

“Community-Based Participatory Research: The Role of Communities and Partnerships”

Supporting Maryland Communities Through Community Infrastructure and Enhanced Capacity

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Xavier University Third Annual Health Disparities Conference - April 2009

Presented at the Xavier University of Louisiana College of Pharmacy's 3rd Annual Health Disparities Conference – April 19-21, 2009

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Learning Objectives

- Discuss Role of Community Partnerships and Engagement in Health Disparity Research
- Discuss Community Roles in Research Translation
- Describe Maryland Community Infrastructure and Models, including MPACT - the statewide “Maryland Program Advancing Clinical Trials”
 - Community engagement (CBPR) and resource sharing
 - Focus on underserved communities
 - Developed through partnerships with communities across the state and state academic health center
- Discuss “National Best Practice Award” from DHHS Secretary and Committee on Science and Policy HHS (2004)

Key Elements of Maryland Comprehensive Approach to Health Disparities

- **Infrastructure and Community Capacity**
- Partnerships:
 - Community organizations, HBCUs, local health care providers, faith-based organizations, local media, FQHCs, and health departments
- Multidisciplinary research across the continuum
- Data and evidence-guided programs
- Science-guided policy and policy research
- Diversity in clinical trials participation
- Leveraging resources for sustainability

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University of Maryland Statewide Health Network (UMSHN)

Infrastructure

Mission: *Reduce morbidity and death from cancer and tobacco-related diseases and to reduce disparity in cancer deaths attributable to racial/ ethnic, cultural, geographic, or socioeconomic barriers*

- The Network is community-based, statewide and regional infrastructure which supports:
 - the delivery of prevention and control evidence based best practices addressing cancer and tobacco related diseases, and
 - faculty-community outreach and research
 - promotion of diversity in clinical trials and research.
- Organizational structure includes:
 - A central office in Baltimore City
 - Regional presence in Baltimore, Southern Maryland, Eastern Shore and Western Maryland
- Supported by Maryland's Cigarette Restitution Fund.

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Network Components

Statewide and regional partnerships.

- Mutually beneficial partnerships in regions focused on community engagement

Community-based infrastructure for community-based participatory research and community engagement.

- Infrastructure also provides mechanism for active participation in research and education by racial/ethnic minorities, low-income whites, and medically underserved residing in rural geographies traditionally underrepresented in such activities.

Enhanced public trust and participation in research

- Best Practice model for increasing availability of community based cancer trials and steady increases in trial accrual is testament to ***grass-roots multi-level approach to enhance public trust and participation in research.***
- Another example is the Breast and Colorectal Cancer Patient Navigation project.

Network Components

Provides non-duplicative dissemination of health information.

- Targeted to local needs
- Jointly identified with input from the community
- Non-duplicative of efforts conducted by partners and/or other entities involved in dissemination of health information.

Credibility and public trust.

- Presence in the community, participation in local coalitions, leadership role in health information dissemination, support of local partners, and assistance to local partners have contributed to the development of a recognizable and trusted entity

Navigation of medically underserved communities

- **Theory based studies on Community Health Workers**
- Linkage of patients with caregivers
- Local Health Department
- UMSHN regional staff and community health workers navigate such requests to appropriate health care organizations/ professionals.

Network Theoretical Framework

Social Ecological Framework

University of Maryland Statewide Health Network (UMSHN)



University of Maryland Statewide Health Network (UMSHN) Community, Telehealth/ Videoconference Linkages Unique Infrastructure



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Assuring Diversity in Clinical Research Participation

- A national priority
- Minority, uninsured, poor, and rural communities have lower participation rates in medical research.
- Underserved communities experience substantial health disparities.
- Substantial barriers across multiple levels impede participation in clinical trials.
- Building community-academic partnerships and community trust is essential.



Clinical Trials: Background

- Clinical trials are critical for discovery and development of new prevention, diagnostic and treatment modalities for disease.
- Participation in clinical trials, including cancer trials, is lower for African Americans, uninsured and poor, and rural patients.
 - Low participation by African Americans, other minorities and rural communities contributes to survival and mortality rate disparities.
 - Low participation impedes research advances, translation and favorable outcomes.

Comis RL, et al. Public attitudes toward participation in cancer clinical trials. *J Clin Oncol.* Mar 1 2003;21(5):830-835.

Sateren WB, et al. How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *J Clin Oncol.* Apr 15 2002;20(8):2109-2117.

Baquet et al. 2006 and 2008 Ca Detection and Prevention and JCO

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Issues in Cancer Clinical Trial Participation

- 2009:
 - Estimated 1.4 million new cancers diagnosed
 - Over 500,000 deaths projected
- 3-5% of cancer patients participate in clinical trials
- Low participation by underserved communities (African American, uninsured, poor, rural)
 - A declining percentage of African Americans participating
- 32% of Americans would be willing to participate in trials if asked; an additional 38% would be inclined to participate if asked but had questions/reservations.*
 - Factors other than patient intent or willingness present barriers to participation in clinical trials.**

*Comis RL, et al. Public attitudes toward participation in cancer clinical trials. *J Clin Oncol*. Mar 1 2003;21(5):830-835.

**Baquet et al. 2008.

Barriers to Research Participation

- Patient
- Health care professional
- Historical
- Structural or organizational
- Knowledge and awareness in general public
- Insufficient community infrastructure to support clinical research and trials
- Historical factors



Researcher Barriers

- Lack of culturally tailored approaches to trial accrual and retention
- Fear or distrust of academic institutions and researchers by patients and community
- Lack of training in:
 - cultural competence
 - culture and health
 - disparities
- Communication skills
 - literacy
 - language
 - sensitivity



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"> • minority • aging and rural • poor access to care • low socioeconomic status
Patient/Community awareness, trust issues and history	<ul style="list-style-type: none"> • mistrust of research / medical system • fear of negative results/effects • historical factors • lack of information on available trials
Physician and researcher barriers	<ul style="list-style-type: none"> • reluctance to refer patients (fear of losing patient) • lack of awareness / knowledge of clinical trials benefits • doctor–patient communications • lack of culturally appropriate researcher training to address patient concerns
Infrastructure, design issues	<ul style="list-style-type: none"> • lack of sufficient number of appropriate clinical trials; • disqualification of patients due to eligibility criteria • lack of sufficient infrastructure to support trials in community settings
Perceived or actual cost barriers	<ul style="list-style-type: none"> • patients may be reluctant to participate due to lack of insurance or fears of additional costs • physicians may be reluctant to refer patients due to real and perceived additional costs • oncologists concern: lack of reimbursement for clinical and research costs (ASCO)

Baquet CR. The Role of State Legislation and Policy in Addressing Disparities in Clinical Trials. Eliminating Disparities in Clinical Trials (EDICT). http://www.bcm.edu/edict/PDF/State_Legislation.pdf.

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Strategies for Overcoming Barriers and Increasing Participation

FORMAL PARTNERSHIPS between academic institutions and community:

- General Public and Ministers Model (Times Community Services)
- Clinical Eastern Shore (Eastern Shore CRN)
- Print Media

COMMUNITY PARTICIPATION AND COMMUNITY CENTERED:

- Faith and community based organizations: Ministerial Alliances
- Local health departments and community hospitals and FQHCs
- Print and broadcast media
- Policy makers

TRAINING for research personnel regarding:

- Community concerns
- Culturally sensitive communication
- Sharing results

INFRASTRUCTURE: Cover regulatory & data expenses

COMMUNITY HEALTH PROFESSIONAL CME/CE:

- Physicians and Nurses
- Rural and Urban



University of Maryland

Barriers to Clinical Trials Research Study

GOAL: examine the health behavior, clinical trials barriers, health care access, screening and health status of Maryland residents

- Survey of 5,154 English-speaking, non-institutionalized men and women aged 18+
- 13 jurisdictions in Maryland (December 2001-March 2003), including:
 - urban Baltimore City
 - rural Western Maryland
 - rural Eastern Shore
- Cross-sectional study design using random digit dialing (RDD) methodology
- *Clinical trial barriers and factors are predictive of participation and attitudes and information channels.*

Baquet CR, et al. Recruitment and Participation in Clinical Trials: Socio-Demographic, Rural/Urban, and Health Care Access Predictors. *Cancer Detection and Prevention*. 2006; 30.

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Maryland Clinical Trial Barriers Research Results

- 80.0% of blacks and 50.9% of whites reported not knowing what a clinical trial is.
- Over 95% reported their physician never discussed clinical research/trials.
- 11.1% reported *previous recruitment* into clinical trials.
 - Of those, 59.4% actually participated in clinical trials.



Baquet CR, et al. Recruitment and Participation in Clinical Trials: Socio-Demographic, Rural/Urban, and Health Care Access Predictors. *Cancer Detection and Prevention*. 2006; 30.

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Maryland Clinical Trial Studies

“Multivariate Predictors of Recruitment and Participation in Clinical Trials”

- **Were significantly more likely to be recruited:**
 - in poor health (OR=1.83, CI=1.21-2.76),
 - had public health insurance coverage (OR=1.98, CI=1.57-2.51), and
 - had some college or higher level of education (OR=2.32, CI=1.84-2.92).
- **Were significantly more likely to actually participate:**
 - informed about clinical trials by their health care provider (OR=1.69, CI=1.08-2.65),
 - knowledgeable about clinical trials (OR=2.09, CI=1.26-3.46), and
 - able to make the time commitment (OR=1.67, CI=1.06-2.63).
- **Black respondents were significantly less likely to be recruited (OR=0.61, CI=0.44-0.85) and less likely to participate (OR=0.38, CI=0.21-0.68) in clinical trials.**

Baquet CR, et al. Recruitment and Participation in Clinical Trials: Socio-Demographic, Rural/Urban, and Health Care Access Predictors. *Cancer Detection and Prevention*. 2006; 30.

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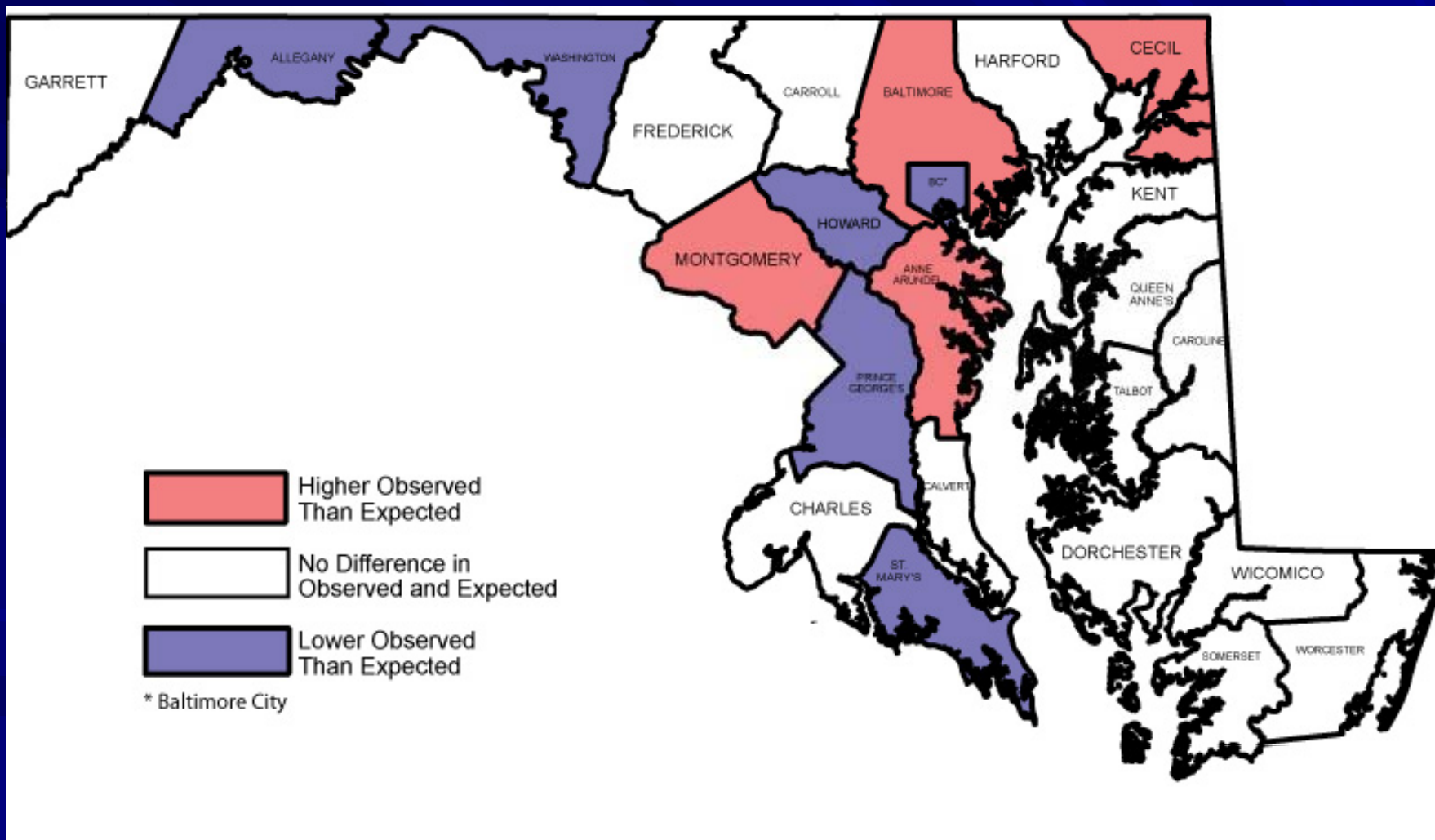
Accrual of Maryland Cancer Patients to NCI sponsored Treatment Clinical Trials Study

- Examined relationship of socio-demographic factors on accrual of MD cancer patients to NCI sponsored cancer treatment trials
 - n=2,240 Maryland cancer patients accrued onto NCI-sponsored treatment trials (1999-2002)
- **Purpose:** To determine extent to which MD cancer patients and patients residing in lower SES and/or rural areas were accrued to cancer trials and were representative of all cancer patients in MD.
- **Data sources:**
 - NCI's Cancer Therapy and Evaluation Program (CTEP) for Maryland cancer patients
 - Maryland Cancer Registry
 - US Census and the Department of Agriculture

Baquet CR, Ellison, G, Mishra, S et al. Analysis of Maryland Cancer Patient Participation in NCI Supported Cancer Treatment Clinical Trials. *Journal of Clinical Oncology*. July 2008.

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Accrual of Maryland Cancer Patients to NCI sponsored Treatment Clinical Trials



Maryland Community Clinical Trial Program Components

- **Research: Barriers and Strategies**
 - Random digit dial (RDD)
 - Qualitative research
 - Results used to target educational/awareness efforts
 - Theory based education/outreach
- **Track accrual rates/trends**
 - CTEP analysis
- **Health care professionals**
 - Trial referral
 - Continuing Education
 - Grand Rounds
- **Training for Researchers**
- **Community engagement**
 - Faith-based
 - Print Media
 - CBOs
 - Local Health Departments
 - FQHCs
 - Mini Medical Schools
 - Formal Partnerships
- **Policy Research and Advocacy**
- **Community based infrastructure**
- **Technical Assistance for elected officials and staff**

Book of Daniel

Daniel said to the steward "Test your servants for ten days; let us be given vegetables to eat and water to drink. Then let our appearance and the appearance of the youths who eat the king's rich food be observed by you, and according to what you see deal with your servants." So he hearkened to them in this matter, and tested them for ten days. At the end of ten days it was seen that they were better in appearance and fatter in flesh than all the youths who ate the king's rich food. So the steward took away their rich food and the wine they were to drink and gave them vegetables.

Book of Daniel, chapter 1

Maryland Community Clinical Trial Program



Dr. Mary DeShields
Director, Eastern Shore Cancer Research Network
CNP Partner

Goal: To increase awareness, availability and diversity in clinical trials in underserved communities.

- The University of Maryland School of Medicine (UMSOM) partnered with Eastern Shore Cancer Research Network.
- Model to increase clinical trial availability, participation and accrual in rural Eastern Shore of Maryland.
 - Intensive patient/physician education
 - Infrastructure support
 - Community engagement

Maryland Community Clinical Trial Program

- Over 5 year period, selected outcomes included:
 - 20 fold increase in cancer protocols open
 - 40 fold patient accrual to trials
 - 25% rural African American cancer patients
- SWOG award for high data quality



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Supported by: NCI MSPN; NCI-MD P60; NCI CNP; Maryland Cigarette Restitution Fund Program

Maryland Community Clinical Trial Program

National Best Practice Award

**US Department of Health and Human Services
Secretary's Committee on Science and Policy**

- A Model For Increasing Availability Of Community-Based Cancer Clinical Trials In Rural Eastern Shore Maryland, September 2004

<http://www.cancer.gov/newscenter/benchmarks-vol6-issue4/page1>

- Claudia Baquet, MD, MPH and Mary DeShields, MD

Supported by: NCI MSPN/CNP; NIH/NCMHD P60; MD CRF; Susan G. Komen For The Cure Maryland

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Maryland Community Clinical Trial Program

Eastern Shore Oncology-UMSOM

- Rural Community Cancer Clinical Trials Education and Availability Focus

Multi-Pronged Approach:

- Community education and awareness
- Physician and other health professional continuing education
- Trial infrastructure: clinical nurse educator and nurse clinical trial data manager

Outcomes:

- In five years: 20 fold increase in cancer protocols open
- 40 fold increase patient accrual
- 25% rural African American cancer patients
- SWOG award for high data quality

“National Best Practice Award” from DHHS Secretary and Committee on Science and Policy HHS

- **“A Model for Increasing Availability of Community-Based Cancer Trials in Rural Eastern Shore, MD (Baquet / DeShields) - September 2004**

Maryland Program Advancing Clinical Trials: “MPACT”

- ***“MPACT”***
 - Statewide strategy to enhance public trust in research and diversity in clinical trial participation.
 - Five years planning and testing (NCI MSPN, NIH P60, NCI CNP, Maryland Cigarette Restitution Fund Program)
 - Launched October 2008
 - All diseases/disorders
- Community participation: programs and education, as well as policy strategies
- Fosters research literacy: removes stigma and mystery of research

Mini Medical School!

Goals:

- Increase health and research literacy
- Foster public trust and community empowerment

Locations:

- Baltimore City
- Montgomery County
- Rural Allegany County
- Lower Eastern Shore Region – UMES
- ESAEHC Mid and Upper Shore
- Rural Southern Maryland

Advances in health, medicine, prevention

- Role of basic, translational, clinical research
- High enthusiasm
- Fosters health and research literacy



Supported by NCMHD/NIH P60 COE

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Network and Other Tobacco-Related Diseases Grants NIH Recognized Research, Community Engagement and Policy Research

- NIH Director's WALSH Lecture presented internationally on UMSH and Maryland's CRF models
- The Cigarette Restitution Funds (CRF) Program has transformed Maryland's academic health center's.
 - research
 - training and community engagement in tobacco use, tobacco-related diseases and health disparities research.
- Building public trust in research and clinical trials and engaging the community in health and research literacy
- Policy research important for translating research into practice
- Community Based Trial Program: "MPACT"
 - **Federally Designated "National Best Practice Award" from DHHS Secretary & Committee on Science and Policy HHS**
- Ongoing Training for NIH Scientists on Barriers and Strategies to increase diversity in clinical research, trial accrual and community engagement in research

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The University of Maryland Breathmobile®

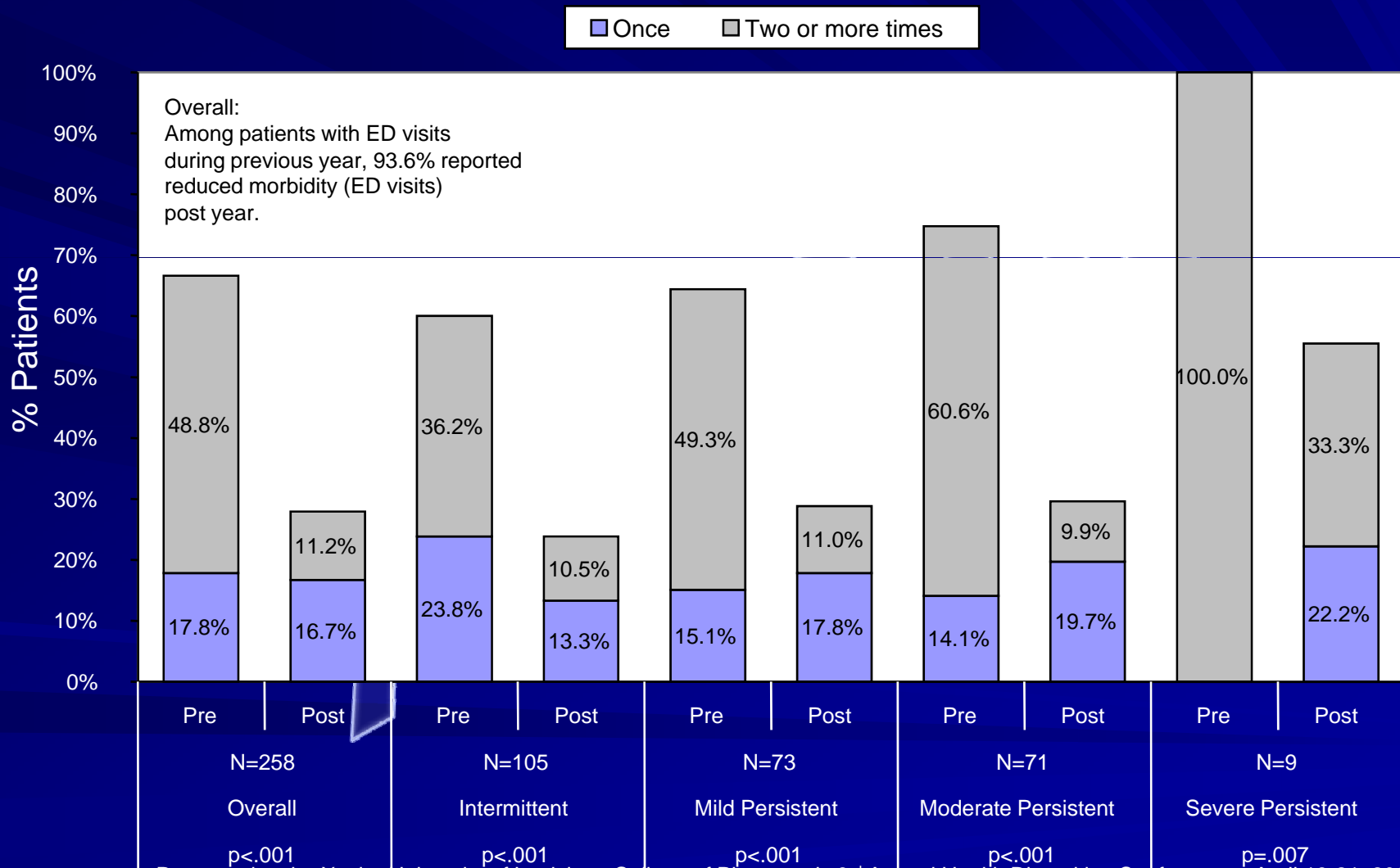
Mary Beth Bollinger DO, et al.



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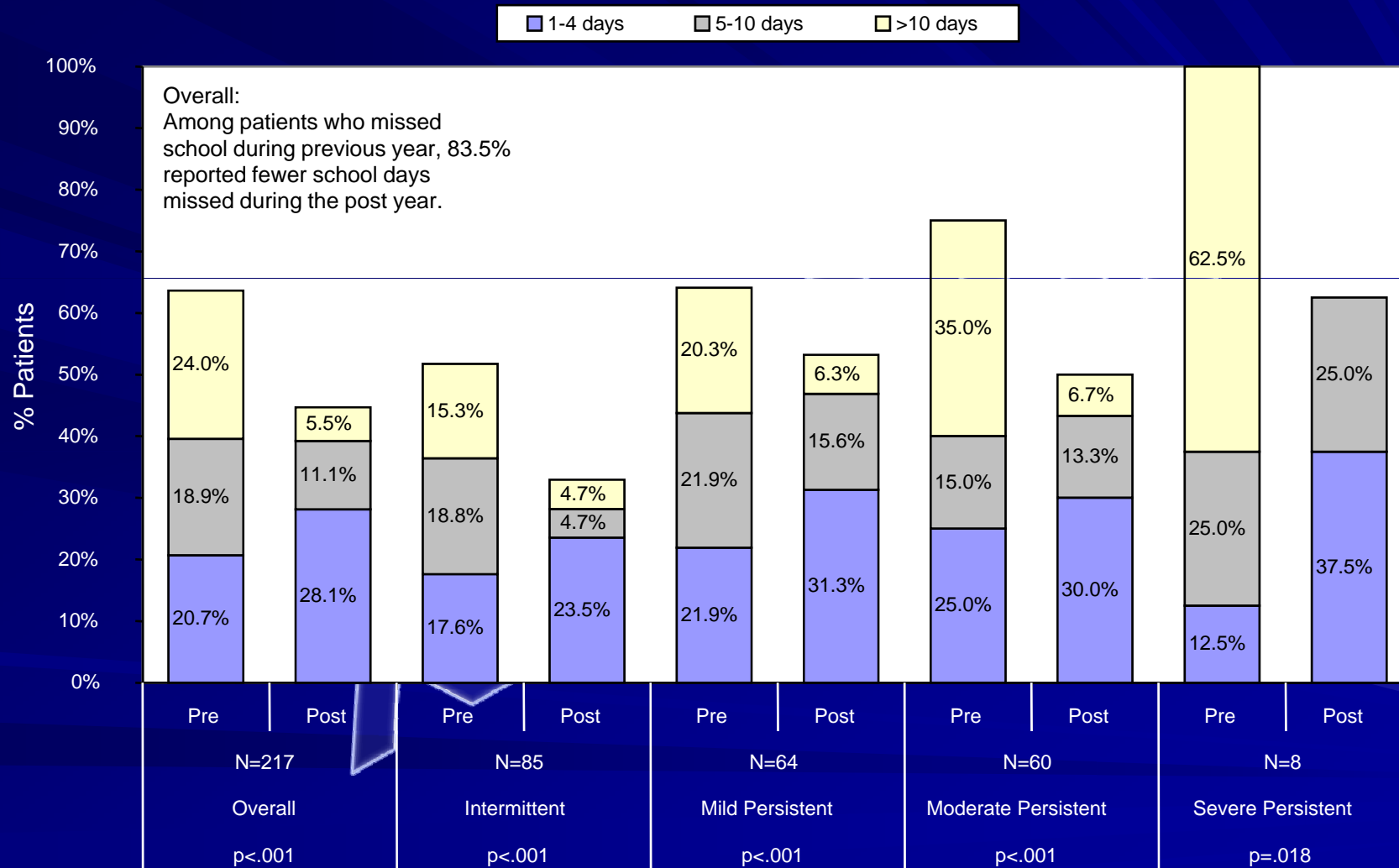
Asthma Outcomes: Impact on ED Visits

Figure 1. Among patients in the program at least one year (N=258), compare percent of patients pre- vs. post- year who visited the ED due to respiratory symptoms:



Asthma Outcomes: Impact on Missed School Days

Figure 2. Among patients in the program at least one year (N=217, age ≥ 5 years), compare % of patients pre- vs. post- year who missed school due to respiratory symptoms:



Good Return

Significant Leveraging of CRF Funds

■ University of Maryland Statewide Health Network (UMSHN)

- Awarded: \$23,459,050
- Leveraged: \$40,658,283
- **For every \$1 from state leveraged \$1.73*

■ Other Tobacco Related Diseases (OTRD)

- Awarded: \$15,511,500
- Leveraged: \$34,946,978
- **For every \$1 from state leveraged \$2.25*

■ Total

- Awarded: \$38,970,550
- Leveraged: \$75,608,261
- **For every \$1 from state leveraged \$1.94*

Summary

- Translating research into practice requires community engagement and fostering public trust.
- Increasing participation in clinical trials for underserved communities is feasible, as illustrated by the University of Maryland models.
- The tobacco settlement grant has transformed an academic health center and has fostered discovery, delivery and development in the area of tobacco related diseases and health disparities.
- Policy research is an essential component in fostering translation of research into practice.
- CBPR and sharing grant resources is essential.
- Data guided and theory supported interventions to increase willingness to participate and accrual.

Acknowledgements and Funding for Models To Eliminate Health Disparities

- Comprehensive Health Disparities Research, Training and Outreach Center (P 60 COE: NCHMD/NIH MD000532 C Baquet PI)
- “Maryland Special Populations Cancer Research Network” and “Maryland Community Network Program”: (NCI 5UO1CA-086249/UO1CA114650 C Baquet PI)
- UMES-UMB Comprehensive MSI/CCP Planning Grant (NCI U56 CA096303) (Okoh/Baquet PI)
- Maryland Cigarette Restitution Fund Program (CRF)

Acknowledgements

- Community Partners
- Maryland General Assembly



- Office of the Governor
- Maryland Department of Health and Mental Hygiene

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