REPORTS

Representation of African-Americans, Hispanics, and Whites in National Cancer Institute Cancer Treatment Trials

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Background: **The National Cancer Institute (NCI)-sponsored clinical trials cooperative groups place more than 25 000 American patients in treatment trials every year. Equal access and proportional representation of all races/ethnicities is desired.** ***Purpose:*** **Our objectives were to evaluate the inclusion of African-Americans, Hispanics, and non-Hispanic whites in NCI-sponsored treatment trials and to determine if there is proportional racial/ethnic representation.** ***Methods:*** **During the period of January 1, 1991, through June 30, 1994, 99 495 cancer patients were enrolled in clinical trials and declared themselves as non-Hispanic black, non-Hispanic white, or Hispanic (of any race). In the analysis, participants in NCI treatment trials were subdivided into three age groups: birth to 19 years, 20-49 years, and 50 or more years. The racial/ethnic composition of each of these age groups was compared with the racial/ethnic makeup of the American population with cancer. Estimates of the number of incident cancer cases per year were made for each racial/ethnic group within each age group using data from the Surveillance, Epidemiology, and End Results (SEER) Program and the 1990 Census. The percentage of all cancer patients who were in each racial/ethnic group were compared with the population that entered clinical trials. Comparisons are also made separately for patients with leukemia and breast, colorectal, lung, and prostate cancers.** ***Results:*** **Among patients 0-19 years old, 20-49 years old, and 50 years old or older there is relatively proportional representation of non-Hispanic blacks, Hispanics, and non-Hispanic whites in trials. It is noted that more than 70% of cancer patients aged 0-19 years are estimated to enter cooperative group clinical trials compared with 4.0% of cancer patients aged 20-49 years and 1.5% of patients aged 50 years or older.** ***Conclusions:*** **Accrual of American cancer patients to NCI-sponsored treatment trials generally parallels the incident burden of disease among non-Hispanic African-Americans, Hispanics, and non-Hispanic whites.** ***Implications:*** **This study shows that the NCI clinical trials are, as a whole, racially/ethnically representative of the American population and suggests that there is equal access to NCI clinical trials. [J Natl Cancer Inst 1996;88:812-6]**

The Clinical Trials Cooperative Group Program constitutes a large part of the National Cancer Institute (NCI) clinical research program. This program, which began in 1954, currently involves 194 universities, 1839 hospitals, and more than 23 700 physicians in North America. The program conducts large phase I, II, and III cancer treatment trials as well as cancer prevention and control clinical trials. The NCI-sponsored clinical trials cooperative research bases are named as follows: Cancer and Acute Leukemia Group B, Children's Cancer Group, Eastern Cooperative Oncology Group, Gynecologic Oncology Group, Intergroup Rhabdomyosarcoma Study Group, M. D. Anderson Cancer Center, North Central Cancer Treatment Group, National Surgical Adjuvant Breast and Bowel Project, National Wilms' Tumor Study, Pediatric Oncology Group, Radiation Therapy Oncology Group, and Southwest Oncology Group.

The appropriate participation of racial/ethnic minority patients in clinical trials has been a conscious goal. There has been a considerable effort to provide wide access to clinical trials (*1*,*2*). Participation of diverse populations is desired out of a sense of social equity and because it may provide more valid and more generalizable results. Analysis of sex accrual patterns in cooperative group cancer treatment trials has shown that women are proportionally represented (*3*) and a lower representation of elderly patients in trials has been noted (*4*); little has been done, however, to formally evaluate participation of racial and ethnic minorities in the cooperative group program.

The purpose of this study is to evaluate inclusion of non-Hispanic African-Americans (hereafter referred to as African-Americans or blacks), Hispanics, and non-Hispanic whites (hereafter referred to as whites) in NCI-sponsored cooperative group treatment trials and to determine whether there is proportional racial/ethnic representation. Proportionality was determined by comparing the racial/ethnic composition of those who had entered trials with the racial/ethnic composition of the American population who had been diagnosed with cancer.

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See "Notes" section following "References."

Materials and Methods

Data were obtained on all patients accrued to NCI-sponsored treatment trials for the 42-month period from January 1, 1991, through June 30, 1994. All participating institutions in the NCI clinical trials network submit information on accrued patients to a central data management office every 3 months. The submitted data include basic demographics, such as age, sex, patient's self-reported race and ethnicity, and protocol information.

Unadjusted age-specific cancer incidence rates provided by the Surveillance, Epidemiology, and End Results (SEER)[1] Program for the years 1988 through 1992 and demographics from the 1990 Census (5) were used to estimate the racial/ethnic composition of the American population newly diagnosed with cancer. The SEER data provided age-specific incidence rates for all cancers diagnosed in the three racial/ethnic groups and for all leukemias and breast (female only), prostate, colorectal, and lung cancers diagnosed in each of the three racial/ethnic groups. The U.S. population census data were used to calculate estimates of incidence.

SEER is a continuing project of the NCI, collecting population-based information on all cancers diagnosed among nearly all residents of 11 defined geographic areas. Approximately 13.8% of the U. S. population resides in these SEER areas (6). Data for blacks, Hispanics, and whites were derived from all 11 SEER registries. Individuals from all other racial/ethnic groups, including Asians, American Indians, Alaskan Natives, and Pacific Islanders, were not analyzed in this study because of the small number of such individuals in the SEER databases.

Results

A total of 107 970 subjects entered cancer treatment trials during the reporting period. Of these, 99 495 declared themselves to be non-Hispanic African-American (or black), non-Hispanic white, or Hispanic (of any race).

Table 1 shows the total number of African-Americans, Hispanics, and whites entering NCI-sponsored cooperative group treatment trials during the 42-month study period, the average annual accrual of these racial/ethnic groups, and the percentage of annual accrual that this number represents. The table also contains an estimate of the number of cancer cases among all blacks, Hispanics, and whites in the United States in 1990 and the proportion of all cancer patients who are black, Hispanic, or white. All percentages of total cancer incidence below are expressed relative to the sum of these three groups. The proportion of African-American, Hispanic, and white cancer patients entering U.S. cooperative group clinical trials is also listed. The above information is also provided for the three age groups 0-19 years, 20-49 years, and 50 years of age or older.

Among patients of all ages, overall accrual of African-Americans corresponds very closely to the estimated proportion of incident cancer cases (9.6% versus 9.4%, respectively). Hispanics make up 5.6% of the patients entering trials but represent only 3.4% of the estimated total number of cancer cases. The percentages for whites are 84.8% and 87.2%, respectively. On the basis of the overall numbers, we can estimate that only 2.5% of all cancer patients enter cooperative group clinical trials.

The data show that 11% of pediatric patients in NCI cooperative group trials are black; it is estimated that 12.4% of the total number of pediatric cancer patients are black. Similarly, 12% of children in NCI-sponsored cooperative group trials are Hispanic, while 11.9% of children

Table 1. NCI's cooperative group treatment trials, accrual by race/ethnicity (all sites combined) (1991-1994)*

	No. of cases in trials			No. of cases in United States§		
	1991-1994†	Yearly average	%‡	1990	%‖	% in trials¶
All ages						
NH blacks	9555	2730	9.6	106 435	9.4	2.6
Hispanics	5606	1602	5.6	38 082	3.4	4.2
NH whites	84 334	24 095	84.8	986 998	87.2	2.4
Total	99 495	28 427	100.0	1 131 515	100.0	2.5
0-19 y old						
NH blacks	3024	864	11.0	1371	12.4	63.0
Hispanics	3315	947	12.0	1326	11.9	71.4
NH whites	21 207	6059	77.0	8395	75.7	72.2
Total	27 546	7870	100.0	11 092	100.0	71.0
20-49 y old						
NH blacks	2219	634	10.6	16 907	11.4	3.7
Hispanics	1007	288	4.8	8944	6.0	3.2
NH whites	17 787	5082	84.6	122 669	82.6	4.1
Total	21 013	6004	100.0	148 520	100.0	4.0
50+ y old						
NH blacks	4312	1232	8.5	88 157	9.1	1.4
Hispanics	1284	367	2.5	27 812	2.9	1.3
NH whites	45 340	12 954	89.0	855 934	88.0	1.5
Total	50 936	14 553	100.0	971 903	100.0	1.5

*NH = non-Hispanic; NCI = National Cancer Institute.

†Includes two quarters of 1994 only.

‡Number of NH black, Hispanic, or NH white cases in trials divided by the total number of cases in the three groups, multiplied by 100.

§Estimated figures using data from the Surveillance, Epidemiology, and End Results (SEER) Program and the 1990 U.S. population census.

‖Number of NH black, Hispanic, or NH white cases estimated for the 1990 U.S. population divided by the total number of cases in those three groups, multiplied by 100.

¶Number of cases in trials divided by the number of cases in the United States, multiplied by 100.

with cancer are Hispanic. The percentages for whites are 77% and 75.7%, respectively. Overall, 71% of all children with cancer enter an NCI-sponsored cooperative group cancer treatment trial. Over a quarter (27.7%) of all patients entering an NCI-sponsored clinical cooperative group treatment trial are under the age of 20 years.

Individuals 20-49 years of age constitute one fifth (21.1%) of all participants in all cancer treatment trials. Black and Hispanic representation is slightly less than, but close to, proportional. Blacks made up 10.6% of those in the trials and 11.4% of all cancer cases. The percentage values were 4.8% and 6.0% for Hispanics and 84.6% and 82.6% for whites, respectively. Approximately 4% of all cancer patients aged 20-49 years enter clinical trials.

The overwhelming majority (85.8%) of people who develop cancer are 50 years of age or older at diagnosis. One half (51.2%) of all cancer patients entering cooperative group trials are 50 years of age or older. Among individuals 50 years of age and older, black and Hispanic participation in clinical trials is near parity; 8.5% of those in clinical trials are black, whereas 9.1% of all new cancer cases in this age group are black. The percentages for Hispanics are 2.5% and 2.9% and for whites are 89% and 88%, respectively. Approximately 1.5% of all patients with cancer in this age group enter cooperative group clinical trials.

Table 2 compares accrual to leukemia and breast (female only), colorectal, lung, and prostate cancer treatment trials. The table contains the average number of African-American, Hispanic, and white patients with these diseases entering NCI-sponsored clinical trials each year during the study period and the proportion that this number represents. The table also contains an estimate of the number of African-American, Hispanic, and white patients diagnosed with these diseases in the United States in 1990 and the proportion belonging to each race/ethnicity. This information is also detailed for patients aged 20-49 years and 50 years of age and older.

Among patients of all ages, there is a somewhat greater than proportional accrual of African-American patients with leukemia, breast cancer, and especially prostate cancer and slightly less than proportional accrual for colorectal and lung cancers. Hispanics make up 9.5% of patients in NCI-sponsored leukemia trials but only 4.8% of all incident cases of leukemia. Hispanic representation is near proportional for the other cancers.

Among patients aged 20-49 years, African-Americans are slightly lower than proportional in terms of accrual to clinical trials for leukemia and colorectal and lung cancers, but their accrual to trial for treatment of breast cancer was near proportionality. Accrual of Hispanics in this age range was near proportional for all diseases, except lung cancer. Prostate cancer was not assessed for the age range of 20-49 years. The number of patients under 50 years of age diagnosed with prostate cancer is extremely small, as are the number of patients under 50 years of age participating in prostate cancer clinical trials.

Among patients 50 years of age and older, black and Hispanic accrual were

Table 2. NCI's cooperative group treatment trials, accrual by race/ethnicity (selected sites) (1991-1994)*,†

	No. of subjects‡	% NH blacks	% Hispanics	% NH whites
All ages				
Leukemias				
Cases in trials§	5986	9.2	9.5	81.3
Cases in U.S.‖	28 048	8.3	4.8	86.9
Breast cancer				
Cases in trials§	3464	10.0	3.2	86.8
Cases in U.S.‖	167 237	8.4	3.3	88.3
Colorectal cancer				
Cases in trials§	2257	8.4	3.2	88.4
Cases in U.S.‖	137 633	9.4	2.8	87.8
Lung cancer				
Cases in trials§	2190	9.8	1.4	88.7
Cases in U.S.‖	164 407	11.1	2.2	86.7
Prostate cancer				
Cases in trials§	1289	14.7	2.5	82.8
Cases in U.S.‖	170 455	10.3	2.6	87.1
20-49 y old				
Leukemias				
Cases in trials§	1532	9.4	8.0	82.6
Cases in U.S.‖	3772	12.4	9.3	78.3
Breast cancer				
Cases in trials§	1437	12.1	4.1	83.8
Cases in U.S.‖	34 350	12.4	5.3	82.3
Colorectal cancer				
Cases in trials§	283	10.2	5.3	84.5
Cases in U.S.‖	7574	15.7	5.9	78.4
Lung cancer				
Cases in trials§	195	17.2	1.8	81.0
Cases in U.S.‖	9258	20.4	3.2	76.4
50+ y old				
Leukemias				
Cases in trials§	1757	8.2	3.3	88.5
Cases in U.S.‖	21 581	7.3	2.7	90.0
Breast cancer				
Cases in trials§	2027	8.6	2.5	88.9
Cases in U.S.‖	132 881	7.4	2.7	89.9
Colorectal cancer				
Cases in trials§	1972	8.2	2.8	89.0
Cases in U.S.‖	130 020	9.0	2.6	88.4
Lung cancer				
Cases in trials§	1992	9.1	1.4	89.5
Cases in U.S.‖	155 108	10.6	2.1	87.3
Prostate cancer				
Cases in trials§	1285	14.7	2.5	82.8
Cases in U.S.‖	169 514	10.3	2.6	87.1

*NCI = National Cancer Institute; NH = non-Hispanic.
†Includes two quarters of 1994 only.
‡Includes NH blacks, Hispanics, and NH whites only.
§Figure represents average number of accrued subjects in 1 year during study period.
‖Estimated figures using data from the Surveillance, Epidemiology, and End Results (SEER) Program and the 1990 U.S. population census.

both slightly more than proportional for patients with leukemia. The pattern for the other cancers in this age group is very similar to that for all ages (not surprisingly, since most of these cancers are in this age group).

Discussion

This report presents a quantitative comparison of the accrual of the three largest American racial/ethnic populations into NCI-sponsored cancer treatment trials versus the incidence of cancer in these populations. The analysis demonstrates that Hispanics, African-Americans, and whites are enrolled in NCI-sponsored treatment clinical trials in proportions closely paralleling the incidence of disease in these groups in the United States. The study also demonstrates that more than 70% of children with cancer enter cooperative group clinical trials, whereas only 4.0% of adults diagnosed with cancer at 20-49 years of age enter trials and only 1.5% of those diagnosed with cancer after 50 years of age enter trials.

Many have called for proportional representation and used the racial/ethnic composition of the general U.S. population as the parameter for comparison. For example, it has been suggested that because 12% of American women are African-American, then 12% of women in breast cancer trials should be African-American, if there is to be true proportionality. This is incorrect reasoning, falsely assuming identical cancer incidence rates across all racial/ethnic groups and similar age distributions among the races and ethnic groups.

This study looks at one portion of the accrual process. It does not assess factors that influence the accrual process in clinical trials, such as knowledge and attitudes among potential participants (*7*) and clinical researchers (*8-10*) or stage of disease. The data do not speak to retention within clinical trials.

Each year, the NCI accrues more than 25 000 patients to treatment trials. True determination of proportional representation in trials is difficult because the United States does not have a national, population-based cancer registry from which the racial/ethnic composition of the population with cancer can be counted. Such a registry would make the determination of racial/ethnic composition of the newly diagnosed population with cancer a simple arithmetic exercise. The method we have chosen to estimate the incidence of disease in the population is the most logical and least biased of any available. We have limited this analysis to the most common cancers, the three largest American racial/ethnic groups, and three broad age groups to provide the most reliable estimates. Accurate incidence estimates are difficult to make for some cancer sites and some minority racial/ethnic groups because of the small number of cases in the SEER database. The estimates are for the year 1990 because the 1990 U.S. Census data were used in the calculations. SEER data from 1988 through 1992 were used because these data coincide with the census data. Cooperative group accrual figures from January 1991 through June 1994 were used in this study because the NCI began collecting race and ethnicity data on patients entering cooperative group trials in 1990.

Published incidence rates are usually age adjusted to a standard population. This eliminates the effect of dissimilar age distributions in different populations and makes more accurate comparisons possible. Age-adjusted rates can be considered as pseudorates. This study uses unadjusted rates that represent the real occurrence of disease in the population. These incidence estimates, based on the SEER database, may deviate to some extent from the real, although unknown, national cancer incident rates (*11*). For example, a major proportion of the Hispanic cases included in the SEER database are from registries in California and New Mexico, while many other areas with large Hispanic populations are not covered by SEER.

While this study shows proportional enrollment of minorities to the overall clinical trials program, the analysis does have limitations. These findings use broad age groups. The high proportion of pediatric patients entering trials and the success of pediatric cooperative groups in accruing black and Hispanic patients distort the overall accrual figures. We are unable to assess for proportionality among smaller-sized age groups, such as one that would include individuals older than 70 years of age. Socioeconomic data were not collected; therefore, it cannot be determined if there is equal representation among social strata. The dataset groups a number of trials together. It is possible that some specific trials have high accrual of minority subjects and others have very low accrual. As such, the study cannot speak to generalizability of specific trial findings. Instead, the report speaks better to the issue of social equity and the availability of clinical trials that are believed to offer state-of-the-art care.

The findings suggest that the availability of, accessibility to, and enrollment in clinical treatment trials are comparable for African-Americans, Hispanics, and whites. This may be partly attributed to the ongoing commitment of a number of large urban university hospitals to the NCI clinical trials network as well as several NCI-sponsored programs designed to make cooperative group trials participation available to minority patients. These programs include the Minority-Based Community Clinical Oncology Program (MBCCOP) of the NCI Division of Cancer Prevention and Control and the Minority Accrual Initiative Program of the NCI Division of Cancer Treatment, Diagnosis, and Centers.

The MBCCOP provides funding to hospitals and groups of physicians providing cancer care to a large number of minority patients. This funding provides for full participation in cooperative group clinical trials. The Minority Accrual Initiative Program, begun in 1991, contributes support to the cooperative groups for additional expenses attributable to minority accrual and retention efforts. These have included training for physicians and staff, interpreters and translators, and community outreach.

The above data provide information on accrual of patients with cancer to cancer treatment trials. It does not speak to accrual of healthy minority subjects to cancer prevention trials. Minority accrual to several large-scale NCI cancer prevention trials has been lower than desired (*12,13*). It should be noted that the same institutions that have provided near racial/ethnic proportionality in cancer treatment trials have not been able to provide similar enrollment to cancer prevention clinical trials. This suggests that the dynamic of recruitment and accrual to cancer treatment trials differs from that of recruit-

ment and accrual to cancer prevention trials (*14,15*).

The National Institutes of Health Revitalization Act of 1993 (Public Law 103-43) mandates inclusion of minorities in clinical trials and outreach to minority communities (*16*). The law and its implementation go further to mandate that women and minorities and their subpopulations must be included so that valid analyses of differences in an intervention's effect can be accomplished. The data in this report are gathered from a number of trials, and the analysis demonstrates inclusion and proportionality. While it suggests parity, it does not directly address the feasibility of subset analysis in individual clinical trials. Some clinical trialists have pointed out that simple proportionality will not allow for precise subgroup analysis of differing effects in small minority groups. Oversampling of these minority populations in clinical trials may be necessary to increase statistical power when there is reason to suspect differences (*17*). Oversampling in and of itself has significant practical and ethical questions. Others (*18*) have noted that race and ethnicity may not be a scientifically meaningful surrogate for genetic difference.

A high proportion (71%) of all American children with cancer enter cooperative group clinical treatment trials, while a much smaller portion of American adults with cancer enter trials. It is likely that such a high proportion of children enter trials for several reasons. The cooperative group clinical trials pursue scientific opportunity, and many opportunities have come in pediatric cancer. Most pediatric patients have leukemia or lymphoma. Pediatric oncology is also primarily practiced in academic centers. One cannot exclude the possibility that parents are more likely to consent to their child entering a trial than adult patients are to consent to entering clinical studies. Issues in inclusion of older Americans with cancer in clinical trials is an area that needs further study.

This study demonstrates that the enrollment of African-American and Hispanic cancer patients is proportional with accrual of white patients in most areas. Where it is not, the differences are small. The lower participation rate of Americans 50 years of age or older in clinical trials is a concern. An ongoing commitment is necessary to ensure that all parts of our society have equal access and equal opportunity to enroll in clinical trials and that this effort is continually assessed.

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Notes

[1] *Editor's note:* SEER is a set of geographically defined, population-based central tumor registries in the United States, operated by local nonprofit organizations under contract to the National Cancer Institute (NCI). Each registry annually submits its cases to the NCI on a computer tape. These computer tapes are then edited by the NCI and made available for analysis.

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