Enrollment and Racial Disparities in Cancer Treatment Clinical Trials in North Carolina

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BACKGROUND Clinical trials provide access to innovative, high-quality cancer treatment. Simultaneously, broad access helps to ensure that trials include heterogeneous patient populations, which improves the generalizability of findings and the development of interventions that are effective for diverse populations. We provide updated data describing enrollment into cancer treatment trials in North Carolina.

METHODS For the period 1996–2009, person-level data regarding cancer clinical trial enrollment and cancer incidence were obtained from the North Carolina Central Cancer Registry and the National Cancer Institute (NCI). Enrollment rates were estimated as the ratio of trial enrollment to cancer incidence for race, sex, and year for each county, Area Health Education Center region, and the state overall. Enrollment rates for common cancers are presented.

RESULTS From 1996 to 2009, North Carolina NCI treatment trial enrollment rates were 2.4% and 2.2% for white patients and minority patients, respectively. From 2007 to 2009, rates were 3.8% for white women, 3.5% for minority women, 1.3% for white men, and 1.0% for minority men; there was greater enrollment among more urban populations (2.4%) than among the most rural populations (1.5%).

LIMITATIONS This study is limited to NCI-sponsored treatment trials in North Carolina. Policies governing collection of original data necessitate a delay in data availability.

CONCLUSIONS Effort is needed to ensure trial access and enrollment among all North Carolina populations. Specifically, we identified racial and sex disparities, particularly for certain cancers (eg, breast cancer). Programs in North Carolina and across the nation can use the methods we employed to assess their success in broadening clinical trial enrollment to include diverse populations.

Randomized controlled clinical trials are a critical tool in improving the science of cancer care. With rapid advancement in basic clinical sciences such as genomics and proteomics, clinical trials provide the primary forum for translating advances in basic sciences into cutting edge, innovative clinical care for patients. As treatments are increasingly tailored to specific genotypes, treatment efficacy may vary across diverse patient groups [1]. To evaluate the efficacy of new treatments, it is important that trials enroll a heterogeneous patient population that is representative of the underlying cancer population. Despite the importance of this diversity, certain groups—including elderly patients, men, and racial minorities—have historically been underrepresented in cancer clinical trials [2]. As a result, new discoveries tested only within a homogenous group may not be widely translatable to real-world clinical settings.

With the goal of improving access to trials and the diversity of enrollees, the National Cancer Institute (NCI) developed 2 cancer-focused practice-based research networks (PBRNs): the Community Clinical Oncology Program (CCOP) was developed in the early 1980s, and the National Community Cancer Centers Program (NCCCP) was developed in the 2000s [1, 3, 4]. NCCCP aims to improve the quality of cancer care delivered in community settings [1, 5], and CCOP engages community physicians in NCI clinical trials [1, 6]. The promise of these programs is to enhance access to cancer trials—particularly NCI Cooperative Group trials—and to boost enrollment of underrepresented groups, thus contributing to broad improvement in future treatment effectiveness and outcomes.

Many states have embraced cancer-related PBRNs as a mechanism for achieving diversity in clinical trial enrollment and for supporting the diffusion of innovation, which are critical to developing interventions that reach the field and are effective in all populations [1]. Moreover, there is growing evidence of PBRNs’ effectiveness in facilitating the diffusion of trial-proven interventions to broader populations. For example, in the context of colorectal cancer, PBRNs have been associated with patients having a greater probability of receiving innovative cancer care [7, 8].

We previously reported on a novel statewide system for ongoing monitoring and public reporting of NCI clinical trial enrollment, which was developed to extend clinical trial access to broader patient populations [3]. In this paper, we present updated enrollment data from this surveillance system. In addition to illustrating the utility of the surveillance system and providing information regarding possible changes in enrollment patterns, this study provides relevant insight that will inform North Carolina as it seeks to enhance...
access to clinical trials and improve quality of care vis-à-vis the broad use of trial-proven interventions. This study can also inform the NCI as it seeks to further promote clinical research in the community by reorganizing NCCCP and CCOP into the NCI Community Oncology Research Program (NCORP) [9].

Methods

Methods have been previously described in detail elsewhere [3]. In brief, person-level cancer incidence data were obtained from the North Carolina Central Cancer Registry (NCCCR) for the years 1996–2009. Person-level NCI clinical treatment trial accrual data were obtained from the NCI Cancer Therapy Evaluation Program (CTEP). This data set includes information on enrollment into NCI-sponsored cancer clinical treatment trials (ie, those funded by NCI and managed primarily through NCI Cooperative Groups). These data sets include age at diagnosis and enrollment, sex, race, county of residence, and primary cancer type (eg, breast, colon, etc.), but they are not sufficiently granular to characterize cancer subtype. Because clinical treatment trials and their relevant populations differ substantially from trials of cancer prevention and control, this analysis focused only on cancer treatment trials [5].

Select socioeconomic and regional health care organization data were obtained from Area Health Resource Files. Counties were categorized as urban or rural on a scale from 1 (metropolitan area core) to 10 (rural area core) based on the US Department of Agriculture’s rural-urban commuting area (RUCA) codes. To differentiate truly rural counties from areas of “sprawling suburbia,” which may have greater health care access, a conservative approach was used to define counties as rural when RUCA equaled 9 or 10. We also evaluated county-level characteristics such as whether the county hosted a CCOP or a medical school.

The primary goal of this study was to provide an updated report of trial enrollment across North Carolina; thus, analysis was primarily descriptive and focused on characteristics of adults (aged 21 years and older) who enrolled in cancer treatment clinical trials. Due to regulations governing data access and data use, there was insufficient identifying information to enable person-level linkages across data sets. The data were pooled and analyzed first at the county level; they were then aggregated and analyzed at the Area Health Education Center (AHEC) level or the state level.

As in our initial analysis [3], trial accrual rate estimates were calculated by dividing the count of annual enrollment by the count of newly incident cases for each race, sex, county, and year combination. We used Pearson’s chi-square tests to evaluate differences in categorical variables. Three-year averages were used to mitigate spurious fluctuations resulting from sparse data for several counties and race-sex combinations. Because the data were structured in this way, a repeated-measures approach was used to fit the logistic model and to calculate the odds ratios (ORs) used to examine enrollment rate trends for race and sex.

Results

From 1996 to 2009, the estimated overall adult enrollment rate for NCI-sponsored cancer treatment trials in North Carolina was 2.3%. Between 2007 and 2009, a total of 154,565 adults were diagnosed with cancer in North Carolina; of these, 3,771 adults were enrolled in NCI-sponsored treatment trials, yielding an estimated overall enrollment rate of 2.4% (see Table 1). This rate is slightly lower than the nationally estimated enrollment rate of 3–5% [10]. The mean age at diagnosis during this time period was 64.7 years, and the mean age at enrollment for those enrolling in trials was 57.4 years. Examining all years (1996–2009) and the most recent period (2007–2009), substantially more women than men enrolled in trials (3.3% of women versus 1.5% of men over all years [OR, 2.26; 95% CI, 2.18–2.34]; 3.7% of women versus 1.2% of men in recent years [OR, 3.08; 95% CI, 2.86–3.32]).

Enrollment rates were significantly lower among minority patients compared to white patients. This was true across all years (2.2% of minority patients versus 2.4% of white patients [OR, 0.90; 95% CI, 0.86–0.94]) and between 2007 and 2009 (2.2% of minority patients versus 2.5% of white patients [OR, 0.89; 95% CI, 0.81–0.96]). White women had the highest enrollment rates, at 3.3% across all years (OR, 2.12; 95% CI, 2.02–2.30; referent, white males) and 3.8% between 2007 and 2009 (OR, 3.03; 95% CI, 2.79–3.28; referent, white males). Minority men had the lowest enrollment rates, at 1.3% across all years (OR, 0.85; 95% CI, 0.78–0.92; referent, white males) and 1.0% between 2007 and 2009 (OR, 0.80; 95% CI, 0.67–0.95; referent, white males).

Because NCI-sponsored trials emphasize reaching community-based settings (ie, beyond academic medical centers), we also examined geographic differences in enrollment (see Table 1 and Figure 4). Consistent with prior years, the treatment trial enrollment rate for the years 2007–2009 was only 1.5% (122 patients enrolled of 8,096 patients with cancer) among those residing in the most rural counties (OR, 0.61; 95% CI, 0.51–0.73).

In general, overall enrollment trends appear to be remaining steady (see Figure 1). However, closer analysis reveals that enrollment among white patients is increasing overall (trend P < .001), although this trend is not present among minority patients (trend P = .278). Figure 2 depicts North Carolina treatment trial enrollment trends by race and sex for the years 1996 through 2009. These data reflect a sex disparity; enrollment is increasing among women (P < .001), but this trend is not present among men (P = .520). Among women, there is no apparent racial disparity in enrollment rates when examining all cancers together, nor is there evidence of a trend towards one (trend P = .133). However, the racial disparity appears to be significant and widening among men (trend P = .002).
### TABLE 1. Cancer Incidence and Clinical Trials Accrual in North Carolina, 1996-2009

| Overall (1996–2009) | Recent (2007–2009) |
|----------------------|-------------------|
| **Cancer incidence** | **Number enrolled** | **Estimated enrollment rate** | **OR** | **95% CI** | **Cancer incidence** | **Number enrolled** | **Estimated enrollment rate** | **OR** | **95% CI** |
| Overall              | 588,317 | 13,795 | 2.34% | 154,565 | 3,771 | 2.44% |
| **Sex**              |         |       |       |         |       |       |
| Male                 | 298,172 | 4,364 | 1.46% | 78,361 | 961 | 1.23% |
| Female               | 290,131 | 9,418 | 3.25% | 76,201 | 2,808 | 3.68% |
| Unknown/not documented | 14 | 13 | — | 3 | 2 | — |
| **Race**             |         |       |       |         |       |       |
| White                | 473,812 | 11,208 | 2.37% | 123,566 | 3,084 | 2.50% |
| Minority             | 110,467 | 2,445 | 2.21% | 29,434 | 652 | 2.22% |
| Unknown/not documented | 4,038 | 142 | — | 1,567 | 37 | — |
| **Sex and race**     |         |       |       |         |       |       |
| White men            | 239,164 | 3,579 | 1.50% | 62,619 | 796 | 1.27% |
| White women          | 234,648 | 7,622 | 3.25% | 60,946 | 2,286 | 3.75% |
| Minority men         | 57,052 | 725 | 1.27% | 14,980 | 153 | 1.02% |
| Minority women       | 53,415 | 1,719 | 3.22% | 14,453 | 499 | 3.45% |
| Unknown/not documented | 4,038 | 150 | — | 1,567 | 37 | — |
| **Age**              |         |       |       |         |       |       |
| Mean age in years (SD): diagnosis, enrollment | 64.7 (13.9) | 57.8 (12.9) | 64.3 (13.9) | 57.4 (12.8) |
| **AHEC region (number of counties)** |         |       |       |         |       |       |
| AHEC Area L (5)      | 22,500 | 437 | 1.94% | 5,668 | 112 | 1.98% |
| AHEC Charlotte (8)   | 91,673 | 2,005 | 2.19% | 25,175 | 539 | 2.14% |
| AHEC Eastern (23)    | 67,129 | 1,683 | 2.51% | 16,938 | 451 | 2.66% |
| AHEC Greensboro (8)  | 76,371 | 1,976 | 2.59% | 19,807 | 600 | 3.03% |
| AHEC Mountain (16)   | 61,806 | 1,391 | 2.25% | 16,349 | 452 | 2.76% |
| AHEC Wake (9)        | 75,569 | 1,505 | 1.92% | 22,343 | 393 | 1.98% |
| **CCOP in county?**  |         |       |       |         |       |       |
| No                   | 376,921 | 8,002 | 2.12% | 56,830 | 1,995 | 3.51% |
| Yes                  | 210,016 | 5,597 | 2.67% | 97,006 | 1,698 | 1.74% |
| **Medical school in county?** |         |       |       |         |       |       |
| No (n = 96)          | 530,976 | 11,947 | 2.25% | 140,275 | 3,213 | 2.29% |
| Yes (n = 4)          | 55,961 | 1,652 | 2.95% | 17,081 | 480 | 3.39% |
| **Percentile uninsured (county-level)** |         |       |       |         |       |       |
| Quartile 1 (fewest uninsured) | 274,330 | 6,094 | 2.22% | 74,309 | 1,720 | 2.31% |
| Quartile 2            | 110,291 | 2,683 | 2.43% | 28,644 | 768 | 2.68% |
| Quartile 3            | 135,417 | 3,376 | 2.49% | 34,973 | 887 | 2.54% |
| Quartile 4 (most uninsured) | 66,899 | 1,444 | 2.16% | 16,510 | 318 | 1.93% |
| **Years**            |         |       |       |         |       |       |
| 1996–1998            | 99,872 | 1,776 | 1.78% | — | — | — |
| 1999–2001            | 113,138 | 2,694 | 2.56% | — | — | — |
| 2002–2004            | 125,370 | 2,729 | 2.18% | — | — | — |
| 2005–2007            | 145,832 | 3,912 | 2.68% | — | — | — |
| 2007–2009            | 154,565 | 3,771 | 2.44% | — | — | — |
| **Geography type**   |         |       |       |         |       |       |
| Urban/metropolitan   | 555,265 | 13,128 | 2.36% | 146,340 | 3,571 | 2.44% |
| Rural                | 31,672 | 471 | 1.49% | 8,096 | 122 | 1.51% |
| **Common cancer types** |         |       |       |         |       |       |
| Lung                 | 87,352 | 1,499 | 1.72% | 21,729 | 244 | 1.12% |
| Colorectal           | 61,227 | 680 | 1.11% | 13,464 | 102 | 0.76% |
| Breast               | 98,655 | 4,274 | 4.33% | 24,911 | 1,482 | 5.95% |
| Prostate             | 82,153 | 640 | 0.78% | 20,817 | 205 | 0.98% |

Note. AHEC, Area Health Education Center; CCOP, Community Clinical Oncology Program; CI, confidence interval; OR, odds ratio; SD, standard deviation.

For the period 1996–2009, county information was missing for cancer incidence (n = 1,380) and number enrolled (n = 196). For the period 2007–2009, county information was missing for cancer incidence (n = 129) and number enrolled (n = 78).

*P < .1  **P < .01  ***P < .001
Among the most commonly diagnosed cancers (breast, lung, colorectal, and prostate), breast cancer treatment trials had the highest enrollment rate both overall and in the 2007–2009 time period. Specifically, the breast cancer enrollment rate was 5.95% (OR, 5.57; 95% CI, 4.86–6.39); the colorectal cancer enrollment rate was 0.76% (OR, 0.67; 95% CI, 0.53–0.85); and the prostate cancer enrollment rate was 0.98% (OR, 0.88; 95% CI, 0.73–1.06), all versus lung cancer (referent). Simultaneously, breast cancer also demonstrated the greatest racial disparity in enrollment, with a trend that suggests this disparity is worsening ($P < .001$; see Figure 3). Across all races, enrollment in breast cancer trials has increased in recent years, but the upsurge is most dramatic for white patients. Enrollment into lung, colorectal, and prostate cancer trials is essentially unchanged over time but is comparable across racial groups.

**Discussion**

The surveillance system described previously [3] can be used for monitoring, public reporting, and potentially improving minority access to cancer clinical trials. When implemented at regular intervals, the surveillance system can provide an updated understanding of cancer trial access and enrollment patterns as they correspond to regional and racial variation in the burden of cancer. In this way, it could be used as an alert system to identify potential populations and/or regions in which clinical trial enrollment is low, thus informing efforts to open select clinical trials or implement interventions to increase awareness of them. Ongoing monitoring of trial enrollment is critical to maintain a pulse on both current enrollment rates and longitudinal trends. There is variation in adult enrollment into cancer treatment trials, which appears to have reached a plateau overall.

This report is timely because of the flattening of the National Institutes of Health (NIH) budget in recent years and the recent sequestration that cut this budget by 5% [11]. This budget change may place downward pressure on treatment trials' ability to enroll patients. There is also the risk of aggravating the existing problem of underrepresentation of diverse populations; enrollment counts are stable, although both cancer incidence and the overall population are growing. Due to structural components of the reporting systems for both data sets (ie, cancer registry and clinical trials), there is a lag in the availability of data for these analyses. As such, repeating this analysis in the future may shed light on the impact of these budget cuts and further inform our understanding of enrolling minority participants in cancer treatment trials.
understanding of their implications for the health of North Carolinians.

Our analysis shows ongoing racial disparities in trial enrollment. This racial difference is troublesome for several reasons, as the following example of breast cancer subtypes illustrates. Recent research has documented how different subtypes of breast cancer may have different morbidity profiles and may be more aggressive among specific subpopulations, including African Americans [12-16]. In this analysis, data were not available regarding the cancer subtype for either the broader incident cancer population or the population enrolled in clinical trials. However, the observed under-enrollment of African American women is likely at least partially due to 2 factors: the 2-3-fold greater incidence of a specific breast cancer subtype (“triple-negative” disease) among African American women compared with white women, coupled with the greater scientific progress and historically greater prevalence of clinical trials for other, non–triple-negative subtypes of breast cancer. Going forward, access to more refined data could provide important insight into how these factors explain the overall under-enrollment of African American women in breast cancer trials, despite comparable enrollment rates in cancer trials overall. Moreover, an empirical connection between these issues would support the call for additional basic science and clinical trial research in triple-negative breast cancer, which has been clearly linked to racial disparities in breast cancer recurrence and mortality. The case of breast cancer exemplifies why enrolling a diverse cohort is imperative for identifying effective therapies for all cancer subtypes among all populations in terms of survival, side effects, and treatment sequelae.

Of note, racial disparities often present as geographic variations in enrollment; for example, our examination found lower enrollment rates in the most rural areas. This finding suggests that, despite CCOP and many other ongoing initiatives, access barriers may still be a problem in many rural communities and/or areas that are far from academic medical centers, and this may disparately impact racial minorities.

This study and the ongoing examination of these data can inform our understanding of the effectiveness of population-based efforts to address these challenges and of programs that seek to reduce cancer health disparities. For example, in North Carolina, the NCI-funded Carolina Community Network to Reduce Cancer Health Disparities (CCN) has addressed these issues through a multifaceted approach that seeks to increase minority participation in clinical trials by first understanding these individuals’ perceptions of clinical trials, as well as through its community outreach and training programs. CCN has advanced our knowledge of how some groups misunderstand the purpose and/or intent of clinical trials, which has contributed to minority patients’ greater rates of refusal to participate compared with white patients [16-18].

Together with the results of this study, we now have a stronger understanding of how interventions aimed at improving minority enrollment must increase geographic
accessibility (by advancing science and opening trials that are most relevant to underrepresented populations), while also establishing trial eligibility criteria that are most likely to be inclusive of minority populations, building trust, and targeting the underlying social constructs that preclude research participation. This study may also inform other NCI programs in North Carolina and nationwide, such as NCORP and other programs, which continue to make strides to extend cancer treatment trials into the community setting. This aim is being addressed by broadening research access points, as well as tackling broader structural challenges such as eligibility criteria that can be unintentionally restrictive for minority populations [19-21].

The current analysis has several limitations. First, this study focuses on enrollment in NCI-sponsored cancer treatment clinical trials in North Carolina, but it does not incorporate data from other clinical trials, such as investigator-initiated trials or industry-sponsored trials. Therefore, our findings do not comprehensively reflect the total cancer clinical trials experience and may not be generalizable to non-treatment trials or other geographic settings. That said, data such as these have been consistently used to assess the state of clinical treatment trial enrollment, and they represent a large portion (if not the majority) of the clinical treatment trial population [1-3]. Second, policy restrictions precluded our ability to make person-level data linkages. Instead, data were pooled and analyzed at the county, AHEC, or state levels, which limits the granularity of the examination. Finally, although this analysis used the most recent data available, it is still a retrospective analysis. Obtaining real-time information would help to improve our understanding of trial enrollment. Despite these limitations, this analysis provides important insight into cancer treatment clinical trial enrollment in North Carolina.

In summary, rates of enrollment into NCI-sponsored cancer treatment clinical trials in North Carolina are generally stable; however, racial, sex, and regional differences indicate that effort is needed to ensure broad access to trials and to maintain the heterogeneity of the population enrolled. We identified important sex and racial disparities, as men and racial minorities in North Carolina experience an equal if not greater burden of cancer while comprising a comparatively smaller and apparently declining proportion of the clinical trials population.

The approach used in this study can be used again in the future to examine whether current and future interventions to resolve these disparities are effective. Programs such as NCORP, CCN, and other local and national programs continue to work to improve trial access for diverse populations. These and other programs may use the methods we describe to examine their programs’ effectiveness in achieving these goals—not only in North Carolina, but also in other states—as they seek to ensure program stability, growth, and enhanced access to community-based trials. NCMJ

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