Novel Method for Benchmarking Recruitment of African American Cancer Patients to Clinical Therapeutic Trials

Keith H. Morgenlander, Sharon B. Winters, Chyongchiou J. Lin, Linda B. Robertson, Dwight E. Heron, and Ronald B. Herberman

ABSTRACT

Purpose

The National Cancer Institute (NCI) has historically evaluated the participation of underserved minorities within University of Pittsburgh Cancer Institute (UPCI) clinical trials in relation to the proportion of African Americans in the general population of the UPCI primary service area of Allegheny County (12%). This standard seemed to be unrealistically high as a result of a younger age distribution of African Americans within the county.

Methods

The proportions of African Americans within the following four separate county populations were compared using data from 2000 to 2004: general population; invasive cancer patients; invasive cancer patients diagnosed or treated at UPCI-affiliated facilities; and patients enrolled onto UPCI's clinical therapeutic trials.

Results

Although the proportion of African Americans within the general population was approximately 13%, only 9.8% of patients diagnosed with invasive cancers were African American. Approximately 9.5% of all cancer patients diagnosed or treated at UPCI facilities were African American, which is comparable to the county-wide percentage of African American cancer patients. Recruitment rate of African Americans to oncology clinical trials from within the UPCI patient population was 7.6%. The NCI benchmark did not reflect the actual invasive cancer incidence rate in African American patients. By comparing the percentage of African Americans contributing to cancer incidence with the percentage of African American cancer patients treated at research-affiliated institutions, a more appropriate benchmark was derived.

Conclusion

The method developed by UPCI is recommended as a useful mechanism for benchmarking recruitment of African American cancer patients to clinical therapeutic trials at other cancer centers.

J Clin Oncol 26:5074-5077. © 2008 by American Society of Clinical Oncology

INTRODUCTION

Reducing disparities in cancer research and service delivery has become a national health priority. Populations experiencing a disproportionate cancer burden include racial and ethnic minorities, uninsured or underinsured, frail elderly, and those residing in rural communities. In response to these national health concerns, organizations such as the National Cancer Institute (NCI) have focused on this opportunity to lessen the burden of cancer and have prioritized this issue within all of their research projects.¹

The University of Pittsburgh Cancer Institute (UPCI) is the only NCI-designated Comprehensive Cancer Center in western Pennsylvania, with a patient base provided largely through a network of

academic and community hospitals of the University of Pittsburgh Medical Center (UPMC) and the UPMC cancer centers. These facilities, located throughout western Pennsylvania, provided either the initial cancer diagnosis or primary cancer-directed treatment for 16,473 patients during 2005. The treatment facilities that have historically supported the UPCI academic mission are located within the heart of the city of Pittsburgh in Allegheny County, Pennsylvania. Approximately 46% of all cancer patients diagnosed during 2005 at the facilities of UPMC and UPMC cancer centers in the county were residents of Allegheny County.² African Americans represent 75% of Allegheny County's minority population and have been the primary focus of UPCI's disparities-related initiatives.³ Consistent with region-specific demographics, African

From the Departments of Hematology/Oncology and Radiation Oncology, University of Pittsburgh School of Medicine; University of Pittsburgh Cancer Institute; Registry Information Services and Cancer Control Services, University of Pittsburgh Medical Center (UPMC), Pittsburgh; and Neighborhood Cancer Care Cooperative, UPMC McKeesport Hospital, McKeesport, PA.

Submitted March 24, 2008; accepted June 16, 2008; published online ahead of print at www.jco.org on September 22, 2008.

Supported in part by funding from the National Cancer Institute, Radiation Research Program, Cancer Disparities Research Partnership Grant No. 1 U56 CA105486-02.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

Corresponding author: Sharon B. Winters, MS, RHIA, CTR, Registry Information Services, University of Pittsburgh Medical Center Cancer Pavilion, 5150 Centre Ave, Office 318, Pittsburgh, PA 15232; e-mail: winterssb@upmc.edu.

© 2008 by American Society of Clinical Oncology

0732-183X/08/2631-5074/\$20.00

DOI: 10.1200/JCO.2008.17.3039

American cancer patients who reside in Allegheny County represent 83% of the minority population diagnosed or treated at UPCI-affiliated facilities.⁴

Similar to the experience of other NCI-designated Comprehensive Cancer Centers, recruitment of minorities to oncology clinical trials has presented a particular challenge. The NCI has historically evaluated the participation of underserved minorities in UPCI's clinical therapeutic trials on the basis of a performance benchmark of 12% minority clinical trial participation. This percentage reflected the percentage of the predominant minority in the general population (13.3% of the Allegheny County population was African American in 2006), without consideration of racially specific, regional incidence rates of cancer.³ Furthermore, cancer incidence is strongly associated with increasing age, with 63% of invasive cancers occurring in patients over the age of 60 years.² In Allegheny County, the African American population represents a significantly younger age distribution, with 85% being younger than age 60 years, whereas the percentage of the white population younger than age 60 years is 75%.³ This evidence made it apparent that the 12% benchmark was an unrealistically high recruitment expectation.

An exhaustive literature review and analysis concerning minority recruitment to cancer clinical trials was conducted by Johns Hopkins University Evidence-Based Practice Center for the Agency for Healthcare Research and Quality in 2005.⁵ This assessment revealed no comprehensive approach to the creation of benchmarks. When recruitment benchmarking methods and goals were addressed, they typically were linked to goals for specific clinical trials or were proposed as broad-based comparisons with the percentage of minorities within the general population. Our reviews of subsequent publications indicate no systematic attempt at measuring success in clinical trial minority recruitment.

METHODS

Our study is a comparison of the proportion of African Americans within the following four populations in Allegheny County: general population; all invasive cancer patients; invasive cancer patients diagnosed/treated at UPCI-affiliated facilities in Allegheny County; and cancer patients enrolled onto UPCI clinical therapeutic trials. The four data sources corresponding to these populations were as follows: US Census Bureau, American FactFinder 2005;³ EpiQMS, Bureau of Health Statistics and Research, Pennsylvania Department of Health (DOH);² UPMC Network Cancer Registry;⁴ and UPCI Clinical Trials Management Application (CTMA).⁶

For the DOH and UPMC Network Cancer Registry data, the inclusion criteria were limited to only invasive cancer patients because patients with invasive cancer have data that are made available through EpiQMS cancer incidence application and monitored by the DOH. Invasive cancer diagnoses also represent the vast preponderance of patients having the potential of being recruited to UPCI's therapeutic research protocols. The data for enrollment of cancer patients in clinical therapeutic trials were limited to those managed by the UPCI's Clinical Research Services and hence entered consistently into CTMA. The initial analysis was based on data from 2003. However, we subsequently expanded our analysis to include 5 years of data (2000 to 2004) to provide a larger, more stable sample of African American patients, as well as to allow for a sufficient sample to permit selected, disease-specific analysis. Patient samples within the UPMC Cancer Registry and CTMA data sets were defined as African American residents of Allegheny County having an invasive reportable condition and diagnosed at and/or having any course of therapy at Allegheny County-based UPMC hospitals or UPMC cancer centers.

To further evaluate the utility of this benchmarking approach, we also analyzed disease-specific data from reportable invasive diagnoses that are

the focus of our top five cancer disease site programs over the period from 2000 to 2004. These included, in order of UPMC Cancer Registry African American Incidence, Gastrointestinal Cancer Program, Prostate and Urologic Cancers Program, Lung and Thoracic Malignancies Program, Breast Cancer Program, and Hematologic Malignancies Program. The combined totals of the top five categories were evaluated using the same methodology as all invasive cancer.

RESULTS

Our overall results are listed in Table 1, which highlights several relevant comparisons. On the basis of census data, the proportion of African Americans within the Allegheny County general population was 13.3%.³ Of all cancer patients residing in the county at the time of diagnosis ($n = 40,631$), 9.8% ($n = 3,982$) were African American.² Approximately 9.4% ($n = 2,205$) of all cancer patients diagnosed or treated by a UPMC facility ($n = 23,561$) were African American, similar to the percentage of all African American cancer patients within the county.⁴ The UPCI recruitment of African Americans to clinical therapeutic trials was 7.6% (118 of 1,550 total accruals), revealing a difference of 1.8% (9.4% – 7.6%) between clinical trial and non-clinical trial patient populations for all invasive cancers.^{4,6}

The disease-specific African American recruitment comparison with the current NCI African American accrual benchmark is summarized in Figure 1. Of all cancer patients residing in Allegheny County at the time of diagnosis and having cancers in the top five disease site categories seen by the UPMC cancer centers between 2000 and 2004 ($n = 33,795$), 10.3% ($n = 3,473$) were African American.⁴ Approximately 9.9% ($n = 1,822$) of invasive cancer patients falling into the top five disease categories diagnosed or treated by a UPMC facility ($n = 18,400$) were African American, similar to the percentage of all African American cancer patients within the county.⁴ The UPCI recruitment of African Americans to clinical therapeutic trials in these top five disease categories was 9.0% (101 of 1,127 total accruals), reducing the difference by 50% between clinical trial and non-clinical trial African American patient populations from 1.8% to 0.9% (9.9% – 9.0%) for all invasive cancers.^{4,6}

Compared with the other top cancer categories during the study period, the Prostate and Urology Malignancies Program placed the greatest number of African American patients onto clinical trials (1.8% higher than the incidence of these patients within Allegheny County and 2% higher than the percentage of prostate and urology cancer patients seen at facilities of UPMC).^{2,4,6} The clinical trial versus non-clinical trial African American patient populations of

Table 1. Proportion of African Americans in Various Sources

Source	Overall No.	African American Population	
		No.	%
Allegheny county, overall population	1,223,411	162,714	13.3
Allegheny county, invasive cancer incidence	40,631	3,982	9.8
UPMC cancer centers, invasive cancer patients	23,561	2,205	9.4
UPCI, clinical trial accruals	1,550	118	7.6

Abbreviations: UPMC, University of Pittsburgh Medical Center; UPCI, University of Pittsburgh Cancer Institute.

Fig 1. Comparison of the National Cancer Institute (NCI) African American accrual benchmark with the proportion of African American cancer patients diagnosed among all facilities in Allegheny County in Pennsylvania, University of Pittsburgh Medical Center (UPMC) cancer centers, and University of Pittsburgh Cancer Institute (UPCI) clinical therapeutic trials. The general African American population of Allegheny County is 13.3%. Heme, hematologic.

both breast and hematologic and lymphatic cancer patients treated at UPCI facilities were roughly comparable to the incidences of these patients within Allegheny County ($\pm 1\%$ difference).^{2,4,6} In contrast, the Gastrointestinal and Lung and Thoracic Malignancy Programs enrolled only 8.3% and 9.6% of African American patients onto therapeutic trials, respectively, reflecting a greater difference between clinical trial and non-clinical trial patient populations (-2.7% and -1.4% , respectively).^{4,6}

DISCUSSION

It is important to realize that the NCI benchmark, even when adjusted, needs to consider the incidence of cancer patients seen in the region rather than at the cancer centers. The NCI benchmark of 12% minority recruitment was based on the proportion of African Americans within the general population and was not reflective of invasive cancer-related comparisons. Therefore, we have proposed a more relevant benchmarking methodology linked to several populations. Use of our new methodology revealed that the standard NCI benchmark overstated a reasonable recruitment target for UPCI by approximately 22% (9.8% cancer incidence rate for African American patients residing in Allegheny County v 12% African Americans in the general population).^{2,3} Our stepwise benchmarking strategy is to compare the percentage of African American cancer patients within the service area population (incidence), the percentage of African American cancer patients within the UPMC cancer center facilities, and the percentage of African Americans within the clinical trial population.

Similar methods were also applied to the five highest cancer diagnoses found within our county-specific African American population. This disease-specific assessment may provide valuable information to researchers concerned with the availability of patients with certain cancers and sample size estimates for patient recruitment, which is especially important for investigator-initiated research. Likewise, this type of profile can be used in support of initiatives to increase community oncologist participation in clinical research.

This study indicates that the divergence between the proportion of African Americans in the cancer patient population and the proportion of African American patients enrolled onto clinical therapeutic trials is substantially less than what would seem to be shortfall according to the standard NCI benchmark. However, a significant under-representation of African American cancer patients on clinical therapeutic trials still remained when using the proposed new benchmark, clearly confirming the need to improve minority recruitment to clinical trials. We attribute this difference to a variety of factors, including community and social dynamics, perceptions of cancer and of clinical trials, previous experiences with the health care system, inadequate recruitment strategies, insufficient outreach and education effort, and a higher proportion of African American cancer patients with comorbidities that exclude them from eligibility to available therapeutic trials (unpublished data).

The availability of a minority patient population must also be considered in relation to the availability of open clinical trials for which minorities can be recruited. Frequently, the availability of clinical trials is limited, slots are more quickly filled by a white/insured population, trials are designed to accrue patients diagnosed at earlier stages of cancer, or trials are focused on rare disease sites. Eligibility criteria should be evaluated for all active clinical trials to determine whether the minority patients being seen at the cancer centers meet trial eligibility criteria and, if not, why. It is hoped that the methodology used here will help to provide insights for future clinical trial development.

The rate of diagnosis of African American cancer patients at the facilities of UPMC and UPMC cancer centers was similar to the county as a whole, but this does not imply that minority outreach has reached performance goals. African American patients usually present with more advanced cancer at the time of diagnosis and more comorbidities than seen within white populations, which may lead to understatement of the current African American incidence rate. Disparities are also associated with lack of health insurance and ability to pay, leading to African Americans being at increased risk for financially

related barriers to care (unpublished data).⁵ Our analysis also highlighted the gap between the percentage of African Americans within the patient population potentially available for recruitment to a clinical trial and the percentage actually participating within a therapeutic trial.

Several initiatives have been developed at UPCI to address this situation within both academic and community treatment settings. These initiatives have included physician education, communication about clinical trial availability, and the development of community-based research capabilities. Community outreach programs have included implementation of patient navigator programs and increased community education and screening through neighborhood collaboration. Financial barriers are also being addressed through an intramural grant program to underwrite financial challenges for African Americans seeking treatment and advocacy for accessing all health insurance coverage opportunities.

Although this approach represents a significant improvement over the previous benchmarking strategy, it is not without limitations. Our data sources do not allow for comparison between the statewide general population, the cancer incidence recorded in the Pennsylvania Cancer Registry, and the cancer incidence in the UPMC Cancer Registry within the same time frame. The time difference between initial diagnoses, primary and subsequent therapy, and clinical trial participation may occur in the same calendar year or years later. For example, a patient with cancer is recorded by the Pennsylvania Cancer Registry based on date of initial diagnosis, whereas the same patient may present to a UPMC cancer center facility for initial diagnosis and/or primary treatment or present in future years for subsequent therapy, which may include recruitment to a clinical therapeutic trial. Evaluating this highly complex and dynamic cancer management environment, our analysis assumes that all cancer patients who are diagnosed will follow through with treatment for invasive cancer at UPCI-affiliated institutions.

There are also challenges related to the sensitivity of our data source to measure the rate of change in the percentage of African Americans on clinical trials in relation to county cancer incidence and to percentage of African American patients diagnosed within the health system. For example, the CTMA system can track an increase or decrease in patients within a relatively short time frame. However, because the current number of African Americans on trials is relatively small, year-to-year changes are subject to a high degree of statistical variability and are not necessarily indicative of the success of recruitment efforts. This will be particularly evident in relation to trends concerning specific diseases, where 3 to 5 years of data may be required to provide sufficient information.

Changes within population-based incidence statistics present the opposite challenge, being relatively insensitive to year-to-year changes. Additionally, geographic-specific incidence data include patients who were diagnosed (and possibly received treatment) at other facilities and could be much more reflective of market-wide trends than trends within the service area of the particular research program. Although this issue may be addressed by narrowly defining the service area to the level of census block or tract, the smaller population base could lead to higher variability within African American incidence rates. This is another reason why we suggest using our approach to benchmarking and the use of comparison groups.

This methodology should be readily applicable to analyses of participation of underserved minority cancer patients in clinical trials at other cancer research programs, using regional and institution-specific cancer registry data and the information from a center's clinical trial tracking application. If adopted by other cancer research programs, it will present a new opportunity for relevant program comparisons of minority recruitment and provide information on barriers to adequate access to clinical trials on a national basis.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

Conception and design: Keith H. Morgenlander, Sharon B. Winters, Chyongchiou J. Lin, Linda B. Robertson, Dwight E. Heron, Ronald B. Herberman

Administrative support: Sharon B. Winters, Linda B. Robertson, Ronald B. Herberman

Collection and assembly of data: Keith H. Morgenlander, Sharon B. Winters, Chyongchiou J. Lin

Data analysis and interpretation: Keith H. Morgenlander, Sharon B. Winters, Chyongchiou J. Lin, Linda B. Robertson, Dwight E. Heron, Ronald B. Herberman

Manuscript writing: Keith H. Morgenlander, Sharon B. Winters, Chyongchiou J. Lin, Linda B. Robertson, Dwight E. Heron, Ronald B. Herberman

Final approval of manuscript: Keith H. Morgenlander, Sharon B. Winters, Chyongchiou J. Lin, Linda B. Robertson, Dwight E. Heron, Ronald B. Herberman

REFERENCES

1. National Cancer Institute: Cancer health disparities. <http://www.cancer.gov/cancertopics/types/disparities>
2. Pennsylvania Department of Health: Epidemiologic Query and Mapping System. <http://app2.health.state.pa.us/epiqms/>

3. US Census Bureau: 2006 American Community Survey. <http://www.census.gov/acs/www/>
4. University of Pittsburgh Medical Center: UPMC Network Cancer Registry Database. <http://cancerregistrynetwork.upmc.com/>
5. Ford JG, Howerton MW, Bolen S, et al: Knowledge and access to information on recruit-

ment of underrepresented populations to clinical trials: Evidence Report/Technology Assessment No. 122. Rockville, MD, Agency for Healthcare Research and Quality, publication 05-E019-2, 2005

6. University of Pittsburgh Cancer Institute: Clinical Trials Management Application (CTMA). <http://www.upci.upmc.edu/trials/non.html>

Acknowledgment

The Acknowledgment is included in the full-text version of this article, available online at www.jco.org. It is not included in the PDF version (via Adobe® Reader®).