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Recruitment and Participation In Clinical Trials: Socio-Demographic, Rural/Urban, and Health Care Access Predictors

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Abstract

Background—Recruitment and participation in clinical trials by minorities, particularly African Americans and rural underserved populations, are low. This report examines predictors of clinical trial recruitment and participation for adult Marylanders.

Methods—A cross-sectional design was used to survey 5,154 adults (18 years and older) residing in 13 of the 24 jurisdictions in Maryland, including urban Baltimore City, and the rural regions of Western Maryland and the Eastern Shore. The survey, conducted between December 2001 and March 2003, used Computer-Assisted Telephone Interviewing and random-digit dialing procedures. Primary dependent variables included “ever asked to participate” (i.e., recruited) and “participated” in clinical trials.

Results—11.1% of the respondents had been recruited to clinical trials. In addition, 59.4% of the respondents recruited to clinical trials actually participated in a clinical trial. Among respondents recruited to clinical trials, black and middle income respondents were significantly less likely to actually participate in clinical trials; whereas, respondents who received information about clinical trials from their health care provider, who were knowledgeable about clinical trials, and those who had the time commitment were significantly more likely to participate in clinical trials.

Conclusions—These results suggest serious gaps in efforts to recruit racial/ethnic minorities and residents of rural regions into clinical trials. The findings provide the basis for the development and implementation of community-based educational programs for both the general public and health care professionals, and to enhance availability of community-based clinical trials, especially in the rural areas of the state.

Author's Key Words (or terms)

clinical trial; cancer disparities; patient selection; research participant recruitment; patient participation; rural or urban population; minority groups; neoplasm; knowledge; attitudes; source of information

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Introduction

Clinical trials are a critical resource for the discovery of new prevention, diagnostic and treatment modalities for disease. For cancer, clinical trials have produced advances in treatment as well as prevention. Despite these advances in cancer prevention and patient care, only about 3-5% of cancer patients participate in clinical trials.[1, 2]

Assuring diversity in clinical trial participation is a national priority. In 1993, the most recent amendment to the National Institutes of Health (NIH) Revitalization Act (Public Law 103-43),[3] mandated the inclusion of women and minorities in clinical research and government sponsored human subject research including clinical trials. This Act states that women and minorities must be included in all clinical research studies and must be included in Phase III clinical trials. Trials must also be designed to permit valid subgroup analyses. The Act states that cost is not an allowable reason for excluding minorities and that the NIH will support outreach efforts to fulfill this mandate. However, for communities that experience high cancer burden as demonstrated by elevated cancer incidence and mortality rates, such as African Americans, the uninsured and poor, and rural patients, participation in cancer clinical trials is particularly low.[2, 4, 5] Moreover, the proportion of trial participants who are African Americans has declined in recent years.[5]

Participation in clinical trials is affected by individual (patient and provider) and structural factors. Some evidence suggests that slightly less than one-third (32%) of Americans would be willing to participate in clinical trials if asked, and, an additional 38% would be inclined to participate if asked but had some questions or reservations.[1] Therefore, factors other than patient intent or willingness seem to impede participation in clinical trials. Some of the salient factors impeding participation in clinical trials include: being a racial minority;[2, 5-7] older age;[2, 5, 7-9] lower socioeconomic status;[2, 6, 7, 10, 11] lack of appropriate clinical trials and the disqualification of patients;[1] the reluctance of physicians to engage in accrual;[1, 12] doctor-patient communications regarding clinical trials;[7, 10, 13] mistrust of academic institutions, research and the medical system;[6, 10, 12, 14-17] fear of negative effects;[11] lack of community and physician awareness and knowledge of clinical trials benefits;[10, 11, 18] lack of sufficient infrastructure (including oncologists and approved cancer programs) to support trials in community settings;[2] lack of researcher training in culturally appropriate patient concerns and communication methods;[13, 17, 19] certain historical factors;[14] lack of adequate support for community outreach; poor access to care;[12] and lack of information on available trials.[10, 12]

The low participation in cancer trials by African Americans and other minorities may contribute to existing cancer survival and mortality rate disparities. These avoidable disparities in cancer research participation are a public health problem in that access to cutting edge advances in cancer prevention and therapy are not equitably available to those populations experiencing substantially higher cancer incidence, morbidity and mortality rates.[20] While numerous studies discuss issues related to the low participation of African Americans in trials, very few discuss possible predictive factors associated with trial participation. The focus of this report is two-fold: first, to present the prevalence of clinical trial recruitment and participation in three regions of Maryland; and second, to determine multivariate socio-demographic, rural/urban geography, source of clinical trial information, enabling factors, and health care access predictors of recruitment and participation. The results from this analysis will be used to document geographic and population-specific barriers and channels for clinical trial education and promotion. Moreover, the report's findings would serve as the basis for the development of educational programs to increase participation in trials and also facilitate the identification of key areas for education and outreach programs to promote greater knowledge and awareness of key facts on trials.

Ultimately, it is hoped that greater awareness and intensive educational programs will increase the availability and likelihood of participation in clinical trials by urban, rural and minority underserved patients.

Methods

The data are derived from a larger investigation on the health behavior, health care access, and screening and health status conducted in 13 of the 24 jurisdictions in the state of Maryland between December, 2001 and March, 2003. [21] The 13 jurisdictions studied included urban Baltimore City, the three counties of rural Western Maryland (Garrett, Allegany, and Washington counties), and the nine counties of the rural Eastern shore (Cecil, Kent, Queen Anne's, Talbot, Caroline, Dorchester, Wicomico, Somerset, and Worcester counties). In this report, we focus on questions included in the clinical trials module, one of the eight modules included in this survey that examined the prevalence and predictors of clinical trial participation for residents in the state of Maryland. The survey was conducted by the Center for Health Policy/Health Services Research at the University of Maryland School of Medicine. The Human Subject Institutional Review Board of the University of Maryland Baltimore approved the research protocol and all study participants provided verbal informed consent.

Study Design and Procedures

A cross-sectional design was used to survey 5,154 English-speaking, non-institutionalized men and women aged 18 years or older. The survey sample was selected using random digit dialing methodology along with selection of eligible respondents within households, and it employed Computer-Assisted Telephone Interviewing (CATI) data collection procedures.[21] To ensure an adequate sample of men surveyed, the study's a priori sample size estimates and response percentages were set for each county at 55% female and 45% male. Based on these estimates, within each eligible household, interviewers solicited the “most available” male member of the household over the age of 18 for the interview. If there was no male in the household or the “most available” male was not willing to or would never be available to respond to the survey, the “most available” female member in the household was requested for the interview. If the most available male was present for the interview at the time of the telephone call, subsequent call attempt efforts were made to contact the eligible male respondent. More than 95% of the Marylanders have telephones (Genesys Sampling Systems, April 2005, personal communications), and random-digit dialing is unimpeded by the non-listing of telephone numbers. Thus, the study results can be considered generalizable only to English-speaking, non-institutionalized adults reachable by telephone within the survey timeframe through the level of effort described below.

Trained interviewers conducted the interviews during optimal calling times, as described by Aday.[22] Interviewers were routinely monitored by staff for quality control, and all interviews were recorded using a digital voice logger. Respondents were called without prior notification and were not paid for their participation. A minimum of 8 attempts were made before a final disposition code was assigned to a telephone number.

A bank of telephone numbers was obtained from Genesys Sampling Systems. Overall, 33,130 numbers were called and assigned a final disposition code: complete, active or passive refusal, unable to contact (non-contact), inaccessible household, or ineligible household or number. Active refusal is defined as eligible respondents who were forthright in refusing to be interviewed and those who started an interview but interrupted it and were not willing to continue. Passive refusal is defined as households where answering machines were repeatedly encountered. Non-contact is defined as households where the eligible respondent interrupted the survey and was willing to continue but did not schedule and complete the survey during the survey timeframe, and households where the potential respondent repeatedly scheduled call attempts but never conducted the interview during the survey timeframe. Inaccessible households were defined as those where there were repeated no answer and where the telephone line was constantly busy. Ineligible households or numbers were defined as business or non-private residence, telephone numbers with inconsistencies (i.e., numbers not in service or disconnected lines), fax or computer lines, wrong numbers, household where the telephone number had changed, households outside the state or without adults (18 years and older), and households with non-English-speaking adults.

Out of the 33,130 telephone numbers used, 9,297 were ineligible. Of the remaining 23,833 eligible numbers, 202 telephone numbers (0.85%) could not be contacted, 11,663 telephone numbers (48.94%) actively refused participation, 1,987 telephone numbers (8.34%) were categorized as passive refusals, and 4,827 telephone numbers (20.25%) were inaccessible. The remaining 5,154 eligible numbers resulted in a completed survey by the designated respondent. The completion rate, defined as the number of completed interviews divided by the sum of completed interviews and active refusals,[23] for the survey was 30.6%. The completion rates for urban and rural jurisdictions were 39.0% for Baltimore City, 31.0% for rural Western Maryland, and 29.3% for rural Eastern Shore.

Measures

The overall survey instrument included 212 questions adapted from the Centers for Disease Control and Prevention's (CDC) Behavioral Risk Factor Surveillance Survey (BRFSS), the Commonwealth Fund Comparative Minority Health Survey, and original survey questions developed from prior research conducted through the Center for Health Policy/Health Services Research at the University of Maryland School of Medicine.[21] The survey instrument was conceptualized on eight general dimensions or modules: health status; health care coverage and satisfaction; lifestyle factors, such as nutrition, exercise, weight control, alcohol and tobacco use (including smokeless tobacco); gender-specific questions on cancers of the breast, cervix, and prostate, as well as colorectal cancer, including utilization of screening and early detection examinations for these cancers; preventive behaviors for cancers of the skin and mouth; other health issues such as hypertension, cholesterol, and cardiovascular disease; clinical trials knowledge, attitudes, sources of information, and potential barriers to participation; and socio-demographics including race/ethnicity, gender, income, education, occupation, and military status. The average length of the survey varied by region: 19.1 minutes for interviews in Baltimore City; 19.6 minutes for the Eastern Shore region; and 23.3 minutes in the Western Maryland region. In this report, we focus on socio-demographics, health status and health insurance coverage, and the module on clinical trials.

The focus on the clinical trial module was to determine attitudes, awareness and knowledge of clinical trial aspects, previous participation, barriers, most likely sources of information on clinical trials, and predictive factors associated with willingness to participate for residents in 13 of Maryland's underserved geographic areas: urban Baltimore City, rural three county Western Maryland, and rural nine county Eastern Shore region. Independent variables included several socio-demographic measures such as age, sex, race/ethnicity, region (county) of residence, education level, and income level; health status; and health insurance coverage. Race/ethnicity was categorized as white or Caucasian, black or African American, or other. Age and health status variables were dichotomized as less than 65 years and 65 years or older for age, and poor or non-poor (including fair, good, very good, or excellent) health status. Education categories reflected the highest grade/level of school completed. Primary health insurance coverage was reported as either through work or union, through someone else's work or union, purchased directly, Medicare, Medicaid, other group, Veterans' Administration (VA), or no insurance. For the multivariate analysis, health insurance coverage was categorized as: no insurance, public insurance, or private insurance. Annual income was categorized as low income (less than $15,000), middle income ($15,000-$50,000), and high income (above $50,000). Finally, respondents were classified as living in Baltimore City, Western Maryland, or the Eastern Shore according to their county of residence. Other independent variables included factors that may influence participation in clinical trials (or "enabling factors"). Respondents were presented with nine separate factors and asked whether or not each would make them more likely to participate in clinical trials. These nine factors included reimbursement, insurance coverage, transportation, childcare, increased knowledge, time commitment, anonymity, medical follow-up, and additional health care. Lastly, respondents were asked whether or not they had received information concerning clinical trials from any of seven possible sources: printed literature, their doctor, the internet, the church, over the radio, from a community group, or via the television.

Dependent variables included being "ever asked to participate" (or recruited) in clinical trials and "participated" in clinical trials. All respondents were asked the question, "Have you ever been asked to participate in a clinical trial?" Response to this question provided the primary information covering efforts to recruit different demographic groups for trials. Respondents who indicated that they had been asked to participate in a clinical trial were then asked, "Did you participate?"

Analysis

Bivariate and multivariate analyses were conducted to determine relationships between the independent variables and the binary outcome variables. Chi-square tests were used to assess differences between each of the two outcome variables (recruited and participated) and independent variables such as socio-demographics (i.e., gender, race/ethnicity, age, income, education level), health status, access to care (i.e., health insurance status), geography of residence, the seven sources of information about clinical trials, and the nine enabling factors. Independent multivariate stepwise, logistic regression models were constructed for the two outcome variables to further explore the effects of the independent variables (i.e., socio-demographics, geography of residence, health status, and access to care, seven sources of information, and nine enabling factors) on being recruited to clinical trials and participating in clinical trials. The independent variables sources of information and enabling factors were only included in the logistic regression model for the outcome variable "participation" in clinical trials. The sample for the logistic regression models included respondents who self-identified themselves as either black or white for race, and those who responded either "yes" or "no" on the individual predictor and outcome variables. Respondents who self-identified themselves as being of "other" race and those who answered "do not know/unsure" or "refused" for the predictor and outcome variables in the model were excluded from the multivariate stepwise logistic regression analyses. For each categorical variable in the model, the referent category had an odds ratio (OR) of 1.0. The logistic regression results appear as odds ratios and 95% confidence interval (CI).[24] Hosmer-Lemeshow test statistics was used to assess the goodness-of-fit.

Results

Sample Characteristics

The sample consisted of 5,154 adults surveyed in urban Baltimore City (n=681), rural Western Maryland (n=1122), and rural Eastern Shore (n=3351). Overall, the majority of adults surveyed were less than 65 years of age (74.7%), white (79.2%), female (53.1%), considered themselves in "not poor" health (94.6%), high school graduate (34.7%) or with some college (25.4%) level of education, with health insurance coverage (90.6%), and with an annual income of less than $50,000 (59.7%). There were significant differences in socio-demographic characteristics of the adults surveyed in the three regions. Urban Baltimore City respondents were more likely to be less than 65 years of age (80.5% vs. 74.0% in Eastern Shore and 73.3% in Western Maryland, p<.001), African American (56.3% vs. 16.3% in Eastern Shore and 1.9% in Western Maryland, p<.001) males or females, and have health insurance coverage provided through their work or union (49.1% vs. 40.9% in Eastern Shore and 38.6% in Western Maryland, p<.001). Furthermore, the sample in urban Baltimore City was less likely to have graduated from high school or have some college education (50.7% vs. 59.7 in Eastern Shore and 67.0% in Western Maryland, p<.001) and have health insurance coverage provided through Medicare (16.5% vs. 24.0% in Eastern Shore and 26.3% in Western Maryland, p<.001).

Prevalence of Clinical Trial Recruitment and Participation

Overall, out of the 5,154 respondents, 574 respondents (11.1%) surveyed in the 13 jurisdictions in Maryland were recruited in clinical trials. Moreover, among the 574 respondents who were recruited, 341 respondents (59.4%) actually participated in clinical trials (data not shown). Table 2 presents the prevalence of recruitment to and participation by socio-demographic characteristics, health status, and insurance coverage. Overall, respondents more likely (p<.001) to be recruited to clinical trials were 65 years or older (14.4%), had poor health status (17.7%), had some college or higher level of education (63.4%), had either private (purchased directly or through work or union, 32.0%) or public health insurance coverage (VA, Medicaid, or Medicare, 51.7%), and were residents of urban Baltimore City (19.7%) followed by rural Western Maryland (13.6%). Among the respondents who were recruited, white females (64.8%), white males (61.1%), male (100.0%) respondents from an other race, and those residing in rural Western Maryland (68.9%) followed by rural Eastern Shore (60.6%) vs. those residing in urban Baltimore City (47.0%) were significantly (p<.001) more likely to actually participate in clinical trials.

Sources of Clinical Trial Information

Table 3 contains data on the seven different sources of information about clinical trials. The most common source of information was television, followed by print media, and radio. The church was the least common source of information about clinical trials. With some exceptions, the television followed by the print media, were the most common sources of information for all race/gender groups, age groups, education level, income groups, and urban or rural region of residence. African American males were more likely to receive information about clinical trials from the television followed by the radio, and African American females more likely to receive information about clinical trials from the television followed by the print media. In addition, increased levels of education and income determined the primary source for clinical trial information; for example, respondents who were college graduates or who had higher levels of education, as well as those reporting incomes of $100,000 or more, were proportionally more likely to receive information about clinical trials from the print media, followed by the television.

Enabling Factors for Clinical Trial Participation

The distribution of the nine factors that enable participation in clinical trials is presented in Table 4. African American respondents were less likely than their white counterparts to be influenced to participate by seven of the nine enabling factors (reimbursement, insurance coverage, greater knowledge, time commitment, follow-up care, and additional medical care). Important determinants for participation in clinical trials included childcare, not having to provide names, and transportation (especially for African American females).

Respondents under age 65 were more likely to be influenced by five of the nine factors, including reimbursement, insurance coverage, increased knowledge, follow-up, and added medical care. Respondents aged 65 and older were likely to be influenced in their participation by increased knowledge, follow-up, and added care. Factors important for respondents who reported “poor” health status included reimbursement, insurance, transportation, more knowledge, follow-up and provision of additional health care.

Education level was associated with five enabling factors, including reimbursement (except for respondents who reported elementary or some high school education or high school graduate), insurance (especially for respondents with some high school or more education), more knowledge (except for respondents with elementary level education), follow-up care (except for respondents with elementary level education), and provision of additional health care. With a few exceptions, both uninsured and insured respondents were more likely to be influenced in their decision to participate in clinical trials by factors such as reimbursement (except those Medicare, other group insurance, or VA insurance), insurance coverage (except those with VA insurance), more knowledge, follow-up, and provision of additional health care. Geographically, residents of both urban and rural setting were more likely to be influenced by factors such as reimbursement (especially for residents of rural Western Maryland and Eastern Shore), insurance, more knowledge, follow-up, and provision of additional health care in their decision to participate.

Multivariate Predictors of Recruitment to and Participation in Clinical Trials

Multivariate stepwise logistic regression analyses were used to evaluate the relative contributions of socio-demographic characteristics, health status, insurance coverage, and geographic area of residence as predictors of recruitment to and participation in clinical trials. To reiterate, the sample for the multivariate stepwise logistic regression analyses included only the respondents who self-identified themselves as either black or white on race, and responded either “yes” or “no” on the predictor and outcome variables. Respondents excluded from the analyses were those who self-identified themselves as “other” for race and responded “do not know/unsure” or “refused” on the predictor and outcome variables. The multivariate model for participation also included as independent variables the sources of clinical trial information and enabling factors.

The independent predictors of recruitment to clinical trials are presented in Table 5. Respondents in poor health (OR = 1.83, CI = 1.21-2.76), having public health insurance coverage (OR = 1.98, CI = 1.57-2.51), and those having some college or higher level of education (OR = 2.32, CI = 1.84-2.92) were significantly more likely to be recruited. Respondents who were black (OR=0.61, CI= 0.44-0.85), residents of rural Western Maryland (OR=0.46, CI=0.33-0.65), and residents of rural Eastern Shore (OR=0.30, CI=0.22- 0.40) were significant less likely to be recruited. Among respondents recruited to clinical trials, blacks (OR = 0.38, CI = 0.21-0.68) and middle-income respondents (OR = 0.57, CI = 0.37-0.89) were less likely to participate (Table 6). In addition, respondents who were informed about clinical trials by their health care provider (OR = 1.69, CI = 1.08-2.65), were knowledgeable about clinical trials (OR = 2.09, CI = 1.26-3.46), and who had the time commitment (OR = 1.67, CI = 1.06-2.63) were significantly more likely to actually participate.

Discussion

Enhancing recruitment and participation in clinical trials, especially for minorities, is a national priority. Addressing avoidable disparities in participation requires better understanding about the specific factors that may lead to recruitment and participation. The results presented in this report shed light on factors associated with clinical trial recruitment and participation in a population-based, rural and urban sample covering 13 of the 24 jurisdictions in the state of Maryland. Moreover, the results are some of the first comprehensive, population-based estimates on clinical trial recruitment and participation prevalence and predictors.

Findings from this study indicate that in Maryland the significant predictors of being recruited included being African American, in poor health, receiving public health insurance, having some college or higher level of education, and residing in either rural Western Maryland or the Eastern Shore. In addition, significant predictors of participation included race/ethnicity, income level, health care professional providing information about clinical trials, knowledge about clinical trials, and time commitment. The television, radio and print media were the important sources for clinical trial information and the preference for these sources varied by socio-demographic factors. In terms of enabling factors, knowledge about clinical trials, insurance coverage for trials, reimbursement for participation, and time commitment required were some of the more important factors identified.

The predictors of self-reported participation in clinical trials in Maryland corroborate those documented in other studies. Similar to findings reported here, other studies have also reported that the likelihood of reported participation was lower among racial minorities (African Americans)[2, 4, 7] and those with less income;[2, 6, 7, 10, 11] and, the likelihood of reported participation in clinical trials was higher when health care professionals provided information about clinical trials [7, 10, 13] and participants had knowledge about clinical trials.[10, 11, 18] An additional factor that may enhance participation in clinical trials is the time commitment required.

The findings presented in this report have several programmatic implications. The results provide evidence for the development of interventions aimed at the community that can be very specific for gender, race/ethnicity, rural and urban settings, educational attainment, and income levels. Moreover, these attributes coupled with the selective preference and influence of different sources of health information provide for the development of intervention that not only target by socio-demographic and geographical attributes but also by the method of communicating health information. Given the extremely low rates of self-reported recruitment, the results also provide evidence for the development of physician and other health professional awareness and education programs.

Future research on clinical trial recruitment and participation needs to explore the individual and structural dimensions. Individual-level dimensions would include the psychological, cultural, and social attributes that influence the decision-making processes of participation. These studies would be especially important to enhance recruitment to prevention trials where the potential benefit/harm is in the distant future. The structural dimensions would include the provision of clinical trials in rural, non-academic community-settings, and methods to enhance physician and health professional awareness and education about available trials. Other areas of research include the evaluation of innovative recruitment strategies in population-based settings.

Policy implications of this research are several. The data reported in this study underscore the importance of population-based studies covering urban and rural settings to document needs and behaviors relevant to specific communities. In addition, the data suggest the scarcity of recruitment efforts in rural settings, among racial/ethnicity minorities, and among lower socioeconomic groups. These data lend themselves to the definition of policy initiatives at the local (i.e., institutional), state, and national levels to address the prevailing disparities in clinical trial recruitment and participation.

Limitations of this study are those inherent in telephone survey research. The data, being self-reported, are subject to recall bias and social desirability bias. These biases may skew the estimations of the true prevalence of population-based recruitment and participation. Although the study utilized rigorous call attempt efforts to encourage potential participants to complete the survey and to contact potential participants, there remains the sample bias due to several factors including the repeated encounter with answering machines, refusal to participate in the survey, and the lack of telephones in households. There is some evidence to suggest that potential bias due to non-completion of telephone health surveys may be minimal.[23]

In summary, this study presents systematically documented population-based prevalence data and identified predictors for recruitment to and participation in clinical trials among Marylanders residing in urban and rural settings. The reported rate of recruitment to clinical trials is very low. It is likely that the reported low rate of recruitment and, subsequently, participation in clinical trials may explain, at least in part, the disparities in health observed among minorities, the underserved, and rural communities in Maryland. The data provide a foundation for targeted educational interventions aimed at both the community and health care professionals.

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Table 1

Sample Characteristics of the 5,154 Survey Respondents by Study Region

Characteristics	All		Baltimore City		Eastern Shore		Western Maryland	
	n	%	n	%	n	%	n	%
Age group, in years***								
Less than 65	3830	74.7	546	80.5	2463	74.0	821	73.3
65 and over	1298	25.3	132	19.5	867	26.0	299	26.7
Race/ethnicity***								
White	4024	79.2	262	39.1	2691	81.7	1071	96.2
Black	935	18.4	377	56.3	537	16.3	21	1.9
Other	119	2.3	31	4.6	67	2.0	21	1.9
Gender*								
Male	2416	46.9	288	42.3	1572	46.9	556	49.6
Female	2738	53.1	393	57.7	1779	53.1	566	50.5
Race/gender***								
White male	1943	38.3	130	19.4	1280	38.9	533	47.9
White female	2081	41.0	132	19.7	1411	42.8	538	48.3
Black male	374	7.4	137	20.5	230	7.0	7	0.6
Black female	561	11.1	240	35.8	307	9.3	14	1.3
Other male	71	1.4	16	2.4	41	1.2	14	1.3
Other female	48	1.0	15	2.2	26	0.8	7	0.6
Health Status								
Poor	279	5.4	31	4.6	175	5.2	73	6.5
Not poor	4867	94.6	648	95.4	3172	94.8	1047	93.5
Education***								
Never attended	11	0.2	2	0.3	8	0.2	1	0.1
Elementary	158	3.1	27	4.0	89	2.7	42	3.8
Some high school	473	9.3	89	13.2	294	8.9	90	8.1
High school graduate	1767	34.7	195	29.0	1142	34.6	430	38.5
Some college	1291	25.4	146	21.7	827	25.1	318	28.5

Characteristics	All		Baltimore City		Eastern Shore		Western Maryland	
	n	%	n	%	n	%	n	%
College graduate	743	14.6	99	14.7	512	15.5	132	11.8
Some graduate school	144	2.8	31	4.6	94	2.9	19	1.7
Graduate degree	504	9.9	84	12.5	335	10.2	85	7.6
Insurance Status***								
Uninsured	482	9.4	72	10.6	288	8.7	122	11.0
Insured								
Through work or union	2117	41.5	333	49.1	1355	40.9	429	38.6
Someone else's work or union	717	14.0	74	10.9	500	15.1	143	12.9
Purchased directly	324	6.4	39	5.8	225	6.8	60	5.4
Medicare	1200	2.5	112	16.5	796	24.0	292	26.3
Medicaid	125	2.5	29	4.3	64	1.9	32	2.9
Other group	73	1.4	9	1.3	45	1.4	19	1.7
VA	68	1.3	10	1.5	44	1.3	14	1.3
Income Level***								
Less than $7,500	220	5.6	43	8.2	115	4.6	62	7.0
$7,500-$14,999	357	9.1	50	8.6	203	8.1	104	11.8
$15,000-$24,999	486	12.4	65	12.5	294	11.7	127	14.4
$25,000-$34,999	625	15.9	89	17.1	377	15.0	159	18.0
$35,000-$49,999	656	16.7	83	15.9	421	16.7	152	17.2
$50,000-$74,999	826	21.0	102	19.5	565	22.4	159	18.0
$75,000-$99,999	372	9.5	42	8.1	259	10.3	71	8.0
$100,000 or more	386	9.8	48	9.2	288	11.4	50	5.7

Note: the sample sizes per variable may not add up to 5,154 due to missing values.

[*] $p<.05$,

[**] $p<.01$,

[***] $p<.001$ by the χ^2 test.

Table 2
Recruitment to and Participation in Clinical Trials

	Recruited N=574		Participated N=341	
	n	%	n	%
Race/Gender				***
White male	204	10.5	124	61.1
White female	262	12.6	169	64.8
Black male	33	8.9	14	42.4
Black female	54	9.7	21	38.9
Other male	6	8.5	6	100.0
Other female	8	16.7	4	50.0
Age Group		***		
Under 65	386	10.1	232	60.3
65 and over	185	14.4	107	58.2
Health Status		***		
Poor	49	17.7	30	61.2
Not poor	524	10.8	311	59.6
Education		***		
Never attended	0	0.0		
Elementary	14	9.0	6	42.9
Some high school	33	7.0	18	54.5
High school grad	133	7.6	87	65.9
Some college	165	12.8	93	56.4
College grad	113	15.2	70	62.5
Some graduate school	26	18.1	13	50.0
Graduate degree	87	17.3	53	60.9
Insurance Status		***		
No insurance	28	5.8	18	64.3
Through work or union	216	10.2	131	60.6
Someone else's work or union	65	9.1	37	56.9
Purchased directly	41	12.7	24	58.5
Medicare	176	14.8	98	56.0
Medicaid	20	16.3	13	65.0
Other group	6	8.2	5	83.3
Veterans' Administration	14	20.6	10	71.4
Income Level				
Less than $7,500	26	11.9	16	61.5
$7,500-$14,999	31	8.8	15	50.0
$15,000-$24,999	54	11.2	32	59.3
$25,000-$34,999	68	10.9	35	51.5
$35,000-$49,999	59	9.0	31	52.5
$50,000-$74,999	98	11.9	58	59.2

	Recruited N=574		**Participated N=341**	
	n	**%**	**n**	**%**
$75,000-$99,999	50	13.5	37	74.0
$100,000 or more	49	12.7	35	71.4
Geographical Area		***		***
Urban Baltimore City	133	19.7	62	47.0
Rural Eastern Shore	289	8.7	175	60.6
Rural Western Maryland	152	13.6	104	68.9

[*] $p < .05$,

[**] $p < .01$,

[***] $p < .001$ by the χ^2 test.

Table 3

Sources of Clinical Trial Information

	Church (N=123)	Community (N=393)	Doctor (N=663)	Print (N=2155)	Internet (N=707)	Radio (N=1843)	TV (N=2650)
	%	%	%	%	%	%	%
Race/Gender	***		***	***	*	***	**
White Male	1.7	6.6	13.8	41.5	14.1	40.4	52.5
White Female	1.5	8.0	14.5	48.1	14.6	34.8	54.6
Black Male	5.1	10.2	8.9	24.9	11.5	31.0	44.2
Black Female	4.3	8.5	8.4	36.0	10.4	31.3	49.5
Other Male	2.8	7.0	5.6	39.4	19.7	35.2	49.3
Other Female	6.3	10.4	12.5	52.1	18.8	45.8	58.3
Age Group	**			***	***	***	***
Under 65	2.1	7.8	12.9	43.6	16.2	40.0	55.3
65 and over	3.4	7.5	13.1	38.2	6.5	25.2	43.0
Health Status			***	*		***	
Poor	3.2	9.5	19.9	35.3	10.2	20.9	49.6
Not poor	2.4	7.6	12.6	42.7	14.0	37.1	52.4
Education		***	***	***	***	***	***
Never attended	0.0	0.0	9.1	36.4	27.3	36.4	36.4
Elementary	2.6	5.2	6.4	15.0	2.5	13.0	26.5
Some high school	3.4	5.8	6.0	18.6	7.0	17.5	39.4
High school graduate	2.3	5.2	10.2	31.4	8.0	29.8	47.5
Some college	2.0	8.2	14.0	47.7	15.8	41.0	57.9
College graduate	2.3	9.8	17.2	59.8	21.7	46.9	57.8
Some graduate school	2.1	11.1	19.6	60.1	21.1	53.8	58.9
Graduate degree	1.8	13.8	21.5	69.3	25.5	51.9	65.2
Insurance Status	*		**	***	***	***	***
No insurance	2.5	5.4	7.1	30.1	11.9	31.9	47.9
through work or union	1.6	8.3	12.8	47.2	16.8	41.8	56.7
Someone else's work or union	2.4	7.7	14.7	47.2	17.1	41.5	56.1
Purchased directly	2.2	8.1	14.5	42.5	16.1	41.4	53.3

	Church (N=123)	**Community (N=393)**	**Doctor (N=663)**	**Print (N=2155)**	**Internet (N=707)**	**Radio (N=1843)**	**TV (N=2650)**
	%	**%**	**%**	**%**	**%**	**%**	**%**
Medicare	3.5	7.5	14.0	37.5	7.1	25.2	43.6
Medicaid	4.0	8.9	18.0	29.2	12.2	28.5	54.5
Other group	5.5	6.9	8.3	44.4	13.7	30.6	53.5
Veterans' Administration	1.5	4.5	13.4	32.8	13.2	29.4	45.6
Income Level	*		***	***	***	***	***
Less than $7,500	4.1	6.9	11.1	29.8	10.0	24.1	44.3
$7,500-$14,999	3.4	8.2	9.0	29.7	8.1	23.6	45.1
$15,000-$24,999	3.9	5.6	11.3	34.2	9.3	31.2	48.5
$25,000-$34,999	1.6	6.6	11.1	35.3	13.1	31.9	50.7
$35,000-$49,999	2.1	7.0	12.3	45.2	13.6	39.8	54.2
$50,000-$74,999	1.9	9.0	12.4	51.6	18.0	42.7	57.3
$75,000-$99,999	1.3	9.0	16.8	55.6	21.6	54.2	63.0
$100,000 or more	0.8	9.6	22.3	61.5	22.0	52.4	60.2
Geographic Area		**		***		***	**
Urban Baltimore City	3.4	9.9	12.4	49.6	15.4	42.3	52.2
Rural Eastern Shore	2.2	6.8	12.6	42.2	13.5	38.2	53.4
Rural Western Maryland	2.2	8.9	14.2	38.2	13.6	26.6	48.5

[*] $p<.05$,

[**] $p<.01$,

[***] $p<.001$ by the χ^2 test.

Table 4

Factor Enabling Participation in Clinical Trials

	Reimburse (n=2612)	Insurance (n=3030)	Transport (n=2022)	Childcare (n=1144)	Knowledge (n=3313)	Time Comt. (n=2345)	No Name (n=1927)	Follow-up (n=3418)	Added Care (n=3302)
	%	%	%	%	%	%	%	%	%
Race/Gender	***	***		***	*		*	***	**
White male	58.0	64.2	40.0	20.4	66.0	48.5	35.7	69.1	66.9
White female	51.3	63.1	39.2	22.1	68.8	48.5	40.9	71.3	68.5
Black male	42.8	49.7	38.6	28.2	64.2	48.4	40.2	59.8	61.4
Black female	44.0	51.3	44.3	26.9	62.2	44.6	41.0	59.5	60.5
Other male	48.5	57.1	47.8	35.3	73.5	43.9	45.6	67.6	67.2
Other female	54.5	47.8	52.2	29.8	68.2	52.2	39.1	67.4	67.4
Age Group	***	***		***	***	***	***	***	***
Under 65	57.3	64.8	40.6	26.8	69.9	49.9	41.8	70.6	69.6
65 and over	37.0	48.5	39.1	10.0	57.2	42.2	29.6	60.5	56.2
Health Status			***				**		
Poor	50.9	62.8	55.1	22.5	64.0	49.0	29.7	64.8	68.6
Not poor*	52.4	60.7	39.4	22.6	66.8	47.9	39.3	68.3	66.1
Education	***	***	***	***	***	**	**	***	***
Never attended	63.6	45.5	36.4	36.4	63.6	45.5	45.5	63.6	63.6
Elementary	36.6	47.1	41.6	17.3	49.3	38.7	29.7	48.6	50.7
Some high school	45.1	51.6	45.1	29.0	58.5	45.8	32.6	55.0	53.8
High school grad	48.0	59.4	43.4	25.3	66.3	47.4	38.3	64.3	64.1
Some college	60.0	66.3	41.2	23.9	72.2	52.2	42.7	74.2	72.9
College grad	53.7	61.8	33.0	16.4	66.2	43.7	38.8	72.2	65.6
Some graduate school	60.3	68.3	41.1	16.5	65.5	54.9	36.2	80.4	77.5
Graduate degree	55.4	62.3	32.0	15.6	68.5	48.8	39.2	75.3	72.1
Insurance Status	***	***	***	***	***	**	***	***	***
No insurance	57.3	63.3	42.8	28.7	68.8	47.9	43.0	70.8	70.4
through work or union	56.4	64.5	38.0	24.4	69.1	50.9	41.7	70.2	68.8
Another's work or union	55.8	62.3	38.6	25.9	68.6	45.7	40.7	69.8	66.0

	Reimburse (n=2612)	Insurance (n=3030)	Transport (n=2022)	Childcare (n=1144)	Knowledge (n=3313)	Time Comt. (n=2345)	No Name (n=1927)	Follow-up (n=3418)	Added Care (n=3302)
	%	%	%	%	%	%	%	%	%
Purchased directly	52.4	62.5	34.2	22.0	67.7	47.7	38.5	66.9	69.4
Medicare	41.0	53.5	44.3	13.4	60.5	44.5	31.1	64.0	60.2
Medicaid	58.5	64.2	57.1	44.3	73.9	57.1	38.1	72.5	73.1
Other group	49.3	51.5	40.8	18.3	64.8	44.3	40.0	65.2	61.4
Veterans' Administration	45.3	41.5	43.9	17.9	53.7	35.4	29.9	50.0	55.2
Income Level			***	***	*		*	**	
Less than $7,500	57.4	62.5	54.5	31.3	73.4	52.2	41.8	69.0	69.8
$7,500-$14,999	52.3	61.1	51.6	26.9	63.5	49.3	39.8	65.7	67.4
$15,000-$24,999	57.6	64.9	50.0	28.9	70.3	50.3	44.8	70.4	69.1
$25,000-$34,999	54.6	64.8	44.7	26.5	71.0	50.8	41.6	68.8	68.8
$35,000-$49,999	57.9	69.5	43.0	26.3	73.8	52.3	41.7	77.2	75.3
$50,000-$74,999	58.1	65.4	37.3	21.1	70.0	51.0	40.4	73.8	69.6
$75,000-$99,999	58.9	64.9	32.2	21.6	69.7	49.2	40.7	73.8	70.5
$100,000 or more	52.8	60.8	25.1	16.0	66.0	52.9	31.4	74.3	66.7
Geographic Area	*	***	***		**	**		***	***
Urban Baltimore City	49.2	52.4	39.1	22.9	61.7	45.3	38.3	60.6	61.2
Rural Eastern Shore	51.7	60.4	38.4	21.9	66.8	47.4	38.6	68.8	65.9
Rural Western Maryland	55.6	66.7	46.1	24.4	68.9	51.1	39.6	70.3	70.1

[*] p<.05,

[**] p<.01,

[***] p<.001 by the χ^2 test.

Table 5

Multivariate Predictors of Recruited ("Ever Asked") to Participate in Clinical Trials

	Recruited to Clinical Trials ("Ever Asked")		
	Odds Ratio	**95% Conf.**	**Interval**
Black	0.61	0.44	0.85
Poor health status	1.83	1.21	2.76
Resident of rural Western Maryland	0.46	0.33	0.65
Resident of rural Eastern Shore	0.30	0.22	0.40
Have public insurance	1.98	1.57	2.51
Some college or higher level of education	2.31	1.84	2.92

Hosmer and Lemeshow Goodness-of-Fit Test p= 0.6746

Table 6

Multivariate Predictors of Participated in Clinical Trials (N=376)

	Participated in Clinical Trials		
	Odds Ratio	**95% Conf.**	**Interval**
Black	0.38	0.21	0.68
Middle income	0.57	0.37	0.89
Informed about clinical trials by a doctor	1.69	1.08	2.65
Knowledgeable about clinical trials	2.09	1.26	3.46
Have the time commitment to participate	1.67	1.06	2.63

Hosmer and Lemeshow Goodness-of-Fit Test p= 0.9280