

Increasing Participation of Physicians and Patients from Underrepresented Racial and Ethnic Groups in National Cancer Institute-sponsored Clinical Trials

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Introduction

Significant disparities exist in cancer incidence among racial and ethnic groups in the United States (1). Cancer incidence and mortality rates by gender and race/ethnicity for the most common cancers are shown in Figs. 1–4. Blacks have a higher mortality rate for these cancers and, for most sites, a higher incidence rate. Mortality rates are particularly striking for prostate cancer, which carries a mortality rate for black males, that is more than double that of white males. Regarding breast cancer, white women have a higher incidence rate, however, the mortality rate from breast cancer is higher in black women. Additionally, the continued downward trend from 1992 to 1996 in mortality because of breast cancer that is reflected among white women is not readily apparent among black women.

Reasons for racial and ethnic disparities in cancer incidence and mortality rates are not entirely clear. However, one factor is the lack of access to equal treatment by some racial/ethnic minority groups. For example, a population-based study of surgical treatment for early-stage non-small cell lung cancer found that black patients received surgery 64% of the time compared with 77% for whites ($P < 0.001$), and 5-year survival rates were 26% for blacks and 34% for whites ($P < 0.001$). Survival rates were similar among blacks and whites that had surgery and also among both groups who did not have surgery (2). Significant differences by race/ethnicity in mammography use rates have been noted, controlling for income and frequency of visits to a primary care physician (3). Differences between blacks and whites regarding colon cancer screening rates have also been noted (4, 5). Cancer is only one of many areas of medical care where disparities in access appear to have deleterious consequences in terms of outcome (Table 1; Refs. 4–17).

Clinical trials represent one approach to understanding and reducing treatment and outcome disparities among racial and ethnic minorities. Large Phase III clinical trials are typically developed by cancer experts participating in multi-institutional cooperative studies. Extensive reviews are conducted by disease committees from cooperative groups, the NCI², the Food and Drug Administration (if applicable), and by local Institutional Review Boards. Patient care conducted on clinical protocols is carefully prescribed, often including follow-up care

after treatment is completed. Audits are conducted on a routine basis to ensure that: patient care has been delivered according to protocol; patients have given informed consent; and that resulting data are accurately reported. Such safeguards protect patients participating in clinical trials and should help ensure that minority patients receive equitable treatment.

Some cancer clinical trials have produced significant results that have extended lives and/or improved quality of life for cancer patients. Chemotherapy can now cure or extend the lives of patients with certain forms of lymphoma, Wilms' tumor, rhabdomyosarcoma, leukemia, testicular and small cell lung cancer. Additionally, chemotherapy is often effectively administered as adjuvant therapy for cancers of the breast, colon, and cervix. Promising results have also emerged for a number of other cancers, including non-small cell lung cancer, bladder, esophageal, gastric, nasopharyngeal, and head/neck tumors. Chemotherapy has also made organ-sparing surgery possible for a number of tumor sites, including cancers of the anus, bladder, breast, esophagus, and larynx, as well as osteogenic and soft tissue sarcomas (18). These advances have resulted in improvements in overall 5-year survival rates to ~60% (Fig. 5). Despite progress in cancer research, many patients consider a cancer diagnosis to be a death sentence, which may lead to delay in seeking appropriate medical care and subsequently result in poorer clinical outcomes. It is important that patients understand the role clinical trials play in defining good evidence-based cancer treatment and the impact such treatment can have on their prognosis.

Clinical Trial Accrual Statistics

According to 2000 United States census data, blacks or African Americans constitute ~13% of the population, Asians 4%, and American Indians <2%. The Hispanic population, now at 35.3 million, is 13% of the United States population, with ~48% being white (Table 2). Data from 2000 provided by the Cancer Therapy Evaluation Program of the NCI reports cancer clinical trial accrual by race (Table 3). For many years, racial and ethnic minority accrual to NCI-sponsored cancer treatment trials paralleled the incidence of new cancer cases among those ethnic groups (19). However, in recent years, a new trend has emerged. Although the number of minority patients enrolled in clinical trials has remained relatively stable, the overall number of individuals admitted to trials has increased, therefore decreasing the minority percentage. For example, from 1998 to 2001, enrollment of black patients into clinical trials remained relatively stable (2309 versus 2347, respectively), however, a 22% increase in overall clinical trial accrual occurred from 23,343 in 1998 to >30,000 in 2001. Data for American Indians, Hispanics, and other ethnic minorities reflect similar trends.

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² The abbreviations used are: NCI, National Cancer Institute; CCOP, Community Clinical Oncology Program; SEER, Surveillance, Epidemiology, and End Results.

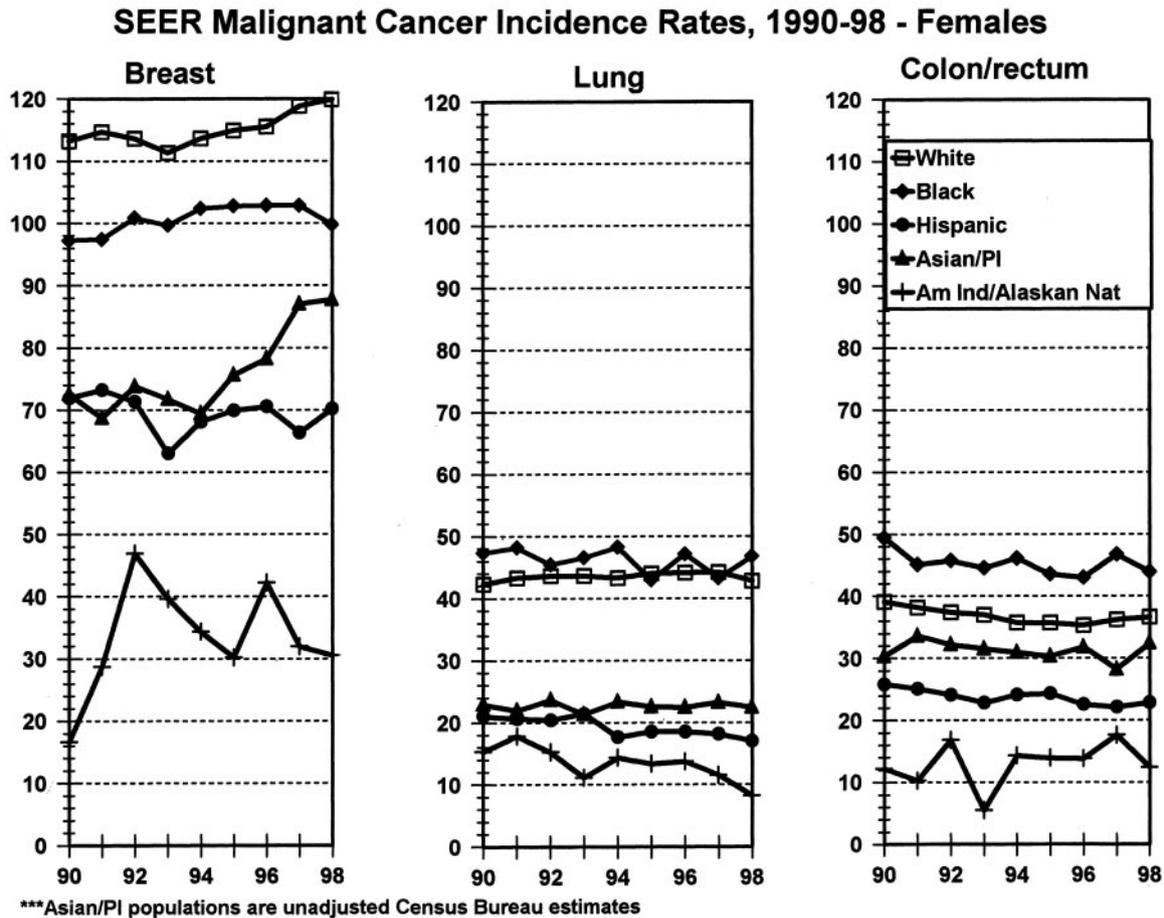


Fig. 1. Cause-specific survival SEER 1988–1995 all sites. Adapted from data obtained from the SEER Program of the NCI available online.⁴ Source: SEER 12 areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, Atlanta, San Jose-Monterey, Los Angeles, and Alaska). Incidence data for Hispanics does not include cases from Detroit or Hawaii. Hispanic is not mutually exclusive from American Indians/Alaskan Natives, Asian/Pacific Islanders, and blacks. Incidence and death rates are age adjusted to the 1990 United States standard population by 5-year age groups.

Overall accrual to NCI-sponsored trials remains low, <2% of new cancer patients. For minority racial and ethnic groups, the number admitted to trials is even lower, producing important consequences. Slow overall accrual means that the answers to important clinical trials questions are delayed. The low number of minority patients admitted to any one trial means that potentially important biological differences may be obscured. For example, genetic polymorphisms in metabolic enzymes that determine drug disposition may result in differences in pharmacokinetics and pharmacodynamics, drug toxicity, or effectiveness (20). However, given the very small minority sample sizes in many trials such observations are difficult, if not impossible, to detect.

Given the importance of clinical trials on a variety of levels, what are some impediments to greater participation, particularly for patients from underserved populations? A variety of factors should be considered, including socioeconomic barriers that limit access to high-quality medical care, lack of information regarding the importance of clinical trials, and

absence of culturally appropriate educational materials and approaches. Persistent mistrust of the medical research community by minority individuals is also cited, which may be attributed to tragic events such as the Tuskegee syphilis study (21, 22). Additionally, the small numbers of minority medical professionals in cancer research may also contribute to mistrust and low patient accrual (22).

Minority Medical Faculty and Funded Clinical Investigators

Academic physicians are typically involved in the development of clinical research protocols. The percentage of racial and ethnic minority physicians choosing to pursue careers in academic medicine is disproportionately low. Data from the Association of American Medical Colleges indicates that United States medical school faculty across all disciplines totaled 88,151 in 2000 (Table 4). Of that number, 3% were black, 3% were Hispanic, and <1% were American Indian. Additionally, faculty tenure status and receipt of funding from the NIH are typical indicators of success in academic medicine. Association of American Medical Colleges data on faculty tenure status

⁴ Internet address: seer.cancer.gov/csr/1973_1999/section.html.

SEER Malignant Cancer Incidence Rates, 1990-98 - Males

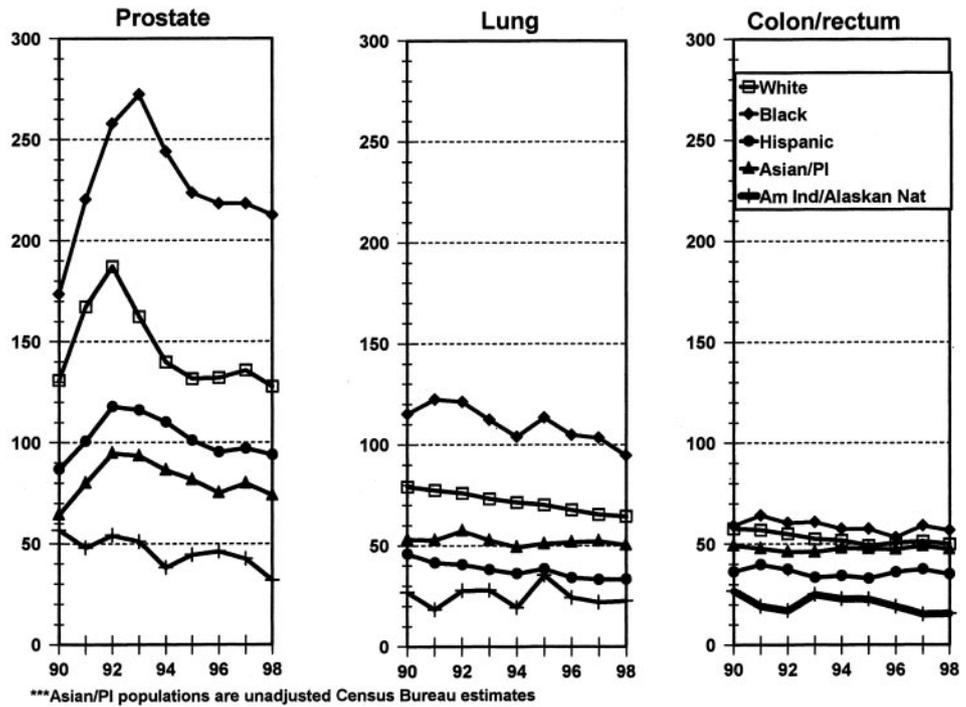


Fig. 2. Cancer mortality rates, 1990–1998, males. Adapted from data obtained from the SEER Program of the NCI available online.⁴ Source: SEER 12 areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, Atlanta, San Jose-Monterey, Los Angeles, and Alaska). Incidence data for Hispanics does not include cases from Detroit or Hawaii. Hispanic is not mutually exclusive from American Indians/Alaskan Natives, Asian/Pacific Islanders, and blacks.

Cancer Mortality Rates, 1990-98 - Females

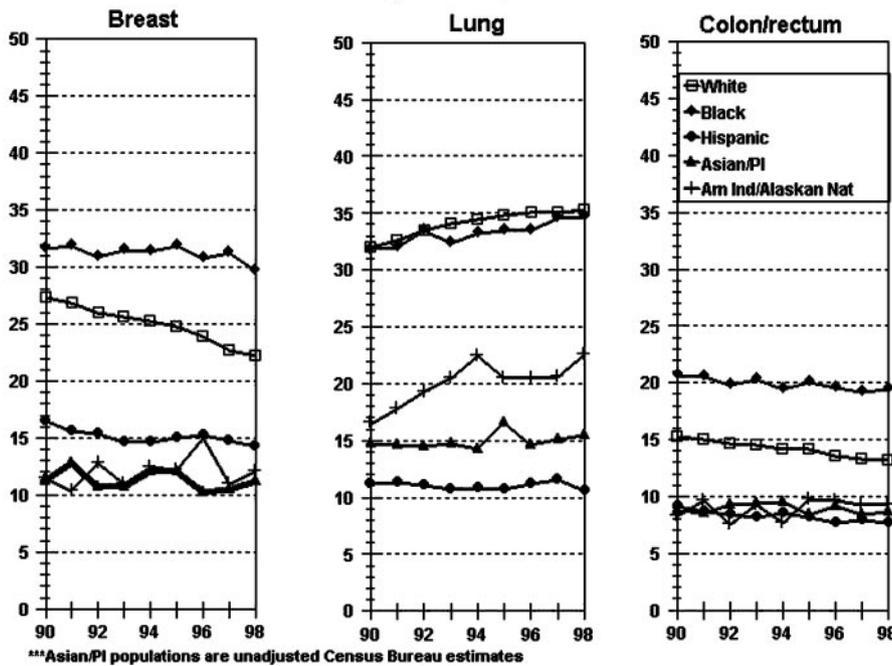


Fig. 3. Cancer mortality rates, 1990–1998, females. Adapted from data obtained from the SEER Program of the NCI available online.⁴ Source: SEER 12 areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, Atlanta, San Jose-Monterey, Los Angeles, and Alaska). Incidence data for Hispanics does not include cases from Detroit or Hawaii. Hispanic is not mutually exclusive from American Indians/Alaskan Natives, Asian/Pacific Islanders, and blacks.

indicates that of 14,685 tenured full professors, 152 were black and 325 were Hispanic (Table 5). Of 5870 tenured associate professors, 197 were black and 153 were Hispanics. Therefore, the pool from which minority academic cancer researchers are typically drawn is extremely small.

This pattern is similar for underrepresented minority re-

searchers holding NCI-funded research grants (Table 6). Voluntary information obtained at the time of grant submission indicates that of 4717 research project grants (RPG grants) awarded in fiscal year 2000, 7 principal investigators were American Indian, 26 were black, 109 were Hispanic, and 396 (8%) did not indicate race. Among 1259 training grants, fel-

Cancer Mortality Rates, 1990-98 - Males

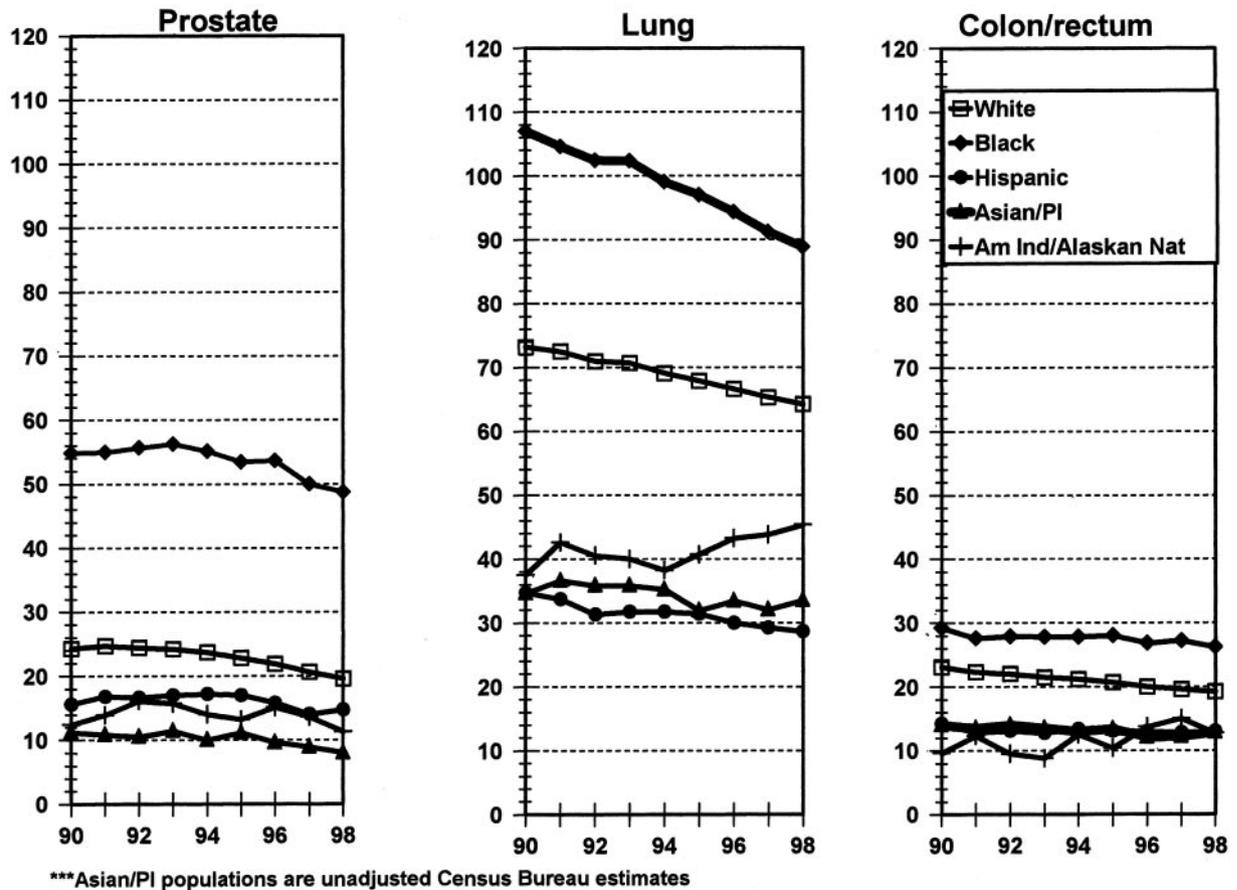


Fig. 4. SEER malignant cancer incidence rates, 1990–1998, males. Adapted from data obtained from the SEER Program of the NCI available online.⁴ Source: SEER 12 areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, Atlanta, San Jose-Monterey, Los Angeles, and Alaska). Incidence data for Hispanics does not include cases from Detroit or Hawaii. Hispanic is not mutually exclusive from American Indians/Alaskan Natives, Asian/Pacific Islanders, and blacks.

lowships, and career awards, 9% were awarded to underrepresented minorities, and 12% did not declare race.³ These data indicate that efforts are urgently needed to recruit minority faculty and clinical investigators committed to clinical research. They are needed to help design studies that are relevant to minority communities to help ensure that underrepresented patient populations enroll. Additionally, minority investigators need to be active members of clinical trials cooperative groups and also at major academic cancer centers where most clinical and translational research occurs.

NCI Efforts to Enhance Racial and Ethnic Patient Accrual

The NCI is the largest sponsor of cancer clinical trials in the United States, with ~150 new agents in clinical development. Approximately 800 trials are ongoing, with >30,000 patients enrolled annually, and ~10,000 investigators at 3,000 sites participating in NCI-sponsored trials. Given the scope of NCI-sponsored trials, the fact that only 2400 black patients and even

fewer Hispanics, Asians, and other patients enroll annually is extremely disappointing.

The NCI has a number of initiatives aimed at increasing participation of underrepresented patient populations. The minority-based Community Clinical Oncology Program (CCOP), funded through the Division of Cancer Prevention, requires that at least 40% of patients seen at an institution come from minority populations. Sites are funded to accrue significant numbers of minority patients to cancer prevention and treatment studies. Additionally, in 1999 and 2000, the Division of Cancer Treatment and Diagnosis established cancer clinical trial units at two historically black medical schools, Howard University Cancer Center and Meharry Medical College. These programs were equipped with state-of-the-art information systems and clinical trials staff and provided access to a menu of Phase III clinical trials into which patients could be enrolled. Both institutions have begun enrolling patients on clinical trials, including Phase III cooperative group trials. Future goals will include not only increased minority accrual but also active participation of physicians from these sites on cooperative group disease committees that will determine the focus of future clinical trial development.

In 2001, NCI staff met with principal investigators from

³ Personal communication from Dr. Belinda Seto based on data from the NIH IMPAC 2 database.

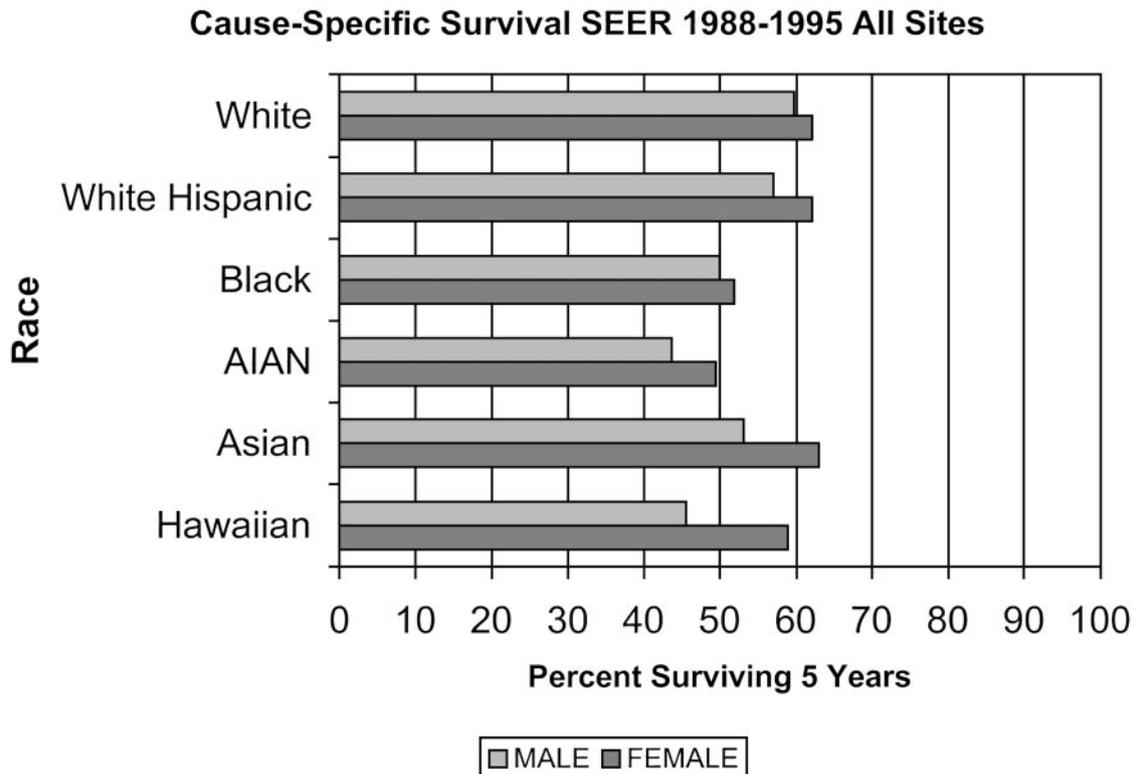


Fig. 5. SEER malignant cancer incidence rates, 1990–1998, females. Adapted from data obtained from the SEER Program of the NCI available online.⁴ Source: SEER 12 areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, Atlanta, San Jose-Monterey, Los Angeles, and Alaska). Incidence data for Hispanics does not include cases from Detroit or Hawaii. Hispanic is not mutually exclusive from American Indians/Alaskan Natives, Asian/Pacific Islanders, and blacks.

Table 1 Racial disparities in access to procedures and care

Significant racial disparities exist in the following:

- Surgery for non-small cell lung cancer (2)
- Screening mammography (3, 4)
- Renal transplant (6, 7), pancreas-kidney transplant (8)
- Coronary artery bypass grafting (4, 9–12)
- Coronary angioplasty (4, 10–12)
- Cardiac Catheterization (4, 11, 12)
- Carotid endarterectomy (4, 13)
- Cataract surgery (4)
- Total knee (4, 14) or hip arthroplasty (4, 15)
- Sigmoidoscopy, colonoscopy (5)
- Anti-HIV therapy (16)
- Anticoagulant therapy (17)

25 institutions having the largest minority patient accrual to NCI-sponsored trials. These sites are funded via a variety of different mechanisms and include cooperative group sites, cancer centers, traditional CCOPs and minority-based CCOPs, and others. The goals of the meeting were to describe effective approaches that could be successfully adopted at other institutions in an attempt to enhance minority accrual and to identify strategies that would enable centers to be more effective. Table 7 includes several recommendations that emerged, including having staff, health-care professionals, and lay advocates from minority patient

Table 2 United States 2000 census data^a

		American Indians	Asian	Black	White	Other
Race alone	#	2.5	10.2	34.7	211.5	19.4
	%	0.9	3.6	12.3	75.1	6.7
Racial combination ^b	#	4.1	11.9	36.4	216.9	
	%	1.5	4.2	12.9	77.1	
Hispanic 35.3 million = 12.5% (47.9% White)						
Total population 281.4 million						

^a Data from the United States Census Bureau available at <http://www.census.gov/prod/cen2000/dp1/2kh00.pdf>.

^b 2.4% of respondents.

Table 3 Racial distribution CTEP^a treatment studies FY00^b

Protocols	845	
Accrual	26,115	
American Indian	77	0.3%
Asian/Pacific Islander	340	1.8%
Black	2,130	8.2%
Hispanic	1,173	4.5%
White	21,568	82.6%
Other	698	2.7%

^a Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI.

^b Data on file, Division of Cancer Treatment and Diagnosis, NCI.

Table 4 2000 Distribution of United States medical school faculty by rank and race/ethnicity^a

Ethnicity	Professor	Associate professor	Assistant professor	Instructor	Other	Total
American Indian	29 0.1%	22 0.1%	63 0.2%	13 0.1%	2 0.1%	129 0.1%
Asian	1,521 6.6%	1,720 8.4%	4,764 13.9%	1,451 16.2%	224 15.7%	9,680 11.0%
Black	260 1.1%	452 2.2%	1,338 3.9%	415 4.6%	48 3.4%	2,513 2.9%
Hispanic	512 2.2%	603 2.9%	1,367 3.9%	360 4.0%	41 2.8%	2,883 3.3%
White	19,946 86.9%	16,991 82.9%	25,504 74.3%	6,504 72.6%	1,076 75.5%	70,021 79.4%
Declined ^b	694 3.0%	702 3.4%	1,278 3.7%	217 2.4%	34 2.4%	2,925 3.3%
TOTAL	22,962 100.0%	20,490 100.0%	34,314 100.0%	8,960 100.0%	1,425 100.0%	88,151 100.0%

^a Adapted from data of the Association of American Medical Colleges, available at <http://www.aamc.org/data/facultyroster/usmsf00/00table3.pdf>.

^b Declined to respond.

^c Excludes missing data on 3,267.

Table 5 2000 distribution of United States medical school faculty by gender, ethnicity, rank, and tenure status^a

	Asian		Black		Hispanic		White		Total ^b
	Male	Female	Male	Female	Male	Female	Male	Female	
Professor									
Tenured	819	138	134	18	276	49	11,792	1,459	14,685
Associate professor									
Tenured	353	91	106	44	113	40	4,036	1,087	5,870
Assistant professor									
Tenured	10	7	9	4	4	3	212	89	338
Instructor									
Tenured	0	0	0	0	0	0	2	2	4
Other									
Tenured	1	1	4	0	1	0	106	10	123

^a Adapted from Data of the Association of American Medical Colleges, available at <http://www.aamc.org/data/facultyroster/usmsf00/00table15.pdf>.

^b Excludes unknown ethnicity (767) and missing data.

Table 6 NCI awards in selected mechanisms, racial/ethnic distribution, fiscal year 2000^a

	Unknown	American Indian/Alaskan	Asian/Pacific Islander	Black	Hispanic	White	Total
NCI RPG (Rs, Ps, Us) %	398 8.4	7 0.1	655 13.9	26 0.6	109 2.3	3522 74.6	4717
NCI training %	71 9.2	13 1.7	140 18.1	23 3.0	26 3.4	499 64.6	772
NCI fellowships %	18 11.3	1 0.6	23 14.5	11 6.9	10 6.3	96 60.4	159
NCI RCP (Career-Ks) %	65 19.8	0 0.0	47 14.3	11 3.4	25 7.6	180 54.9	328

^a Adapted from data from the NIH IMPAC 2 database, courtesy of Dr. Belinda Seto.

communities; greater accountability by cancer centers and state/local governments; and assistance with outcomes research to better address racial and ethnic disparities in cancer outcomes. The NCI provided additional funds to eight of these sites to hire a nurse case manager or clinical research associate to further increase minority enrollment on clinical trials. NCI will continue to explore these and other strategies in coming months.

In conclusion, additional efforts and new strategies are

urgently needed to address the existing widespread disparities in care and the unequal burden of cancer experienced by the nation's underserved minorities. Several recommendations have been made, including strong and effective mentoring and other programs to develop minority academic faculty, recruitment initiatives to hire minority faculty; enhanced efforts at minority patient recruitment and retention to clinical trials; and increased emphasis on outcomes research, training, and dissemination of medical information. Success will require sus-

Table 7 Recommendations of successful centers of minority recruitment

- 1 Provide patient navigators from the patient's community at clinical trials sites
 - Research nurse/case manager, patient advocate, or other dedicated staff.
 - Promote incorporation of lay program leaders to go into community as spokespeople.
 - Include as a shared resource in core funding for NCI Cancer Center grants.
- 2 Simplify consent forms
 - Toxicity lists are intimidating.
 - Defray costs of translating consent forms.
- 3 Increase patient access
 - Expect greater accountability by cancer centers.
 - Require NCI-funded cancer centers to report on inclusion of underserved populations and demonstrate commitment and consider redefining the catchment areas that define accrual targets.
 - Consider new partnerships with public hospitals.
 - Engage state and local governments to provide mechanisms for access by uninsured and underinsured patients.
 - Partner with professional societies such as the American Society of Clinical Oncology to lobby state and local governments for more effective coverage and access for uninsured and underinsured patients.
- 4 Provide greater support for research relevant to underserved populations
 - Issue requests for applications for research on minority-oriented issues with molecular correlates and, especially, outcomes research.
 - Assist grant applicants with statistical support to include aid in defining adequate outcomes endpoints and addressing methodology issues that have been recurrent issues in peer review.
- 5 Concentrate funding in urban centers and sites where underserved patients are treated.
- 6 Increase numbers of minority healthcare professionals and support staff.
- 7 Provide training for nonminority physicians in speaking to minority patients about clinical trials, health disparities, and access issues.
- 8 Develop education and marketing tools directed to underserved populations, especially in rural settings.
- 9 Provide support and incentives for patients to participate in clinical trials such as transportation vouchers for cab fares (not buses or vans).

tained, aggressive action, and new partnerships between policymakers, healthcare professionals, professional societies, and underserved communities.

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