Building the Plane While Flying It:

Implementing genomics activities in states while establishing the evidence base

CDC Office of Public Health Genomics Webinar
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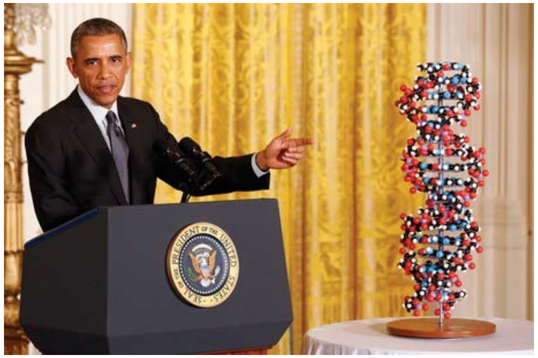
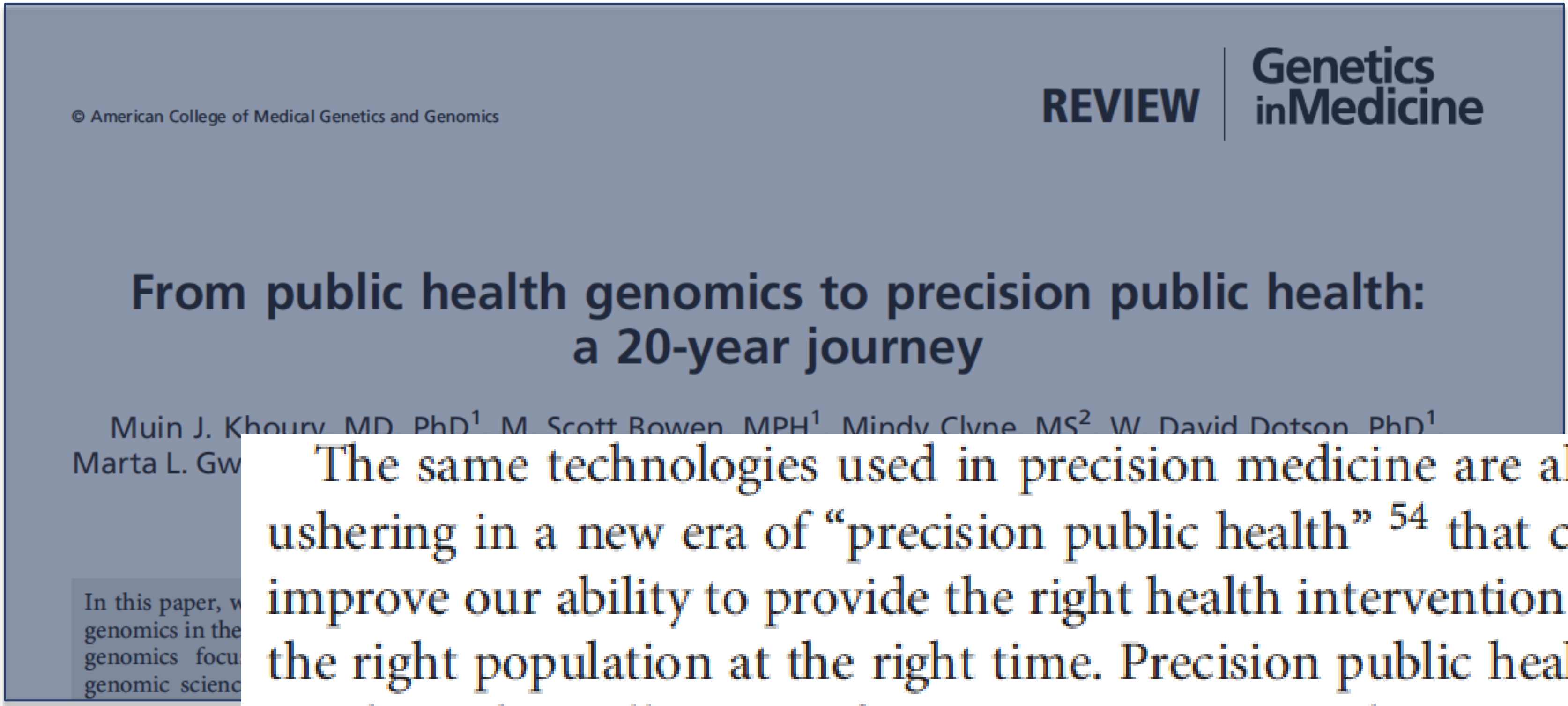
Overview of Presentation

- From Precision Medicine to Precision Public Health
- A framework of outcome measures and performance objectives for public health genomics programs
- What are states doing now?
  - Interventions that entail varying levels of complexity/investment of resources
  - Interventions with diverse partners
  - Multiple levels of evaluation

Moving from Precision Medicine to Precision Public Health

- Precision Medicine Initiative:
  - Great expectations (and some doubts) that genetic testing and genome sequencing will yield significant improvements in clinical care.
  - *Great concern that precision medicine could also exacerbate existing health inequalities or create new ones.*





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REVIEW | Genetics inMedicine

From public health genomics to precision public health: a 20-year journey

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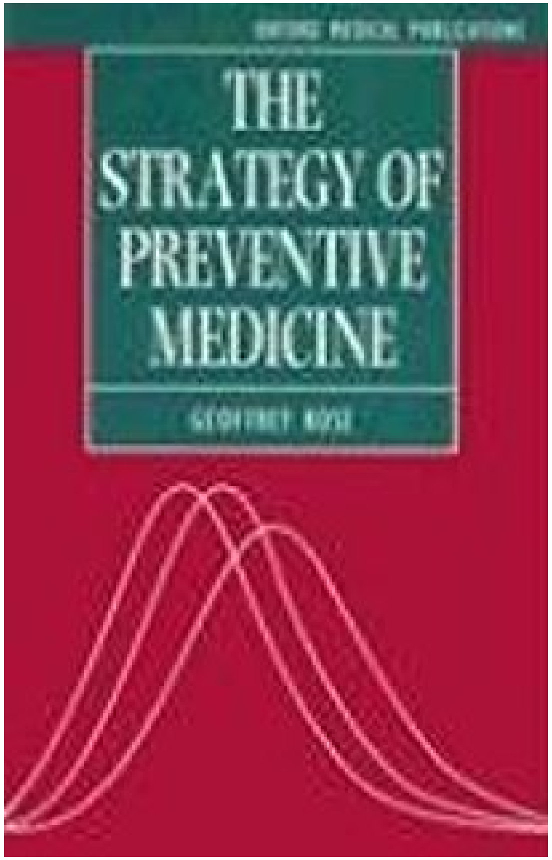
The same technologies used in precision medicine are also ushering in a new era of "precision public health" [54] that can improve our ability to provide the right health intervention to the right population at the right time. Precision public health involves the collection of more accurate population- and individual-level data on genes, exposures, behaviors, and other social/economic health determinants; enhancing public health action for improving health in subpopulations in need of recommended prevention measures; and addressing and reducing health disparities in the population by using more precision data for action.

Geoffrey Rose Meets the Era of Precision Health

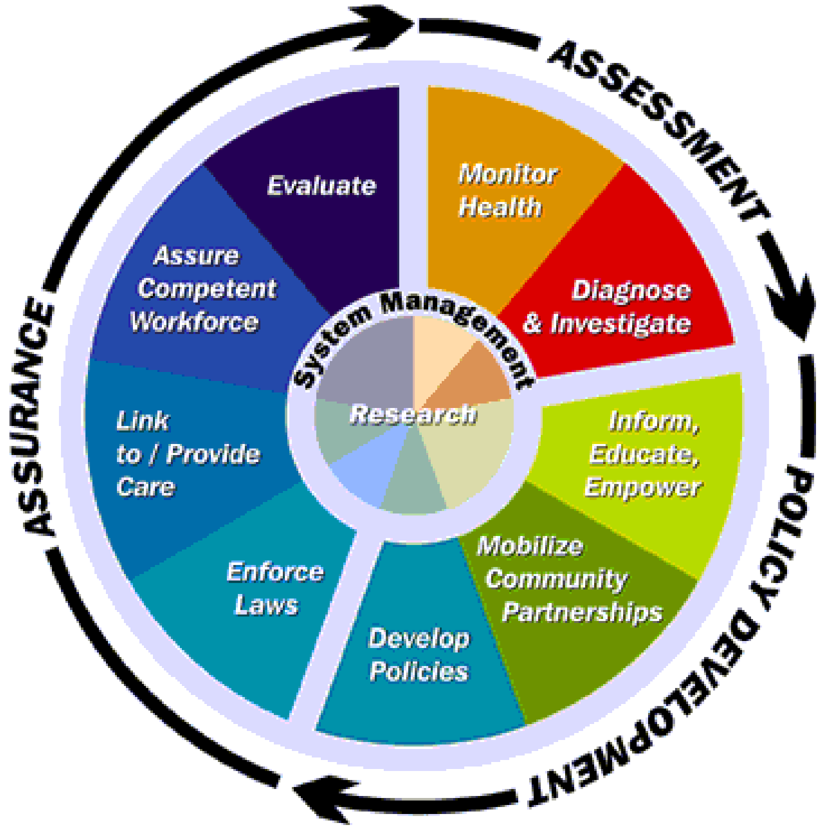
- Two health promotion strategies:
  - Population-level: bring general health promotion messages to a wider audience
    - General campaigns to encourage biennial mammograms after age 50
  - High risk: find people at greatest risk of disease, offer individualized intervention
    - Women with family history of breast cancer: genetic counseling, testing, earlier screening



Genomics and Precision Public Health

- Core Public Health Functions:
  - Assessment: surveillance
  - Policy development: educate providers and the public
  - Assurance: link to care

- Precision Public Health
  - Assessment: monitor the health of subgroups who are at especially high risk for disease
  - Policy development: identify partners who can help to reach those groups
  - Assurance: evaluate programs for success



Institute of Medicine, 1988

CDC's Three-Tier Classification

Which Genomics Applications Should We Be Working On?

Tier 1	Tier 2	Tier 3
• FDA label requires test to inform choice or dose of drug • CMS covers testing • Clinical practice guidelines based on systematic reviews recommend testing	• FDA label mentions biomarkers or premarket approval • Clinical practice guidelines provide weak evidence for testing	• FDA label cautions against use • CMS decision against coverage • Clinical practice guidelines recommend against testing

Current Tier 1 Applications in Cancer Genomics

Lynch Syndrome

- Condition: Hereditary form of colorectal cancer
- Prevention strategy: Genetic testing of newly-diagnosed patients and cascade testing to identify at-risk relatives
- Clinical practice guidelines: Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group (2009)

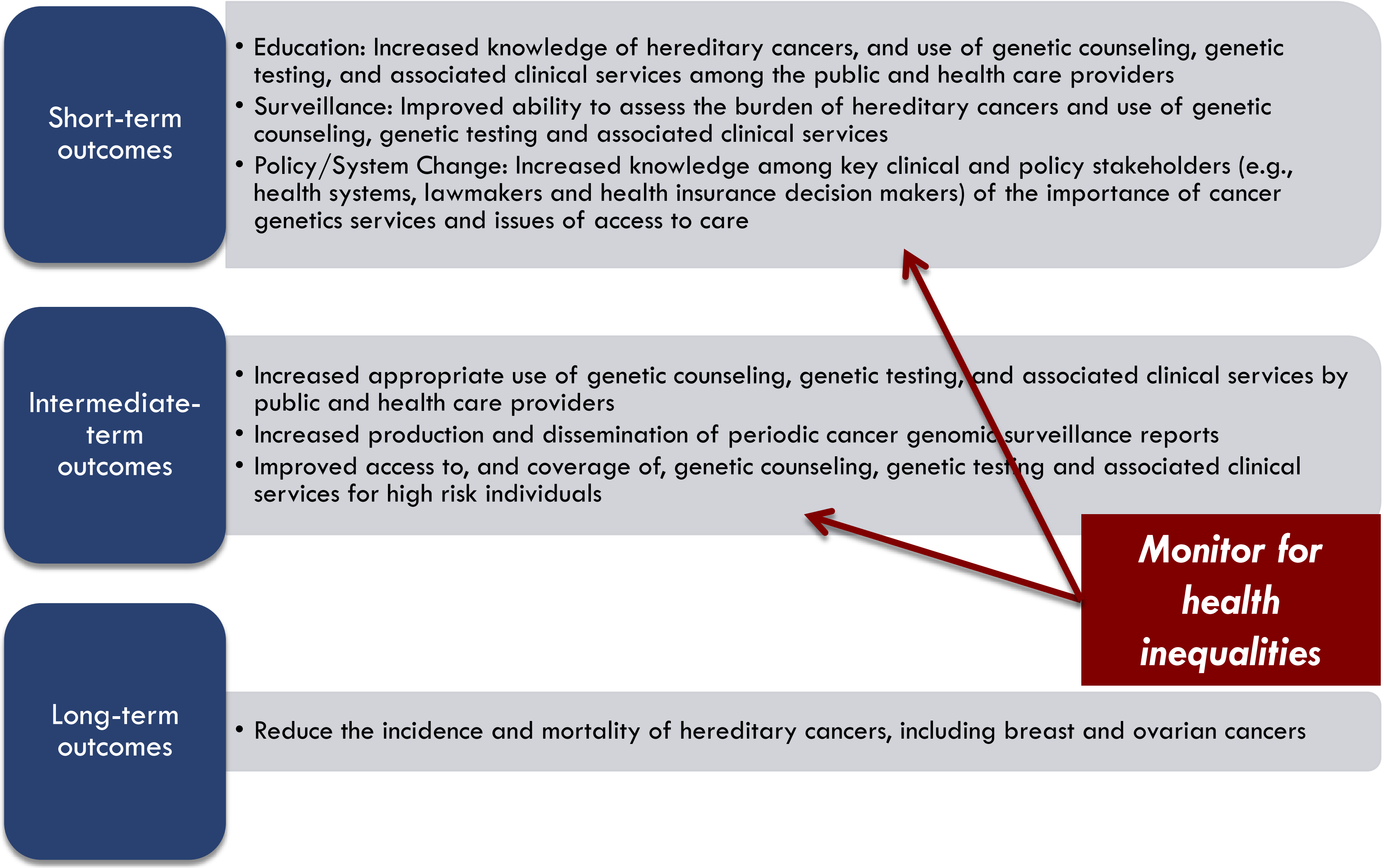
Hereditary Breast & Ovarian Cancer

- Condition: Breast and ovarian cancers commonly associated with variants in BRCA1/2
- Prevention strategy: Identify women with a strong family history of the disease and refer for genetic counseling
- Clinical practice guidelines: U.S. Preventive Services Task Force (2005; 2014)

CDC Cancer Genomics Grantees

- Enhancing Cancer Genomics Best Practices Through Education, Surveillance, and Policy
- FY2014-2019; $8.75 million
- Five states funded:
  - Colorado
  - Connecticut
  - Michigan
  - Oregon
  - Utah

CDC Cancer Genomics Grants: Expected Outcomes



Short-term outcomes

- Education: Increased knowledge of hereditary cancers, and use of genetic counseling, genetic testing, and associated clinical services among the public and health care providers
- Surveillance: Improved ability to assess the burden of hereditary cancers and use of genetic counseling, genetic testing and associated clinical services
- Policy/System Change: Increased knowledge among key clinical and policy stakeholders (e.g., health systems, lawmakers and health insurance decision makers) of the importance of cancer genetics services and issues of access to care

Intermediate-term outcomes

- Increased appropriate use of genetic counseling, genetic testing, and associated clinical services by public and health care providers
- Increased production and dissemination of periodic cancer genomic surveillance reports
- Improved access to, and coverage of, genetic counseling, genetic testing and associated clinical services for high risk individuals

Monitor for health inequalities

Long-term outcomes

- Reduce the incidence and mortality of hereditary cancers, including breast and ovarian cancers

The Road From Evidence to Practice

- "If we want more evidence-based practice, we need more practice-based evidence."
  - L.W. Green & R. Glasgow, 2006

- We will need:
  - Multiple kinds of evidence
  - Multiple levels of intervention
  - Multiple targets of evaluation

The Evidence-Based Public Health Cycle

Assessing your community

Establishing goals and objectives

Finding evidence

Selecting best-fitting EBS

Adapting

Implementing

Evaluating

Evidence-Based Strategies for Public Health Practice

Types of Evaluation

Systematic Reviews

Critically-Appraised Topics [Evidence Syntheses]

Critically-Appraised Individual Articles [Article Synopses]

Randomized Controlled Trials (RCTs)

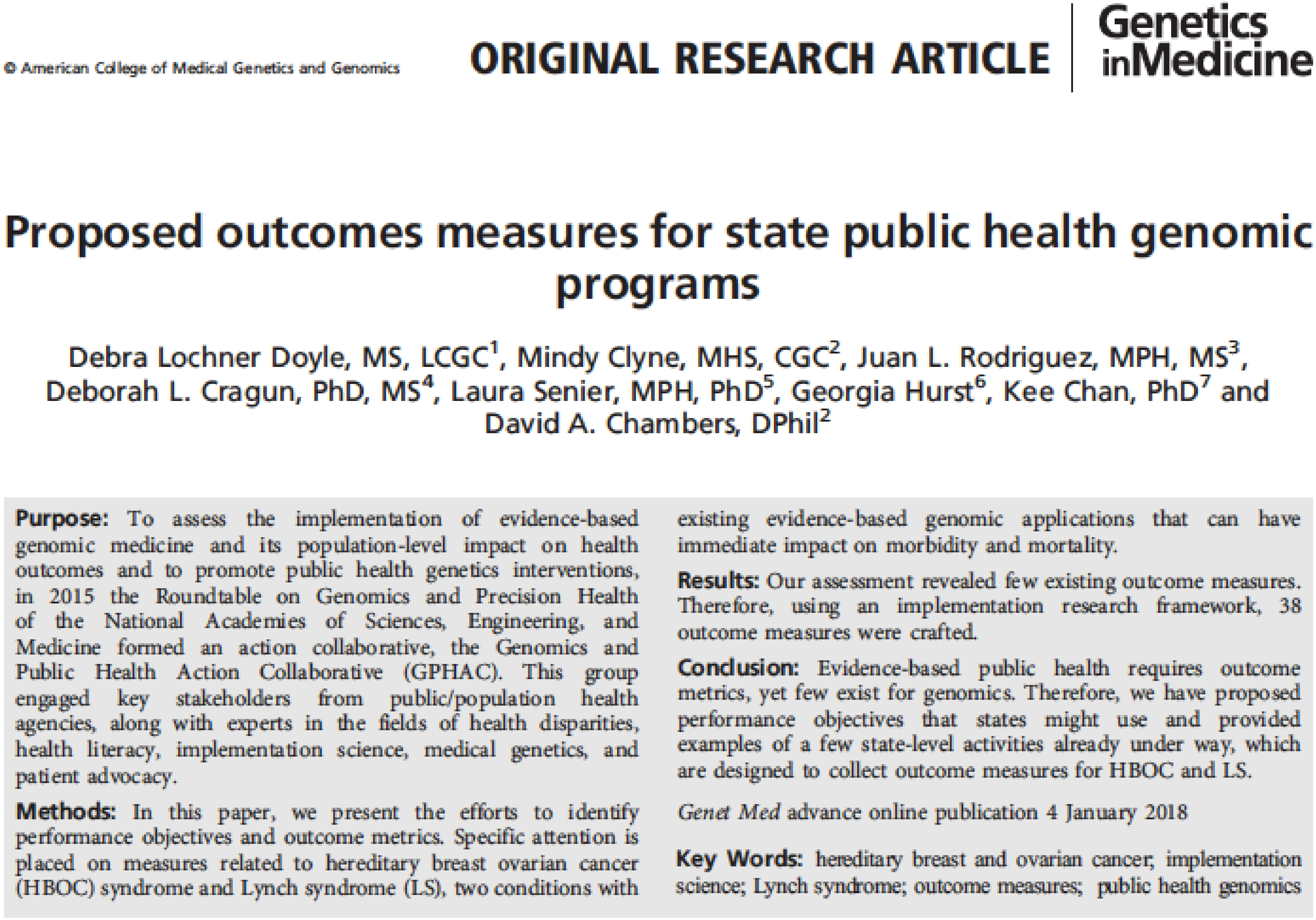
Cohort Studies

Case-Controlled Studies
Case Series / Reports

Background Information / Expert Opinion

Building the Evidence Base

An Implementation Framework, Performance Objectives, and Data Sources



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ORIGINAL RESEARCH ARTICLE | Genetics inMedicine

Proposed outcomes measures for state public health genomic programs

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Purpose: To assess the implementation of evidence-based genomic medicine and its population-level impact on health outcomes and to promote public health genetics interventions, in 2015 the Roundtable on Genomics and Precision Health of the National Academies of Sciences, Engineering, and Medicine formed an action collaborative, the Genomics and Public Health Action Collaborative (GPHAC). This group engaged key stakeholders from public/population health agencies, along with experts in the fields of health disparities, health literacy, implementation science, medical genetics, and patient advocacy.

Methods: In this paper, we present the efforts to identify performance objectives and outcome metrics. Specific attention is placed on measures related to hereditary breast ovarian cancer (HBOC) syndrome and Lynch syndrome (LS), two conditions with existing evidence-based genomic applications that can have immediate impact on morbidity and mortality.

Results: Our assessment revealed few existing outcome measures. Therefore, using an implementation research framework, 38 outcome measures were crafted.

Conclusion: Evidence-based public health requires outcome metrics, yet few exist for genomics. Therefore, we have proposed performance objectives that states might use and provided examples of a few state-level activities already under way, which are designed to collect outcome measures for HBOC and LS.

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Key Words: hereditary breast and ovarian cancer; implementation science; Lynch syndrome; outcome measures; public health genomics

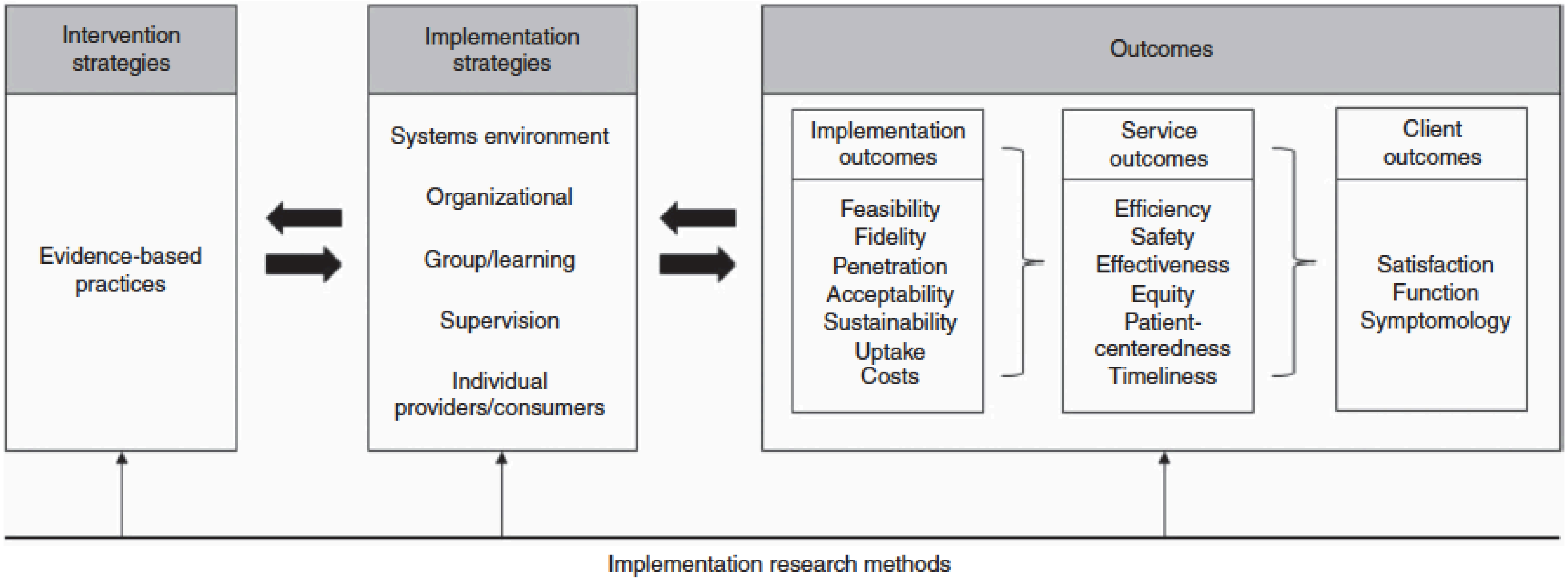


Figure 1 The implementation framework developed by Proctor et al.[2]

Implementation Framework

Outcomes	Definition
Implementation outcomes	Feasibility, Fidelity, Penetration, Acceptability, Sustainability, Uptake, Costs
Service outcomes	Efficiency, Safety, Effectiveness, Equity, Patient-centeredness, Timeliness
Client outcomes	Satisfaction, Function, Symptomology
Access to services	Public health system efforts to embed screening and testing in healthcare organizations
Healthcare performance	Increasing number of providers or health systems implementing evidence-based or recommended health services
Public health infrastructure	Processes essential to the success of the implementing health agency

Developing the Framework

- Systematic review of the literature to identify studies of interventions
- Identified specific performance objectives, relative outcomes measures, possible data sources
- Prioritized performance objectives in four categories:
  - Top-priority outcomes that all states are encouraged to pursue
  - Outcomes that states should pursue
  - Outcomes that states should pursue if data sources are available
  - Aspirational outcomes

Top Priority Outcomes

Access to Services

Performance Objective	**State Outcome Measure**	**Data Source**
Increase proportion of women with family history of HBOC/LS who receive genetic counseling	Number of women with a family history of HBOC/LS who receive genetic counseling	National Health Interview Survey; state BRFSS; state PRAMs cancer module; claims data
Increase proportion of persons with newly diagnosed CRC who receive genetic testing to identify LS	Number of persons with newly diagnosed CRC who receive genetic testing to identify LS	State cancer registries; SEER; state BRFSS

Top Priority Outcomes

Healthcare performance

Performance Objective	State Outcome Measure	Data Source
Increase the number of family members screened through cascade testing	Number of family members screened following identification of HBOC/LS mutations	Claims data; data collected from genetic providers in clinics across the state; number of single mutation tests ordered (as reported by largest cancer genetic testing laboratories)

Outcomes States Can Readily Perform

PH infrastructure

Performance Objective	State Outcome Measure	Data Source
Increase partnerships with regional clinics, academic institutions, CDC-funded programs, state programs, nonprofits, insurance groups, and industry to ensure efforts are sustainable	Number of partnerships, Partner satisfaction with partnership projects	Survey and focus group data

What Are States Doing Now?

Example: Michigan Cancer Consortium

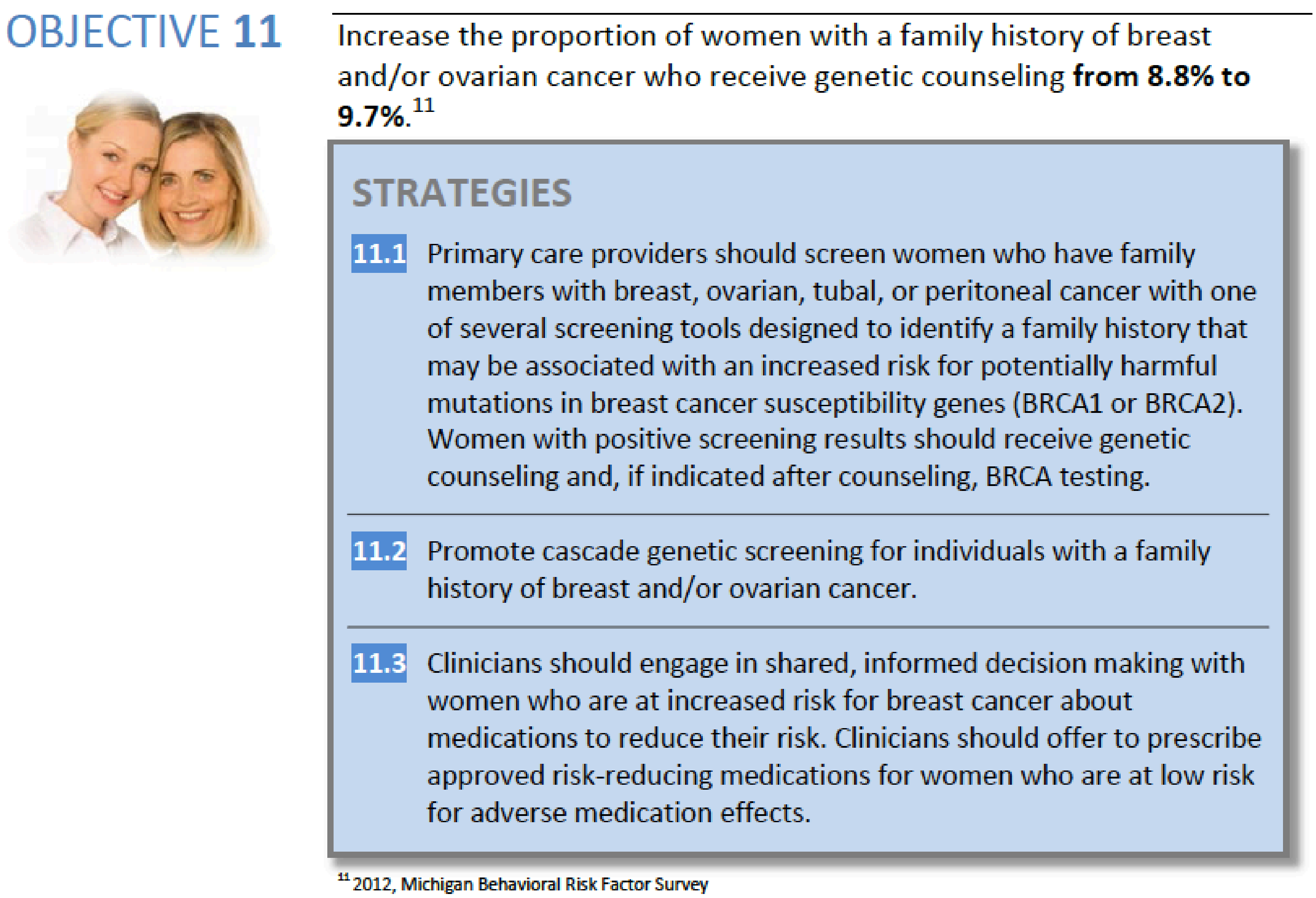
Cancer Plan for Michigan

2016-2020

MCC

Michigan Cancer Consortium

Example: Michigan Cancer Consortium



OBJECTIVE **11**

Increase the proportion of women with a family history of breast and/or ovarian cancer who receive genetic counseling **from 8.8% to 9.7%.**[11]

STRATEGIES

11.1 Primary care providers should screen women who have family members with breast, ovarian, tubal, or peritoneal cancer with one of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (BRCA1 or BRCA2). Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing.

11.2 Promote cascade genetic screening for individuals with a family history of breast and/or ovarian cancer.

11.3 Clinicians should engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk. Clinicians should offer to prescribe approved risk-reducing medications for women who are at low risk for adverse medication effects.

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[11] 2012, Michigan Behavioral Risk Factor Survey

Example: Connecticut's Family Health History Education Program

Penetration

- Connecticut's Genomics Program analyzed BRFSS data; realized that people who collect FHH and share with their provider are largely white, upper-income, highly educated

Service equity

- Solution: Partner with 4 community-based organizations that serve underrepresented groups; tailor FHH materials to their audiences

We all have a family history of something!

The Surgeon General has provided a tool to help you to create a portrait of your family's health. The following worksheet will help you organize your family tree and identify common diseases that may run in families. Use this information to fill out the online version at **www.hhs.gov/familyhistory**.

Grandmother

Grandfather

M
F

M
F

M
F

Aunts | Uncles

Mother

Father

M
F

M
F

M
F

Aunts | Uncles

Grandmother

Grandfather

M
F

M
F

M
F

Brothers | Sisters

M
F

YOU

M
F

Spouse | Partner

M
F

M
F

M
F

M
F

Your Children

Type of information to include:

- Major medical conditions & cause of death (where applicable)
- Age of person at disease onset
- Age of person if/when deceased from disease
- Ethnic background

Name: ____________________

Age: ____________________

Date: ____________________

Northeast District Department of Health

Khmer Health Advocates

Community Health Center, Inc.

Hispanic Health Council
Health. Hope. Community.

Connecticut's Family Health History Program: Results

- Mixed-methods evaluation
- Process and outcome measures
- Post-test survey results (N=152)
    - 85.6% agreed/strongly agreed that it is important to know one's FHH
    - 75% agreed/strongly agreed that they want to share their FHH with their relatives
    - 82.9% agreed/strongly agree that they want to share their FHH with their healthcare provider

Connecticut’s Family Health History Program: Results

- Insights from process evaluation about program sustainability:
  - Site coordinators said the FHH intervention fit naturally with other health promotion initiatives; i.e., already discussing heart disease, cancer, mental health with their clients
  - Site coordinators appreciated the Connecticut Genomics Program staff’s willingness to let them tailor delivery of the FHH intervention to their existing routines
    - Community Health Center had been using AmericCorps volunteers to deliver all types of health promotion materials

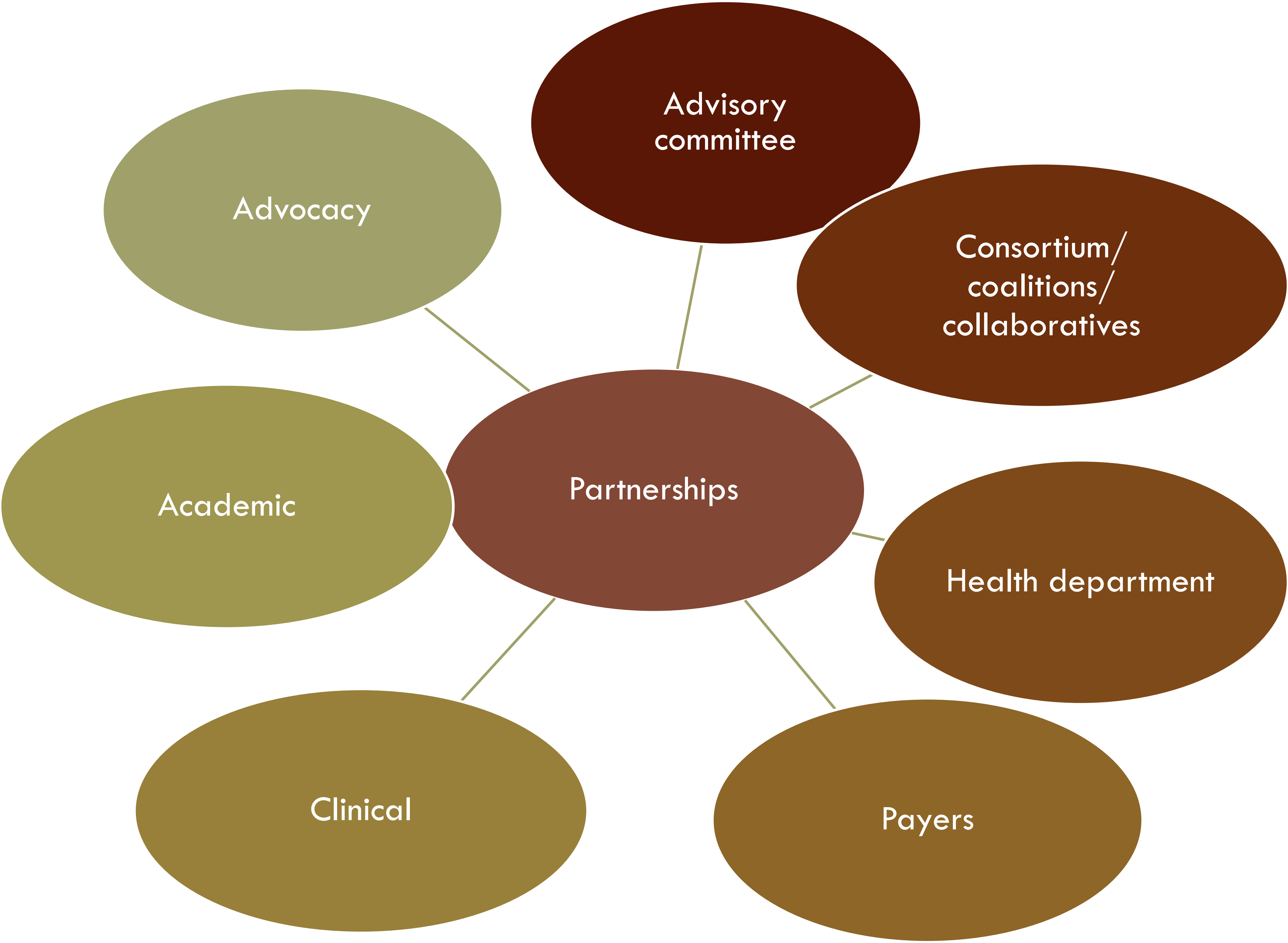
Connecticut's Family Health History Program: Results

- Barriers to further routinizing FHH in clinical practice
  - Even community-based organizations that deliver clinical services did not attempt to layer this into primary care providers routines
  - Instead chose to deliver it with other health promotion programing provided by health educators and community health workers

Outcomes States Can Readily Perform

PH infrastructure

Performance Objective	State Outcome Measure	Data Source
Increase partnerships with regional clinics, academic institutions, CDC-funded programs, state programs, nonprofits, insurance groups, and industry to ensure efforts are sustainable	Number of partnerships, Partner satisfaction with partnership projects	Survey and focus group data



Partnerships

Advisory committee

Consortium/ coalitions/ collaboratives

Health department

Payers

Clinical

Academic

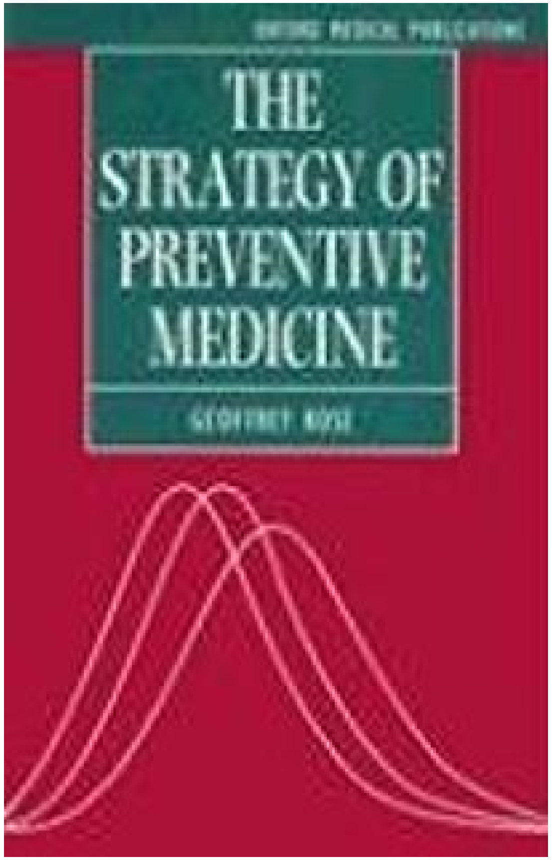
Advocacy

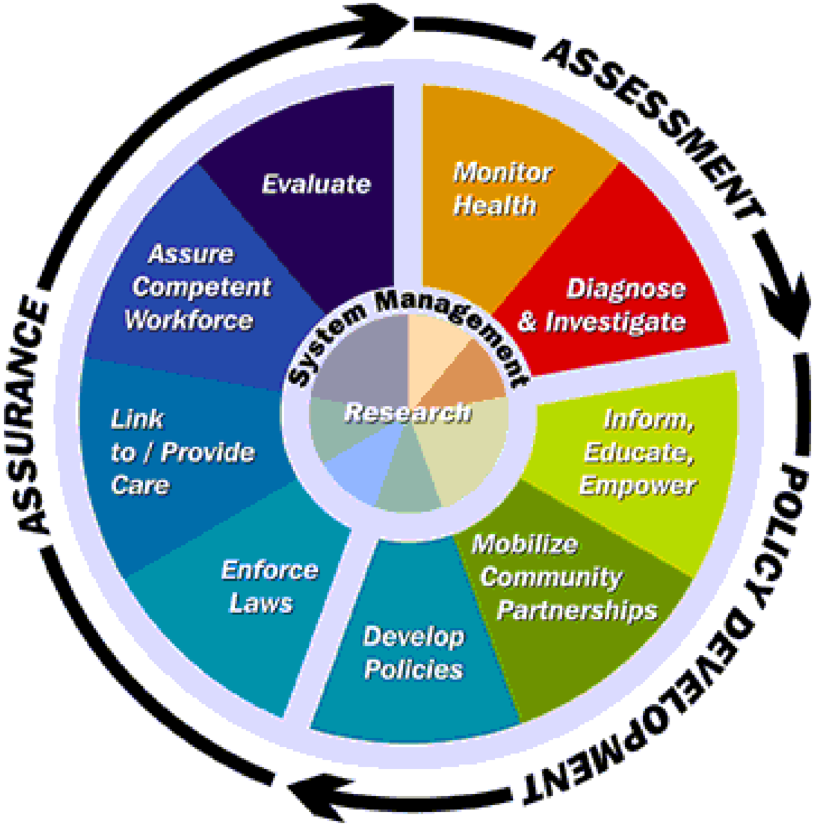
Example: Michigan Genomics Program Steering Committee

- Type of evaluation: Process
- Method: use interactive Audience Response System (ARS) software in an interactive PowerPoint presentation with the Steering Committee to:
  - Engage committee members by having them rank the value of MDCH projects, services, and resources in real-time
  - Facilitate discussion from instant feedback on ARS results (via presentation graph)
  - Potentially assess balance between costs and benefits of services to make sure program funds are being used proportionally for the most valued services

Conclusions

The Familiarity of Precision Public Health





Getting Started with Precision Public Health

- Select some start up projects
  - CDC-OPHG's Tier 1 toolkit
- Identify partners
- Select a few evaluation targets
- Design evaluation activities
  - Mix of process/outcome evaluations are fine
  - Focus initially on short- and intermediate-term outcomes

Building the Plane While Flying It

- By starting with the Tier 1 conditions, we can pilot interventions and evaluate them to determine what works
  - Building the basis for Precision Public Health for educational and clinical interventions
- By covering all 3 Core Public Health Functions, we can build evidence base that covers a continuum of public health and clinical services
  - Building the basis for Precision Public Health that builds capacity of public health agencies and healthcare systems; honors partnership development

Questions?