Published in final edited form as:
J Health Care Poor Underserved. 2009 May ; 20(2 0): 120–134.

Analysis of Maryland Cancer Patient Participation in NCI Supported Cancer Treatment Clinical Trials

Claudia R. Baquet, MD, MPH[1], **Gary L. Ellison, PhD, MPH**[2], and **Shiraz I. Mishra, MBBS, PhD**[3]

[1]Department of Internal Medicine, Office of Policy and Planning, the University of Maryland Comprehensive Center for Health Disparities Research, Outreach, and Training, University of Maryland School of Medicine, Baltimore, MD

[2]Department of Family and Community Medicine, Center for Health Policy/Health Services Research, Office of Policy and Planning, University of Maryland School of Medicine, Baltimore, MD

[3]Department of Family and Community Medicine, Office of Policy and Planning, the University of Maryland Comprehensive Center for Health Disparities Research, Outreach, and Training, University of Maryland School of Medicine, Baltimore, MD

Abstract

Purpose—We examined the relationship of sociodemographic factors, urban/rural residence, and countylevel socioeconomic factors on accrual of Maryland patients with cancer to National Cancer Institute (NCI)-sponsored cancer treatment clinical trials.

Patients and Methods—Data were analyzed for the period 1999 to 2002 for 2,240 Maryland patients with cancer accrued onto NCI-sponsored treatment trials. The extent to which Maryland patients with cancer and patients residing in lower socioeconomic and/or rural areas were accrued to cancer trials and were representative of all patients with cancer in Maryland was determined. Data were obtained from several sources, including NCI's Cancer Therapy Evaluation Program for Maryland patients with cancer in Cooperative Group therapeutic trials, Maryland Cancer Registry data on cancer incidence, and United States Census and the Department of Agriculture.

Results—For Maryland patients with cancer accrued onto NCI-sponsored treatment trials between 1999 and 2002, subgroups accrued at a higher rate included pediatric and adolescent age groups, white patients, female patients (for sex-specific tumors), patients with private health insurance, and patients residing in the Maryland National Capitol region. Moreover, between 1999 and 2002, there was an estimated annual decline (8.9% per year; $P < .05$) in the percentage of black patients accrued onto cancer treatment trials. Logistic regression models uncovered different patterns of accrual for female patients and male patients on county-level socioeconomic factors.

Conclusion—Results highlight disparities in the accrual of Maryland patients with cancer onto NCI-sponsored treatment trials based on patient age, race/ethnicity, geography of residence, and county-level socioeconomic factors. Findings provide the basis for development of innovative tailored and targeted educational efforts to improve trial accrual, particularly for the underserved.

Address correspondence and reprint requests to: Claudia R. Baquet, MD, MPH, University of Maryland School of Medicine, 685 West Baltimore Street, Suite 618, Baltimore, MD 21201. Tel: (410) 706-1742. Fax: (410) 706-6150. cbaquet@som.umaryland.edu.

Where/When Study Presented: Not applicable

Disclaimers: Not applicable

Keywords

cancer; clinical trials; participation; accrual; socio-demographic; minorities; urban/rural; disparities; women's health; men's health

INTRODUCTION

Factors contributing to cancer disparities are numerous and complex, including lower participation of racial/ethnic minority and underserved patients in clinical trials[1-4]. Assuring diversity in clinical trials is essential to eliminating health disparities, as lower participation of racial/ethnic minority and underserved patients reduces the generalizability of therapeutic and drug development trials to these groups, thus impeding treatment and survival advances.

Clinical trials have produced prevention, treatment and outcome advances, and nowhere has this been more evident than for cancer treatment trials[3,5]. While trials are proven to contribute to cancer therapy and prevention advances, clinical trial participation for the general cancer patient population is low (5-9%)[3,5]. Despite federal legislation and regulatory efforts to improve accrual[6], African Americans, rural, and underserved cancer patients continue to participate in cancer trials at even lower rates than the general population[1,2,4,7-10].

Some contributing factors remain unclear, yet modifiable factors do contribute to disparities in clinical research and trial participation[2-5,7,8,10-17]. Factors include: lack of awareness of available trials by community physicians and patients; lack of community awareness of the role and potential benefits of research participation; historical concerns, including Tuskegee and more recent exploitive research; distrust of academic institutions; poor researcher communication skills; lack of cultural competence of research personnel; modifiable design barriers, including rigid and exclusionary eligibility criteria; and reimbursement for trial associated costs. Although an extensive community cancer trial infrastructure exists in the National Cancer Institute's (NCI) Community Clinical Oncology program (CCOP) and Minority Based (MB)-CCOP, not all community oncology practices are eligible for inclusion due to small accrual and other factors. This includes the single oncologist practice that is part of the Maryland Best Practice[18].

In Maryland, we have implemented data-driven, targeted community-based participatory programs to enhance accrual to trials. The University of Maryland School of Medicine (UMSOM) has an intensive, multi-level program to increase cancer trial accrual and availability in minority and rural underserved communities. Eastern Shore Cancer Research Network, a single community oncologist practice located on the Eastern Shore of Maryland, and UMSOM shared a National Best Practice award from the Secretary of the Department of Health and Human Services Committee on Science and Policy in September 2004[18]. An earlier Maryland study reported that 11.1% of Marylanders reported being recruited to clinical trials; of those, 59.4% actually participated[4].

This study characterizes participation of Maryland cancer patients in NCI-sponsored therapeutic trials for the period 1999-2002 by key demographic, racial/ethnic, geography of residence (rural/urban), and county-level socioeconomic factors. The extent to which Maryland cancer patients accrued onto NCI-sponsored treatment trials were representative of all Maryland cancer patients was also examined.

PATIENTS AND METHODS

Maryland Patients With Cancer

Maryland geographic and demographic cancer burden was determined using cancer incidence data from the population-based Maryland Cancer Registry (MCR) for all newly diagnosed cancer patients from 1999 to 2002. Data were obtained on primary cancer site, 10-year age group, race (white, black, other), gender, and jurisdiction of residence at diagnosis. Maryland jurisdictions, consisting of 23 counties and Baltimore City, were used for geographic analyses.

Cancer Treatment Clinical Trial Patients

We received summary data submitted to the Cancer Therapy Evaluation Program (CTEP) by NCI-sponsored Clinical Trials Cooperative Groups (CTCG) on therapeutic cancer trial accrual in Maryland from 1999 to 2002. CTCGs include researchers, cancer centers, and community physicians throughout North America and Europe. Data did not include information from non-CTCG sponsored trials, such as investigator-initiated or industry sponsored trials. This CTCG dataset limits our ability to determine whether Maryland cancer patients participating in NCI-sponsored CTCG clinical treatment trials are representative of all Maryland cancer patients participating in clinical trials.

For each patient, data included zip code of residence, 10-year age group, gender, race/ethnicity, and payment method (private insurance, Medicare or Medicaid, military, or self-pay). In addition, patients were assigned to a specific jurisdiction based on zip code data from the Maryland Department of Planning[19]. Data have been analyzed by zip code of residence; thus, data on Maryland cancer patients treated in Maryland and non-Maryland based institutions are included in the analyses.

County Level Socioeconomic and Demographic Data

County-level socioeconomic and demographic characteristics data were derived for Maryland jurisdictions from the 2000 US Census[20]. Jurisdiction-level variables included material deprivation measures (percentage of persons living in poverty, households without a car, unemployed persons age 16 and older, and owner-unoccupied housing), social class measures (percentage of high school graduates age 25 and older, persons with graduate/professional degrees, persons employed in white collar jobs, and median household income), and population composition (percentage of white, black, and Hispanic). Standardized composite measures[21] were created for material deprivation and social class to address multicollinearity among individual variables comprising these measures. Each composite measure had high reliability (Cronbach's alpha=0.94 for each measure).

Two methods were used to examine urban/rural composition of Maryland jurisdictions. The Beale classification system[22] classified counties as: 1) metropolitan area with ≥1 million population, 2) metropolitan area of <250,000 population, and 3) non-metropolitan area with urban population of ≥2,500 and adjacent to a metropolitan area. Estimates were based on the county's population and its proximity to metropolitan areas[23]. The US Census Bureau's classification of percentage of persons residing in rural areas helped to categorize rural percentage into quartiles based on the Maryland county distribution of rural percentage.

Healthcare System Level Variables

Healthcare system level variables included availability of oncologists in a county per number of cancer patients and availability of an American College of Surgeons Commission on Cancer-approved cancer program hospital[24].

Analysis

χ^2 statistics were used to compare accrual of Maryland cancer patients onto NCI-sponsored treatment trials for 1999 to 2002 by age groups, gender, and race/ethnicity. In addition, observed versus expected accrual onto treatment trials in Maryland for 1999 to 2002 was compared, with the assumption that each incident cancer patient had equal probability of participating in NCI-sponsored treatment trials. This assumption is consistent with a previous report by Sateren et al.[3] For each Maryland recognized region and jurisdiction, expected number of cancer patients accrued onto treatment trials was calculated by weighting the age-specific proportion of cancer patients who participated to the number of cancer patients within each county and age group.

Accrual onto NCI-sponsored treatment trials was also examined by several county-level socioeconomic and demographic variables. We estimated odds ratios (OR) and 95% confidence intervals (95% CI) using logistic regression and used generalized estimating equations (GEE) to account for clustering of individuals within county[25] Accrual onto treatment trials was modeled as a function of county-level socioeconomic and demographic factors and health system-level characteristics of Maryland counties. Each demographic variable was categorized into quartiles. Continuous socioeconomic, demographic or health system level variables were placed in logistic regression models to assess linear trends. Statistically significant estimates from Wald chi-square statistics (p-values<0.05) indicate an increase or decrease in the rate of treatment trial accrual with an increase in one unit of the continuous variable. Analyses were conducted for the total sample and by sex. Sex-specific models were adjusted for age distribution of Maryland patients with cancer and racial and rural composition of the county. All analyses were completed using SAS software version 9.1 (SAS Institute, cary, NC)[26].

RESULTS

For 1999 to 2002, 2,240 Maryland patients with cancer were accrued onto NCI-sponsored treatment trials, representing an average accrual rate of 2.3% (data not shown). The percentage of Maryland patients with cancer accrued onto treatment trials increased from 1.9% in 1999 to 2.9% in 2002 (χ^2_{trend}=86.4; df=1; p<0.0001).

Accrual by Age Group

Pediatric (0 to 9 years) and adolescent (10 to 19 years) cancer patients represented 13.8% of treatment trial patients (Table 1). Overall, 37.9% of Maryland pediatric and adolescent incident cancer patients were accrued onto treatment trials.

Accrual by Gender and Cancer Site

Males (31.4%) and females (30.0%) were almost identical with regard to Maryland's cancer burden percentage for non-sex-specific cancer sites (Table 2). For these cancer sites, males were significantly more likely than females (46.8% vs. 21.8%; p<0.0001) to be on treatment trials. However, for sex-specific tumors, the Maryland cancer burden for males was 32.3%, but only 21.6% of male patients participated in reproductive system neoplasms trials. For female patientss, although the Maryland cancer burden was 33.6%, 53.7% participated in breast cancer treatment trials, and 12.3% in reproductive neoplasm trials.

Accrual by Race/Ethnicity and Sex

For 1999 to 2002, there were modest fluctuations in accrual for whites; however, there was a significant decline in accrual of blacks (Table 3). Estimated annual decline in the percentage of blacks accrued onto treatment trials was approximately 8.9% per year (p<.05). The highest percentage of individuals accrued onto treatment trials was white female patients,

followed by white male patients, black female patients, and black male patients. During the same period, the accrual of female patients was significantly higher than male patients (59.2% vs. 40.8%, p<0.01). Within each racial/ethnic group, with the exception of American Indian or Alaska Native, a higher percentage of females were accrued than males. Overall, the racial distribution of patients enrolled in trials was similar to the racial distribution of Maryland patients with cancer.

Accrual by Insurance Status

Compared with the general Maryland population, a lower percentage of trial patients were uninsured (3.4% vs. 13.4%), were insured with Medicaid (3.2% vs. 6.5%), and had private insurance (65.4% vs. 77%) (data not shown). Although no differences were observed in government coverage (i.e., Medicare, Medicaid, and/or Military-Veterans Administration (VA)) as a whole, a larger percentage of Maryland trial patients than the general population were covered by some form of Military-VA insurance (6.5% vs. 3.9%).

Accrual by Maryland Regions

Observed accrual was 10% higher than expected in the National Capitol region, 31% lower than expected in the Northwestern region, and 18% lower than expected in rural Southern Maryland region (Table 4). Within the Baltimore Metro region, there was significantly higher observed than expected accrual for Anne Arundel (Standardized Accrual Ratio (SAR)=1.44, 95% CI=1.28-1.61) and Baltimore (SAR=1.44, 95% CI=1.32-1.57) Counties but lower observed than expected accrual for Howard County (SAR=0.57, 95% CI=0.44-0.74) and Baltimore City (SAR=0.53, 95% CI=0.45-0.62) (see Figure 1). Within the National Capitol region, there was significantly higher observed than expected accrual in Montgomery County (SAR=1.33, 95% CI=1.20-1.46) but lower than expected accrual in Prince George's County (SAR=0.82; 95% CI=0.71-0.94).

Accrual by County-level Socio-demographic and Health System Characteristics

Logistic regression models suggest different accrual patterns for female patients and male patients (Table 5). For female patients, odds of accrual onto treatment trials was lower among women in the highest quartile of deprivation scores than among those in the lowest (OR=0.45, 95% CI=0.23-0.89). For both female and male patients, the trend of lower accrual onto trials with increasing deprivation scores was statistically significant (p<0.001). Similarly, county social class was strongly associated with treatment trial accrual among women (OR=2.29; 95% CI=1.84-2.83 for the highest compared to the lowest quartiles) and men (OR=1.57; 95% CI=1.32-1.86). Accrual among female patients and male patients increased as the county social class score increased (p=0.011 for female patients; p=<0.001 for male patients). The adjusted odds of accrual decreased with each 2% increase in counties' non-white population composition among females and 1% among males (p=0.001).

DISCUSSION

This study comprehensively examined Maryland cancer patients' participation in NCI-sponsored CTCG treatment trials. Our findings show, for the period 1999 to 2002, Maryland patients with cancer enrolled in treatment trials at higher rate included pediatric and adolescent age groups, male patients for non-sex-specific tumors and female patients for sex-specific tumors, those with private health insurance, and those residing in the Maryland National Capitol (specifically Montgomery County) and parts of the Baltimore Metro (especially Baltimore and Anne Arundel Counties) regions. In addition, there were different patterns of accrual for female and male patients on county level socioeconomic factors.

This study was modeled on the report by Sateren et al.[3] that examined accrual onto NCI-sponsored treatment trials nationally for a 12-month period. Our study differs from Sateren et al. in several key ways. We present data on accrued patients, cancer rates, and accrual trends from one state for a four-year period and provide more detailed measures of material deprivation and rural residence. Although accrual data were presented for all racial/ethnic groups, because of low numbers of patients other than black or white, analyses were not possible for these groups. Additionally, while cancer sites (colorectal, lung, leukemia and lymphoma) were selected to make appropriate comparisons with the national analysis, additional cancers of significance to Maryland residents (i.e., female breast and male reproductive [prostate included]) were also examined. Although requested from NCI, accrual data on race by age group were not obtained; therefore, such analyses were not possible in this report.

From 1999 to 2002, there was an increase in accrual of Maryland patients with cancer to NCI-sponsored treatment trials. Moreover, the overall accrual rate of Maryland patients with cancer to NCI-sponsored treatment trials was comparable to national CTCG accrual rates[3]. As reported elsewhere[3], accrual was highest for pediatric cancer patients and lowest among adults age 60 and over. Low accrual of adults age 60 and older is disconcerting, as they are at high risk for a cancer diagnosis and are insured through Medicare, which instituted a coverage policy for beneficiary trial participation in 2000 and amended it in July 2007.

Despite comparable cancer burden for some cancers, there were significant sex differences in accrual for Maryland cancer patients. Male and female patients had relatively similar rates for colorectal cancer, leukemia and lymphoma; however, male patients were significantly more likely to be enrolled onto treatment trials. On the other hand, despite comparable sex-specific cancer rates (reproductive cancers for male patients and breast cancer for female patients), there was significantly higher accrual of female patients to sex-specific treatment trials. The majority of Maryland's accrual data by race is for blacks and whites. While modest fluctuations in accrual for whites occurred during this period, decline in accrual of blacks, who experience significant cancer rates, should be noted and is similar to that reported nationally[3]. Decline in enrollment of African Americans warrants immediate study and may be due to factors such as distrust, lack of available trials, limited information, age, and exclusionary criteria for comorbidity (also see[2,4]).

Lack of insurance coverage and reimbursement for trials is a real and perceived barrier to clinical trial accrual[27]. Overall, the majority of Maryland patients with cancer in treatment trials were covered by health insurance. Similar to national data[3], the majority of Maryland trial patients were privately insured. However, unlike the national data[3], a lower proportion of Maryland trial patients were covered by Medicaid, a higher proportion were government insured, and the percentage of Medicare patients accrued on trials was similar to the percentage of individuals covered by Medicare in the state.

Clinical trial participation cost is a concern. The majority (60%) of patients do not take part in clinical trials due to fear of having their insurance denied [27,28] and oncologists have reported denial for routine care costs as an obstacle to enrollment[27,29]. In 1998 and 1999, Maryland passed state health insurance mandates into law on coverage of trial associated clinical costs[28,28]. Although the Maryland law mandates coverage for trial associated costs, restrictions in application of this law make this benefit, and other mandated health benefits, available to only 25% of the insured [28].

There were substantial differences in trials accrual for Maryland regions, with higher observed than expected accrual in the National Capitol region (comprised of Montgomery and Prince George's Counties), equivalent accrual in the rural Eastern Shore, and lower than

expected accrual in rural Northwest and Southern Maryland regions. Although viewed as a wealthy county, Montgomery County has pockets of underserved communities and is the location of the NIH and its Clinical Center, which may explain higher than expected trial accrual. Prince George's County, adjacent to Montgomery County with a large African American community, had lower than expected accrual. Unlike the lower than expected accrual observed in the rural Northwest and Southern Maryland regions, the Eastern Shore observed versus expected accrual was equivalent. This could be explained by the intensive, multi-level programs and partnership with Eastern Shore Cancer Research Network and UMSOM that includes concentrated education, trial infrastructure and outreach to the public, local physicians, and nurses to increase cancer trial accrual and availability in the rural Eastern Shore[18].

These findings present a compelling case for future research on declining trends in accrual of black patients onto treatment trials, differential accrual by sex for comparable prevalence of specific cancer burden, differential accrual by gender within racial/ethnic groups, and lower than expected accrual rates in Prince George's County and rural Northwestern and Southern Maryland regions. There is a need to enhance targeted educational and outreach efforts to communities and community-based health professionals to increase trial availability and to foster trial participation, accrual and retention. Educational efforts should inform minorities and community physicians on design, regulatory and reporting aspects on clinical trials and foster public trust, health literacy, and community understanding of the importance of representative numbers in clinical research, Institutional Review Boards, informed consent, and potential for research benefits.

This study has important features. It extends existing research by Sateren et al.[3] in several key areas. In the absence of individual socioeconomic data, study limitations include use of demographic data for county population and not for individual Maryland patients with cancer. Therefore, it is difficult to determine the independent effect of geography of residence and individual-level racial and socioeconomic differences on treatment trial accrual. Observed multivariable logistic regression results may be due to uncontrolled confounding by individual social and economic resources, as well as barriers to participation, which may bias results in an unpredictable manner. We examined accrual of Maryland patients with cancer to NCI-sponsored treatment trials from CTCGs; thus, individuals participating in prevention or industry trials or investigator-initiated treatment trials supported by NCI cannot be commented on and results cannot be extended to the general population of patients participating in all clinical trials.

This examination of participation of Maryland patients with cancer in NCI-sponsored treatment trials has identified significant disparities in trial accrual among Maryland patients with cancer. Findings provide a compelling argument for intensive, ongoing efforts to understand and address barriers to clinical research and trial participation in Maryland and for tailored and targeted educational efforts to improve accrual.

Acknowledgments

Supported by grants from the National Center for Minority Health and Health Disparities (P60MD000532) and National Cancer Institute (U01CA114650 and U56CA096302). The National Cancer Institute Cancer Therapy Evaluation Program provided patient data based on a freedom of information request by C.R.B.

REFERENCES

1. McCaskill-Stevens W, Pinto H, Marcus AC, et al. Recruiting minority cancer patients into cancer clinical trials: a pilot project involving the Eastern Cooperative Oncology Group and the National Medical Association. J Clin Oncol. 1999; 17:1029–39. [PubMed: 10071298]

2. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. Jama. 2004; 291:2720–6. [PubMed: 15187053]
3. 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; 20:2109–17. [PubMed: 11956272]
4. Baquet CR, Commiskey P, Daniel Mullins C, Mishra SI. Recruitment and participation in clinical trials: Socio-demographic, rural/urban, and health care access predictors. Cancer Detect Prev. 2006; 30:24–33. [PubMed: 16495020]
5. Comis RL, Miller JD, Aldige CR, Krebs L, Stoval E. Public attitudes toward participation in cancer clinical trials. J Clin Oncol. 2003; 21:830–5. [PubMed: 12610181]
6. Freedman LS, Simon R, Foulkes MA, et al. Inclusion of women and minorities in clinical trials and the NIH Revitalization Act of 1993--the perspective of NIH clinical trialists. Control Clin Trials. 1995; 16:277–85. discussion 86-9, 93-309. [PubMed: 8582146]
7. Brown DR, Fouad MN, Basen-Engquist K, Tortolero-Luna G. Recruitment and retention of minority women in cancer screening, prevention, and treatment trials. Ann Epidemiol. 2000; 10:S13–21. [PubMed: 11189088]
8. Harris Y, Gorelick PB, Samuels P, Bempong I. Why African Americans may not be participating in clinical trials. J Natl Med Assoc. 1996; 88:630–4. [PubMed: 8918067]
9. Hutchins LF, Unger JM, Crowley JJ, Coltman CA Jr. Albain KS. Underrepresentation of patients 65 years of age or older in cancer-treatment trials. N Engl J Med. 1999; 341:2061–7. [PubMed: 10615079]
10. Lewis JH, Kilgore ML, Goldman DP, et al. Participation of patients 65 years of age or older in cancer clinical trials. J Clin Oncol. 2003; 21:1383–9. [PubMed: 12663731]
11. Ellis PM, Butow PN, Tattersall MH, Dunn SM, Houssami N. Randomized clinical trials in oncology: understanding and attitudes predict willingness to participate. J Clin Oncol. 2001; 19:3554–61. [PubMed: 11481363]
12. Giuliano AR, Mokuau N, Hughes C, et al. Participation of minorities in cancer research: the influence of structural, cultural, and linguistic factors. Ann Epidemiol. 2000; 10:S22–34. [PubMed: 11189089]
13. Mandelblatt JS, Yabroff KR, Kerner JF. Equitable access to cancer services: A review of barriers to quality care. Cancer. 1999; 86:2378–90. [PubMed: 10590381]
14. Mouton CP, Harris S, Rovi S, Solorzano P, Johnson MS. Barriers to black women's participation in cancer clinical trials. J Natl Med Assoc. 1997; 89:721–7. [PubMed: 9375475]
15. Shavers VL, Lynch CF, Burmeister LF. Racial differences in factors that influence the willingness to participate in medical research studies. Ann Epidemiol. 2002; 12:248–56. [PubMed: 11988413]
16. Shavers-Hornaday VL, Lynch CF, Burmeister LF, Torner JC. Why are African Americans under-represented in medical research studies? Impediments to participation. Ethn Health. 1997; 2:31–45. [PubMed: 9395587]
17. Zhu K, Hunter S, Bernard LJ, Payne-Wilks K, Roland CL, Levine RS. Recruiting elderly African-American women in cancer prevention and control studies: a multifaceted approach and its effectiveness. J Natl Med Assoc. 2000; 92:169–75. [PubMed: 10976173]
18. US Department of Health and Human Services. A model for increasing availability of community-based cancer clinical trials in rural eastern shore Maryland. 2004. Available at: http://www.phs.os.dhhs.gov/ophs/BestPractice/MD_cancer.htm/
19. Maryland Department of Planning. Planning Data Services. Available at: http://www.mdp.state.md.us/
20. US Census. 2000. Available at: http://www.census.gov/
21. Klassen AC, Curriero FC, Hong JH, et al. The role of area-level influences on prostate cancer grade and stage at diagnosis. Prev Med. 2004; 39:441–8. [PubMed: 15313082]
22. United States Department of Agriculture. Measuring Reality: Rural-Urban Continuum Codes. Apr 28. 2004 update; Available at: http://www.ers.usda.gov/briefing/rurality/RuralUrbCon/
23. United States Department of Agriculture. Data Sets: Urban Influence Codes. Available at: http://www.ers.usda.gov/Data/UrbanInfluenceCodes

24. American College of Surgeons. Commission on Cancer. May 02. 2006 Available at http://www.facs.org/cancerprogram/

25. Stokes, ME.; Davis, CS.; Koch, GG. Categorical Data Analysis Using the SAS System. Second Edition. SAS Institute Inc; Cary, NC: 2000.

26. SAS Institute Inc. SAS/STAT for Windows (Version 9.1). SAS Institute; Cary, NC: 2001.

27. Baquet, CR. The role of state legislation and policy in addressing disparities in clinical trials. Available at: http://www.bcm.edu/edict/PDF/State_Legislation.pdf

28. American Cancer Society. Clinical Trials: State Laws Regarding Insurance Coverage. Available at: http://www.cancer.org/docroot/ETO/content/ETO_6_2x_State_Laws_Regarding_Clinical_Trials.asp [accessed on January 8, 2008]

29. American Society of Clinical Oncology. Coverage of Routine Patient Care Costs in Clinical Trials: Position Statement. Approved by the ASCO Board of Directors; 2005. Available at: http://www.asco.org/ASCO/Legislative+%26+Regulatory [accessed on January 03, 2008]

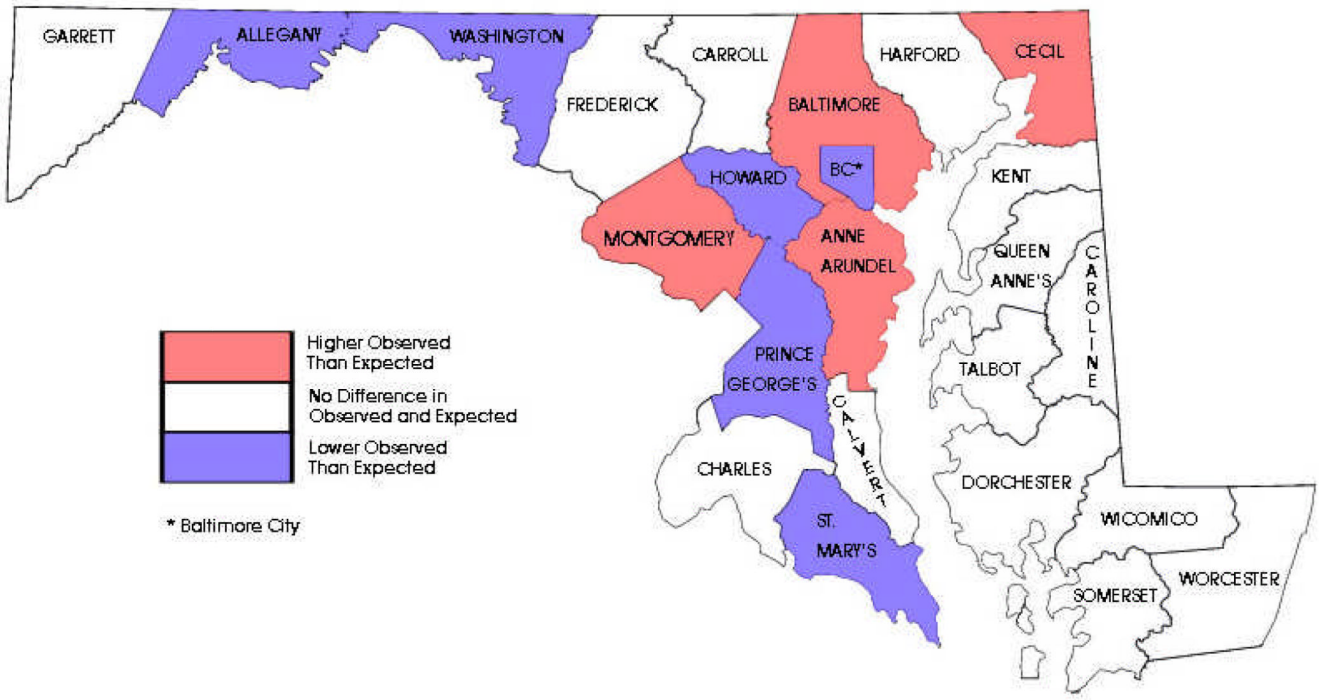

Figure 1.
Maryland Jurisdiction-specific Observed to Expected Accrual onto NCI Clinical Treatment Trials, 1999 to 2002.

Table 1

Distribution of Maryland NCI-Sponsored Cancer Treatment Clinical Trial Patients and percentage of Cancer Patients Accrued onto Treatment Trials by Age Group, 1999 to 2002

Age Group	Number of Maryland Cancer Patients	Number Accrued onto Treatment Trials (n=2240)	Percentage of Treatment Trial Patients	Within Age Group Percentage of *Maryland Cancer Patients* Accrued onto Treatment Trials
0-9	341	188	8.4	55.1
10-19	476	122	5.4	25.6
20-29	1355	30	1.3	2.2
30-39	3874	147	6.6	3.8
40-49	9803	345	15.4	3.5
50-59	18506	559	25.0	3.0
60-69	23469	451	20.1	1.9
70-79	25230	343	15.3	1.4
80+	13852	55	2.5	0.4

Table 2

Comparison of Percentage of Patients Accrued to Specific Cancer Trials with Percentage of Cancer Cases in Maryland by Sex and Cancer Site, 1999 to 2002

Cancer Subtype	Male				Female			
	No. of Annual Cases	No. of Trial Patients	% - MD Cancer Burden*	% - Cancer Trial Patients**	No. of Annual Cases	No. of Trial Patients	% - MD Cancer Burden*	% - Cancer Trial Patients**
Non sex-specific tumors								
Colorectal	5253	68	10.5	7.4	5283	64	11.2	4.8
Lung	7371	38	14.8	4.2	6208	38	13.2	2.9
Lymphoma	2047	120	4.1	13.1	1822	55	3.9	4.2
Leukemia	994	202	2.0	22.1	804	131	1.7	9.9
Sex-specific tumors								
Male Reproductive System Neoplasm	16086	197	32.3	21.6	~	~	~	~
Female Breast	~	~	~	~	14620	712	31.1	53.7
Female Reproductive System Neoplasm	~	~	~	~	1179	163	2.5	12.3

* % MD Cancer Burden is the site-specific number of cancer cases/total number of cancer cases*100; data are from the Maryland Cancer Registry

** % Cancer Trial Patients is the site-specific number of clinical treatment trial patients/total number of clinical treatment trial patients; data are from CTEP

Table 3

Maryland Clinical Trial Accrual by Year of Accrual, Race/Ethnicity and Sex

	1999		2000		2001		2002		1999-2002**				% - Patients Accrued by Gender Within Race/Ethnic Group***		% - MD Cancer Population****
									Males		Females				
Race/Ethnic Group	No. Accrued	%	No. Accrued	%	No. Accrued	%	No. Accrued	%	No. Accrued	%	No. Accrued	%	Males	Females	
White	318	71.9	330	76.0	448	75.2	588	76.6	609	29.5	941	45.6	39.3	60.1	74.4
Black	105	23.8	88	20.3	114	19.1	137	17.8	198	9.6	213	10.3	48.2	51.8	21.2
Hispanic **	7	1.6	6	1.4	14	2.3	10	1.3	15	0.7	21	1.0	41.7	58.3	
Asian, Pacific Islander or Native Hawaiian	6	1.4	6	1.4	12	2.0	21	2.7	12	0.6	27	1.3	30.8	69.2	2.7**
American Indian or Alaska Native	3	0.7	0	0.0	3	0.5	2	0.3	5	0.2	3	0.1	62.5	37.5	-
Unknown	10	2.3	10	2.3	19	3.2	20	2.6	18	0.9	37	1.8	32.7	67.3	-
Total	442		434		596		768		842	40.8	1222	59.2	40.8	59.2	1.7

* Hispanic ethnicity is not mutually exclusive of race–Percentage is for “other” race/ethnic groups

** Denominator is 2064 males and females with race/ethnicity and gender reported

*** Denominator is total with race/ethnic group

**** Source: Maryland Cancer Registry

Table 4

Standardized Accrual Ratios* for Maryland Regions, 1999-2002

Region**	Number of Counties	Observed Accrual	Expected Accrual	Standardized Accrual Ratio	95% Confidence Interval	
Baltimore Metro	6	1180	1137	1.04	0.98	1.10
Eastern Shore	9	188	188	1.00	0.87	1.16
National Capitol	2	637	579	1.10	1.02	1.19
Northwestern Maryland	4	130	188	0.69	0.58	0.82
Southern Maryland	3	91	110	0.82	0.66	1.01

* Ten-year age group and county standardized accrual ratios

** Baltimore Metro-Anne Arundel, Baltimore, Carroll, Harford, Howard Counties, and Baltimore City; Eastern Shore-Cecil, Queen Anne's, Somerset, Wicomico, Caroline, Dorchester, Kent, Talbot, Worcester; National Capitol-Montgomery, Prince George's; Northwestern Maryland-Allegany, Frederick, Washington, Garrett; Southern Maryland-Calvert, Charles, St. Mary's

Table 5

Age- and Multivariable-Adjusted Odds Ratios for County Sociodemographic Variables and Clinical Treatment Trial Accrual in Maryland, 1999 to -2002

County Variable	Female				Male			
	Percentage Accrued		Age-Adjusted	Adjusted*	Percentage Accrued		Age-Adjusted	Adjusted*
	n	%	OR (95% CI)	OR (95% CI)	n	%	OR (95% CI)	OR (95% CI)
Material Deprivation Summary Score								
Quartile 1	195	2.91	1.00	1.00	110	1.48	1.00	1.00
Quartile 2	527	3.22	0.79 (0.51-1.23)	0.76 (0.50-1.15)	340	1.67	1.05 (0.81-1.36)	1.03 (0.81-1.30)
Quartile 3	367	2.14	0.72 (0.46-1.14)	0.66 (0.42-1.04)	238	1.47	0.95 (0.72-1.27)	0.91 (0.71-1.18)
Quartile 4	223	1.58	0.34 (0.19-0.60)	0.45 (0.23-0.89)	225	1.62	0.71 (0.49-1.03)	0.83 (0.49-1.40)
p for trend			<0.001	<0.001			<0.001	<0.001
Social Class Summary Score								
Quartile 1	102	1.67	1.00	1.00	120	1.46	1.00	1.00
Quartile 2	91	2.29	2.16 (1.01-4.61)	1.60 (0.86-2.98)	65	1.44	1.46 (0.97-2.20)	1.31 (0.87-1.99)
Quartile 3	558	2.73	2.67 (1.86-3.84)	2.12 (1.82-2.46)	359	1.50	1.44 (1.13-1.82)	1.34 (1.15-1.56)
Quartile 4	561	3.15	3.01 (2.21-4.12)	2.29 (1.84-2.83)	369	1.85	1.71 (1.38-2.11)	1.57 (1.32-1.86)
p for trend			0.018	0.011			<0.001	<0.001
Percent Non-White **								
Quartile 1	141	2.57	1.00	1.00	92	1.25	1.00	1.00
Quartile 2	302	2.64	1.20 (0.70-2.07)	1.19 (0.69-2.04)	174	1.59	1.09 (0.83-1.44)	1.08 (0.83-1.42)
Quartile 3	396	2.23	1.01 (0.57-1.76)	1.02 (0.59-1.75)	260	1.70	1.14 (0.86-1.51)	1.15 (0.86-1.53)
Quartile 4	473	2.34	0.66 (0.31-1.38)	0.67 (0.33-1.38)	387	1.71	0.95 (0.65-1.39)	0.97 (0.66-1.40)
p for trend			0.001	0.001			0.001	0.001
Percent Rural ***								

County Variable	Female				Male			
	Percentage Accrued		Age-Adjusted	Adjusted*	Percentage Accrued		Age-Adjusted	Adjusted*
	n	%	OR (95% CI)	OR (95% CI)	n	%	OR (95% CI)	OR (95% CI)
Quartile 1	981	2.82	1.00	1.00	698	1.94	1.00	1.00
Quartile 2	174	2.27	1.28 (0.86-1.91)	1.06 (0.66-1.68)	112	1.41	0.98 (0.78-1.24)	0.90 (0.69-1.17)
Quartile 3	105	2.54	1.50 (1.02-2.23)	1.21 (0.81-1.80)	69	1.56	1.10 (1.02-1.19)	1.01 (0.89-1.15)
Quartile 4	52	2.22	1.24 (1.04-1.49)	1.03 (0.87-1.21)	34	1.34	0.93 (0.70-1.23)	0.85 (0.63-1.15)
p for trend			0.124	0.456			0.295	0.809
ACOS Approved Hospitals	~	~	1.02 (0.79-1.31)	0.91 (0.80-1.02)	~	~	1.01 (0.91-1.12)	0.95 (0.88-1.04)
Oncologists	~	~	0.93 (0.73-1.17)	0.96 (0.87-1.06)	~	~	1.03 (0.91-1.16)	1.04 (0.98-1.12)

OR=Odds Ratio and CI= Confidence Interval; %=number of trial participants/number of cancer cases*100

NOTE: Material deprivation measures include percent of: persons living in poverty, households without a car, unemployed persons age 16 and older, and owner-unoccupied housing. Social class summary score includes percent of: high school graduates among persons 25 and older, persons with graduate or professional degrees, persons employed in white collar jobs, and median household income.

*Models are adjusted for racial composition of county, age distribution of clinical trials patients, and rural classification of counties.

**Adjusted model is adjusted for age distribution of clinical trials patients and the rural classification of counties.

***Adjusted model is adjusted for racial composition of county and age distribution of clinical trials patients.