8048 (81.9)	1511 (83.0)	1,933,885 (66.0)
Asian	520 (5.3)	63 (3.5)	289,161 (10.0)
Other	1255 (12.8)	252 (13.5)	730,619 (24.0)
Total	9823 (100.0)	1826 (100.0)	2,929,126 (100.0)

[a] See U.S. Census Bureau, 2004[40]

TABLE 2

Demographic Characteristics

Variable	Race/ethnicity: No. (%)					*P* value
	White	Asian	Other	Not reported	Total	
Education						< 0.0001
Some high school or less	50 (5)	4 (6)	37 (18)	0 (0)	91 (8)	
High school or GED	192 (22)	8 (12)	51 (25)	3 (10)	254 (22)	
Some college or AA	336 (38)	18 (27)	69 (34)	3 (10)	426 (37)	
College graduate	168 (19)	23 (34)	31 (15)	6 (19)	228 (18)	
Postgraduate	134 (15)	12 (18)	13 (7)	7 (22)	166 (13)	
Not reported	6 (1)	2 (3)	2 (1)	12 (39)	22 (2)	
Income						< 0.0001
Under $25,000	139 (16)	13 (19)	92 (45)	1 (3)	245 (21)	
$25,000-49,999	218 (25)	15 (22)	45 (22)	8 (26)	286 (24)	
$50,000-74,999	189 (21)	8 (12)	24 (12)	2 (6)	223 (19)	
$75,000-99,999	78 (9)	6 (9)	10 (5)	5 (16)	99 (8)	
≥ $100,000	135 (15)	11 (17)	13 (7)	3 (10)	162 (14)	
Decline to state	127 (14)	14 (21)	19 (9)	12 (39)	172 (14)	
Insurance payer[a]						
Employer	288 (32)	29 (43)	57 (28)	8 (26)	382 (32)	0.0685
Medicare	238 (27)	8 (12)	30 (15)	7 (23)	283 (24)	< 0.0001
Spouse employer	134 (15)	11 (16)	10 (5)	3 (10)	158 (13)	0.0005
Self/spouse	131 (14)	4 (6)	24 (12)	5 (16)	164 (14)	0.0883
Medi-Cal	53 (6)	5 (7)	53 (26)	1 (3)	112 (9)	< 0.0001
No insurance	24 (2)	2 (3)	12 (6)	0 (0)	38 (3)	0.0690
Military/VA benefits	29 (3)	1 (1)	6 (3)	1 (3)	37 (3)	0.7135
Do not know	8 (1)	3 (4)	11 (5)	0 (0)	22 (2)	< 0.0001
At today's clinic visit you are:						0.0194
Cancer patient	471 (53)	23(34)	94 (46)	8 (26)	596 (52)	
Family (support person)	397 (45)	41 (61)	103 (51)	18 (58)	559 (46)	
Not reported	18 (2)	3 (5)	6 (3)	5 (16)	32 (2)	
Total	886 (74.6)	67 (5.6)	203 (17.1)	31 (2.6)	1187 (100)	

GED: general education degree; AA: Associate of Arts; VA: Veterans Administration.

[a]Participants were allowed to state more than one source of medical insurance.

TABLE 3

Awareness Survey Responses

Survey question	Race/ethnicity No. (%)					*P* value
	White	Asian	Other	Not reported	Total	
Heard term "clinical trial"						< 0.0001
Yes	662 (75)	39 (58)	100 (49)	22 (71)	823 (69)	
No	178 (20)	23 (34)	78 (39)	5 (16)	284 (24)	
Not sure	42 (5)	5 (8)	23 (11)	1 (3)	71 (6)	
No response	4 (0)	—	2 (1)	3 (10)	9 (1)	
A clinical trial is (all that apply):						
New drug treatment	710 (80)	45 (67)	113 (56)	18 (58)	886 (75)	< 0.0001
An experiment	277 (31)	25 (37)	58 (28)	9 (29)	369 (31)	0.4022
Test or procedure in clinic	230 (26)	24 (36)	46 (23)	7 (23)	307 (26)	0.1033
Cancer treatment	133 (15)	12 (18)	34 (17)	6 (19)	185 (16)	0.7044
Legal or court case	17 (2)	2 (3)	4 (2)	1 (3)	24 (2)	0.8337
"A clinical trial tests how safe and useful a new drug is against cancer and other diseases"						< 0.0001
Agree (correct)	673 (76)	46 (69)	122 (60)	20 (65)	861 (73)	
Disagree (incorrect)	25 (3)	3 (4)	7 (3)	1 (3)	36 (3)	
Unsure	184 (20)	14 (21)	71 (35)	6 (19)	275 (23)	
No response	4 (1)	4 (6)	3 (2)	4 (13)	15 (1)	
"In a clinical trial, the sponsor pays for the new drug being tested"						0.0823
Agree (correct)	291 (33)	23 (34)	68 (33)	6 (19)	388(33)	
Disagree (incorrect)	165 (19)	8 (12)	42 (21)	4 (13)	219 (18)	
Unsure	419 (47)	32 (48)	89 (44)	15 (49)	555 (47)	
No response	11 (1)	4 (6)	4 (2)	6 (19)	25 (2)	
"There is a new California law that makes health insurers pay most of the costs for cancer patients in clinical trials"						0.0034
Agree (correct)	153 (17)	13 (19)	55 (27)	5 (16)	226 (19)	
Disagree (incorrect)	150 (17)	9 (14)	33 (16)	4 (13)	196 (17)	
Unsure	571 (65)	41 (61)	110 (54)	16 (52)	738 (62)	
No response	12 (1)	4 (6)	5 (3)	6 (19)	27 (2)	
Know someone or have been in a trial						0.0007
Yes	185 (21)	7 (10)	22 (11)	5 (16)	219 (18)	
No	562 (63)	50 (75)	135 (67)	19 (61)	766 (65)	
Unsure	134 (15)	8 (12)	42 (20)	1 (3)	185 (16)	
No response	5 (1)	2 (3)	4 (2)	6 (20)	17 (1)	
Willingness to consider a trial						< 0.0001
Very likely	348 (39)	10 (15)	58 (28)	8 (26)	424 (36)	
Somewhat likely	400 (45)	35 (52)	87 (43)	13 (42)	535 (45)	
Not likely	116 (13)	14 (21)	48 (24)	4 (13)	182 (15)	
No response	22 (3)	8 (12)	10 (5)	6 (19)	46 (4)	
Total	886 (74.6)	67 (5.6)	203 (17.1)	31 (2.6)	1187 (100)	