Title

Five National Cancer Institute—designated cancer centers' data collection on racial/ethnic minority participation in therapeutic trials

Journal

Cancer, 120(S7)

ISSN

1097-0142

Authors

Hawk, Ernest T

Habermann, Elizabeth B

Ford, Jean G

et al.

Publication Date

2014-04-01

DOI

10.1002/cncr.28571

Peer reviewed

Published in final edited form as:
Cancer. 2014 April 1; 120(0 7): 1113–1121. doi:10.1002/cncr.28571.

Five NCI-designated Cancer Centers' Data Collection on Racial/Ethnic Minority Participation in Therapeutic Trials – A Current View and Opportunities for Improvement

ET Hawk, MD, MPH,
MD Anderson Cancer Center

EB Habermann, PhD, MPH,
Mayo Clinic-Rochester

JG Ford, MD,
Weill Cornell School of Medicine

J Wenzel, RN, PhD,
Johns Hopkins University

JR Brahmer, MD,
Johns Hopkins University

MS Chen Jr., PhD, MPH,
University of California, Davis

LA Jones, PhD,
MD Anderson Cancer Center

TC Hurd, MD,
University of Texas, San Antonio

LM Rogers, MS,
University of Minnesota

LH Nguyen, MPH,
MD Anderson Cancer Center

JS Ahluwalia, MD, MPH,
University of Minnesota

M Fouad, MD, MPH, and
University of Alabama, Birmingham

SM Vickers, MD
University of Minnesota

Abstract

Corresponding author: SM Vickers, MD, Department of Surgery, 420 Delaware St SE, Minneapolis, MN 55455, 612-626-1999/Fax 612-626-0654.

Background—To insure that NIH-funded research is relevant to the population's needs, specific emphasis on proportional representation of minority/gender groups into National Cancer Institute's (NCI) cancer centers' clinical research programs is reported to the NCI.

Methods—EMPaCT investigators at five regionally-diverse comprehensive cancer centers compared data reported to the NCI for their most recent Cancer Center Support Grant (CCSG) competitive renewal to assess and compare the centers' catchment area designations, data definitions, data elements, collection processes, reporting, and performance regarding proportional representation of race/ethnicity and gender subsets.

Results—Cancer centers' catchment area definitions differed widely in terms of their cancer patient vs. general population specificity, levels of specificity, and geographic coverage. Racial/ethnic categories were similar, yet defined differently across institutions. Patients' socioeconomic status (SES) and insurance status were inconsistently captured across the five centers.

Conclusions/Recommendations—Catchment area definitions and the collection of patient-level demographic factors vary widely across the five comprehensive cancer centers. This challenged the assessment of success by cancer centers in accruing representative populations into the cancer research enterprise. . Accrual of minorities was less than desired for at least one racial/ethnic subcategory at four of the five centers. Institutions should clearly and consistently declare their primary catchment area and the rationale; and should report how race/ethnicity and gender are defined, determined, collected, and reported. More standardized, frequent, consistent collection, reporting, and review of these data are recommended, as is a commitment to collecting socioeconomic data, given that SES is a primary driver of cancer disparities in the U.S..

Keywords

Minority Enrollment; Clinical Trials; Health Disparities; Cancer Center Support Grant; Quantitative Data; Catchment Area; Data Definitions

Introduction

Recent Surveillance, Epidemiology and End Results[1] data highlight important disparities in cancer outcomes, including death rates, among racial/ethnic subsets of the American population.[2,3] For example, African Americans are more likely to die from all cancers compared to other racial/ethnic categories. This disparity is most pronounced for colon, breast and prostate cancers.[1,3,4] Causes of this differential death rate are multi-factorial involving socioeconomic, cultural, environmental, biological, behavioral, and genetic factors.[5–15] Efforts to reduce cancer disparities must be similarly broad, sustained, and impactful, but effective interventions begin with evidence detailing the distribution and impact of these causes across institutions, population subsets, and time.[16,10,17–18] Therefore, the collection and analysis of consistent, accurate, reliable, and adequately detailed data across time and cancer centers is critical.

The NCI Cancer Centers Program includes 67 designated cancer centers across the United States (27 cancer centers and 41 comprehensive cancer centers). A cancer center earns NCI cancer center designation following peer review which evaluates the breadth and depth of the center's scientific excellence in cancer research. Comprehensive cancer centers (n=41)

demonstrate a significant transdisciplinary accomplishment in each of three major scientific domains (lab, clinic, and population), as well as excellence in connecting with the needs of their community through outreach, service, education, and dissemination research activities.

Fig.1 highlights the populations relevant to the core functions of NCI-designated comprehensive cancer centers (NCI-CCC). A comprehensive cancer center's broadest reach is through cancer control activities which may involve policy initiatives, educational programs, and public services often focused on the poor, underserved, or difficult to reach. A center's next mission is to attract cancer patients from the community into its center to provide high-quality cancer care that meets or exceeds the community standard and to contribute to the discovery and translation of new knowledge. Specifically, clinical care is advanced by enrolling patients onto clinical trials which test new devices or interventions. This is a NCI-CCC's most important and unique role, but it is obviously dependent on their success in attracting these populations into the center.

To succeed in its cancer control mission, a center provides broad outreach, education, screening/prevention services, and undertakes policy initiatives that address the needs of the entire population in its sphere of influence. Clinical mission success requires a center to bring together exceptional clinical expertise with state-of-the-art imaging, pathologic, surgical, and medical technologies and resources that are competitive in the community's marketplace. To succeed in its scientific mission, a center must assemble highly-specialized research personnel, state-of-the-art research technologies, data and analytic infrastructures, IRB and regulatory capabilities, relationships with biotechnology and pharmaceutical suppliers, and a broad portfolio of funded research protocols well-matched to its population's specific needs. These elements are necessary, but insufficient for the success of an NCI-CCC, which must ensure that it attracts populations roughly representative of the gender and racial/ethnic distribution of their "catchment area." Specifically, NCI-CCCs are mandated to accrue women and minorities to interventional clinical trials – therapeutic and non-therapeutic – in rough proportion to the cancer patient population of the center's primary catchment area.[19] This criterion was made a part of the NCI's guidelines to comply with the NIH Revitalization Act of 1993 (Section 429B) and current NIH policies on minority/gender representation, and is intended to insure that NIH-funded research is relevant to the needs of the population.[20,21]

To address this issue, a center ideally defines its catchment area, or geographic region that it expects to influence through its programs, prospectively. Next, a center takes stock of the gender, racial/ethnic distribution of the cancer patient population within that region and strives to attract cancer patients of all genders and ethnicities/races into its center, at least in representative proportions to its catchment area (i.e., external representativeness or "street to center"). Finally, a successful center enrolls these patients into its interventional trials in roughly the same proportions (i.e., internal representativeness or "center to trials"). Ideally, these populations would be proportional in all regards, but given the unequal burden of cancer in minority populations, and past underperformance in attracting women and racial/ethnic minorities into clinical research, NIH places specific emphasis on proportional representation of these groups into NCI cancer centers' clinical research programs.

To monitor success, reports relating to a center's overall clinical patient population (drawn from its cancer patient registry), and its clinical trial participants are reported (i.e., Summary 3) annually and every five years as part of the Cancer Center Support Grant (CCSG) noncompetitive and competitive renewals, respectively, for the primary purpose of providing information to reviewers as to whether the center is offering therapeutic trials relevant to its patient base and enrolling patients onto those trials. [19] Although these data are routinely collected by all NCI-designated centers, they are not routinely publicly-available, or compared across centers to assess program-wide performance. However, through regular assessment of these data, a center's performance can be evaluated with regard to minorities' and women's proportional representation in each aspect of the center's programs. These data are critical to assess the center's success in meeting benchmark ratios for participation of minority and gender subsets in the center's programs cross-sectionally, across time, and in comparison to its own goals and performance of other centers. If deficiencies are identified, strategic solutions and actions may be identified to address specific needs and opportunities. In addition, these data are compared to data from the catchment area quinquennially as a part of the CCSG competitive renewal process. These evaluations are peer-based and may identify critical deficiencies requiring corrective actions prior to funding.

The central hypothesis underlying this brief descriptive survey was that NCI-designated cancer centers' catchment area designations, population demographic data definitions, collection processes, and reporting were heterogeneous, challenging accurate and reliable evaluations of center performance in accruing representative populations into clinical trials across time and institutions. As Lord Kelvin has been popularly quoted, "If you cannot measure it, you cannot improve it."

In this study, EMPaCT investigators collected and compared data reported to the NCI by five NCI-CCC of different sizes and types located in different areas of the country to assess and compare the centers' catchment area designations, data definitions, data elements, collection processes, reporting, and performance regarding proportional representation by race/ethnicity and gender in each center's patient populations and clinical trials programs, comparing them to proportions of cancer patients in their respective catchment areas. These data are critical elements of NCI's efforts to lay a data-driven foundation that can be used to improve data collection, reporting, monitoring, and review processes in an attempt to improve minority and women's entry into NCI-CCC, as well as enrollment and retention into clinical trials. EMPaCT investigators' goals were to answer three fundamental questions: 1) is reporting regarding recruitment of minorities and women into cancer centers and onto clinical trials standardized, accurate, and reliable? 2) are improvements advisable? 3) if so, which are most critically needed?

Methods

EMPaCT sites were chosen to broadly represent the NCI-CCC enterprise based on the centers' type (i.e., public or private; matrix-based or free-standing), size (i.e., number of scientific research programs) and geographic location in the United States, as reflected in Table 1. EMPaCT investigators collected data from each of the five NCI-CCCs to describe the recent status of clinical trial enrollment across racial/ethnic categories relative to the

racial/ethnic distribution of their self-declared “catchment areas,” their state’s general population, and their state’s cancer patient population. For this report, quantitative data are defined as numerical data reported to the NCI on the “Summary 3 Forms” as part of the quinquennial CCSG renewal process. From June -December, 2010, each EMPaCT-affiliated center provided the documentation submitted to the NCI for its most recent CCSG competitive renewal, including text and tables from the required section, “Inclusion of Women and Minorities”. In addition, each center was asked to provide the most recent version of the annual “Summary 3 Form”. Finally, information was gathered from each center on its approach to defining their self-declared primary catchment area; patient-level demographic data definitions such as the age, gender, minority status of patients; the methods of data collection; as well as the extent to which accrual could be characterized across subdivisions of the catchment area (e.g., at the zip code level). Routinely collected additional data elements (e.g., socioeconomic status, insurance status) were also captured.

Qualitatively based on self-reported surveys, EMPaCT investigators evaluated similarities and differences in data definitions, and collection processes across centers to identify opportunities for standardization of data definitions, collection and reporting procedures. Finally, suggestions to improve the process of reporting minority participation in therapeutic and non-therapeutic cancer clinical trials were discussed.

Results

A total of 8,652 encounters by all racial/ethnic groups (less than 0.6% of all center cancer diagnoses in 2010) participated in therapeutic cancer clinical trials across the five cancer centers, ranging from 290 enrollees at the smallest center to 6,524 enrollees at the largest (Table 2). The proportion of white participants ranged from 73.1–86.8%, Black or African American participants from 4.6–22.7%, Hispanic or Latino participants from 0.3–10.8%, and Asian participants from 0.2–6.2% (Table 2). Overall, proportionate accrual of minorities vs. whites to therapeutic trials exceeded goals at center #2, was roughly equivalent to goals at centers #4 and 5 (although center #4 failed to achieve goals for Hispanics and blacks, and center #5 failed to achieve goals for Hispanics and Asians), and minority accrual was several percentage points less than desired for centers #1 and 3. Partially counterbalancing the apparent under-representation of ethnic/minority subgroup accruals to therapeutic trials and causing some dilemma regarding each institution’s performance in achieving targeted goals, was the 2.8% to 13.8% representation of “other” or “unknown” trial participants across centers. It is important to note that the data in Table 2 categorizes the Cancer Center trial accrual relative to the populations of its self-determined catchment area, the states’ cancer patient population, and the states’ general population.

Summary 3 Forms

Summary 3 Forms provide two pieces of information about each disease site: The number of patients (A) newly registered and (B) newly enrolled in therapeutic protocols. These forms were standardized across institutions. Race and ethnicity are not required elements on this annual form, but one institution additionally reported the percent of minority accrual on therapeutic clinical trials.

Reports on the Inclusion of Women and Minorities

At the five-year competitive CCSG renewal, clinical and comprehensive cancer centers must report their efforts to include women and minorities in clinical research with supporting data and documentation. A typical reporting format includes responses to reviewers' feedback at the last competitive renewal, the center's philosophical approach to the issue, ongoing efforts in the community and within the institution, and data on clinical trial participation. While NCI does offer general guidelines based on its guiding principles for the participation of minorities and women to clinical trials, it leaves the specificity of how and which information is reported to the cancer centers' discretion.

Gender was similarly defined and collected across all five cancer centers (Table 3). Additionally, three institutions reported minority accrual by gender. Racial/ethnic categories were generally similar across institutions (e.g., White, Black/African American, Asian, Native American, Hispanic or Latino, and "other/unknown"), except one center inexplicably captured patients' Hispanic background as a racial, rather than an ethnic, variable. Yet the means of race/ethnicity data collection differed across institutions; each institution collected self-reported data on race/ethnicity, but two centers included data from staff observations. Two institutions compared the proportions of racial/ethnic groups enrolled in clinical trials to those of their catchment area(s) while the others did not, leaving it to reviewers and/or NCI staff to make such comparisons.

Catchment Areas

The NCI allows flexibility in how a cancer center defines its primary catchment area and is currently unable to assess or enforce consistency across time. Because the racial/ethnic and gender proportions of cancer patients within the catchment area serve as the primary elements of comparison, this is a crucial issue. Consequently, some centers consider the entire state its catchment area, while others use a smaller geographic focus, such as the counties surrounding the center.

Cancer centers' catchment area definitions differed widely in terms of their cancer patient vs. general population specificity (e.g., 3 centers referred to cancer patient populations; 2 centers focused on general populations), levels of specificity (e.g., 3 centers referred to multiple population level comparators; 2 centers focused on a single population level), and geographic coverage (2 centers included the nation; 4 centers included their home state; 1 center included a regional area; 1 center included a region defined by market share). One cancer center defined its catchment area as the county with the largest number of residents coming to the center, essentially describing its accrued population, rather than establishing an *a priori* goal or a true population to be served by the center, making assessments of service to the catchment area "successful" by definition. Importantly, the rationale underlying a center's decision for its catchment area is rarely provided, therefore impossible to evaluate with regard to appropriateness, or to its consistency across time.

Varying collection of patient-level factors

The five EMPaCT centers varied widely in patient-level data definitions (beyond gender and race/ethnicity reported above), data collection methods, and patient-level factors collected

and reported (Table 3). Age was collected specifically at 3 centers, but only as a date of birth at another center allowing for the subsequent calculation of age. At the fifth center, age was collected as a binomial variable categorized as 18 years and over versus less than 18 years (that is, as adult vs minor). Patients' geographic homes were routinely collected by all centers, typically though home zip codes, though one center restricted researchers' access to this information. Patients' socioeconomic status (SES) was not documented in any center. Patients' insurance status was routinely documented in two centers, collected for non-research patients only in another center, collected for billing of researcher enrollees in another center, and not documented at all in another center.

Discussion

The National Institute on Minority Health and Health Disparities (NIMHD) and NCI are committed to documenting and reporting information that would improve the recruitment and retention of minorities to clinical trials, as outlined in the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research-Amended, October, 2001.[20] This is currently demonstrated by NCI-CCC grant requirements and the reasonably held standard that NCI-CCCs must reach a relevant target for accrual of minorities in therapeutic and non-therapeutic clinical interventional trials. Since the initiation of this study, additional reporting on representative participation in non-interventional trials has been adopted via the 2013 Guidelines for CCSGs.[22] The relevant targets, which should reflect *the percentage of the minority cancer patient population within each center's catchment area*, provide a reasonable goal as surrogates for service delivery and discovery of new knowledge that accurately reflect the diversity of the U.S. population. However, this goal is commonly misunderstood or misinterpreted as the center's trial population must be proportionally representative either of the *center's* cancer patient population, or of the *general population* of the catchment area. Table 2 demonstrates the wide possible variations in the minority representation of a center's catchment area, its state's general population, and its state's cancer patient population. Indeed, the racial/ethnic distribution of cancer patients is often very different than that of the general population. [2,4] For example, a state's Hispanic population is often younger than the general population; therefore the ethnic representation within the cancer patient population is quite different than in the general population.[23] In addition, the needs for these populations might be quite different from the majority population based on age, socioeconomic status, educational attainment, etc. Recognition of this issue provides a great opportunity to build a more relevant, accurate, and standardized process for quantifying our current efforts and progress in minority accrual.

Drawing on the data from this study and the experiences of our institutions, we recommend greater standardization of data definitions, collection, and reporting processes as components of NCI's CCSG renewals. Each institution should report how race, gender, and race/ethnicity are defined, determined, collected, and reported. It is important to know whether these factors are determined by the patient (preferred), by the provider, or by another method. Second, it is important for an institution to clearly and consistently declare its primary catchment area and the rationale for its catchment area choice. Admittedly, given the heterogeneity of the cancer centers and their target populations, it may be challenging to

achieve a standard approach to catchment area definition (e.g., cancer cases in the state population), but greater clarity would be helpful, and consistency across time should be evaluated in peer review to evaluate accrual performance vs. *a priori* catchment area needs/goals, rather than permitting catchment area re-definitions based on accrual performance. Third, based on our experience, it would be important to reinforce the goal of NCI's minority/gender accrual requirements – to accrue to interventional trials in proportion to the minority/gender distribution of the cancer patient population of the center's self-declared catchment area, not the center's clinical population or the general population of the state or city. Fourth, we believe that more frequent and consistent collection, reporting, and review of the data (e.g., every 2–3 years) would help to reinforce the importance of the goal.

Given the rapid and substantial changes in the American population with regard to several key factors strongly related to cancer incidence and mortality beyond racial/ethnic distribution, including age, socioeconomic status, insurance status, and geographic proximity, we feel that the collection and reporting of clinical trial data could be enhanced if it is thought of in a dynamic, rather than a static, sense.[1,2,24] For example, to improve upon the data currently collected for CCSG renewal, the collection of additional measures could be most helpful. However, to weigh whether additional collections are worth the additional effort, they should be prioritized as: 1) valuable in assessing the current or emerging state of proportionate enrollment to clinical trials and associated barriers; 2) feasible to collect across a variety of NCI-designated cancer centers; and 3) provide reasonable feedback and opportunity to improve the process of collection of data and the recruitment and retention of disparate populations to clinical trials. That said, we believe the following variables should be considered for collection to properly prepare NCI-designated centers for future challenges.

Starting with the 2013 guidelines each cancer center describes in detail how the primary catchment area was selected.[22] We believe this to be an important advance. In addition to the racial/ethnic composition of the catchment area, it is suggested that the gender (including consideration of lesbian, gay, bisexual, and trans-sexual designations) and age distributions are reported. Second, socioeconomic status (SES) variables are rarely, if ever, collected, yet there are compelling data suggesting that SES and cancer outcomes are strongly related. SES-associated variables that may be valuable include a patient's income level, educational attainment, preferred language/language abilities, health literacy, and proportion of life spent living in the United States. Further, it is suggested that cancer centers collect patient zip code and patient insurance status. With these variables available it would be possible to assess differences in access to trials by geography (e.g., are frontier, rural, suburban, and urban populations appropriately represented?) and insurance coverage. We especially think it is important to study the effect of insurance status on enrollment in trials as health care reform proceeds. Finally, the collection of cancer site distribution in the catchment area, by race/ethnicity, would provide an important point of comparison for the cancer site distribution of patients enrolled in a cancer center's clinical trials, suggesting additional opportunities to address disparities. For example, if a center's catchment area has a large African-American population of patients with prostate cancer or myeloma, it could prioritize

the development of trials focused on these patients, as well as education, screening and prevention initiatives in the community.

There are ongoing efforts to provide qualitative data (including the EMPaCT study) to guide in the selection of credible points of intervention and themes to address barriers that affect recruitment of minorities to clinical trials. In order to most effectively document our progress, evaluate, and build upon this initiative, we believe the limited but substantive proposal of how comprehensive cancer centers can more accurately document current efforts and be able to capture future gains will be credited in reducing our current disparities in minority clinical trial accrual.

Conclusions

The impact of this proposal will be best determined through Institutional Review Board (IRB) processes that will help document the overall feasibility of improvement to the current system of data collection. The EMPaCT program is the first consortium of U.S. NCI-designated cancer centers from across the United States working together to evaluate and improve the participation of racial and ethnic minorities in cancer clinical trials. Data provided by these five, broadly-representative centers highlight opportunities and challenges for data standardization and future data collection so that enrollment and retention of minorities in trials can be measured, shortfalls identified, interventions applied, and participation improved. We believe that current U.S. census demographic definitions and collection methods (i.e., self-report for most measures) represent reasonable standards for adoption across NCI-designated cancer centers. This is not only important for each individual center, but for the NCI's Cancer Centers Program as a whole, as the information may help to prioritize centers and whether they are adequately aligned with the needs of established or emerging trends in their catchment areas' populations. To reduce and eliminate disparities in cancer outcomes, the NCI's center-based research enterprise must be continually re-assessed and progressively re-aligned to meet the most compelling needs of our population.

Acknowledgments

Funding: EMPaCT I, 5RC2MD04797; EMPaCT II, U24MD006970; MD Anderson CCSG, 5P30CA016672-37

Bibliography

1. Jemal A, Clegg LX, Ward E, et al. Annual report to the nation on the status of cancer, 1975–2001, with a special feature regarding survival. Cancer. 2004 Jul; 101(1):3–27. [PubMed: 15221985]
2. Howlander, N.; Noone, AM.; Krapcho, M., et al., editors. SEER Cancer Statistics Review, 1975–2009 (Vintage 2009 Populations). Bethesda, MA: National Cancer Institute; 2012. http://seer.cancer.gov/csr/1975_2009_pops09/.
3. Surveillance Epidemiology and End Results. US and SEER Death Rates:Table 1.20 (2004 – 2008). 2011. http://seer.cancer.gov/csr/1975_2008/results_single/sect_01_table.20_2pgs.pdf.
4. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. JAMA. 2004 Jun; 291(22):2720–2726. [PubMed: 15187053]
5. National Institutes of Health Office of Intramural Research. National Institutes of Health President's Cancer Panel-Annual Reports America's Demographic and Cultural Transformation:implications

for Cancer. 2010. http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp/annualreports/pcp09-10rpt/pcp09-10rpt.pdf.

6. AHRQ. Disparities in Health Care Quality Among Racial and Ethnic Minority Groups. Washington, DC: Agency for Healthcare Research and Quality; 2011.
7. Kogevinas M, Porta M. Socioeconomic differences in cancer survival: a review of the evidence. IARC Sci Publ. 1997; (138):177–206. [PubMed: 9353665]
8. Dovidio, JF.; Brigham, JC.; Johnson, BT.; Gaertner, SL. Stereotypes and Stereotyping. New York: Guilford; 1996. Stereotyping, prejudice and discrimination:Another look; p. 276-319.
9. House, JS.; Williams, DR. Promoting Health: Intervention Strategies from Social and Behavioral Research. Vol. 81. Washington, DC: National Academy Press; 2000. Understanding and reducing socioeconomic and racial/ethnic disparities in health.
10. Blumenthal DS, Sung J, Coates R, Williams J, Liff J. Recruitment and retention of subjects for a longitudinal cancer prevention study in an inner-city black community. Health Serv Res. 1995 Apr; 30(1 Pt 2):197–205. [PubMed: 7721592]
11. LaVeist TA, Nickerson KJ, Bowie JV. Attitudes about racism, medical mistrust, and satisfaction with care among African American and white cardiac patients. Med Care Res Rev. 2000; 57(Suppl 1):146–161. [PubMed: 11092161]
12. LaVeist TA. On the study of race, racism, and health: a shift from description to explanation. Int J Health Serv. 2000; 30(1):217–219. [PubMed: 10707307]
13. Mayberry RM, Mili F, Ofili E. Racial and ethnic differences in access to medical care. Med Care Res Rev. 2000; 57(Suppl 1):108–145. [PubMed: 11092160]
14. Phillips KA, Mayer ML, Aday LA. Barriers to care among racial/ethnic groups under managed care. Health Aff (Millwood). 2000 Jul-Aug;19(4):65–75. 2000. [PubMed: 10916961]
15. Wenneker MB, Epstein AM. Racial inequalities in the use of procedures for patients with ischemic heart disease in Massachusetts. JAMA. 1989 Jan; 261(2):253–257. [PubMed: 2521191]
16. Swanson GM, Ward AJ. Recruiting minorities into clinical trials: toward a participant-friendly system. J Natl Cancer Inst. 1995 Dec; 87(23):1747–1759. [PubMed: 7473831]
17. Eng E. The Save our Sisters Project. A social network strategy for reaching rural black women. Cancer. 1993 Aug; 72(3 Suppl):1071–1077. [PubMed: 8334660]
18. Fouad MN, Partridge E, Dignan M, et al. A community-driven action plan to eliminate breast and cervical cancer disparity: successes and limitations. J Cancer Educ. 2006; 21(1 Suppl):S91–100. [PubMed: 17020510]
19. National Institutes of Health National Cancer Institute. Policies and Guidelines Related to the Cancer Center Support Grant. 2010. http://grants.nih.gov/grants/guide/pa-files/PAR-11-005.html.
20. National Institutes of Health Office of Intramural Research. Inclusion of Women and Minorities as Participants in Research. 2001. http://grants.nih.gov/grants/funding/women_min/women_min.htm.
21. National Institutes of Health Office of Intramural Research. NIH Policy on Reporting Race and Ethnicity DAta:Subjects in Clinical Research. 2001. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-0153.html.
22. National Institutes of Health NCI. Policies and Guidelines Relating to P30 Cancer Center Support Grant. 2012. http://cancercenters.cancer.gov/documents/CCSG_Guidelines.pdf.
23. U.S. Census Bureau Population Division. Population by Race or Hispanic or Latino Origin, for the United States, Regions, Divisions and States, and for Puerto Rico: 2000. 1 ed. Washington, DC: U.S. Census Bureau, Population Division; 2001:U.S. Census Bureau, Census 2000 Redistricting Data (P.L. 2094-2171) Summary File for states and Census 2000 Redistricting Summary File for Puerto Rico.
24. Sateren WB, Trimble EL, Abrams J, et al. How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. J Clin Oncol. 2002 Apr; 20(8):2109–2117. [PubMed: 11956272]

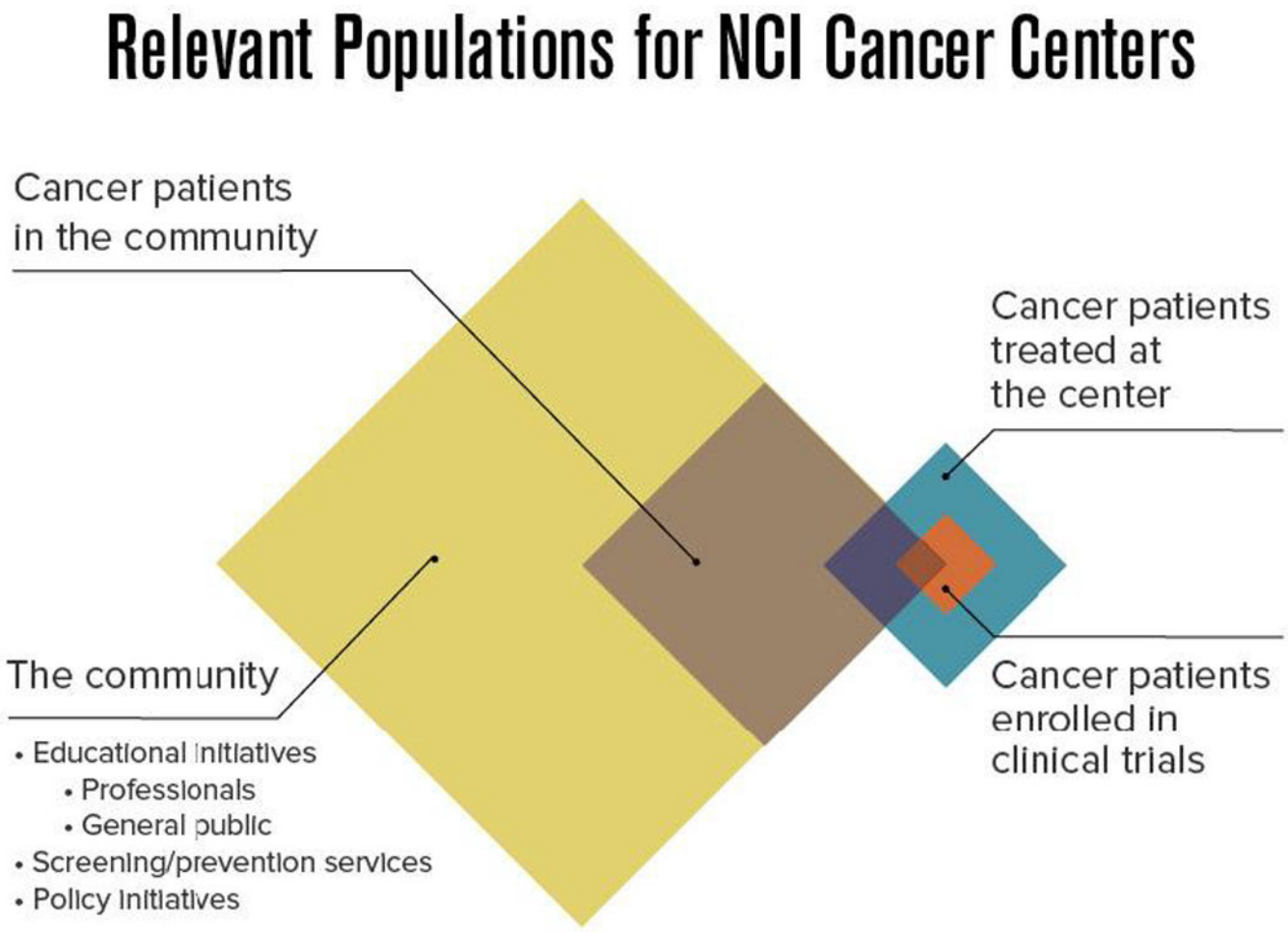

Figure 1.
Populations relevant to a NCI-designated cancer center

Table 1

Characteristics of the Five Participating EMPaCT Sites

	Cancer Center Type	Number of Research Programs	Geographic Representation
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University	Private, matrix-based	11	East
University of Alabama Birmingham Comprehensive Cancer Center	Public, matrix-based	7	Southeast
University of California, Davis Comprehensive Cancer Center	Public, matrix-based	6	West
Masonic Cancer Center at the University of Minnesota	Public, matrix-based	6	Northern Midwest
University of Texas MD Anderson Cancer Center	Public, free-standing	19	Southwest

Cancer. Author manuscript; available in PMC 2015 April 01.

Table 2

Minority Enrollment in Therapeutic Trials, by Institution, Compared to State Populations (n=8,652)

			Ethnicity (%)			Race(%)							
			Hispanic or Latino	**Not Hispanic or Latino**	**Unknown**	**Am. Indian**	**Asian**	**Native Hawaiian / Pacific Islander**	**Black or African American**	**White**	**More than one race**	**Other**	**Unknown**
Cancer Center	One	Cancer Center	10.8[a]	89.2	nr	0.1[c]	0.2[d]	nr	7.1	79.0	nr	13.6	0.2
		Catch. Area	18.4	81.1	nr	nr	nr	nr	10.8	67.3	nr	3.0	nr
		State general pop'n*	36.9	63.1	nr	0.8	0.8	0.1	12.0	82.1	1.4	nr	nr
		State cancer cases**	18.4	81.1	nr	nr	nr	nr	10.8	67.3	nr	3.0	nr
	Two	Cancer Center	0.3	99.7	nr	0.0	1.1	nr	22.7	73.1	nr	nr	3.1
		Catch. Area	0.7	99.3	nr	0.2	0.5	nr	20.3	78.3	nr	nr	nr
		State's general pop'n*	2.7	97.3	nr	0.5	1.0	nr	26.2	70.4	nr	nr	nr
		State's cancer cases**	0.7	99.3	nr	nr	nr	nr	20.6	77.9	nr	1.5	nr
	Three	Cancer Center	6.6	89.7	3.8	0.0[c]	6.2	1.4	6.2	83.4	0.0	nr	2.8
		Catch. Area	9.6	85.0	2.7	0.5	7.3[d]	nr	6.2	73.7	nr	nr	2.7
		State's general pop'n*	37.0	63.0	nr	nr	nr	nr	6.3	41.3	nr	2.6	nr
		State's cancer cases**	16.0	84.0	nr	nr	nr	nr	6.4	82.1	nr	11.5	nr
	Four	Cancer Center	1.3[b]	98.7[b]	nr	nr	nr	nr	14.3	80.5	nr	5.2	nr

			Ethnicity (%)			Race(%)							
			Hispanic or Latino	**Not Hispanic or Latino**	**Unknown**	**Am. Indian**	**Asian**	**Native Hawaiian / Pacific Islander**	**Black or African American**	**White**	**More than one race**	**Other**	**Unknown**
		Catch. Area	nr	nr	nr	nr	nr	nr	16.33	80.4	nr	3.2	nr
		State's general pop'n*	7.2	92.8	nr	0.4	5.2	0.1	29.7	63.0	1.7	nr	nr
		State's cancer cases**	2.0	98.0	nr	nr	nr	nr	22.9*	73.1	nr	4.0	nr
	Five	Cancer Center	2.2	93.5	4.3	1.0[c]	2.1	0.2	4.6	86.8	nr	nr	5.3
		Catch. Area	3.8	95.9	nr	1.2	3.5	0.1	4.5	89.3	1.5	nr	nr
		State's general pop'n*	3.8	95.9	nr	1.2	3.5	0.1	4.5	89.3	1.5	nr	nr
		State's cancer cases**	1.0	99.0	nr	nr	nr	nr	2.0	94.2	nr	3.7	nr

*population demographic information

**Distribution of Cancer Cases 2003–2007 North American Association of Cancer Registries “Cancer in North America” 2009

[a]Hispanic/Latino counted as racial data, not ethnicity per se

[b]Includes non-therapeutic trials

[c]Includes Alaskan native

[d]Includes native Hawaiian, other islander

nr= not reported by Cancer Center

Cancer Center = Cancer Center Therapeutic Trials Enrollment

Catch. Area = Center’s self-declared Catchment Area

- Center #1=state cancer registry
- Center #2=state cancer registry

- Center #3=13 adjacent counties or state
- Center #4=counties adjacent to city-see table 2 for exact method
- Center #5=state, but not CX cases

Table 3

Measures Collected by Each of the Five EMPaCT Cancer Centers

	Cancer Center				
	One	**Two**	**Three**	**Four**	**Five**
Catchment Area	The national population as well as the institutions state cancer cases are both reported.	The national state cancer cases.	Populations from the United States, state, and a 13-county region/registry area surrounding the institution are reported.	Counties that contributed to the geographically nearest 75% or the highest 75% market share of count cases.	The institution's state population.
Newly Registered Patients	Patients initially registered at the cancer center during the reporting period with a reportable cancer (ICD-O codes ending in 2 or 3, excluding superficial skin cancers).	Patients who come to the institution and receive a definitive diagnosis and receive a specific treatment.	N/A (No Summary 3 form).	Cases from the tumor registry who are diagnosed and/or receive all or part of their first course of treatment at the institution.	A patient seen for the first time at one of two hospitals affiliated with the institution.
Age	Specific age is documented.	Specific age is documented for those evaluated or treated.	Age is documented.	Date of birth is collected when a patient is enrolled in a study.	Only age at/over vs. under 18 is documented.
Gender	Male or female documented.	Male or female documented.	Male or female documented.	Male or female documented.	Male or female documented.
Race/ethnicity	Self-reported; if unreported, the patient's records are searched.		Self-reported by the patient or observed and then recorded by the staff.	TBD	Self-reported by the patient; if unreported the patient's records are searched.
Socioeconomic Status or Other Measures of Poverty	Not documented.	Not documented.	Not documented.	Not documented.	Not documented.
Insurance Status	Documented.	Documented.	Not documented for research patients; collected for all other patients.	Tracked by the institution for those patients enrolled in studies where there is research billing (mostly therapeutic).	Not documented.
Geographic Region	Zip codes are documented.	Zip code and county are documented.	Zip code and county are documented.	Zip codes are documented.	Zip codes are documented but not easily available to researchers.