Advisory Panel on Addressing Disparities

July 22, 2015

9:00 a.m. – 3:30 p.m.

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Welcome and Setting the Stage

Romana Hasnain-Wynia, PhD, MS
Program Director, Addressing Disparities

Doriane Miller, MD
Chair, Advisory Panel on Addressing Disparities

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Housekeeping

- Today's webinar is open to the public and is being recorded.
- Members of the public are invited to listen to this teleconference and view the webinar.
- Anyone may submit a comment through the webinar chat function, although no public comment period is scheduled.
- Visit www.pcori.org/events for more information.
- Chair Statement on COI and Confidentiality

Agenda

- Introduction of PCORI Addressing Disparities Advisory Panel Members
- Addressing Disparities Program Updates
  - Where We Are Now: Program and Portfolio Overview
- Community Health Workers in the Addressing Disparities Portfolio
- Awardee Presentation: Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors
- Discussion of CDC HIV Topics
- Wrap Up and Next Steps

Introduction of PCORI Addressing Disparities Advisory Panel Members

Romana Hasnain-Wynia, PhD, MS
Program Director, Addressing Disparities

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Introductions

- Please tell us the following in 2 minutes or less:
  - Name.
  - Stakeholder group you represent.
  - Position title and organization.
  - What have you gained or would like to gain from being a member of the advisory panel.

Introductions (cont.)

Alfiee M. Breland-Noble, MHSc, PhD

Director of The AAKOMA Project and Assistant Professor, Department of Psychiatry

Georgetown University Medical Center

Representing: Researchers

Introductions (cont.)

Ronald Copeland, MD, FACS

Chief Diversity and Inclusion Officer and Senior Vice President of National Diversity and Inclusion Strategy and Policy, Kaiser Permanente

Representing: Hospitals and Health Systems

Introductions (cont.)

Echezona Edozie Ezeanolue, MD, MPH, FAAP, FIDSA

Associate Professor, Pediatrics and Director, Maternal-Child HIV Program, University of Nevada School of Medicine

Representing: Clinicians

Introductions (cont.)

Martina Gallagher, BSN, MSN, PhD

Assistant Professor, University of Texas Health Science Center

Representing: Clinicians

Introductions (cont.)

Martin Gould, MA, EdD

Senior Policy Analyst, US Department of the Treasury

Representing: Researchers

Introductions (cont.)

Sinsi Hernández-Cancio, JD

Director of Health Equity, Families USA

Representing: Patients, Caregivers, and Patient Advocates

Introductions (cont.)

Chien-Chi Huang, MS

Founder, Asian Breast Cancer Project
Executive Director, Asian Woman for Health

Representing: Patients, Caregivers, and Patient Advocates

Introductions (cont.)

Elizabeth A. Jacobs, MD, MAPP, FACP

Associate Vice Chair, Health Services Research in the Department of Medicine and Population Health Science

Representing: Researchers

Introductions (cont.)

Grant Jones, BS (Co-chair)

Founder, Executive Director, Center for African American Health

Representing: Patients, Caregivers, and Patient Advocates

Introductions (cont.)

Patrick Kitzman, MS, PhD

Associate Professor, Physical Therapy, University of Kentucky

Representing: Clinicians

Introductions (cont.)

Barbara L. Kornblau, JD, OTR

CEO, Coalition for Disability Health Equity

Representing: Patients, Caregivers, and Patient Advocates

Introductions (cont.)

Kenneth Mayer, MD

Medical Research Director, Fenway Health and Professor, Harvard Medical School and School of Public Health

Representing: Researchers

Introductions (cont.)

Doriane C. Miller, MD (Chair)

Director, Center for Community Health and Vitality
University of Chicago Medical Center

Representing: Patients, Caregivers, and Patient Advocates

Introductions (cont.)

Alan R. Morse, MS, JD, PhD

President and Chief Executive Officer, Jewish Guild Healthcare
Adjunct Professor of Opthalmology, Columbia University

Representing: Health Systems

Introduction (cont.)

Cheryl Pegus, MD, MPH

Director of the Division of General Internal Medicine and Clinical Innovation, NYU Langone Medical Center

Representing: Patients, Caregivers, and Patient Advocates

Introduction (cont.)

Danielle Pere, MPM

Associate Executive Director, American College of Preventive Medicine

Representing: Clinicians

Introduction (cont.)

Carmen E. Reyes, MA

Center and Community Relations Manager, Los Angeles Community Academic Partnership in Research in Aging, UCLA

Representing: Patients, Caregivers, and Patient Advocates

Introduction (cont.)

Russell Rothman, MD, MPP

Associate Professor of Internal Medicine and Pediatrics; Director, Vanderbilt Center for Health Services Research; Chief of Internal Medicine/Pediatrics
Vanderbilt University

Representing: Researchers

Introduction (cont.)

Mary Ann Sander, MBA, MHA

Vice President, Aging and Disability Services, UPMC Community Provider Services

Representing: Researchers

Introduction (cont.)

Elinor R. Schoenfeld, PhD

Research Associate Professor of Preventive Medicine and Ophthalmology, Stony Brook University

Representing: Researchers

Introduction (cont.)

Deborah Stewart, MD

Medical Director, Florida Blue

Representing: Clinicians

Addressing Disparities Program Staff

Romana Hasnain-Wynia, MS, PhD
Program Director

Randa Abu-Rahmeh
Program Assistant

Ayodola Anise, MHS
Program Officer

Mira Grieser, MHS
Program Officer

Cathy Gurgol, MS
Program Officer

Katie Lewis, MPH
Senior Program Associate

Tomica Singleton
Sr. Administrative Assistant

Mychal Weinert
Program Associate

Addressing Disparities Program Updates Where We Are Now: Program and Portfolio Overview

Romana Hasnain-Wynia, PhD, MS
Program Director, Addressing Disparities

Cathy Gurgol, MS
Program Officer, Addressing Disparities

Overview

- Program Overview
- Updates on:
  - Hypertension
  - Immunotherapy
  - Obesity
- Topics in the Pipeline

Addressing Disparities Program has Committed $148M in CER (as of April 2015)

Broad Projects	Targeted Projects	In the Pipeline
45 CER projects, $80M	• Treatment Options for Uncontrolled Asthma in African American and Hispanics/Latinos: 8 CER trials, $23.2M • Obesity treatment options in primary care for underserved populations: 2 CER trials, $20M • Reducing Hypertension Disparities in collaboration with NHLBI/NINDS: To be awarded in Sept '15; up to 2 CER trials, $25M	Sickle Cell Disease, HIV, other topics in development

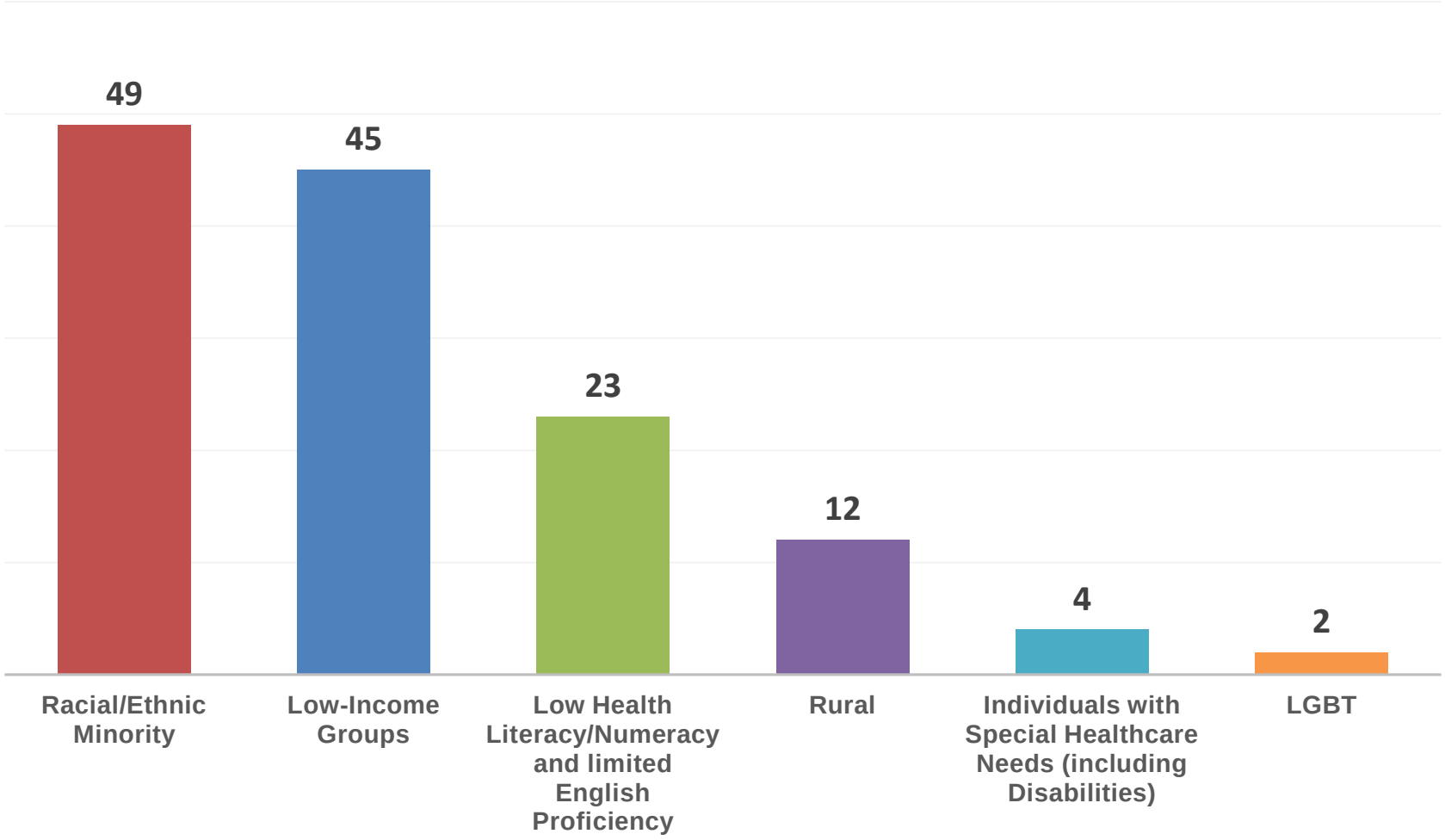
New Projects Awarded through Addressing Disparities Broad PFA

- **4** new projects awarded in April 2015, totaling $8.2M

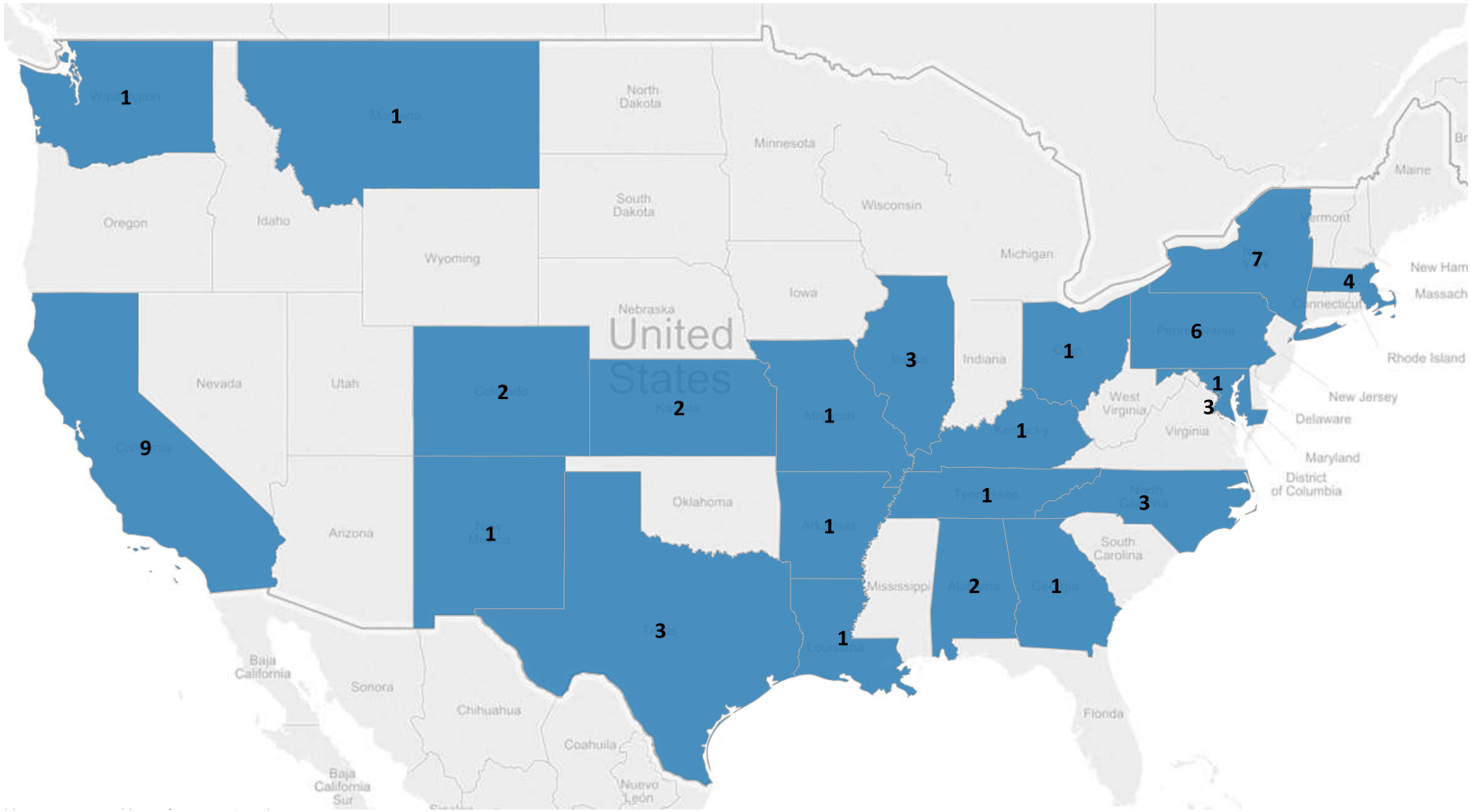
Project Title	Organization
Pain coping skills training for African Americans with Osteoarthritis	University of North Carolina Chapel Hill
Comparative effectiveness of a virtual reality platform for neurorehabilitation of hemiparesis	The Ohio State University
GWTG Interventions to reduce disparities in AHF patients discharged from the ED (GUIDED HF)	Vanderbilt University
Clinician language concordance and interpreter use: impact of a systems intervention on communication and clinical outcomes	University of California San Francisco

Addressing Disparities Populations of Interest

*not mutually exclusive

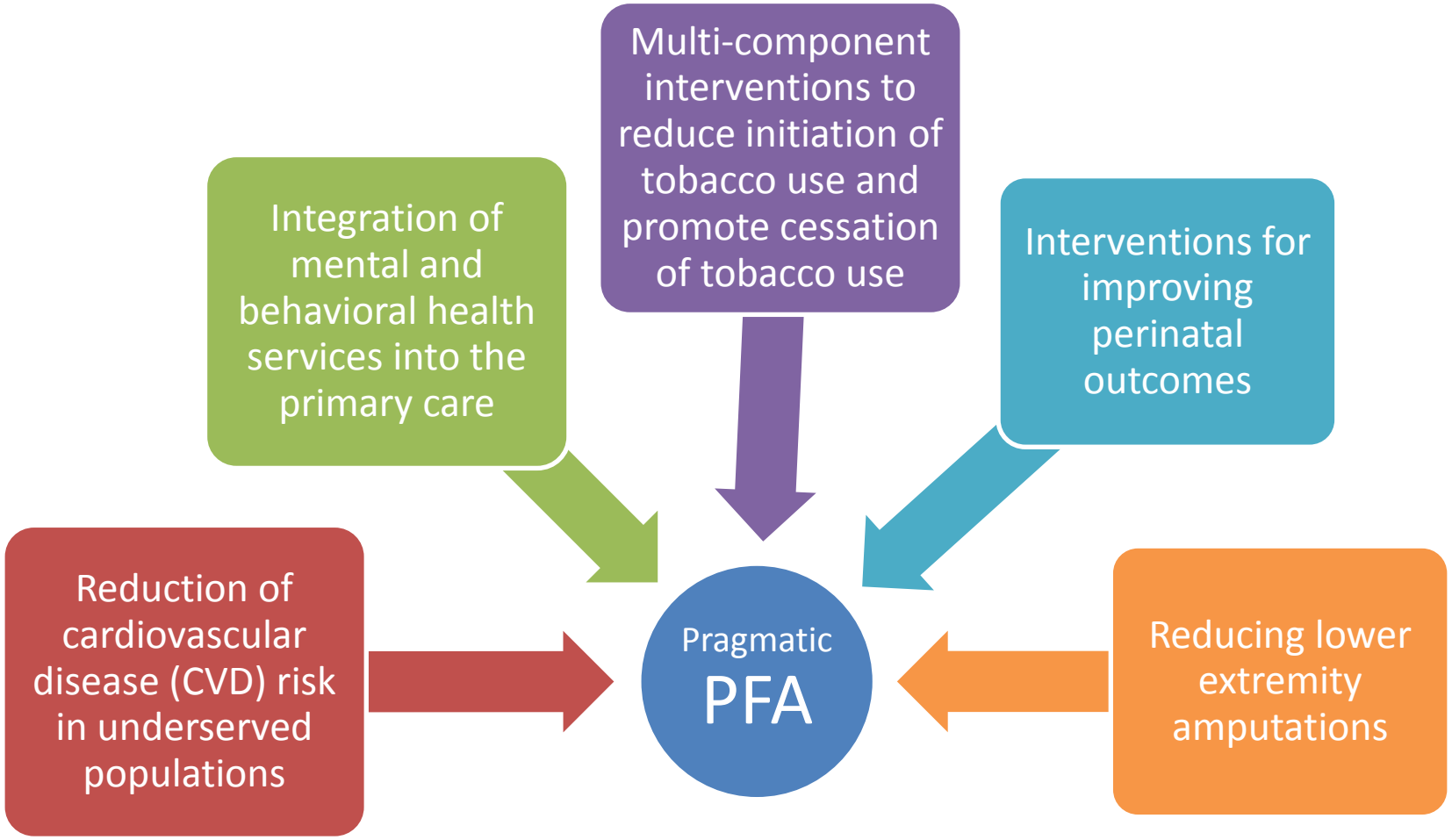


Where the Addressing Disparities Program Has Funded



Large Pragmatic Studies Update

- Five of the PCORI priority topics in the pragmatic trials announcements came from the Addressing Disparities Advisory Panel:



Update: Testing Multi-Level Interventions to Improve Blood Pressure Control in Racial/Ethnic Minority, Low Socioeconomic Status, and/or Rural Populations

Hypertension Update

Targeted PCORI/NIH Hypertension Funding Announcement

- **Background:** In December 2014, we released funding announcement in partnership with NIH/ National Heart, Lung, and Blood Institute/National Institute of Neurological Disorders and Stroke
- **Goal:** Solicit comprehensive CER studies testing multi-component interventions, with strong patient and stakeholder engagement, to reduce hypertension disparities among racial/ethnic minorities, and/or low SES, and/or rural populations
- **Objective:** Fund up to two multi-component CER trials up to $25M to assess the best strategies to achieve superior blood pressure control levels (>75%) among high-risk patients
- **Status**: Review took place in May 2015; awards to be announced in September 2015

Update: Immunotherapy Options for Treatment of Allergic Asthma

Topic Recap and Overview

- 1 in 10 people has asthma, and more than half of these individuals have allergic asthma
- There are three treatment options: 1) allergen avoidance, 2) pharmacotherapy, and 3) immunotherapy.
- Despite available treatments, many do not have their asthma under control – a problem that disproportionately affects racial and ethnic minorities
- Immunotherapy (IT) is recommended for those who cannot otherwise control their asthma and is only true hope for "cure"
- The two main forms of IT are subcutaneous and sublingual
  - Both are proven to be safe and effective, though insufficient evidence to favor one over the other
  - Increasing interest in sublingual IT because of more patient-centered administration

The Addressing Disparities Program has been exploring the possibility of funding a trial comparing subcutaneous and sublingual IT

Broad Stakeholder Interest

- Stakeholder interest in this area
  - **NIH/National Institute of Allergy and Infectious Diseases** has designated this topic a research priority
  - **Agency for Healthcare Research and Quality** published a comparative effectiveness review on the topic, pointing out evidence gaps
  - **American Academy of Allergy, Asthma and Immunology** has called for trials in this area
  - **National Asthma Education and Prevention Program (coordinated by NIH/National Heart, Lung, and Blood Institute)** is revisiting their asthma care guidelines *to incorporate guidance on immunotherapy*

NIH National Institute of Allergy and Infectious Diseases

NIH National Heart, Lung, and Blood Institute

AHRQ Advancing Excellence in Health Care

American Academy of Allergy Asthma & Immunology

Advisory Panel Input – April 2015

- Panel members were very enthusiastic and gave strong endorsement to move forward; raised important issues, mostly around target populations and access:
  - Need to target geographic areas based on prevalence of allergens and asthma (e.g., if we target kids, should hone in on urban areas)
  - Also strong case for rural areas, where patients have access to PCPs but limited access to specialists.
  - Need to consider who is trained to deliver intervention.
    - Are there opportunities for distance learning/training?
- Panel members suggested specific stakeholders for further input:
  - Disparities expert (perspective on barriers to access)
  - Private and public payer reps (e.g., Medicaid Medical Director, Blues)
  - Rural representation (e.g., IHS)
  - Parent/caregiver (perspective on barriers to adherence)

Workgroup – June 2015

- Workgroup held on June 30th to answer specific questions about a trial comparing sublingual and subcutaneous IT
  - Comprised 11 stakeholders, with representation from NIH, AHRQ, patients, pediatricians and immunologists, scientific and disparities experts, and payers
- Workgroup discussed:
  - Allergen choice (e.g., seasonal vs. perennial, impact on target population and setting)
  - Feasibility of trial
  - Access issues (e.g., PCP vs. specialty setting, rural vs. urban)
- Consensus that population with most potential to benefit from immunotherapy are low income, inner city children
- CER question with most potential for PCORI study: *What is the comparative effectiveness of inhaled corticosteroids (i.e., guidelines-based care) vs. inhaled corticosteroids + immunotherapy (subcutaneous and sublingual) on the treatment of allergic asthma among children?*

Challenges

Use of immunotherapy (SCIT and SLIT) for treating allergic asthma is an important topic for clinicians, patients, gov't agencies, members of Congress, and stakeholder groups. BUT,

- Challenges at this time:
  - Would require multi-allergen off-label use of IT, at doctor's discretion for SLIT
    - FDA representative at meeting said multi-allergen off-label use and investigational new drug approval "**could get complicated"**
  - In addition -- the allergen with biggest potential for impact (particularly on inner city kids with asthma) is cockroach, for which there is no standardized dose.

Additional Consideration: Trials at NIH/NIAID

- **NIH/National Institute of Allergy and Infectious Disease (NIAID) provided the following guidance:**
  - If targeting low income, inner city kids, **cockroach and mouse are most important allergens to include**
  - NIH/NIAID currently supporting trials with Inner City Asthma Consortium to investigate use of cockroach allergen specifically. Completed in 2016

Next Steps

- Presented this topic to the Strategic Oversight Committee of the PCORI Board on July 13, 2015.

- Staff will continue exploring this topic and working with colleagues at NIH to determine the right timing for a feasible, high-impact study
  - Will revisit topic as potential targeted funding announcement in 4-6 months

Update: Progress with the Targeted Obesity Pragmatic Studies

Cathy Gurgol, MS

Overview

- Summary of Obesity Portfolio
- Progress of Funded Projects
- Next Steps

Summary of Obesity Portfolio

Project Title	Org.	Target Population(s)	Number of Study Pts	Primary Outcome	Start Date
The Louisiana Trial to Reduce Obesity in Primary Care	Pennington Biomedical Research Center	African Americans; low socio-economic individuals	1,080	Percent change in body weight from baseline	January, 2015
Midwestern Collaborative for Treating Obesity in Rural Primary Care	University of Kansas Medical Center	Rural; low socio-economic individuals	1,400	Weight loss at 24 months	January, 2015

Progress

- Collaboration between trials
  - In-person Meeting, Jan. 2015
  - Teleconference, April 2015
    - Outcome measures
    - Inclusion/exclusion criteria
- Project preliminary work is underway
  - DSMB set-up
  - Finalizing study protocols
  - Meetings with stakeholders
  - On-boarding practices
  - Planning for participant recruitment

Next Steps

- Continue discussions about trial collaboration
- Begin planning for implementation of Obesity Evidence to Action Network (E2AN)
- Continue monitoring project progress
  - Participant recruitment

Questions on Program Updates

Topics in the Pipeline

Romana Hasnain-Wynia, PhD, MS

Topics of Focus for 2015

- Two topics in the pipeline
  - HIV
  - Sickle cell disease

Introduction of Sickle Cell Disease Topic

Rationale for this Topic

- NHLBI released guidelines in 2015 focusing on the treatment and management of Sickle Cell Disease
- Many recommendations were based on consensus of the expert panel or on current practices for which there was low-quality evidence.

U.S. Department of Health and Human Services; National Institutes of Health; National Heart L, and Blood Institute. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014.

Background

- Sickle cell disease (SCD) is a chronic genetic disorder affecting the body's red blood cells (RBCs).[1]
- It is estimated that between 70,000 and 100,000 Americans, predominately African Americans, have SCD.[2]
- The hallmark complication for patients with SCD is recurrent acute pain episodes, or "pain crises".[1]
- Acute pain crises account for approximately 90% of hospital admissions among patients with SCD.[3]
- Majority of deaths occur after 18 years of age and after transfer to an adult provider.[4]

1. Molter BL, Abrahamson K. Self-Efficacy, Transition, and Patient Outcomes in the Sickle Cell Disease Population. Pain Management Nursing: Official Journal Of The American Society Of Pain Management Nurses. 2014. PubMed PMID: 25047808.
2. 2U.S. Department of Health and Human Services; National Institutes of Health; National Heart L, and Blood Institute. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014.
3. Dunlop R, Bennett Kyle CLB. Pain management for sickle cell disease in children and adults. Cochrane Database of Systematic Reviews [Internet]. 2014; (4).
4. DeBaun MR, Telfair J. Transition and Sickle Cell Disease. Pediatrics. 2012 November 1, 2012;130(5):926-35.

Patient-Centeredness

- Numerous studies show that patients and clinicians are dissatisfied with the quality of SCD pain management.[1]
- SCD patients report not having enough involvement in decisions about their own care.[1]

1. Lanzkron S, Carroll CP, Hill P, David M, Paul N, Haywood C, Jr. Impact of a dedicated infusion clinic for acute management of adults with sickle cell pain crisis. American Journal Of Hematology. 2015;90(5):376-80. PubMed PMID: 25639822.

Next Steps and Discussion

- Next Steps
  - Present topic brief focusing on a variety of evidence gaps to Addressing Disparities Advisory Panel in Fall 2015.
- Discussion
  - Are there specific areas for addressing the management and treatment of sickle cell disease that you would like us to consider in the topic brief?

Questions?

Community Health Worker Interventions in the Addressing Disparities Portfolio

Cathy Gurgol, MS
Program Officer, Addressing Disparities

Mira Grieser, MHS
Program Officer, Addressing Disparities

Mychal Weinert
Program Associate, Addressing Disparities

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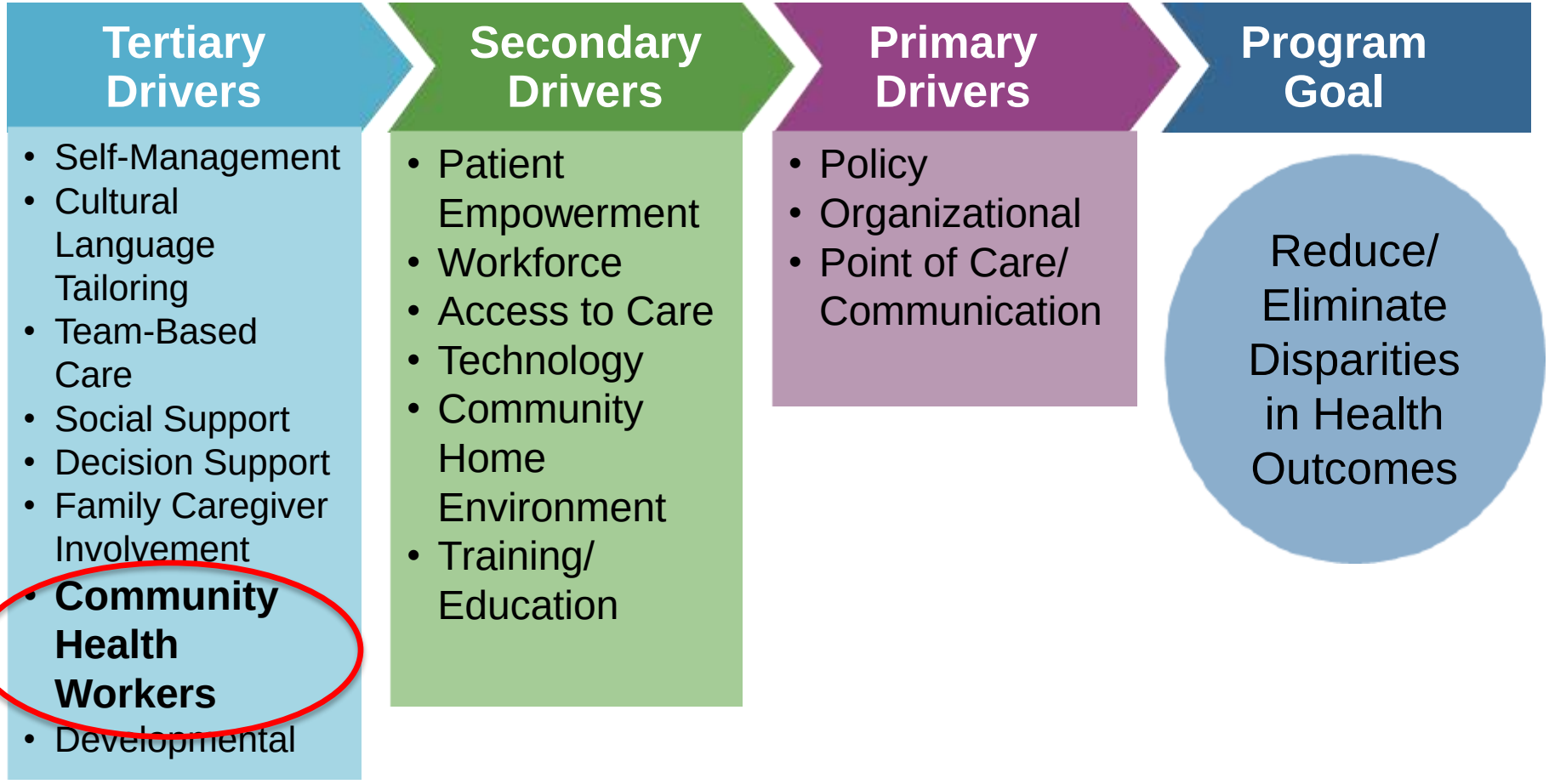
AD Driver Model



Background

- CHWs have the potential to ease the access to health care system for patients at risk of experiencing disparities.
- CHWs provide a link between the healthcare system and the community.
- Value-based payment model based on outcomes in healthcare system and community.
- The effectiveness of CHWs has not been widely reported.
- **40%** of Addressing Disparities projects utilize CHW in the intervention (*n=22*).

Portfolio Analysis

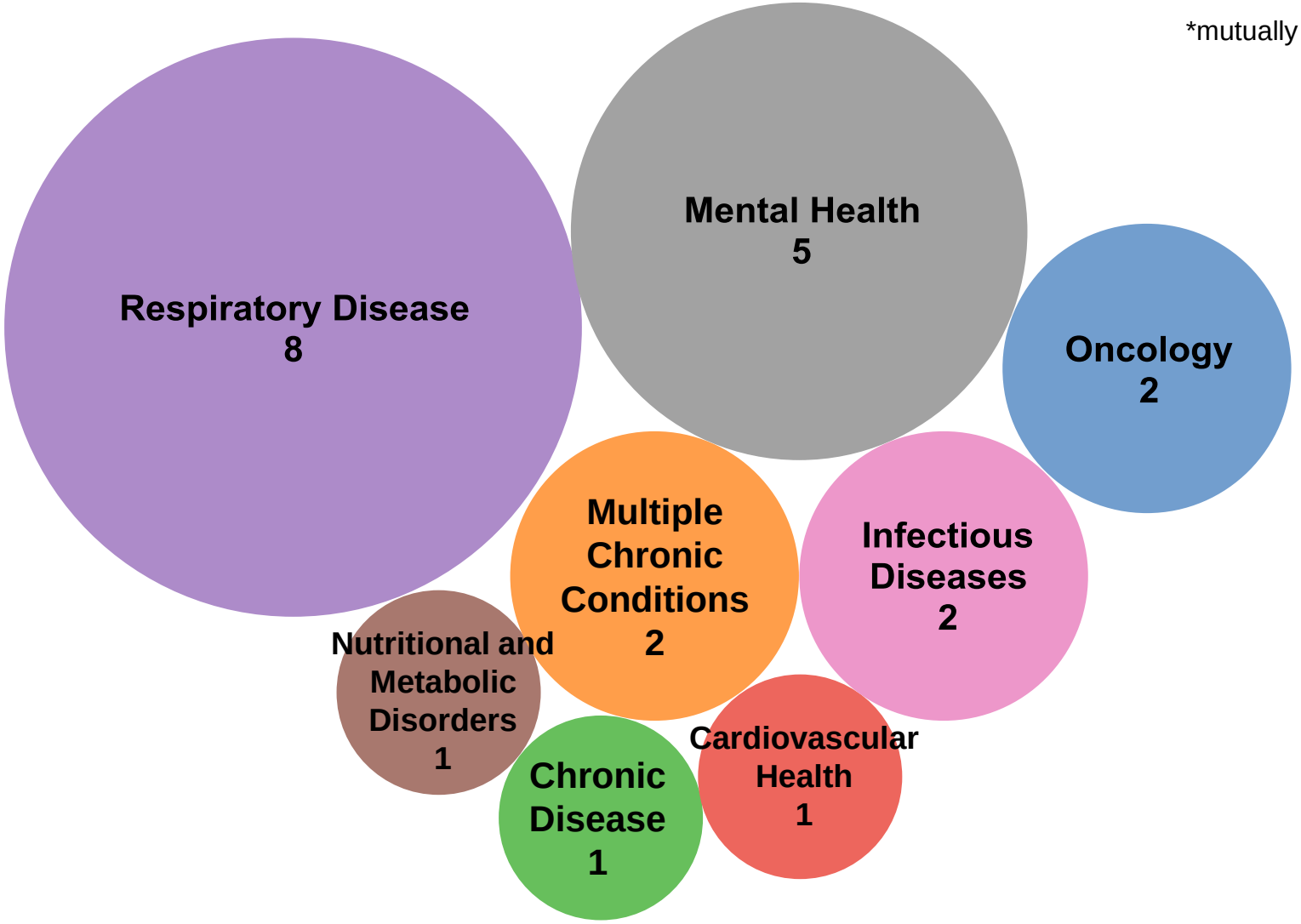
- We have begun to analyze the projects we have funded in this area
  - Extracted information from the applications
  - Surveyed project investigators for additional information
    - Education requirements
    - Credential requirements
    - Experience requirements
    - Training provided
    - Intensity of CHW interaction/exposure with participants

CHW Projects in the AD Portfolio

- Domains
  - Conditions being studied
  - CHW alignment with patient population
  - Qualifications
  - Credentialing
  - Training
  - Compensation
  - Caseload
  - Intervention intensity

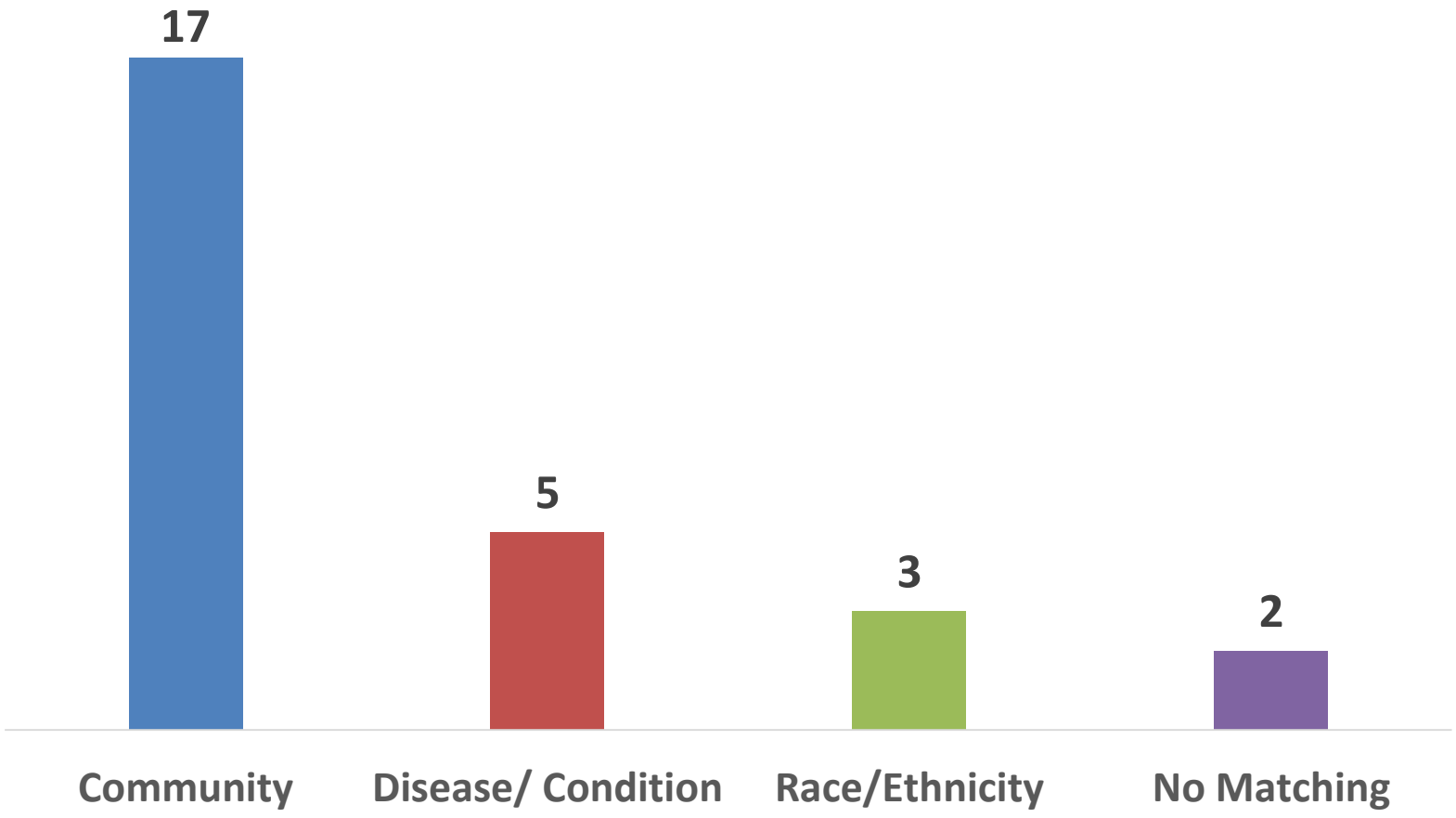
Conditions Studied

*mutually exclusive



CHW Alignment with Participant Population

- CHWs matched with participant population based on:



*not mutually exclusive

CHW Qualifications

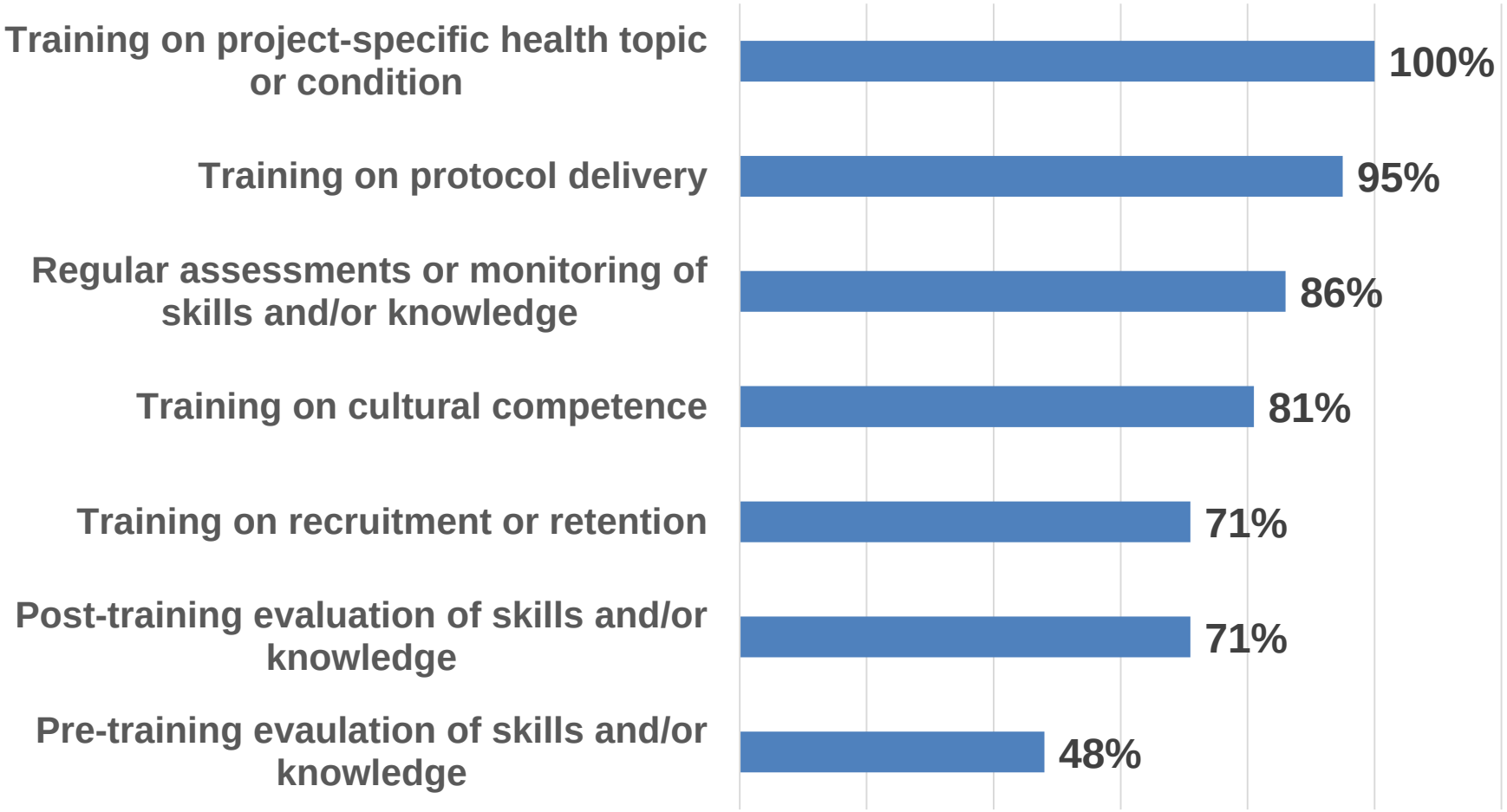
- Out of 22 projects:
  - 16 projects require that the CHW have prior experience working:
    - with the community, population, or condition being studied
    - as a CHW
  - 3 require CHWs to be credentialed

- Minimum Educational Requirement:
  - Bachelor's Degree (N=4)
  - High School Diploma or GED (N=11)
  - Other (N=2)
  - No Educational Requirement (N=5)

CHW Training

- All projects provide study-specific training.
- On average, projects provide 86 hours of training to CHWs (range of 8-320 hours).
- Most projects (N=21) offer interim training.

Training Components



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CHW Compensation and Caseload

- Compensation:
  - The average yearly salary is $33,000, (range of $22,000 to $52,000.)
- Caseload:
  - The average caseload is 66 participants, (range of 12 to 200.)
- Number and length of sessions with participant:
  - The average number of sessions with each participant is 11 (range 2-55).
  - The average session is 54 minutes (range 10 -120).

Intensity of Interaction

- Based on an AHRQ evidence report[1], a high intensity CHW intervention includes at least 4 of the 6 following elements:
  - 1:1 interactions
  - Face to face interactions
  - 1 hour per session or more
  - 3 months duration or more
  - 3 or more interactions
  - Tailored materials
- **91%** of our CHW projects meet the criteria of “high intensity.”

[1]Viswanathan M, Kraschnewski J, Nishikawa B, et al. Outcomes of Community Health Worker Interventions. Rockville (MD): Agency for Healthcare Research and Quality (US); 2009 Jun. (Evidence Reports/Technology Assessments, No. 181.) Available from: http://www.ncbi.nlm.nih.gov/books/NBK44601/

Effectiveness of Collaborative Goal-Setting versus IMPaCT Community Health Worker Support for Improving Chronic Disease Outcomes

Potential Impact

- Could influence how community health workers (CHWs) are incorporated into care of low-income patients with multiple chronic conditions.

Engagement

- The research team will incorporate patient and stakeholder perspectives in the research as the study progresses; the patient advisory board is led by a patient and includes a caregiver from each site.

Methods

- Randomized controlled trial

Evaluates whether the Individualized Management for Patient-Centered Targets (IMPaCT) model is more effective than goal setting alone at improving self-related physical health and patient-centered outcomes in three primary care settings: academic, federally qualified health center, and Veterans Affairs hospital.

Judith Long, MD
University of Pennsylvania
Philadelphia, PA

Addressing Disparities Research Project, awarded July 2014

Eliminating Patient Identified Socio-legal Barriers to Cancer Care

Potential Impact

- Could change practice by providing evidence for a medical-legal intervention that can be quickly replicated to improve patient experience and survival nationwide.

Engagement

- Employs interviews and focus groups to evaluate patient experience.

Methods

- Randomized controlled trial

Seeks to address delays in cancer care that are caused b socio-legal factors, such as unstable housing, unlawful utility shutoffs, or other issues that could be remedied by public policy. Tests the effectiveness of a medical-legal patient navigation intervention in improving outcomes and other patient-centered metrics.

Tracy A. Battaglia, BA, MD, MPH
Boston Medical Center
Boston, MA

Addressing Disparities Research Project, awarded September 2013

Questions

- What are the next steps for this analysis?
- What types of studies could PCORI consider to complement our current portfolio and/or fill current gaps?
  - For example, head-to-head studies comparing CHWs to other personnel

Q&A

Lunch

We will resume at 1:00 p.m.

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Reducing Health Disparities in Appalachians with Multiple CV Risk Factors

Debra K. Moser, DNSc, RN, FAAN, FAHA

Professor and Gill Endowed Chair

Director, RICH Heart Program

Director, Center for Biobehavioral Research in Self-Management

University of Kentucky, College of Nursing

dmoser@uky.edu

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RICH HEART PROGRAM | Research and Interventions for Cardiovascular Health

Team

* Debra Moser
* Terry Lennie
* Martha Biddle
* Gia Mudd-Martin
* Susan Frazier
* Francis Feltner
* Johnnie Lovins
* Wayne Noble
* Jonathon Butler
* Kristin Ashford
* Jenna Hatcher-Keller
* Alison Bailey
* Mary Kay Rayens
* Misook Chung
* Frances Hardin-Fanning

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RICH HEART PROGRAM | Research and Interventions for Cardiovascular Health

Acknowledgements

* Community members
* Ephraim McDowell Hospital, Danville
  * Audrey Powell, Laverne Sloane
* Trover Medical Center, Madisonville
  * Robert Brooks, Leigh England, Lacey Sapp, Hannah Adams, Jessica Holmes
* St. Clair Regional Medical Center, Morehead
  * Mary Horsley, Greg Bausch

Acknowledgements

* Center for Excellence in Rural Health-Hazard
  * HRSA studies
    * Fran Feltner, Beth Bowling, Debbie Pennington, Tonya Godsey, Becky Conley
  * PCORI
    * Fran Feltner, Johnnie Lovins, Wayne Noble, Megan Combs, Ashley Gross, Tonya Bowling

Acknowledgements

- Health Resources and Services Administration (HRSA)
- National Institutes of Health
- National Institute of Nursing Research
- UK Centers for Excellence in Rural Health
- Patient Centered Outcomes Research Institute

Overview

* CVD Disparities in Appalachia
* Patient/Stakeholder Input
* Study Overview
* Impact on Community
* Dissemination Outlets

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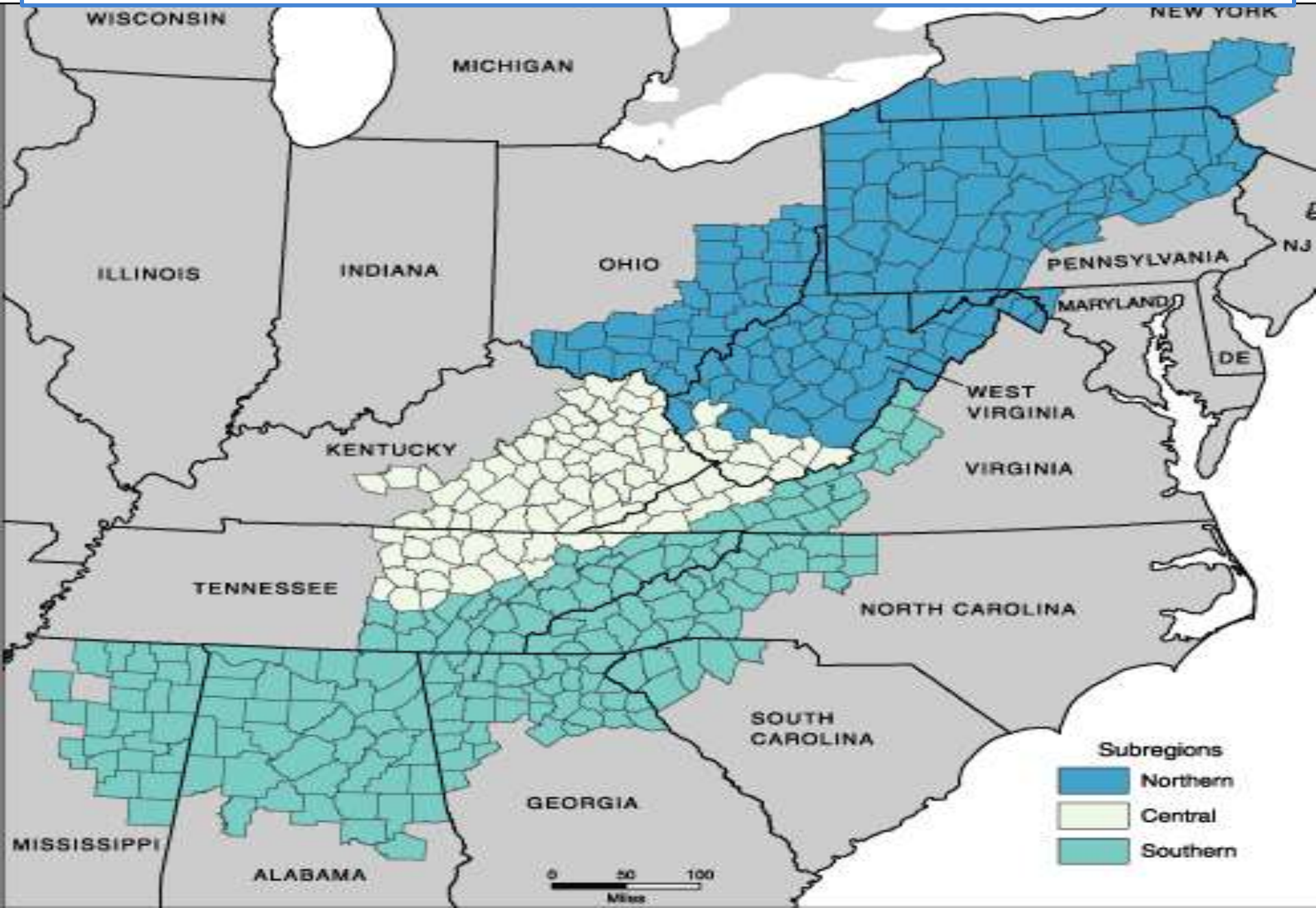
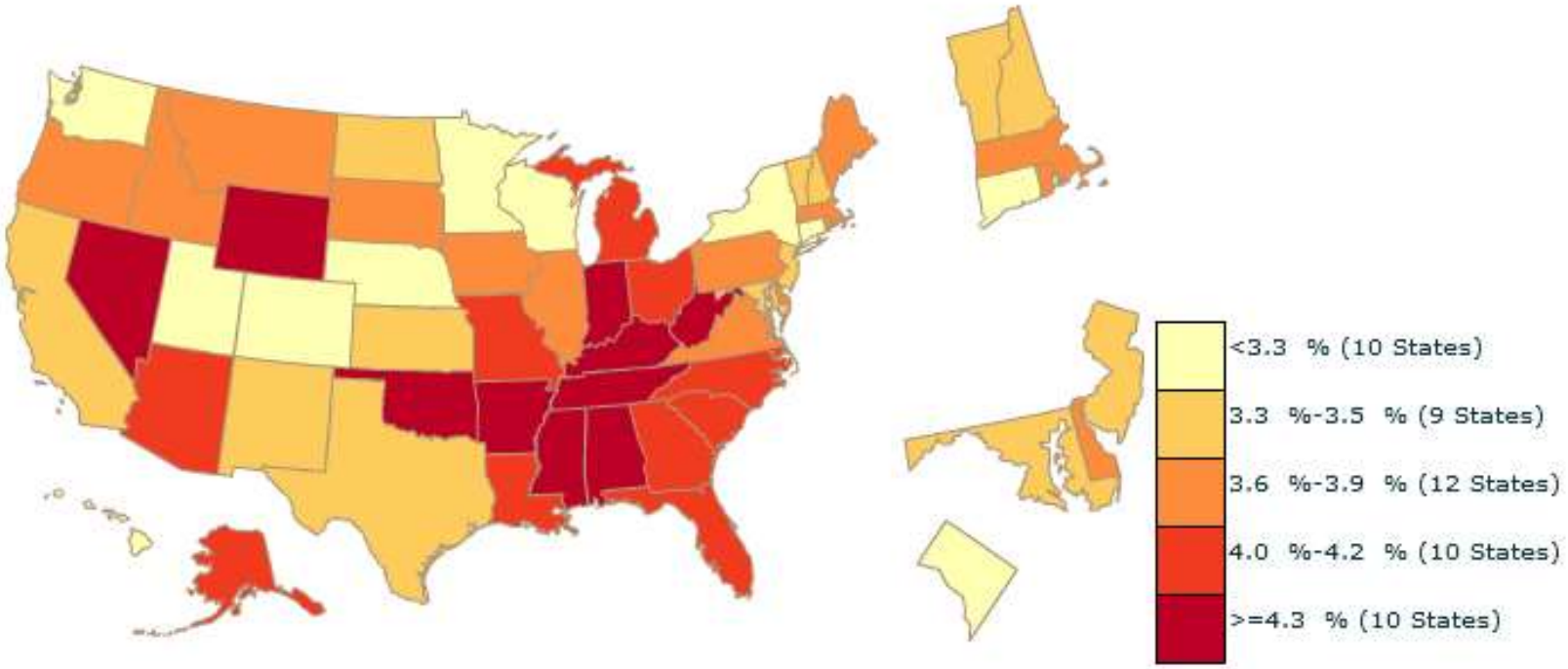
RICH HEART PROGRAM | Research and Interventions for Cardiovascular Health

Appalachia and the Heart & Stroke Belt



Acute Myocardial Infarction

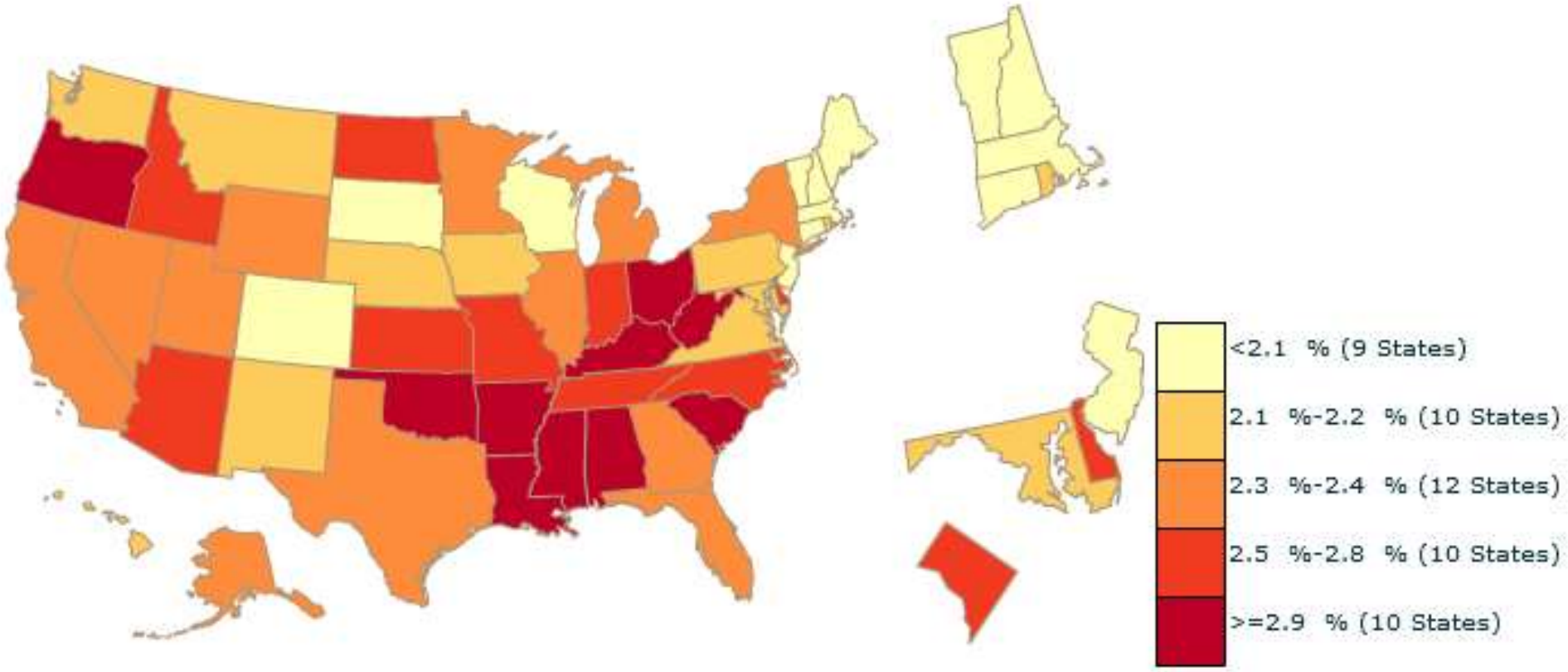
2009 Prevalence of acute myocardial infarction (heart attack) among US adults (18+) (Percentage)†



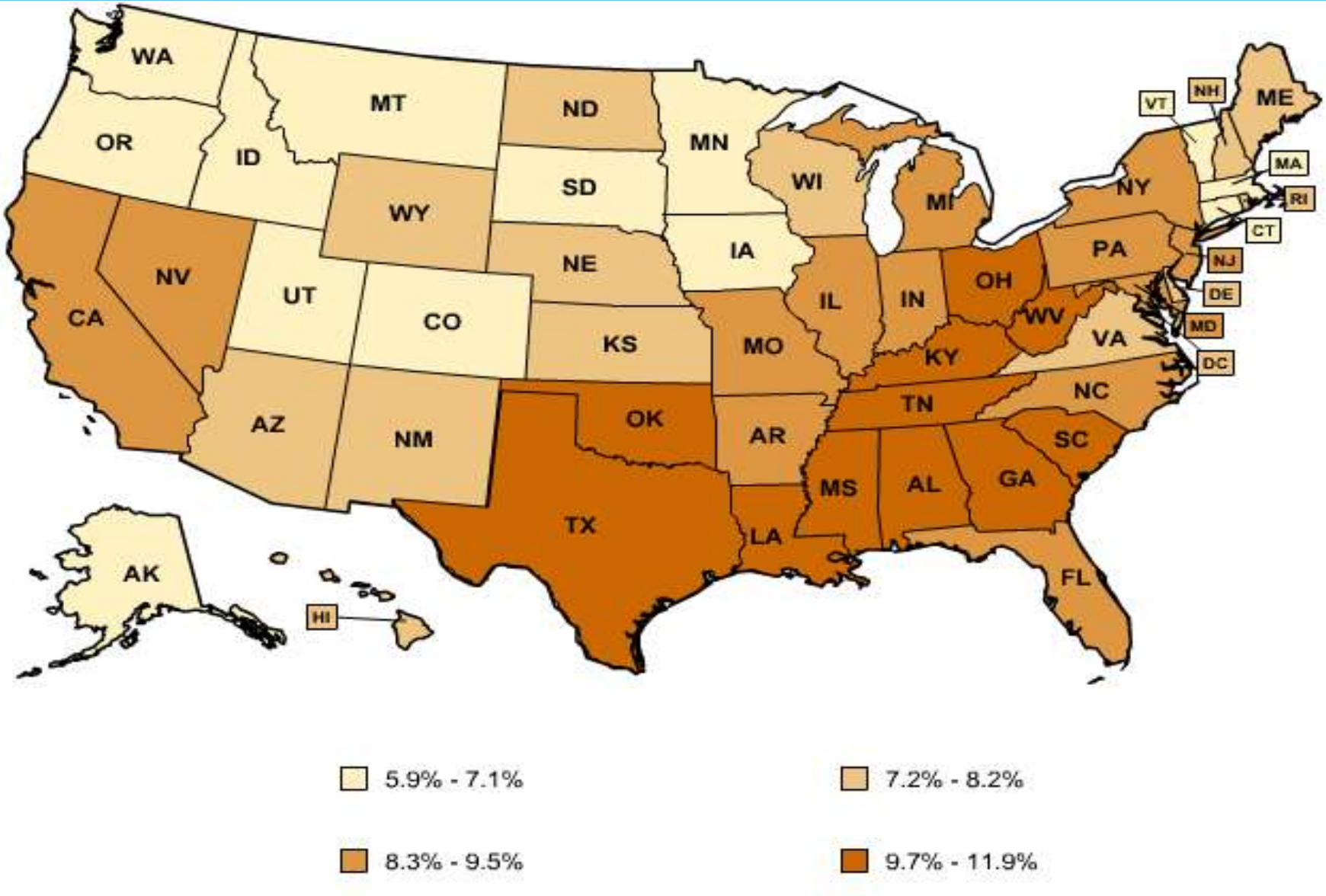
Suggested Citation: Division for Heart Disease and Stroke Prevention: Data Trends & Maps Web site. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion, Atlanta, GA, 2010. Available at http://www.cdc.gov/dhdsp/.

Stroke

2009 Prevalence of stroke among US adults (18+) (Percentage)†



Diabetes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MD
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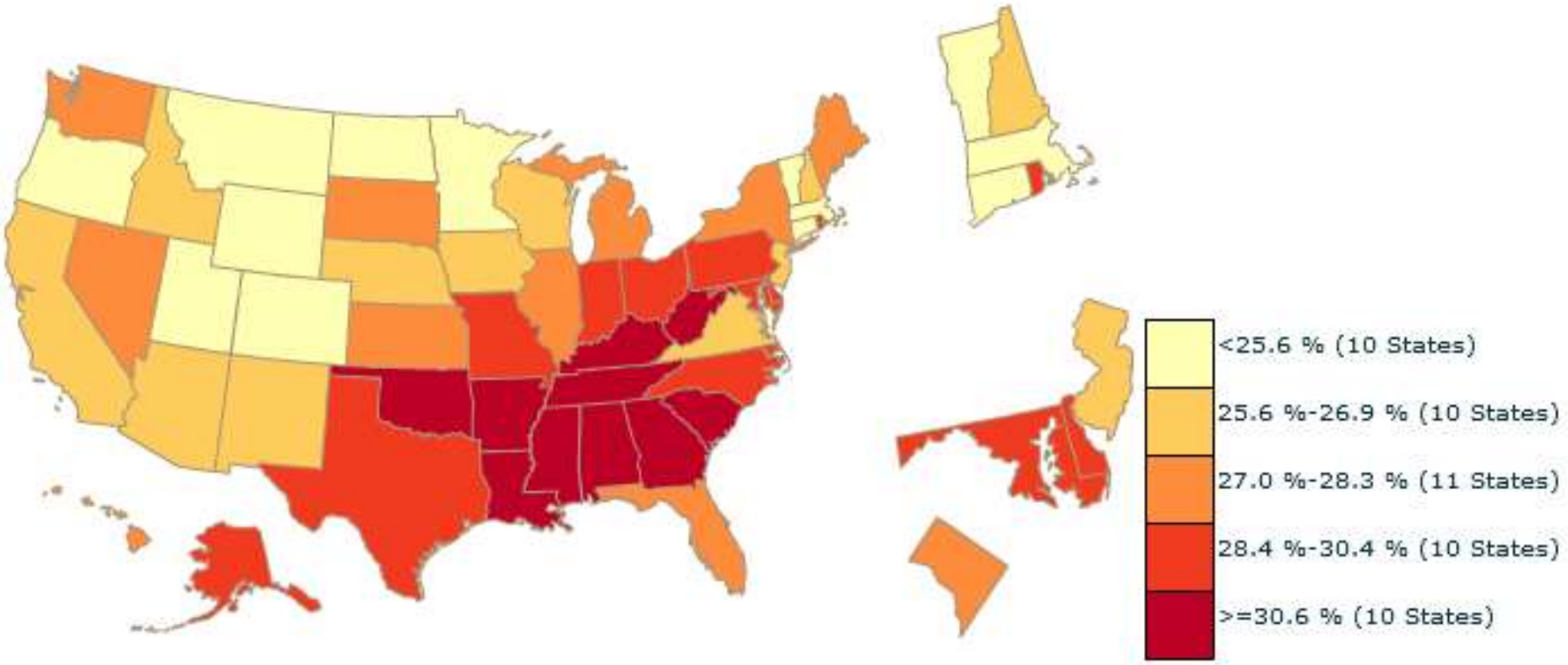
HI
5.9% - 7.1%
7.2% - 8.2%
8.3% - 9.5%
9.7% - 11.9%

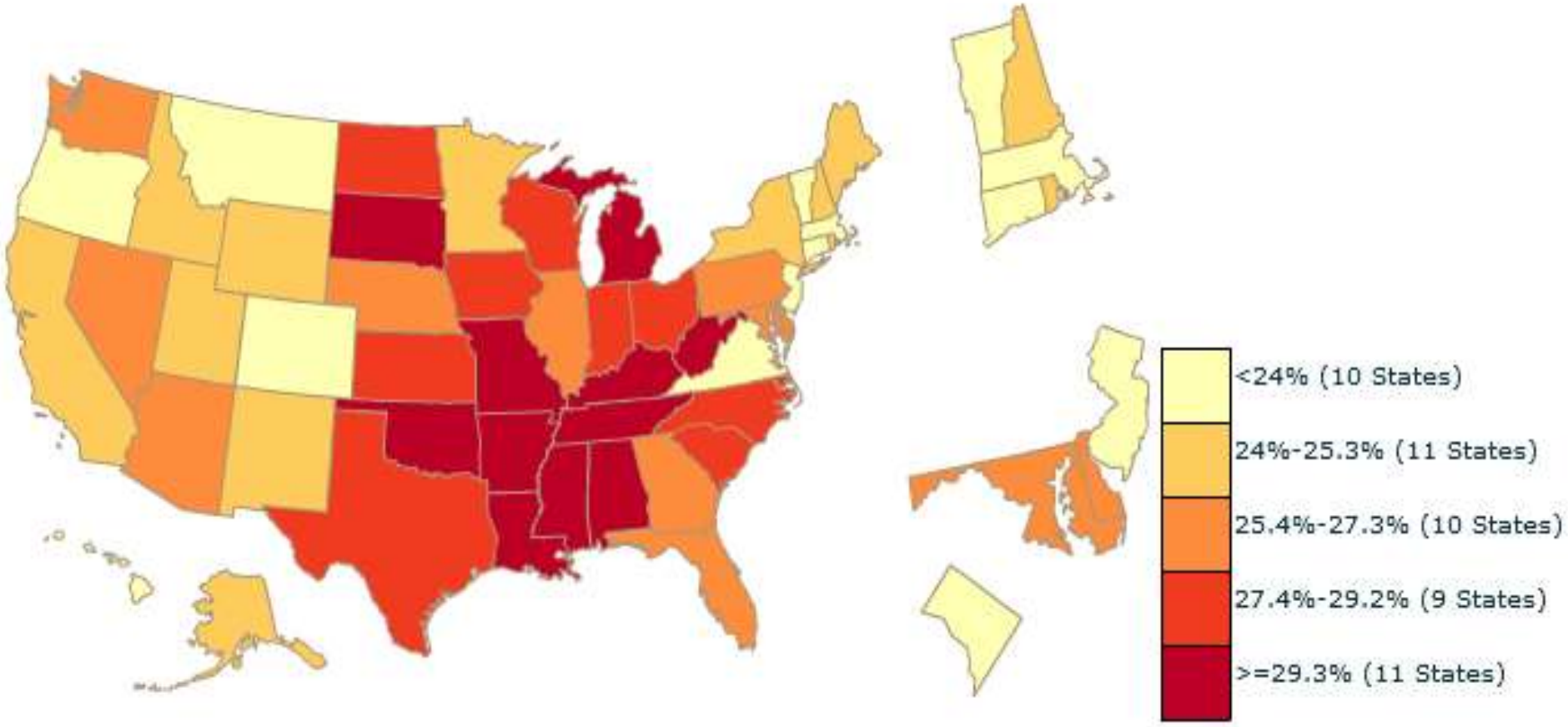
Hypertension

2009 Prevalence of hypertension among US adults (18+) (Percentage)†

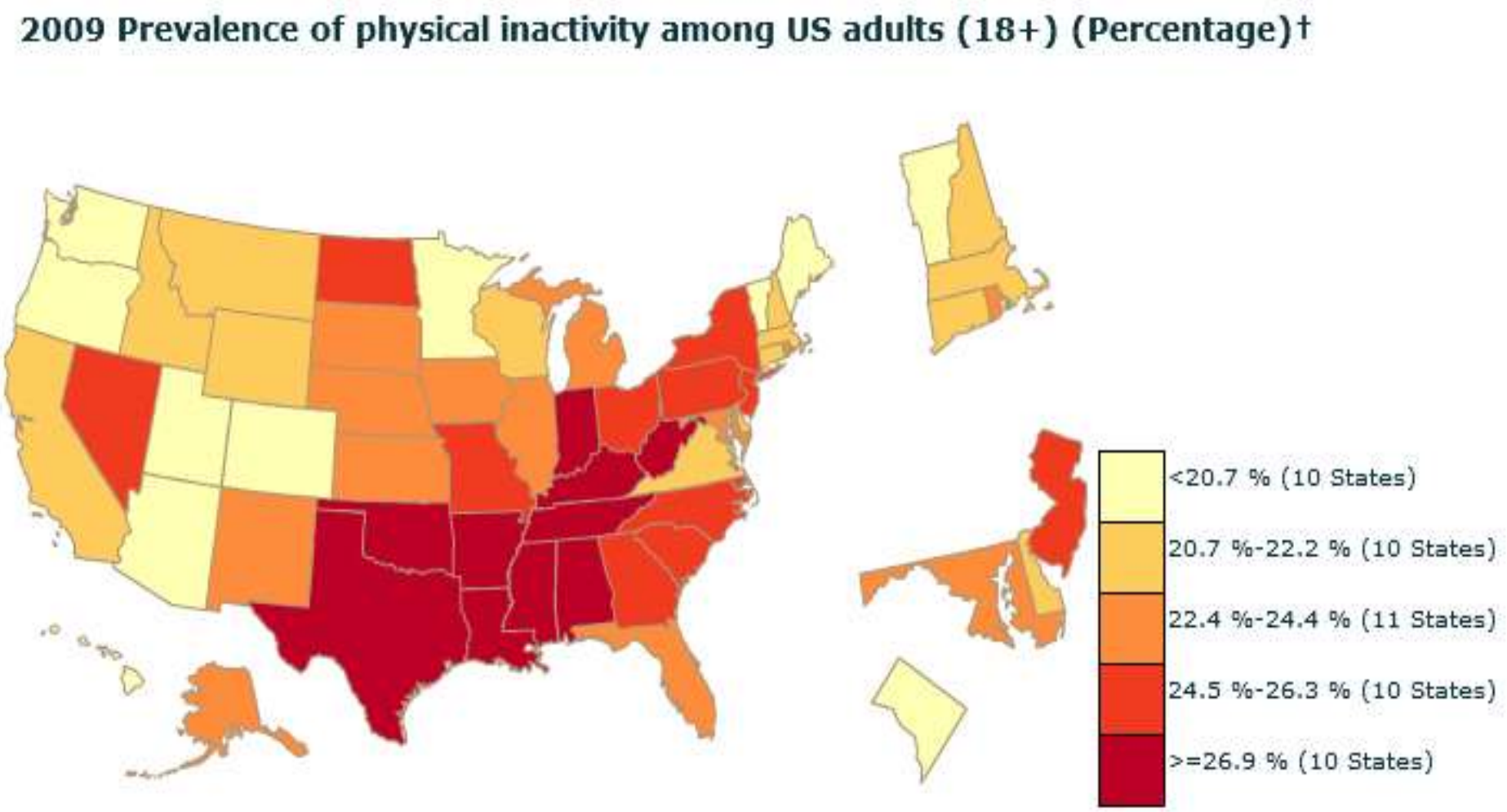


Obesity

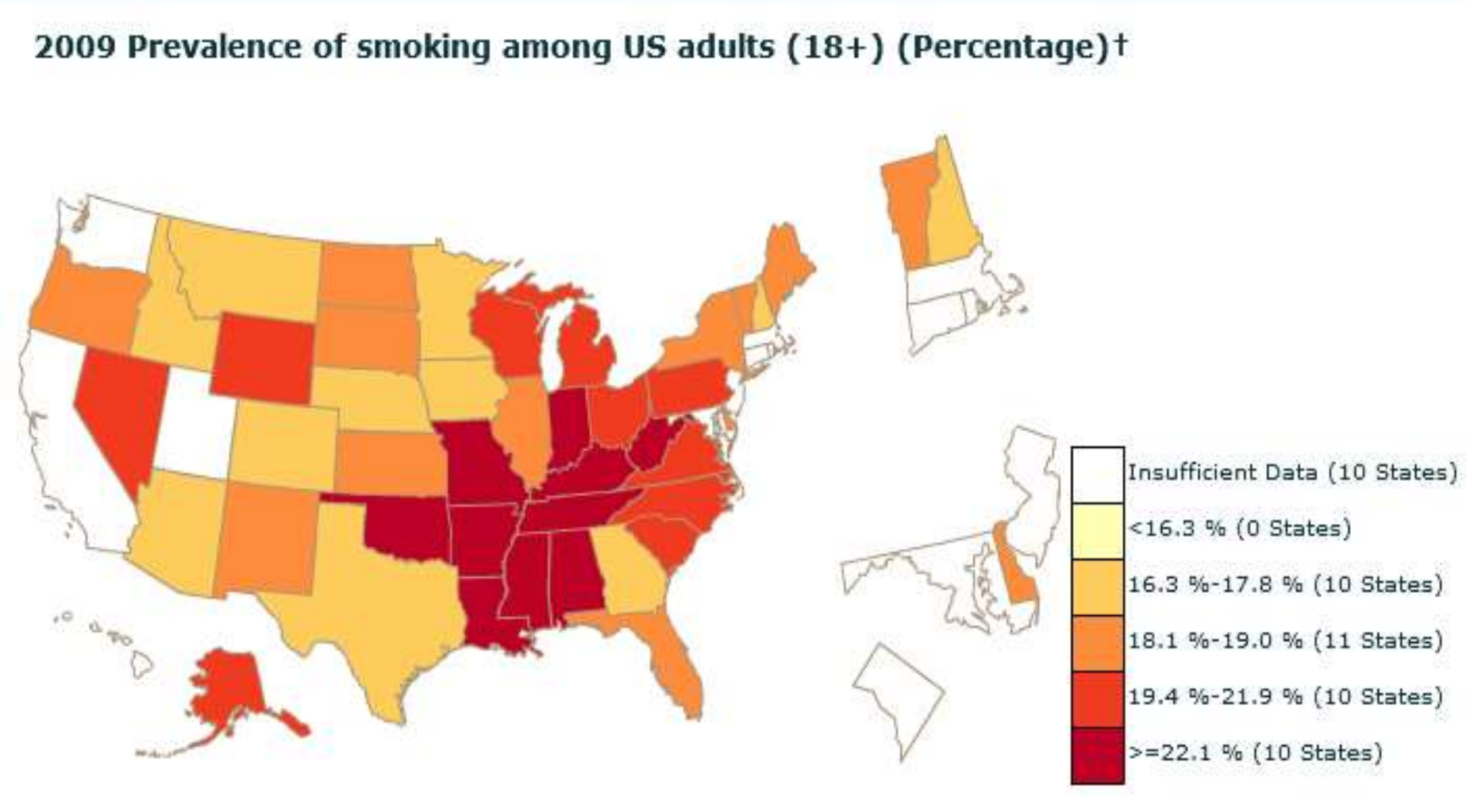
2009 Prevalence of obesity among US adults (18+) (Percentage)†



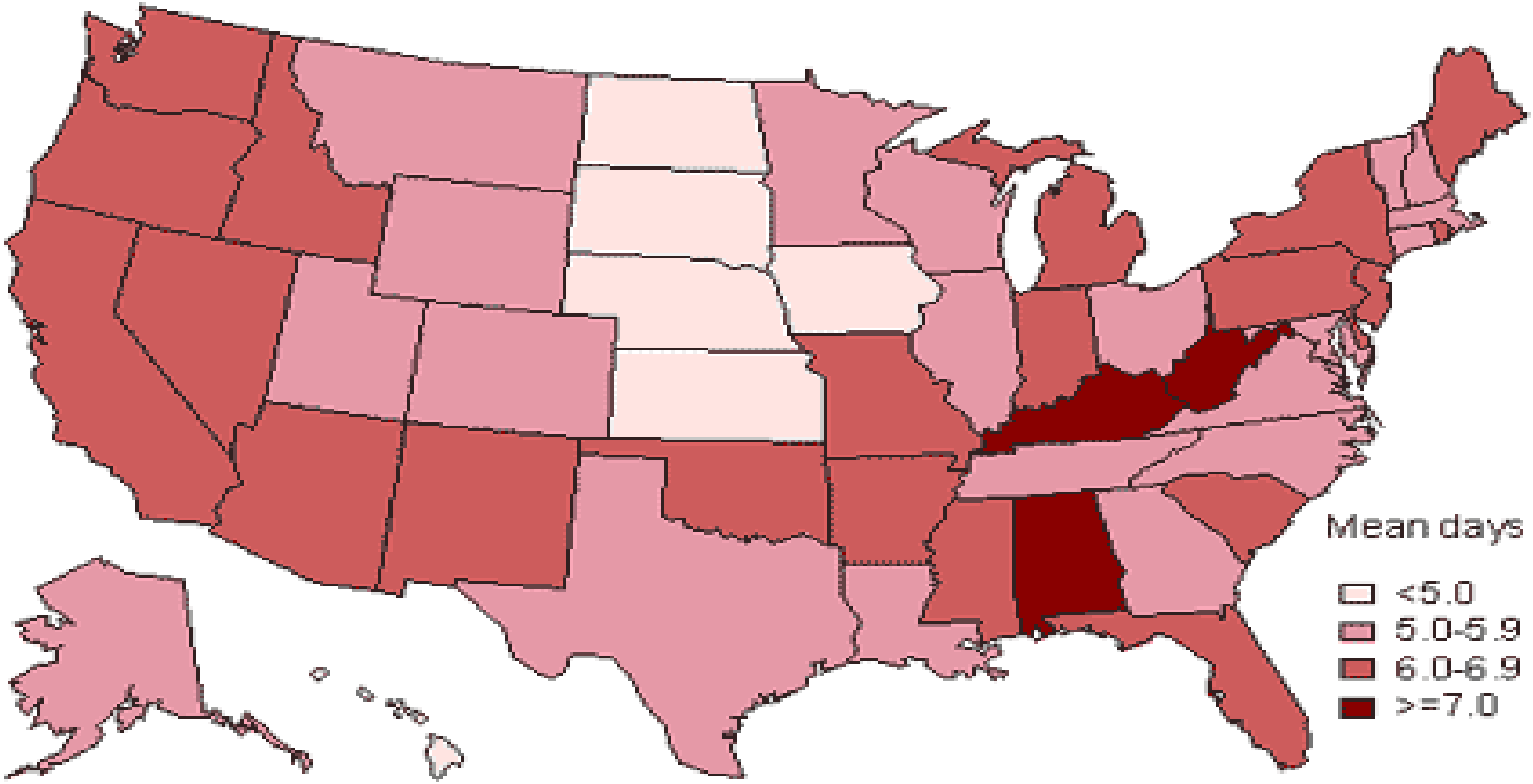
Physical Inactivity



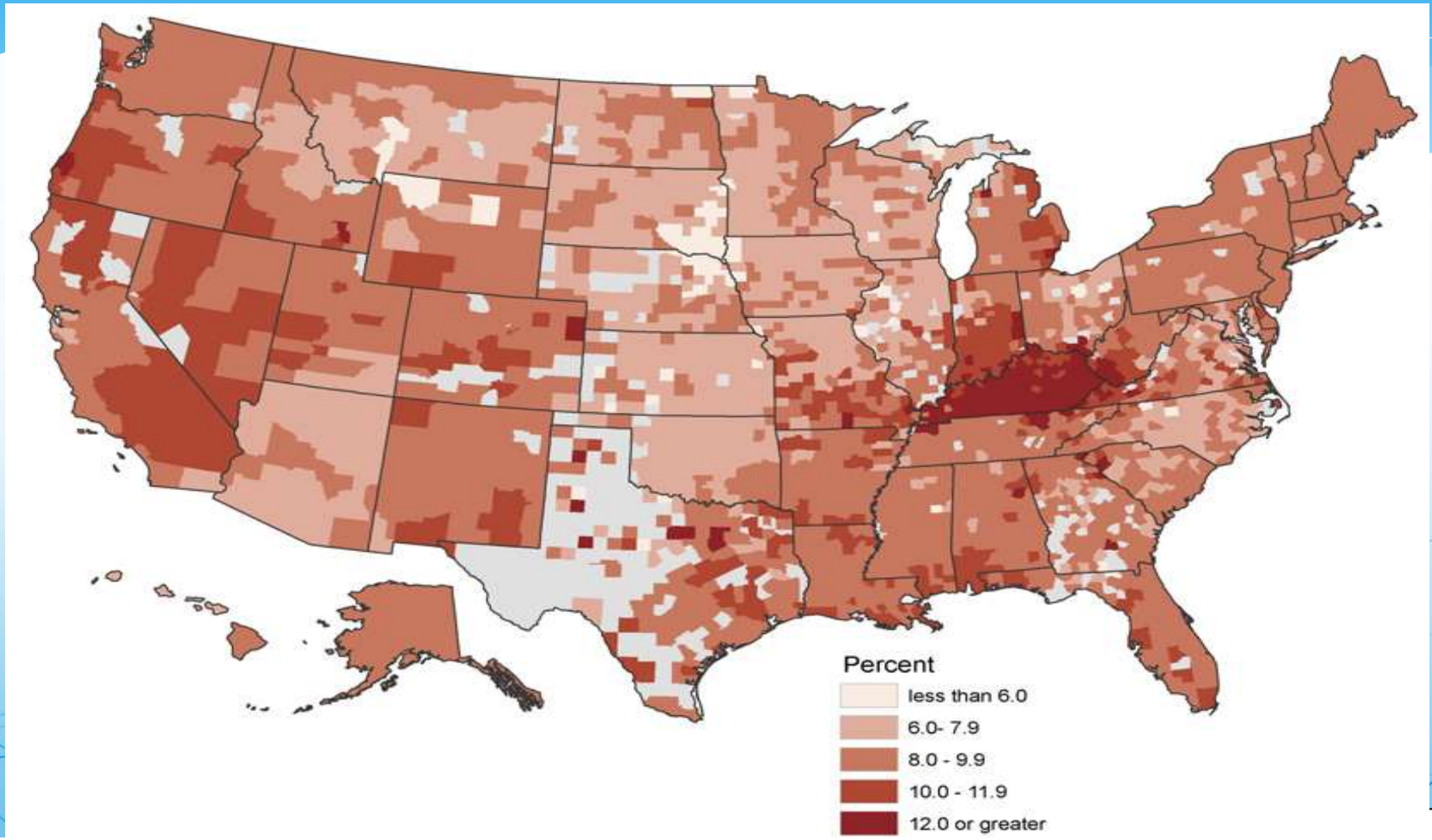
Smoking


2009 Prevalence of smoking among US adults (18+) (Percentage)†
Insufficient Data (10 States)
<16.3 % (0 States)
16.3 %-17.8 % (10 States)
18.1 %-19.0 % (11 States)
19.4 %-21.9 % (10 States)
>=22.1 % (10 States)

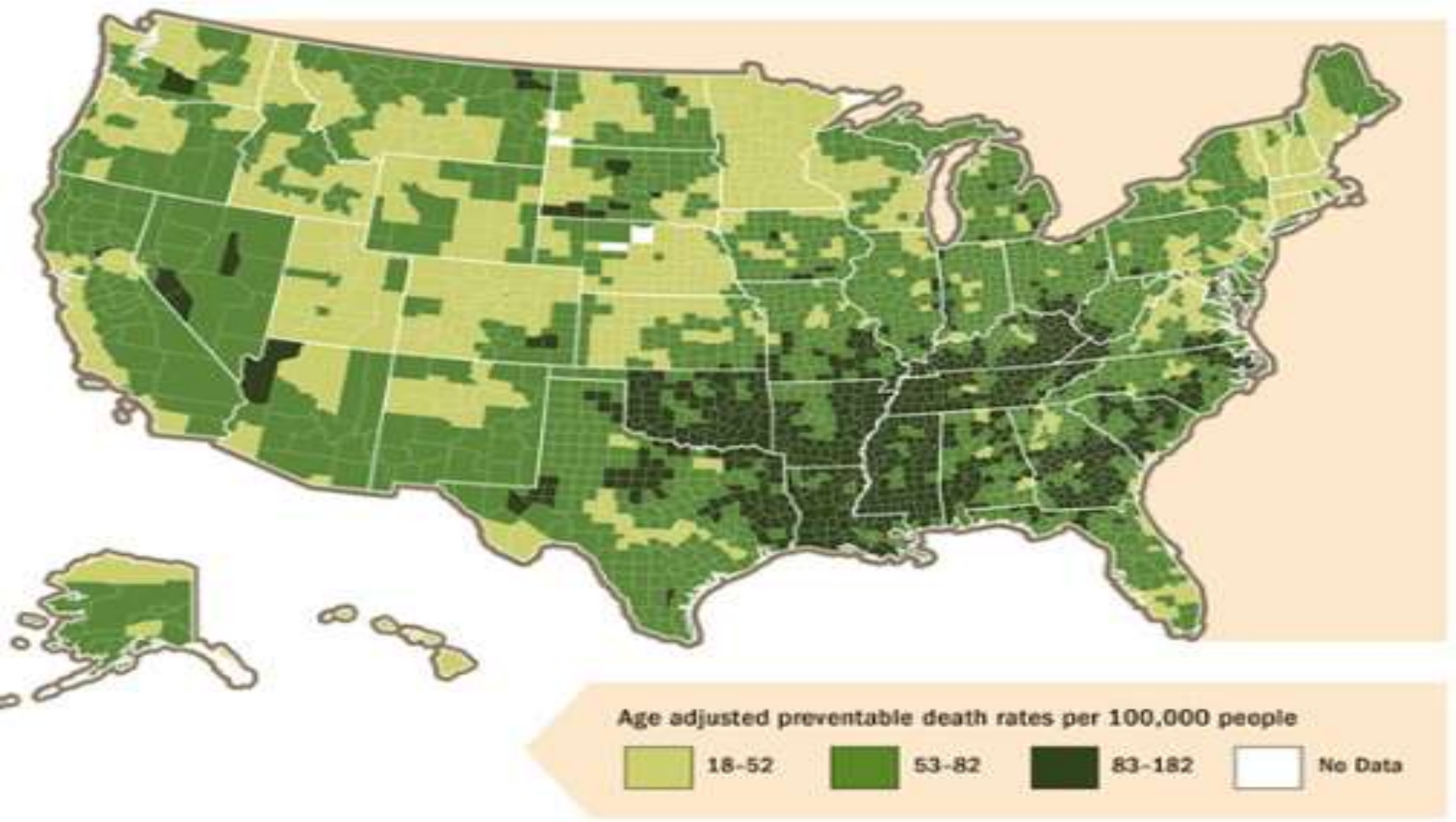
Mean Number of Unhealthy Days Among Adults by State



Geographic Patterns of Frequent Mental Distress



Moriarty DG, Am J Prev Med 2009;36(6):497–505



National Vital Statistics System, US Census Bureau, 2008-2010.

Risk of preventable death from heart disease and stroke varies by county, even within the same state. Counties in southern states have the greatest risk overall

Health Disparities and Community-Engaged Research

* "Health disparities that lead to uneven access and quality and high costs will persist without a community-engaged research agenda that finds answers to both medical and public health questions"

Michener et al., Acad Med. 2012 Mar; 87(3): 285–291

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Why Community Engagement?

* Concerns about
  * deficits in applying new research findings to the health problems communities face
  * reluctance of community members to participate in research
  * balancing the mismatch between community needs and goals of researchers

Community Engaged Research

* Process of inclusive participation that supports mutual respect of values, strategies and actions for authentic partnerships of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community of focus

National Institutes of Health Director's Council of Public Representatives

Core Principles

* Definition and scope of community engagement in research
* Strong community-academic partnerships
* Equitable power and responsibility
* Capacity building
* Effective dissemination of plans

Ahmed & Palermo, Am J Public Health. 2010 Aug; 100(8):1380-7.

CVD Health Disparities and Appalachia

* Appalachian Kentucky is in the top 1% of the nation in cardiovascular disease (CVD) morbidity and mortality
* Individuals in Appalachian Kentucky have the highest rates of multiple CVD risk factors seen in any state
* Problem amplified by the distressed environment
* There is a critical need to test sustainable CVD risk reducing interventions appropriate for Appalachia
  * In the absence of such interventions, the dramatic CVD disparities seen in this area will continue

Solutions

* Community-engaged research
  * Stakeholders engaged
* Focus on problems identified by stakeholders
* Culturally appropriate recruitment, follow-up and intervention
* Employ local staff and resources
* Sustainability plans

Patient and Stakeholder Engagement

* Multiple focus groups with patients, care providers, community leaders prior to study
* Advisory board composed of members of these groups convened before grant submission and reviewed grant
* Advisory board members on the grant
* Advisory board members attend the monthly research meetings
  * Successes, problems, barriers
  * Equal members
* Staff from community of focus and community health workers

Community Input

* Majority (65%) life-time residents of Appalachian Kentucky
  * Great concern about poor cardiovascular health
    * Aware of high rates and causes
  * Concern for all generations
  * Psychological distress important to maintenance of unhealthy behaviors
  * Believed fatalism drove unhealthy lifestyles
  * "Fast food" culture; increase in sedentary lifestyle

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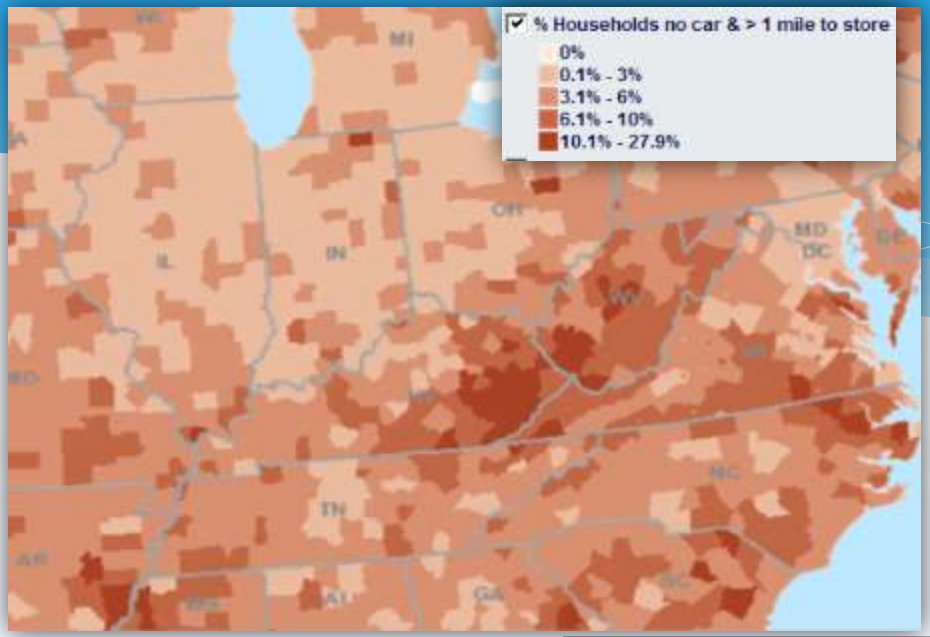
EAT IN OR
CARRY OUT
EARLY TILL LATE
7UP
HOME COOKED
MEALS
OPEN


PHARMACY
OPEN

Food Desert



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Community Input

* Majority (65%) life-time residents of Appalachian Kentucky
  * Traditional diet and eating patterns
  * Impediments in the built environment
  * Lack of accessibility to healthy foods
  * Preventative healthcare too expensive
  * Lack of local cardiovascular healthcare
  * Information from media and social community more valued than that from healthcare provider

Community Strengths

* Strong tradition of community mobilization when awareness of a local problem occurs
* Potential for "home-grown change"
* Neighborliness and concern for neighbors, friends, family and community
* Cultural strengths of honesty, sense of family, a strong work ethic, self-reliance and pride in community
* Desire to correct misperceptions about the area
  * "Mountain Dew swilling hillbillies"

Potential Approaches

* Lifestyle interventions can reduce CVD risk by 44%
* Lifestyle change is most effective when patients are given the tools to engage in self-care
  * patient-centered interventions individualized to patients' needs and barriers are more effective than interventions that are not
* Our central hypothesis is that to be successful in distressed environments, CVD risk reducing interventions must focus on patient-centered lifestyle change that increases individuals' abilities to engage in self-care, be culturally appropriate, and have components that overcome barriers in such environments.

Specific Aims

* Compare 4 month (short-term) and 1 year (long-term) impact of the interventions on
  1. CVD risk factors selected by patients (i.e., tobacco use, blood pressure, lipid profile, HgA1c for diabetics, body mass index, waist circumference, depressive symptoms, or physical activity level)
  2. all CVD risk factors for each patient
  3. quality of life
  4. patient and healthcare provider satisfaction
  5. desirability and adoptability by assessing adherence to recommended CVD risk reduction protocols, and retention of recruited individuals.

Inclusion Criteria

* Do not have a primary care provider or haven't seen one for more than 1 year and are at risk for CVD as reflected by having two or more:
  1. diagnosis of hypertension or taking medications diagnosed for hypertension or found to be hypertensive by us
  2. diagnosis of hyperlipidemia or taking medication for treating abnormal lipid levels, or any lipid abnormality found on our screening
  3. diagnosis of type 2 diabetes or HgA1c > 7% found on our screening
  4. overweight or obese (body mass index ≥ 25 kg/m^2)
  5. clinical diagnosis of depression, on medications for depression or found to have depressive symptoms (score of > 9 on the PHQ-9) by our baseline screening
  6. sedentary lifestyle meaning that the individual does not engage in at least 30 minutes of moderate activity for at least 4 days per week
  7. Consumes a diet high in saturated fats and low in fruits and vegetables

Exclusion Criteria

* Excluded if they
  1. have known coronary artery disease, cerebrovascular disease, history of acute coronary syndrome or PAD
  2. are taking medications (e.g., protease inhibitors) that interfere with lipid metabolism
  3. have cognitive impairment (cognitive impairment will be assessed using the Mini-Cog);
  4. are chronic drug abusers
  5. have end-stage renal or liver or pulmonary disease or current active cancer
  6. have gastrointestinal disease that requires special diets (e.g., Crohn's disease; celiac disease)

Recruitment and Setting

* Lay community health workers from HomePlace
* Advertising in local newspapers and gazettes
* Advertising at local churches, community centers, agricultural extension offices, senior centers, local business organizations, public health departments, public fairs of all types, county court houses, beauty shops and barbers, convenience stores, gas stations, and drug stores
* Advertising on the local radio and television stations that have a specific time set aside for local happenings
* Word of mouth
* Data collection and intervention at HomePlace sites

Procedure

* IRB approval – everyone who comes in contact with clients needs to take Human Subject training
* CHW and our research staff = team who do all aspects of protocol together
* Members of the team are trained together in all aspects of measurement, protocol maintenance and fidelity to the protocol
* All staff performing data collection are trained and certified by the PI and other expert clinician-researcher team members, with retraining every 3 months
* Fidelity is assured by oversight, review of recruitment and intervention activities at baseline and then every 3 months
* Monthly team meetings in which protocol and data overviews done

Interventions

* Standard of care
  * Secure an appointment with a primary care provider
    * all individuals enrolled in the study will receive referral to a primary care provider for management of the CVD risk factors identified in our screening
    * free or at a low cost depending on the resources of the patient
    * we will not otherwise influence the delivery of care with the exception that we will highlight all CVD risk factors to the provider in a report and provide them with evidence-based guidelines for CVD risk factor reduction

Intervention

* Heart Health Package
  * Whole health approach
* Promotion of self-care of CVD risk factors
* Skill-based
* Individualized
  * Feedback
  * Unique barriers addressed
* Culturally sensitive

Interventions

- HeartHealth
  - 6 interactive modules:
    - 1) principles of self-care and CVD risk reduction;
    - 2) nutrition (includes portion control, eating a diet high in fruits and vegetable and whole grains, reducing saturated and trans fats, reducing sodium intake, reducing total fat intake, clearing up the "good fat vs bad fat" issue);
    - 3) physical activity;
    - 4) depression control and stress reduction;
    - 5) managing multiple comorbid risk factors; and
    - 6) smoking cessation and/or medication adherence
  - Delivered over a 12-week period by community health workers every two weeks to groups of 10 people over a 2 hour period using specific behavior change principles

Intervention

* Considerations in planning interventions
  * Literacy
  * Health Literacy
  * High prevalence of depression
  * Limited resources
  * Poverty
  * Limited social networks
  * Personal limitations
  * Environment
  * Culture

Summary of Study Measures

Endpoint	Measure	When Measured
Screening **- cognitive function**	**-Mini-Cog**	**Screening prior to enrollment**
Specific Aims 1 and 2 **- blood pressure** **- lipid profile** **- body mass index** **- waist circumference** **- HgA1c** **- depressive symptoms** **- physical activity**	**-Sphygmomanometer using AHA guidelines** **-Cholestech POC** **-Height and weight** **-Anthropometric tape** **-Bayer POC** **-PHQ-9** **-Actigraphy**	**Baseline, 4 months, 1 year**
Specific Aim 3 **- quality of life**	**- SF-36version2**	**Baseline, 4 months, 1 year**
Specific Aim 4 **- patient and healthcare provider satisfaction**	**- Patient and provider intervention and care delivery satisfaction questionnaire**	**4 months, 1 year**
Specific Aim 5 **- desirability and adoptability**	**- Adherence to CVD risk reducing recommendations assessed using the Medical Outcomes Study Specific Adherence Scale** **- Patient retention**	**Baseline, 4 months, 1 year** **4 months, 1 year**

Dissemination

* Local, county, city and state media outlets
  * TV, radio, newspapers
* American Heart Association
* European Society of Cardiology
* International venues (South Korea, Taiwan, Sweden, Ireland)
* Journal of Rural Health
* Circulation

Impact on Community and State

* Program added to HomePlace deliverables
  * Working on insurer payments
  * Training all CHWs
* Became the program for community firefighters and police
* Became a wellness choice (with reduced insurance premiums) for local employment plans and businesses and community services
* Considered a fixture in the community
* Sustainability

Questions?

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Module 2
The Facts About Fats

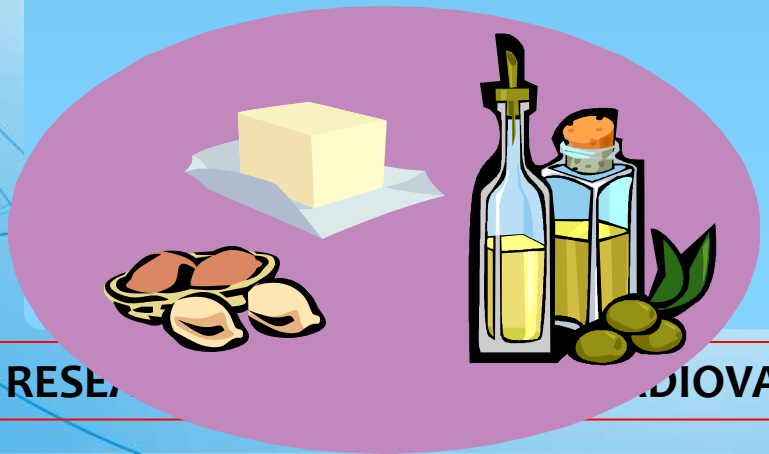
Heart Health

A Community Program for Life

Reduce risk factors for heart disease

Support lifestyle changes

Improve quality of life



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Fat and Your Health

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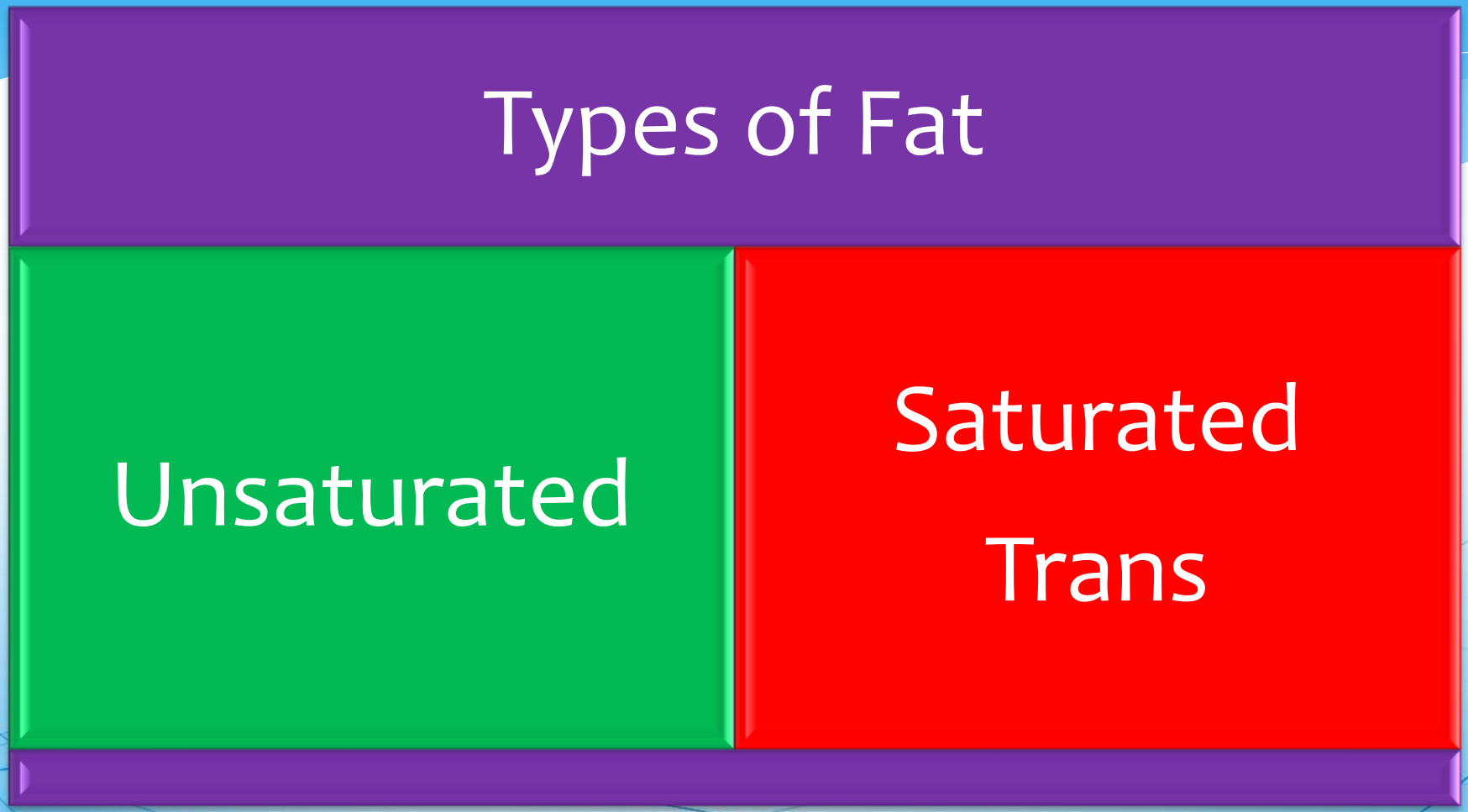
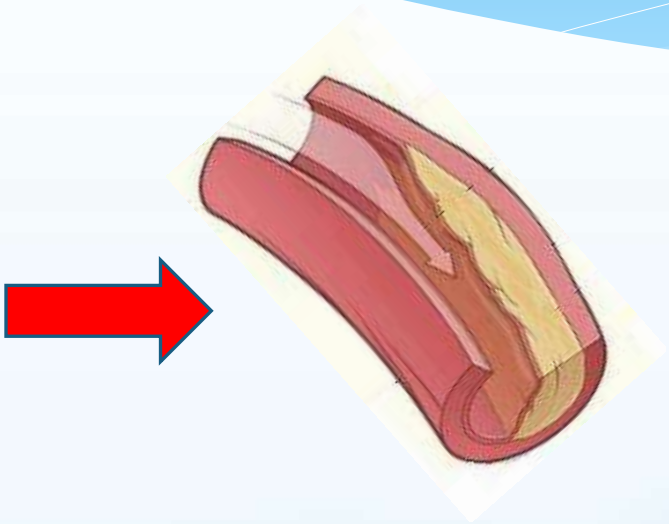
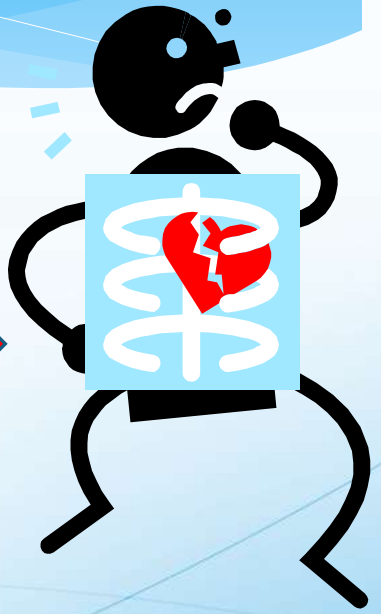
Are There Different Types of Fat?



Saturated and Trans Fat





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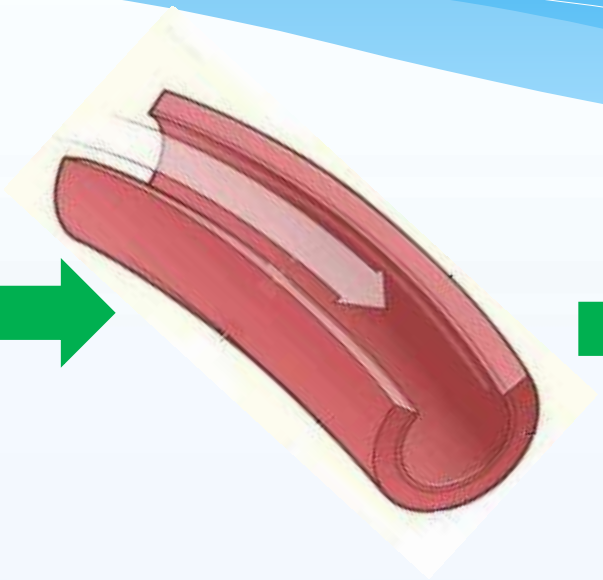
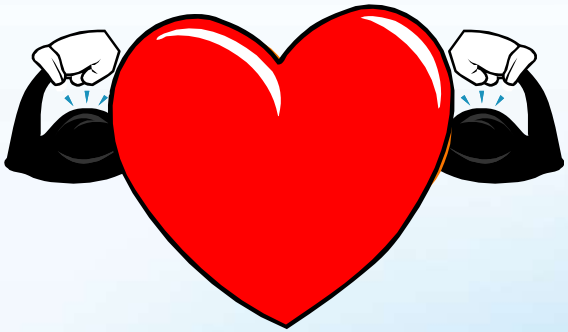
Unsaturated Fat





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Fats and Oils

Vegetable oil
Canola oil

Olive oil

Soft tub margarine

Nuts

Butter

Stick margarine

Shortening

Lard

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Fats and Oils: Milk

1% and skim milk

Light or low fat yogurt

2% milk

Cheese singles with less than 5 grams of fat

Whole milk

Ice cream

Cheese with 5 or more grams of fat

Fats and Oils: Meat

Chicken and turkey without the skin

Lean and Extra Lean ground beef (90% lean)

Round roasts and steaks

Top sirloin

Top loin

Fish

Deer

Pork tenderloin

Canadian Bacon***

Turkey or chicken lunch meat***

Bacon

Sausage

Bologna

Hot dogs

Chicken skin

Some red meat

***High in sodium

Fats and Oils: Snacks

Fruit

Nuts

Graham crackers

Fig bars

Ginger snaps

Jello

Sherbet

Instant pudding***

Donuts

Little Debbie

Hostess

Honey buns

Cookies

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***High in sodium

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Foods with 3 grams of total fat or less are best.

Nutrition Facts

Serving Size ½ cup (114g)
Servings Per Container 4

Amount Per Serving

Calories 90	Calories from Fat 30

	% Daily Value*
Total Fat 3g	5%
Saturated Fat 0g	**0%**
Cholesterol 0mg	**0%**
Sodium 300mg	**13%**
Total Carbohydrate 13g	4%
Dietary Fiber 3g	12%
Sugars 3g	
Protein 3g	

Vitamin A 80%	•	Vitamin C 60%
Calcium 4%	•	Iron 4%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

What Healthier Fats Are You Already Eating?

* _____
* _____
* _____
* _____
* _____
* _____
* _____

What Makes it Hard for You to Eat Healthier Fats?

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Why Are Healthier Fats Better for Your Health?

*
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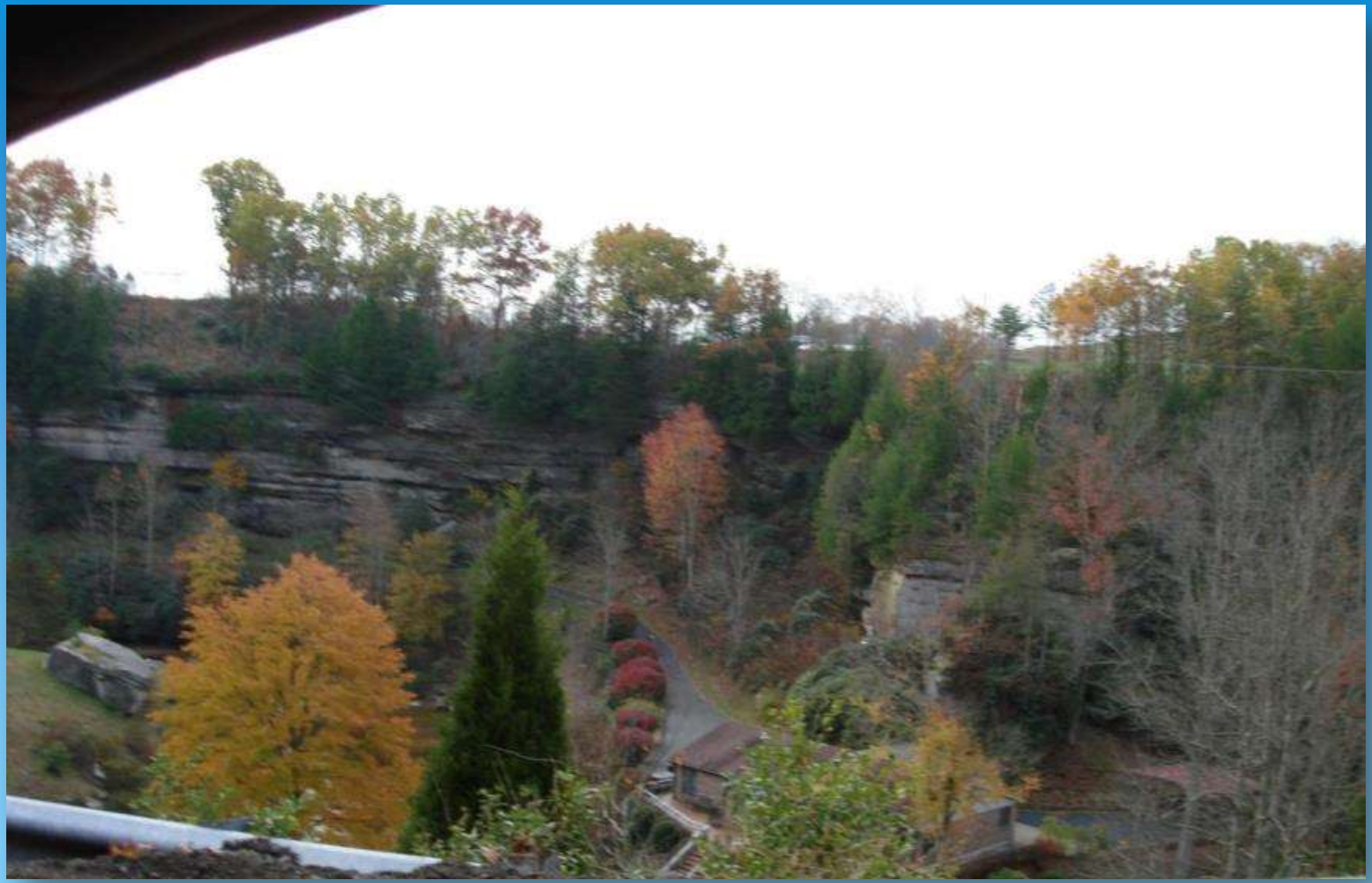
*



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Discussion of CDC HIV Topics

Romana Hasnain-Wynia, PhD, MS

pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Topics to Be Discussed

- **Topic #1:** *Early HIV Treatment to Optimize Patient Health and HIV Prevention: A Comparative Effectiveness Study of Immediate Antiretroviral Therapy for Persons with Acute or Early HIV Infection*
- **Topic #2:** *Comparative Effectiveness Trial of Innovative Models of Delivery of HIV Prevention and Care Services for People Living with HIV (PLWH)*

PCORI Criteria

1. **Patient-Centeredness**: Is the comparison relevant to patients, their caregivers, clinicians or other key stakeholders and are the outcomes relevant to patients?
2. **Impact of the Condition on the Health of Individuals and Populations**: Is the condition or disease associated with a significant burden in the US population, in terms of disease prevalence, costs to society, loss of productivity or individual suffering?
3. **Assessment of Current Options**: Does the topic reflect an important evidence gap related to current options that is not being address by ongoing research?
4. **Likelihood of Implementation in Practice**: Would new information generated by research be likely to have an impact in practice? (e.g., do one or more major stakeholder groups endorse the question?)
5. **Durability of information**: Would new information on this topic remain current for several years, or would it be rendered obsolete quickly by new technologies or subsequent studies?

Topic #1

- *Early HIV Treatment to Optimize Patient Health and HIV Prevention: A Comparative Effectiveness Study of Immediate Antiretroviral Therapy for Persons with Acute or Early HIV Infection*
- **Presenter:** Liz Jacobs
- Questions to keep in mind:
    - Are there other CER questions embedded in the questions proposed by the CDC?
    - What are contextual factors that could be considered for this topic (e.g., access, specialty care)?

PCORI Criteria

1. **Patient-Centeredness**: Is the comparison relevant to patients, their caregivers, clinicians or other key stakeholders and are the outcomes relevant to patients?
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Topic #2

- *Comparative Effectiveness Trial of Innovative Models of Delivery of HIV Prevention and Care Services for People Living with HIV (PLWH)*
- **Presenter:** Cheryl Pegus
- Questions to keep in mind:
    - Are there other CER questions embedded in the questions proposed by the CDC?
    - What are contextual factors that could be considered for this topic (e.g., access, specialty care)?

PCORI Criteria

1. **Patient-Centeredness**: Is the comparison relevant to patients, their caregivers, clinicians or other key stakeholders and are the outcomes relevant to patients?
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Wrap Up and Next Steps

- We are planning to have out next meeting via webinar sometime in October.
  - Please be on the lookout for an email to poll what dates and times work best.

Adjourn

Thank you for your participation!

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