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A Descriptive Analysis of State Legislation and Policy Addressing Clinical Trials Participation

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Abstract: Objectives. This report describes state policy and legislation related to clinical trials participation and Maryland's model to enhance clinical trial availability and participation. **Methods.** Descriptive review of state policy and legislation related to coverage for clinical trials costs based on data from the National Cancer Institute (NCI) State Cancer Legislative Database, the American Cancer Society, and NCI; additionally, discussion of Maryland's comprehensive multilevel clinical trial model comprising policy initiatives, community engagement, research, education, and infrastructure support. **Results.** Twenty-four states have mandated clinical trial coverage through specific legislation or agreements since 1994. Covered benefits varied among the states. **Conclusions.** Besides cost and insurance barriers, there is a need to address important patient, physician and researcher, and structural barriers to clinical trial participation. Maryland provides a comprehensive model to address the multi-faceted clinical trial participation determinants as it tracks state and federal policy, documents trial barriers, and conducts community education.

Key words: Clinical trials participation, policy, legislation, insurance coverage, Maryland clinical trials, diversity.

Clinical trials have produced advances in therapy and prevention for many diseases including cancer. These advances have occurred despite considerable challenges, including low participation of cancer patients in general,^{1,2} low participation by underserved groups (African American, uninsured, poor, rural),^{2,3} and a declining percentage of African American participation, both nationally and in Maryland.³ Low participation rates in cancer trials by African Americans and other minorities may contribute to avoidable disparities in cancer, including higher cancer morbidity and mortality rates.⁴

One of the barriers to participation in clinical trials is actual or perceived costs related to health insurance coverage for trials anticipated by both patients and physi-

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cians,^{2,5-10} especially for communities experiencing health disparities such as minorities and the medically underserved. The American Cancer Society (ACS) reported that 60% of patients do not take part in clinical trials due to fears of having their insurance denied.¹¹ According to the American Society of Clinical Oncology (ASCO), this is a valid concern as denial for routine care costs was reported by oncologists as an obstacle to enrollment in cancer trials.⁵ Despite concerns about the cost of cancer trials among insurers and other payers, it is noteworthy that the incremental costs of Phase II⁶ and Phase III^{6,12} clinical trials over standard treatment costs are modest.

The National Cancer Institute (NCI) identifies two main types of costs associated with clinical trials: *patient care costs* and *research costs*.^{7,9,13-18} Patient care costs are classified as either *usual care costs* or *extra care costs*. Usual care costs (the costs of undergoing treatment) are usually reimbursed by private insurance or Medicare. The extra care costs (additional tests and services associated with trial participation) may or may not be fully covered by the trial sponsor, the research institution, and/or the trial participant's private insurance. Research costs (administrative and staffing costs) are typically not as much of a concern because they are generally fully covered by the research institution and/or the clinical trial sponsor.

Decisions regarding coverage for clinical trial participation, historically, were based on type of costs and assessment of whether the care (i.e., treatment in the trial) is established or investigational. Patient care costs for investigational treatments are not routinely covered by health insurance plans, particularly for patients participating in Phase I or Phase II trials,^{7,9,13-18} as many insurers are reluctant to support the costs for "investigational" rather than "established" clinical trials. Established treatments have typically been available long enough to be considered safe and effective. Insurers review the sponsorship of the clinical trial and the type of trial (Phase III trial is more likely to be accepted than Phase I or II trial) as part of the determination of the trial as investigational or established. Other factors that influence the decision to cover clinical trial costs are whether the treatment is "medically necessary" and cost neutral, whether other treatment options are available, and what the qualifications of the facility and staff are.

In 1993, the National Institutes of Health (NIH) Revitalization Act (Public Law 103-43)¹⁹ was amended to require the inclusion of women and minorities in clinical and government sponsored human subject research, including Phase III clinical trials. This Act states that cost is not an allowable reason for excluding minorities and that the NIH will support outreach efforts to fulfill this mandate. In 2001, NIH policy and guidelines on the inclusion of women and minorities as participants in clinical research were further amended to require all NIH-funded clinical research be carried out in a manner sufficient to elicit information about individuals of both sexes/genders and diverse racial/ethnic groups and, particularly in NIH-defined Phase III clinical trials, to examine differential effects on such groups. In 2001, NIH adopted the definition of clinical research to include patient-oriented research (i.e., research conducted with human subjects, or on materials of human origin, for which an investigator directly interacts with human subjects); epidemiologic and behavioral studies; and outcomes research and health services research.²⁰

Given this complicated set of circumstances regarding cost of care for patients in

clinical trials, the role of policy and state legislation or regulation has emerged as an important consideration for addressing access, coverage and participation in clinical trials. This consideration has led to advocacy and state and federal efforts addressing reimbursement policies. The U.S. federal government and a number of states have implemented policies related to enhancing accrual to clinical trials, especially among patients who might otherwise not enroll in a trial,⁶ which have translated into federal policy or state legislation and/or entered special agreements that require state health plans to pay the cost of routine medical care provided during clinical trials. In some cases, this also includes agreements with state Medicaid programs to assure coverage of clinical trial costs. The state policies and legislative activities have focused on providing increased access to clinical trials by mandating insurance coverage for clinical costs associated with trial participation, and fostering informed consent and public disclosure of trial results and adverse events/errors that may occur.

A number of states have passed legislation to mandate coverage of costs, usually clinical costs associated with trial participation, such as uncovered blood work, x-rays and, even more importantly, clinical costs that result from diagnosis of unexpected medical conditions found during the course of the trial monitoring and not covered by the trial sponsor. In 2000, in an Executive Memorandum, the U.S. President directed the Department of Health and Human Services to revise Medicare payment policy to reimburse the routine patient care costs of clinical trials.²¹ In 2007, the Center for Medicare Medicaid Services (CMS) amended the clinical trials coverage policy. In addition, several states require health plans to pay for the costs of federally supported clinical trials.¹⁸

This paper describes the role of policy and state legislation in addressing disparities in clinical trial participation. Moreover, given that patient care costs and insurance payments as addressed through state mandates are important, albeit not primary determinants of enrollment into clinical trials, this paper describes a case study of Maryland's experience with trial availability and participation policy. Maryland's case study describes a comprehensive model to increase awareness and educational programs, and insurance coverage to enhance the enrollment into clinical trials particularly of minorities and the rural underserved.

Methods

The data presented herein were prepared as a report for a national policy roundtable meeting held at Baylor College of Medicine in Houston, Texas in September 2006 as part of the Eliminating Disparities in Clinical Trials (EDICT) project.⁸ The EDICT Policy Roundtable convened over 150 experts and focused specifically on the disproportionate disease burden for minority and underserved populations in the areas of oncology and asthma. Roundtable participants reviewed existing data on the scope and impact of disparities in clinical trials to create an agenda for current and future policies.

As part of the EDICT Policy Roundtable, the lead author was asked to develop a report which examined state policies related to clinical trial coverage by insurers. The primary sources of data for the state review were the NCI State Cancer Legislative Database, ACS, and NCI. Existing data from the ACS and the NCI provided the basis

for this review, which was conducted to determine the following: (1) the policy basis for trial insurance coverage (i.e., mandated legislated benefit or rule or “special agreement”), (2) the year of enactment, (3) the types of services or benefits covered, and (4) the payment source required.

Results

Box 1 provides a summary of state mandates related to clinical trial coverage. Twenty four states have mandated clinical trial coverage through specific legislation or agreement since 1994. Of those, 11 states cover routine and/or medically necessary patient costs for Phase I–IV clinical trials (Arizona, California, Georgia [2002 agreement], Maine, Massachusetts, Nevada, New Hampshire, New Jersey, Tennessee, Vermont, and Wisconsin). Seven states cover patient costs for Phase II–IV clinical trials only, including Illinois, Louisiana, New Mexico, North Carolina, Rhode Island, Virginia, and West Virginia.

The remaining six states vary in coverage levels. Connecticut covers routine patient care costs for Phase I, II and IV cancer clinical trials, but only Phase III prevention trials. Delaware covers routine patient care costs for clinical trials for the treatment of life threatening diseases as specified in the legislation. Maryland covers patient costs incurred in Phase I–IV cancer treatment, supportive care, early detection, and prevention trials; however, patient costs are covered only in Phase II–IV for other life-threatening conditions and coverage for Phase I trials are considered on a case-by-case basis. Michigan allows patient care costs for Phase II and III clinical trials only, but includes treatment costs from side effects of the trial including hospitalization. Missouri allows coverage of routine patient care costs for Phase III or IV clinical trials for the prevention, early detection, or treatment of cancer. Ohio mandates coverage of costs from NCI-sponsored Phase II and III clinical trials for state employees insured by the Ohio Medical Plan.

The required payers of mandated services and benefits differ by state and range from private health plans, hospital or medical service corporations, health care service or health maintenance organizations, managed care plans, disability insurers, and Medicaid and other state medical assistance programs.

Discussion

Policy role and state legislation on mandating coverage for associated costs. While an important step, state insurance mandates and federal policy do not guarantee access to or coverage of costs for trials for the most vulnerable populations. Evidence suggests that federal and state policy and legislation may have a mixed effect on enhancing recruitment into clinical trials. In one study, Medicare policy change in 2000 was reported to have resulted in higher enrollment of older patients in cancer clinical trials, especially those who supplemented their Medicare insurance with private insurance;²² another study²³ did not find a significant increase in the enrollment of older patients in cancer trials. The 2002 California law (SB37) requiring health plans to reimburse routine costs of care for cancer trials resulted in insurance (government and/or private)

Box 1.**SUMMARY OF MANDATED CLINICAL TRIALS COVERAGE BY STATE^a**

State	Year	Services and benefits covered	Who is required to pay
Arizona	2000	Patient costs for Phase I–IV clinical trials	Hospital or medical service corporations, benefit insurers, health care service organizations, disability insurers, group disability insurers and accountable health plans
California	2001	Routine patient care costs for Phase I–IV cancer clinical trials	All California insurers, including Medicaid and other medical assistance programs
Connecticut	2001	Routine patient care costs for Phase I, II and IV cancer clinical trials. Prevention only for Phase III.	Private insurers, individual and group health plans
Delaware	2001	Routine patient care costs for clinical trials for the treatment of life threatening diseases (conditions specified in the legislation)	Every group of blanket policy, including policies/contracts issued by health service corporations
Georgia ^b	2002* 2000	<i>2002 Agreement:</i> Routine patient costs for Phase I–IV clinical trials for children and adults. <i>2000 Law:</i> Routine patient costs for Phase II–III prescription drug clinical trial programs for the treatment of children's cancer	Insurers and the state health plan
Illinois	2004 1999	Routine patient care for approved Phase II–IV cancer research trial	HMOs and individual/group insurance policies to offer coverage to the applicant or policyholder. (2004: Plans may not be canceled or not renewed based on participation in a qualified clinical trial.)
Louisiana	1999	Patient costs for Phase II–IV cancer clinical trials	HMOs, PPOs, State Employee Benefits Program and other specified insurers
Maine	2000	Routine patient care costs associated with Phase I–IV clinical trials	Managed care organizations and private insurers, HMOs, PPOs

(Continued on p. 29)

Box 1. (continued)

State	Year	Services and benefits covered	Who is required to pay
Maryland	1998	Patient costs for Phase I–IV cancer treatment, supportive care, early detection, and prevention trials; Phase II–IV for other life-threatening conditions; Phase I on a case-by-case basis	Private insurers and other specified managed care organizations
Massachusetts	2002	Patient care services for Phase I–IV qualified cancer clinical trials	All health plans issued or renewed after Jan. 1, 2003
Michigan*	2002	Patient care costs for Phase II and III clinical trials, including treatment costs from side effects of the trial including hospitalization	Private plans, HMOs, Michigan Medicaid
Missouri	2002	Routine patient care costs for Phase III or IV clinical trials for the prevention, early detection, or treatment of cancer	All health benefit plans operating in the state
Nevada	2005 2003	Routine patient care costs and health care services required for clinically appropriate monitoring of the policy holder during Phase I–IV clinical trials	Group and individual insurers, HMOs
New Hampshire	2000	Medically necessary routine patient care costs for Phase I–IV cancer treatment trial for a life-threatening diseases	Private insurers and specified managed care plans
New Jersey ^b	1999	Patient care costs for Phase I–IV cancer clinical trials	All insurers in the state, including those affiliated with New Jersey Association of Health Plans
New Mexico	2004 2002 2001	Routine patient care costs for Phase II–IV cancer clinical trials	Private insurers, specified managed care plans, and Medicaid and other state medical assistance programs
North Carolina	2001	Medically necessary costs of health care services for Phase II–IV of covered clinical trials	All health insurance plans and teachers' and state employees' comprehensive major medical plan.

(Continued on p. 30)

Box 1. (continued)

State	Year	Services and benefits covered	Who is required to pay
Ohio*	1999	NCI sponsored Phase II and III clinical trials for Ohio State employees insured in Ohio Med Plan	Ohio Med Plan
Rhode Island	1999 1997 1994	Coverage for new cancer therapies if treatment for Phase II–IV cancer clinical trial	Private insurers and specified managed care plans
Tennessee	2005	Routine patient care costs for Phase I–IV cancer clinical trials	All health benefit plans, excluding individually underwritten policies
Vermont	2005 2001	Routine patient care costs for Phase I–IV cancer clinical trials	All health insurance policies and benefit plans, including Medicaid
Virginia	2001 1999	Patient costs for Phase II–IV cancer clinical trials (case-by-base basis for Phase I)	Private insurers, specified managed care plans, and public employee health plans
West Virginia	2003	Patient costs for Phase II–IV clinical trial for treatment of life-threatening condition or the prevention, early detection and treatment of cancer	Individual/group insurers, health service corporations, health care corporations, HMOs, public employees insurance agency, Medicaid, and the children's health insurance program
Wisconsin	2006	Routine patient care for Phase I–IV	State and specified insurers

*In 2008, the state of Wyoming passed legislation to mandate coverage of routine patient care for some clinical trials. Because this legislation was passed after this analysis had been finalized, specific details about this legislation were not included.

^bIndicates special agreement rather than legislation.
 Sources: American Cancer Society. *Clinical Trials: State Laws Regarding Insurance Coverage*. Updated: 1/30/06. Accessed: 7/31/06. http://www.cancer.org/docroot/ETO/content/ETO_6_2x_State_Laws_Regarding_Clinical_Trials.asp.
 National Cancer Institute, State Cancer Legislative Database, Bethesda, MD: SCLD. Accessed: 09/11/2006. <http://www.sclld-nci.net/>
 National Cancer Institute, *Insurance Coverage: All States*. Updated 8/23/2005. Accessed: 09/17/2006. <http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs-all-states>

not being a factor in determining whether patients would enroll in trials and there was a higher willingness on part of the patients to enroll in trials.²⁴ States with mandated coverage of routine medical care costs for cancer clinical trials compared to states without such policies had higher enrollment into NCI Phase II trials but not in Phase III Clinical Trials Cooperative Group trials.²⁵ In 1998 and 1999, Maryland passed state health insurance mandates into law including coverage of trial associated clinical costs.¹¹ However, although Maryland law mandates coverage for costs associated with participation in clinical trials, the Employee Retirement Income Security Act (ERISA) and restrictions in application of this law mean that this benefit, as well as other state mandated benefits, may cover only 25% of the insured population.

Disclosure of adverse events and results. Some states support clinical trial registries as a tool for providing information on open trial protocols, trial results, and disclosure of errors or adverse events. Clinical trial registries, beyond federally supported trial registries (i.e., state trial registries), have been receiving increased interest in some states.

Elimination of disparities in trial participation and enrollment. The increase in state legislation and regulation on insurance coverage for clinical trials was an attempt to address the real and perceived cost barriers to trial participation. In the absence of such state policies and regulatory actions, cost barriers to trial participation would persist for the populations that are actually covered under state mandates. Removing costs as a barrier through state mandates does not necessarily increase access or participation in trials due to ERISA, particularly if the mandate is not widely known.

Patient, physician, and structural barriers to enrollment in clinical trials. While federal and state policies may address some of the cost and payment related barriers to clinical trials, the actual participation in clinical research and clinical trials in particular is influenced by several factors. Although a majority of Americans express willingness or an inclination to participate in clinical trials,^{1,26} there are several non-cost-related and non-insurance-related patient, health care professional and researcher, and structural factors that impede clinical trial participation (see Box 2).

A case study: Maryland's experience with trial availability and participation policy. Maryland has developed a community-based model to expand the availability and awareness of clinical trials in underserved areas. The model includes parts for improving awareness and knowledge of trials and how to refer patients for community physicians, education of the general public, and support for infrastructure to support clinical trials in community settings. Moreover, the Maryland program on clinical trial addresses several of the patient, provider, and structural barriers listed in Box 2. Support from key state policymakers and ongoing technical assistance were developed with elected officials. As part of a multilevel strategy, both qualitative and quantitative research has helped to elucidate existing attitudes toward clinical research and to identify specific barriers that may exist for participation among Maryland residents. Comprehensive community-based programs to educate the general public and health professionals have been developed. Efforts to support clinical trial infrastructure, including adding resources, such as data collection tools and research staff, have been put in place. Some of these initiatives are described below.

The University of Maryland Statewide Health Network (UMSHN). The University of

Box 2.

SELECTED EXAMPLES OF FACTORS THAT IMPEDE PARTICIPATION IN CLINICAL TRIALS

Barriers to clinical trial participation	Examples
Patient factors or demographics	<ul style="list-style-type: none">• racial/ethnic minority^{2,3,27,31-36}• older age^{2,3,23,32,34-39}• rural geography of residence²• poor access to health care services⁴⁰• low socioeconomic status^{2,27,31-34,41-43}• comorbid conditions³⁴• gender-based preferences and beliefs⁴⁴• time commitment to participate in trials²⁷
Patient/community awareness, trust issues and history	<ul style="list-style-type: none">• mistrust of research/medical system^{31,40,42,44-48}• fear of negative results/effects⁴¹• historical factors⁴⁸• lack information about clinical trials²⁷• lack information about available trials^{40,42}• not receiving information about clinical trials from health care professionals²⁷
Physician and researcher barriers	<ul style="list-style-type: none">• reluctance to refer patients to trial (fear of losing them^{1,40,48,49})• distrust institutions conducting trials^{10,49}• lack of awareness/knowledge about clinical trials and/or the benefits of clinical trials^{41,42,50-52}• poor communication skills of researchers and health professionals to discuss and inform potential trial participants about the trials^{10,27,32,42,53}• perceptions of the lack of proven therapy with reasonable results^{10,51}• perceptions that clinical trial protocols are complex^{10,51}• lack of culturally appropriate researcher training to recruit patient to trials and address their concerns^{46,53,54}
Infrastructure, design issues	<ul style="list-style-type: none">• lack of sufficient number of appropriate clinical trials• disqualification of patients due to eligibility criteria or the failure to comply with specified research protocols^{1,10,33}• lack of sufficient infrastructure to support trials in community settings^{2,10,51}• lack of proximity of enrollment centers³⁶• physicians' practice type/setting in non-academic settings⁵²
Perceived or actual cost barriers	<ul style="list-style-type: none">• lack health insurance to cover the cost of trials and/or associated medical care⁷• physicians may be reluctant to refer patients to trials due to real and perceived additional costs^{2,10}• oncologists concern for lack of reimbursement for clinical and research costs^{5,10}

Maryland Statewide Health Network is a regional and statewide, community-based infrastructure established in 2000 with support from Maryland's Cigarette Restitution Fund Program to promote a broad range of prevention and control activities on cancer and other tobacco-related diseases (Principal Investigator: Dr. Claudia R. Baquet). The overall goals of the UMSHN are: (1) to reduce morbidity and mortality from cancer and other tobacco-related diseases; (2) to reduce or eliminate disparities in cancer deaths attributable to racial/ethnic, cultural, geographic, or socioeconomic barriers; and, (3) to foster increased awareness of and participation in clinical trials, especially in community settings. The UMSHN has established a central office and community regional offices across the state in urban and rural areas. The offices provide locations for ongoing community and physician educational programs, community-based research and educational programs on available trials, human subject protections and trial best practices. Goal three was a formal policy for the UMSHN in order to assure statewide focus on increasing awareness, availability, and participation in trials in the state. Analyzing barriers to trials including perceived cost barriers and the role of policy are components of our programs.

The University of Maryland Statewide Health Network Baseline Health Survey. In order to identify Maryland's clinical trial barriers, we implemented a population-based telephone survey of households in Maryland. This comprehensive survey included self-reported information on health status and health behaviors as well as knowledge, barriers and attitudes regarding clinical trials.^{27,28} A cross-sectional design was used to survey English-speaking, non-institutionalized men and women aged 18 years or older in 13 jurisdictions. This survey was conducted in English only because there are a limited number of non-English speaking populations in the geographic areas targeted for this study. Of the 5,154 respondents, 574 respondents (11.1%) reported recruitment in clinical trials. Of those, 341 respondents (59.4%) actually participated in clinical trials. The data showed that respondents who were significantly more likely to participate in clinical trials received information from their health care providers, were knowledgeable about clinical trials, and could commit time for participation. Those significantly less likely to participate in clinical trials were African Americans and middle-income respondents. The majority of the study participants reported that the lack of physician discussion about clinical trials was a major reason for little patient interest in trials. These results supported the need for increased targeted efforts to educate physicians as well as minority and rural patients and to provide the basis for development and implementation of community-based educational programs for both the general public and health care professionals.²⁷ Anecdotal data from Maryland primary care physicians suggest physician concern about lack of reimbursement for patient participation in trials is a barrier for clinical trial discussions with their patients. Additional information that details the rationale and methodology for this study has been documented elsewhere.²⁸⁻³⁰

Qualitative focus group study of mandated health care and cancer trial coverage in Maryland. A series of six focus groups were conducted across the state to determine awareness by the general public and understanding of Maryland's state legislative initiatives for assuring health benefits for specific diseases including cancer. These sessions revealed a number of important themes. The focus group participants, in general,

were unaware of legislative initiatives in place in Maryland for mandated health coverage including the clinical trial coverage benefit. In addition, the participants were not aware that a governing body was in place that enacted laws to mandate insurers, health maintenance organizations, and non-profit health services to provide coverage for clinical trial-related patient care costs. For both male and female participants, this lack of information about mandated benefits was considered a barrier for access to health care and clinical trial participation.*

U.S. Secretary of Health and Human Services National Best Practice Designation. In the fall of 2004, the University of Maryland School of Medicine (UMSOM) and Eastern Shore Oncology, PC, received a prestigious peer reviewed national “Best Practice” award from the U.S. Secretary of Health and Human Services for a proven model to increase cancer trial availability and cancer patient trial participation on the rural Eastern Shore of Maryland.²⁹ With support from the Maryland Special Populations Cancer Research Network (principal investigator: Dr. Claudia R. Baquet; NCI U01 CA86249-03), the Maryland affiliate of the Susan Komen Foundation (principal investigator, Dr. Mary DeShields) and the state tobacco settlement fund, the program dramatically increased clinical trial availability and participation in the rural Eastern Shore of Maryland. The model program has established a clinical-academic partnership that fosters increased availability of cancer trials; provides intensive health care professional continuing education on clinical trials; provides intensive community awareness and education programs on clinical trials for the general public and minority communities; and provides clinical trials infrastructure support. Results of this comprehensive program are presented elsewhere.³⁰

The Maryland Special Populations Cancer Research Network. The Maryland Special Populations Cancer Research Network (MSPN) was one of 18 five-year grants funded from 2000–2005 by the NCI.³⁰ Its primary goal was to reduce and eliminate cancer disparities in Maryland minority and underserved populations; however, increasing clinical trials availability was an essential component of the Maryland Network. Through MSPN, the UMSOM has provided education and clinical trials access to underserved populations in urban Baltimore City, and rural populations in Southern Maryland, the Eastern Shore, and Western Maryland. Clinical trials education has been provided to underserved communities in urban Baltimore City, to Tribal populations in rural Southern Maryland and along the rural Eastern Shore. In addition to the Best Practice designation,²⁹ key accomplishments of relevance of MSPN that influenced clinical trials work conducted in Maryland included the leveraging of several million dollars in grant funding to support community programs, and research and development of tools for technical assistance with key state policymakers.

Technical assistance for elected officials and their staff. Fostering science and data-driven advocacy and policy contributes significantly to addressing health disparities and

*Baquet CR. Qualitative focus group study of mandated health care and cancer coverage in Maryland: awareness and understanding among rural and urban underserved. Baltimore, MD: The University of Maryland School of Medicine and the UMB Center for Health Policy/Health Services Research. Draft #3. (In preparation.)

underrepresentation in clinical research. As part of our efforts in Maryland, ongoing dialogue with the Maryland state legislature (the Maryland General Assembly) has been an essential part of our research on policy related to health disparities and clinical trials. Legislative champions quickly merged in the both the Maryland Senate and House in the area of health disparities and clinical trials access. The recognition of the importance of clinical research and trials participation to their constituents was of obvious benefit to members of the General Assembly.

Conclusions

While the University of Maryland School of Medicine initiatives have shown progress in increasing the knowledge and availability of clinical trials in certain areas of Maryland, additional research, consistent resources, data reporting and state policy tracking initiatives are needed to improve clinical trials participation locally and nationally. This analysis has generated a number of specific recommendations designed to increase understanding of clinical trials accrual and retention, including documentation of barriers that lead to decreased participation in trials and successful strategies to influence participation. Specific recommendations are described below.

- In order to increase understanding of disparities in trial participation, specific and systematic policy research should be supported on the role of state and federal insurance mandates in addressing barriers to trial participation.
- Tracking population-specific data on trial participation trends and barriers, studies on accrual and reasons for trial withdrawal (drop outs) by race and insurance status would lead to greater understanding of the specific issues that affect clinical trials accrual issues for both health professionals and patients.
- Development, adaptation, and widespread dissemination of best practices that increase trial availability and trial participation are essential. Development of state policy and regulatory best practices is also an important component of efforts to address disparities in trial participation. Technical assistance for elected officials and their staff and other policymakers is of benefit and should be systematically undertaken.
- Advocacy is critical for consistent funding and resources to support community-based trials, infrastructure, and accrual.

Acknowledgments

This research was supported by the National Institutes of Health (NIH) National Center for Minority Health and Health Disparities (NCMHD) University of Maryland Comprehensive Center for Health Disparities Research, Training, and Outreach (grant number:1P60MD000532) and the National Cancer Institute (NCI/NIH) Maryland Regional Community Network Program to Eliminate Cancer Health Disparities (grant number: 5U01CCA114650) and EDICT.

The authors would like to acknowledge Barbara McLean, Patricia Commiskey, and Rachel Shada for their contributions to this project.

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