APPLYING AN IMPLEMENTATION SCIENCE APPROACH TO GENOMIC MEDICINE: A WORKSHOP

November 19, 2015

Session III: Population Health and Genomics:

Incremental Implementation or Radical Reform?

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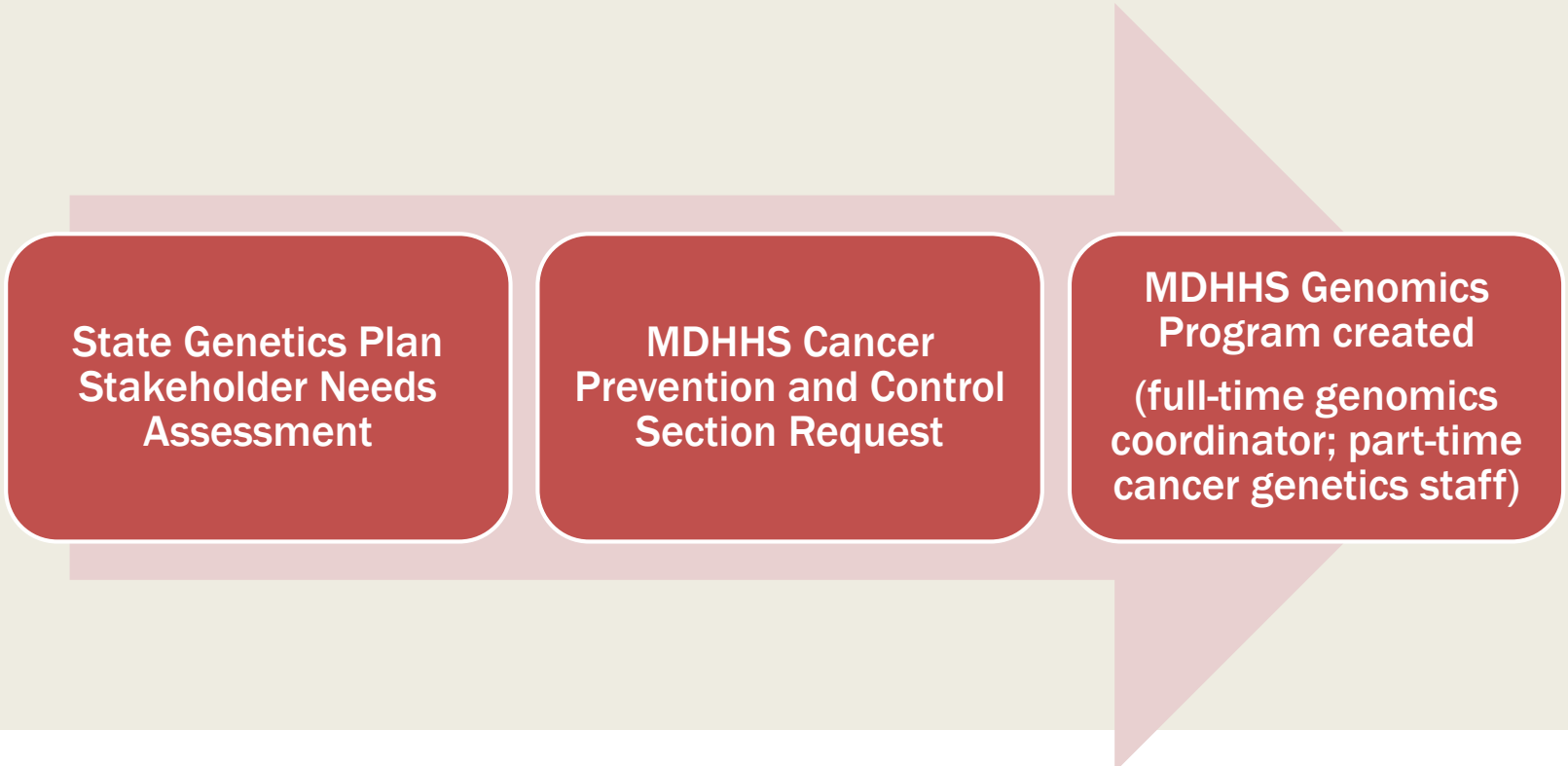
MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS) DECISION TO INTEGRATE GENOMICS, 2002

- Request from multiple stakeholders in state genetics plan needs assessment in 2000-2002
- Request from MDHHS Cancer Prevention and Control Section to hire staff with cancer genetics expertise in 2002

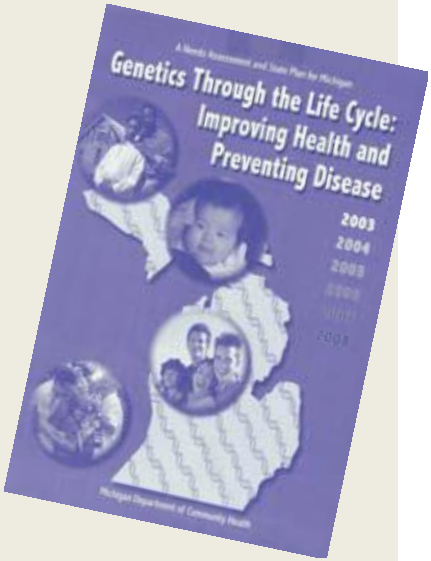


CANCER GENOMICS & STATE GENETICS PLAN, 2003-2008*

- Goal #1: Increase genetic literacy in the State of Michigan
  - Expand public and provider knowledge regarding the impact of genetics on health

- Goal #2: Assess the public health impact of heritable conditions and the utilization of genetic services
  - Conduct public health surveillance and research regarding hereditary cancer in Michigan

- Goal #3: Improve access to genetic information, prevention strategies and services
  - Educate health insurance plans and providers about the value of genetic services



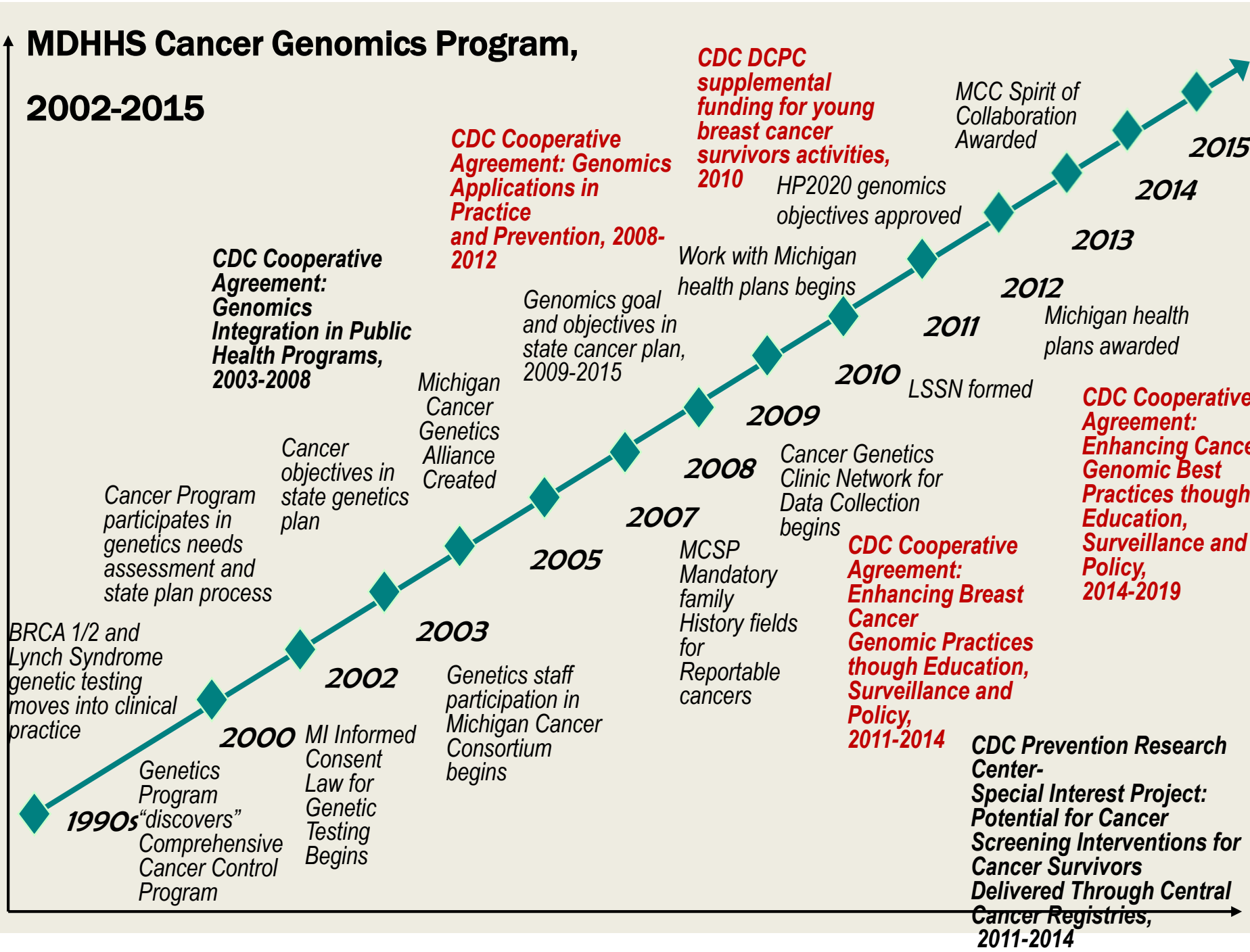
** Funding for the Michigan genetics needs assessment and state plan provided by grants from the Maternal and Child Health Bureau (Title V. Social Security Act), Health Resources and Services Administration, Department of Health and Human Services, 2000-2006.*

CANCER GENOMICS & THE STATE GENETICS PLAN, 2003-2008*

- Goal #4: Promote early identification and treatment of individuals with birth defects, heritable disorders or genetic susceptibilities throughout the life cycle
  - Promote use of family history for genetic risk assessment of common chronic conditions
  - Reduce morbidity and mortality related to hereditary cancer by increasing utilization of appropriate cancer risk assessment services

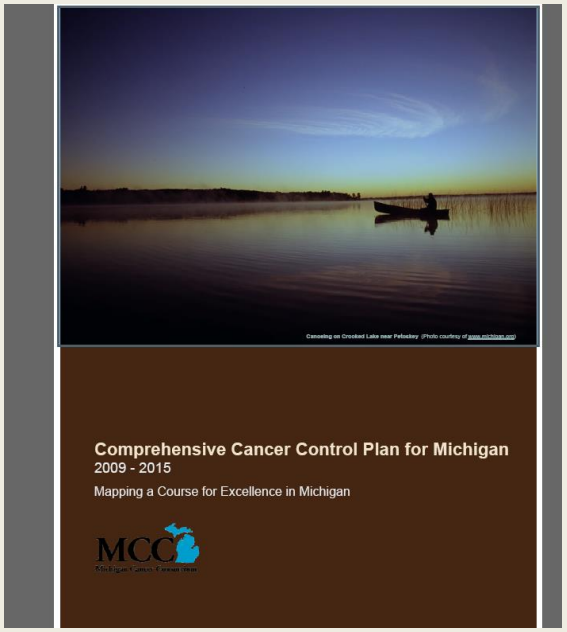
- Goal #6: Promote appropriate public health responses to advances in genomics medicine and technology
  - Enhance communications with genetic service providers and promote partnerships with relevant stakeholders
    - Form a new organization of cancer genetics professionals to promote communication, serve as a source of expert information, and participate in the Michigan Cancer Consortium

** Funding for the Michigan genetics needs assessment and state plan provided by grants from the Maternal and Child Health Bureau (Title V. Social Security Act), Health Resources and Services Administration, Department of Health and Human Services, 2000-2006.*


MDHHS Cancer Genomics Program,
2002-2015
1990s
BRCA 1/2 and Lynch Syndrome genetic testing moves into clinical practice
2000
Genetics Program "discovers" Comprehensive Cancer Control Program
Cancer Program participates in genetics needs assessment and state plan process
2002
MI Informed Consent Law for Genetic Testing Begins
CDC Cooperative Agreement: Genomics Integration in Public Health Programs, 2003-2008
Cancer objectives in state genetics plan
2003
Genetics staff participation in Michigan Cancer Consortium begins
Michigan Cancer Genetics Alliance Created
2005
Genomics goal and objectives in state cancer plan, 2009-2015
CDC Cooperative Agreement: Genomics Applications in Practice and Prevention, 2008-2012
2007
MCSP Mandatory family History fields for Reportable cancers
2008
Work with Michigan health plans begins
CDC DCPC supplemental funding for young breast cancer survivors activities, 2010
2009
Cancer Genetics Clinic Network for Data Collection begins
2010
LSSN formed
HP2020 genomics objectives approved
2011
CDC Cooperative Agreement: Enhancing Breast Cancer Genomic Practices though Education, Surveillance and Policy, 2011-2014
2012
Michigan health plans awarded
MCC Spirit of Collaboration Awarded
2013
2014
CDC Cooperative Agreement: Enhancing Cancer Genomic Best Practices though Education, Surveillance and Policy, 2014-2019
2015
CDC Prevention Research Center- Special Interest Project: Potential for Cancer Screening Interventions for Cancer Survivors Delivered Through Central Cancer Registries, 2011-2014

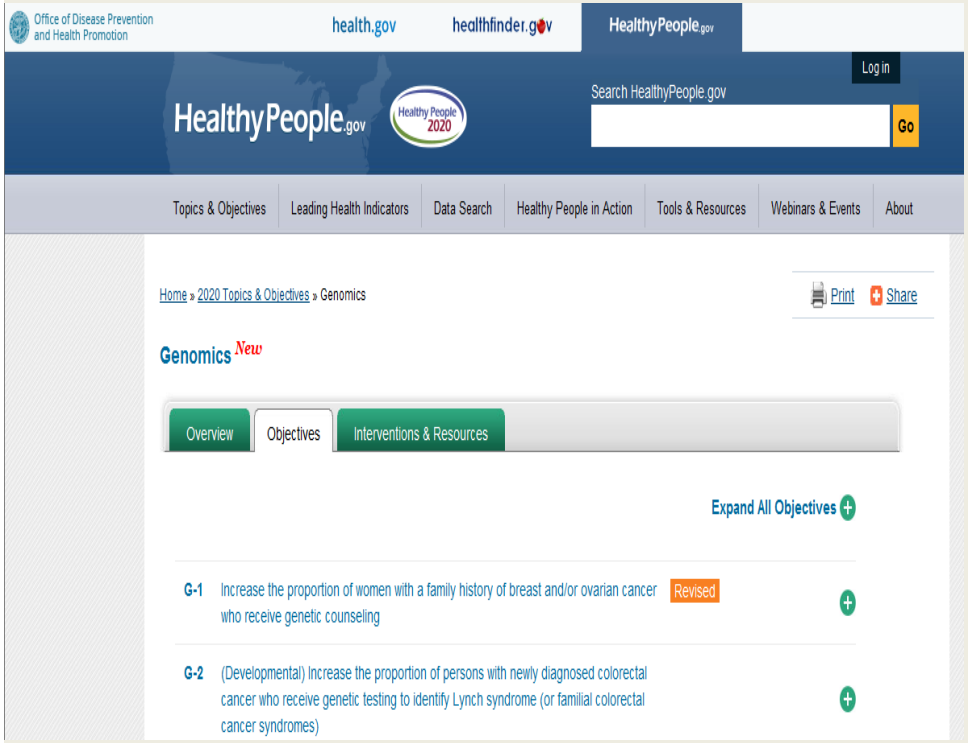
COMPREHENSIVE CANCER CONTROL PLAN FOR MICHIGAN, 2009-2015

- ***Goal:*** Increase availability of cancer-related genetic information to the Michigan public and decrease barriers to risk-appropriate services
  - ***Implementation Objective 1:*** By 2011, expand public knowledge about the impact of genetics on cancer risk and management (breast, ovarian, and colorectal cancers)
  - ***Implementation Objective 2:*** By 2015, expand provider knowledge about the impact of genetics
  - ***Implementation Objective 3:*** By 2015, <u>improve genetic health care financing and access to testing and support services</u>



http://michigancancer.org/

HEALTHY PEOPLE 2020 (HP 2020) CANCER GENOMICS OBJECTIVES, 2010-2020

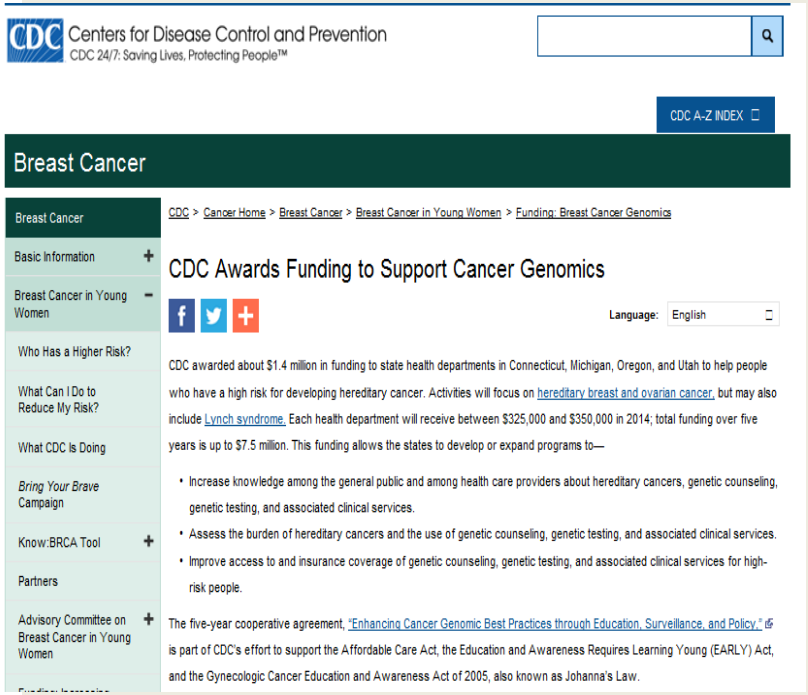


http://www.healthypeople.gov/2020/topics-objectives/topic/genomics/objectives

- HP 2020 marks first time for genomics objectives
- Increase the proportion of women with a family history of breast and/or ovarian cancer who receive genetic counseling
- Increase the proportion of persons with newly diagnosed colorectal cancer who receive genetic testing to identify Lynch syndrome (or familial colorectal cancer syndromes)

2014 CDC FUNDING ANNOUNCEMENT

ENHANCING CANCER GENOMIC BEST PRACTICES THROUGH EDUCATION, SURVEILLANCE AND POLICY, 2014-2019

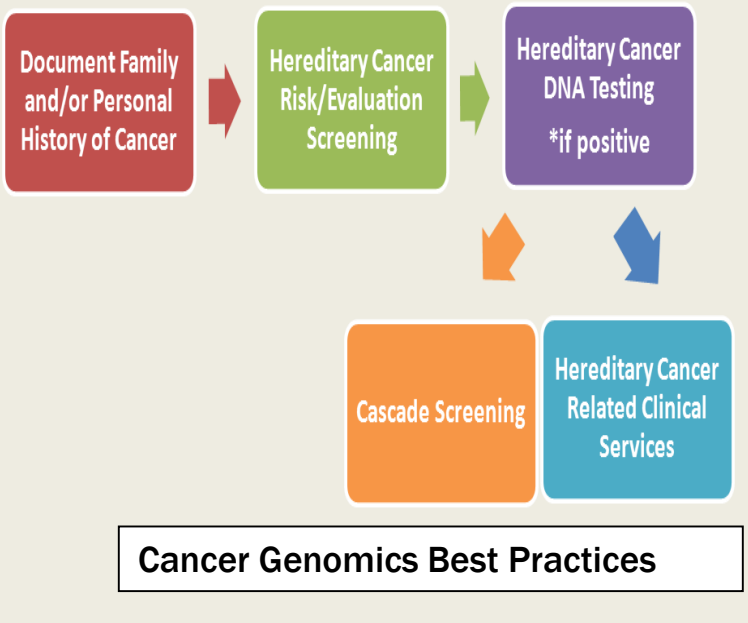


- **5 year CDC cooperative agreement**
  - **Authorized from Affordable Care Act (EARLY Act) and Gynecologic Cancer Education and Awareness Act (Johanna's Law)**
  - **Projects awarded to Colorado, Connecticut, Michigan, Oregon and Utah**
  - **Funds cannot be used for research, clinical services, lobbying efforts or fundraising**
- **Purpose: Enhance state health department capacities to promote and apply evidence-based breast and ovarian cancer genomics guidelines in public health practice**
  - Develop, enhance and evaluate education, surveillance and policy/systems change
  - Emphasis on partnerships
  - Focus on *BRCA* but may also include Lynch syndrome
  - May identify target populations disproportionately affected by HBOC and lack genetic services

PROMOTING SYSTEM CHANGE THROUGH EDUCATION, SURVEILLANCE & POLICY TO ADVANCE CANCER GENOMICS BEST PRACTICES IN MICHIGAN, 2014-2019

- **Purpose:**

  Reduce breast, ovarian and colorectal cancer incidence and mortality rates by overcoming barriers and advancing health system changes to promote cancer genomics best practices



- **Short- and intermediate term outcomes:**
  - Increase knowledge among key clinical and policy stakeholders about cancer genetic best practices; improved access to and coverage of cancer genomics best practices **[Policy/system change]**
  - Improve ability to assess the burden of hereditary cancers and use of cancer genomics best practices; increased production and dissemination of periodic cancer surveillance reports. **[Surveillance]**
  - Increase knowledge of hereditary cancers and appropriate use of cancer genomics best practices among the public and health care providers. **[Education]**
  - Improve partnerships and coordination among key stakeholder groups regarding cancer genomics services and care. **[Partnerships]**

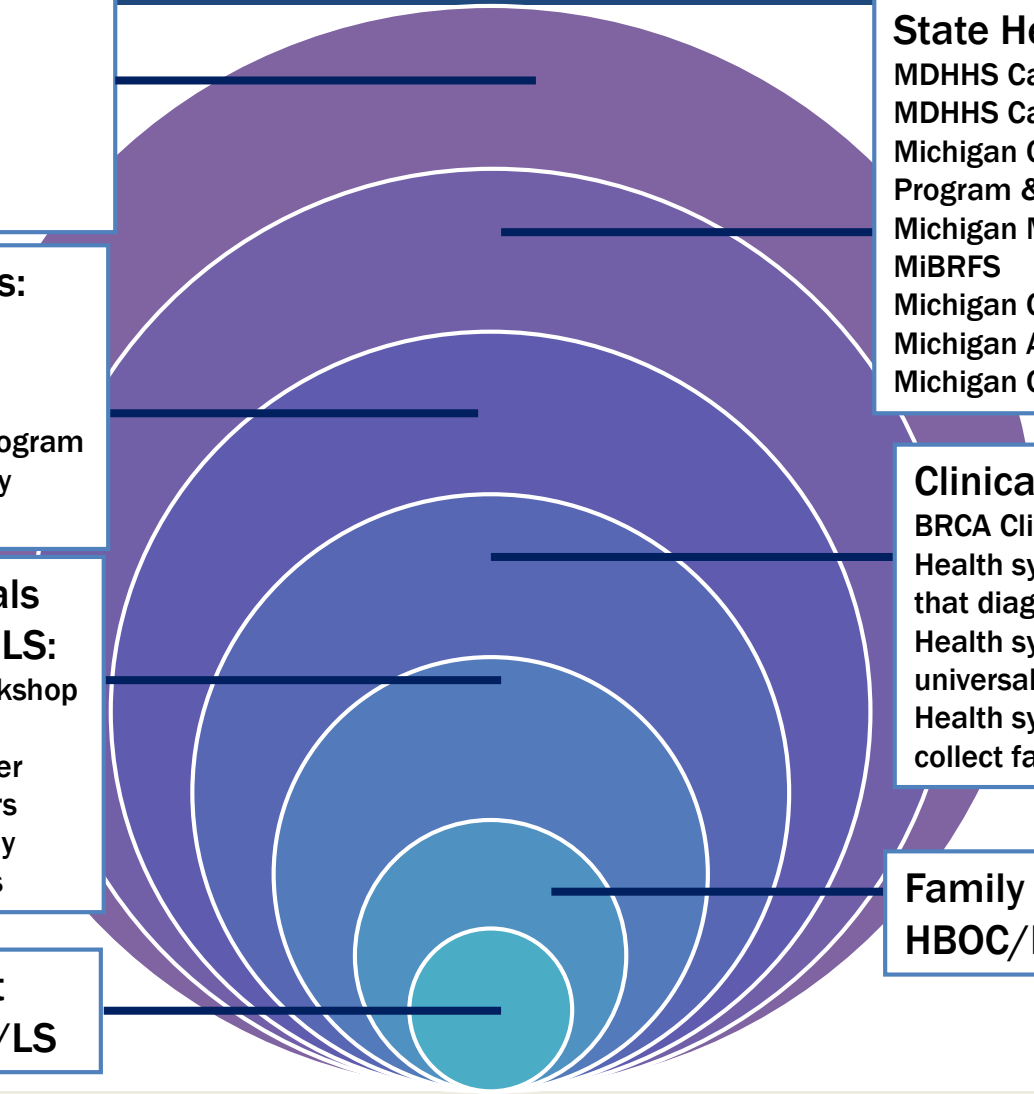
MULTI-LEVEL & MULTIDISCIPLINARY PARTNERS

National Health Partners:
CDC DCPC
CDC OPHG
NCCN Experts
ASHG/Jackson Laboratory
LSSN
Kintalk.org/UCSF

Local Health Partners:
BCBSM
Priority Health
Other health plans
WSU Genetic Counseling Program
Grand Valley State University
Local cancer registrars

Providers of individuals at risk or with HBOC/LS:
Primary Care Providers Workshop Participants
Providers who care for cancer patients and cancer survivors
Providers who care for family members of cancer patients

Michigan residents at risk for or with HBOC/LS



State Health Partners:
MDHHS Cancer Genomics
MDHHS Cancer Prevention & Control
Michigan Cancer Surveillance Program & Vital Records
Michigan Medicaid
MiBRFS
Michigan Cancer Consortium
Michigan Association of Health Plans
Michigan Cancer Genetics Alliance

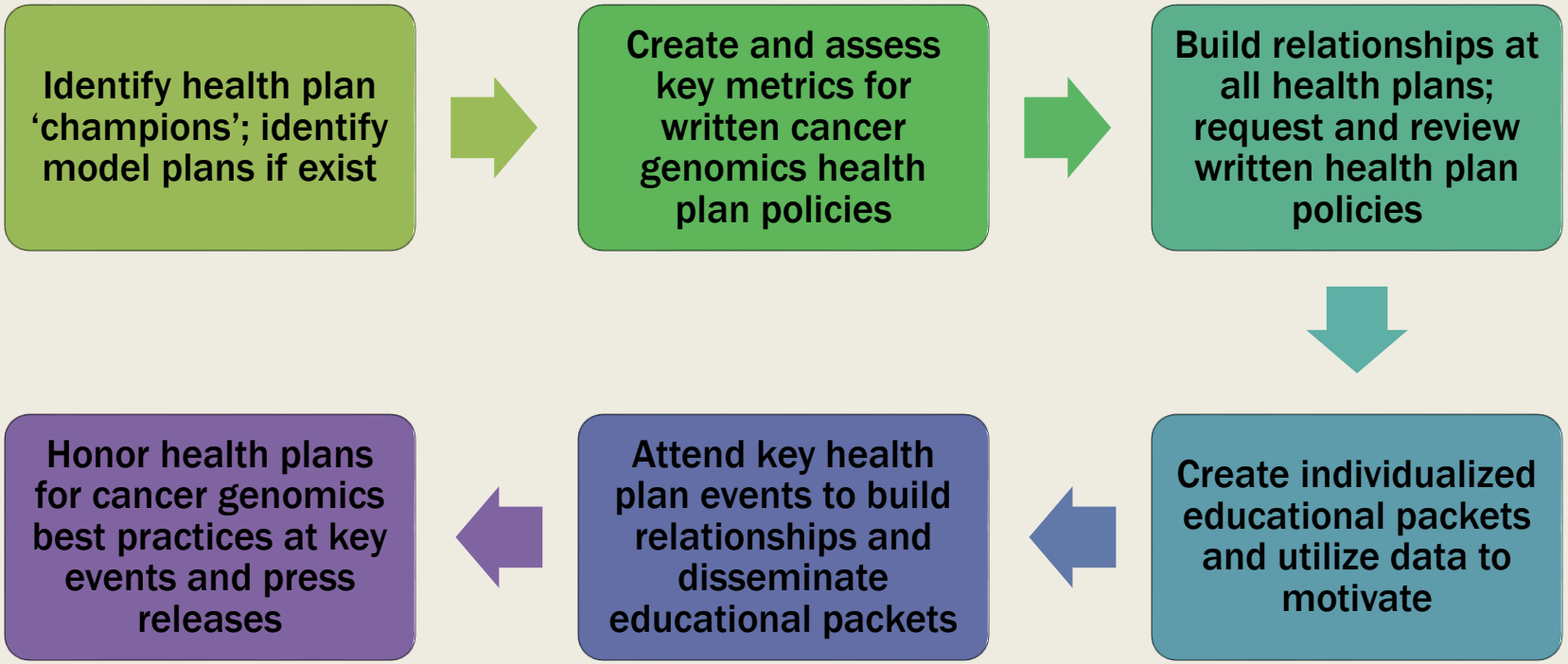
Clinical Practices:
BRCA Clinical Network
Health systems/clinical practices that diagnose cancer
Health systems that perform universal/routine LS screening
Health systems/practices that collect family history

Family members at risk for HBOC/LS

Taplin et al, Multilevel Intervention Clinical-Public Health Collaboration, 2011

STATE HEALTH DEPARTMENT EFFORTS TO INCREASE WRITTEN HEALTH PLAN CANCER GENOMIC BEST PRACTICES POLICIES

Activity P4: In years 1-5, MDHHS will continue to partner with Michigan Association of Health Plans and Michigan Cancer Genetics Alliance to recognize health plans that are aligned with Cancer Genomics Best Practices for HBOC and Lynch syndrome as recommended by USPSTF, NCCN, EGAPP and Michigan law



EXAMPLES OF MDHHS AND MAHP PARTNERSHIP ACTIVITIES

mahp
Michigan Association of Health Plans

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Genomics: Hereditary Cancer Risk and Management

The MAHP Foundation, MAHP member plans and the Michigan Department of Community Health Cancer Genomics Division are collaborating to promote cancer genomics best practices in genetic counseling and testing.

Several resources are available to help you learn more about hereditary cancer risk, and evidence based guidelines for genetic testing for breast and ovarian cancer risk. Information for patients and families is also available. Links to access information are available below:

- Herediatary Breast and Ovarian Cancer: Is Your Patient at High Risk?
- Michigan Cancer Genetics Alliance/Michigan Cancer Consortium Position Paper on Genetic Counseling and Testing for Hereditary Cancer
- Healthy People 2020
- GeneTests
- National Comprehensive Cancer Network (NCCN) Guidelines
- US Preventive Services Task Force (USPSTF) Grade B Recommendation for BRCA
- Michigan Informed Consent Law Brochure PDF
- Michigan Cancer Genetics Alliance (MCGA) – Cancer Genetics Clinical Directory
- BRCA1 and BRCA2 Hereditary Breast and Ovarian Cancer review
- Centers for Medicare and Medicaid Services – Criteria for coverage of BRCA1/2 testing
- Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Lynch Syndrom Recommendation
- Resource Order Form PDF - Michigan Department of Community Health (MDCH) Cancer Genomics Program
- Michigan Genetics Resource Center - Cancer Genetics Information

2015 Marks an Important Year for Ovarian Cancer and Genomics

September is National Ovarian Cancer Awareness Month and Sept. 27 - Oct. 3 is National Hereditary Breast and Ovarian Cancer (HBOC) Week. Appro
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effects included: nausea, fatigue, anemia, diarrhea and vomiting.

Genetic Assessment for All Ovarian Cancer Patients and their Relatives- In

This is due to the association of other ovarian cancer subtypes with hereditary cancer syndromes.

Expansion of genetic testing to

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Next-Generation Sequencing Panels The New Era in Cancer Genetic Testing

Next-generation sequencing (NGS) is poised to be one of the most significant technological advances in the biological sciences of the last 30 years. The cost of DNA s
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contrast, switching to a NGS procedure leads to a reduction in cost and turn-around time, meaning patients can get timely results for surgical decision making

June 17, 2015 through August 3, 2015, stating that BRCA1 and BRCA2 genetic testing for breast or ovarian cancer susceptibility with multigene panels is

The Importance of Universal Screening for Lynch Syndrome on all Newly Diagnosed Colorectal Cancers

March 22 – 28 marked Lynch syndrome awareness week in the State of Michigan. Lynch syndrome, formerly known as hereditary nonpolyposis colorectal cancer (HNPCC) is the most common cause of hereditary colon cancer, accounting for up to 3-5 percent of colon cancer cases. It also increases the risk of endometrial cancer and other types of cancer. Lynch syndrome is inherited in an autosomal dominant manner and is typically caused by a

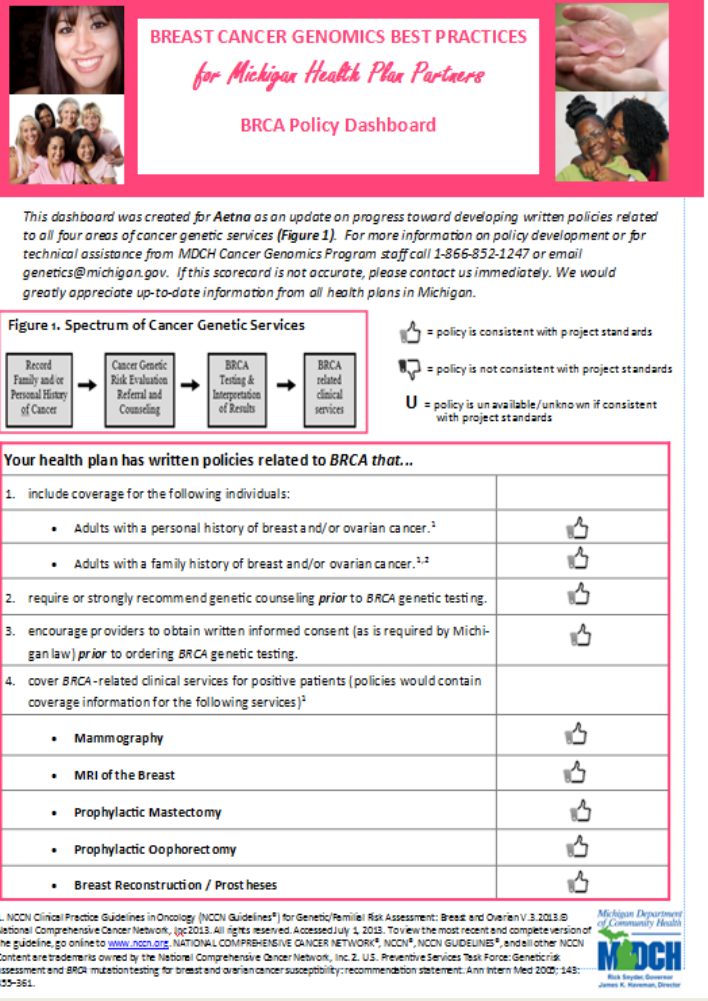
It is well established that the vast majority of colorectal/endometrial tumors from individuals with Lynch syndrome exhibit microsatellite instability (MSI) as well as abnormal immunohistochemistry (IHC) staining for the proteins associated with the four MMR genes. Tumor analysis as a pre-screen prior to mutation analysis using a blood sample can be very informative in determining who may be at risk for Lynch syndrome including at-risk relatives, as well as

found sufficient evidence to recom
offering Lynch syndrome
screening consisting of MSI a
and/or IHC testing to all indiv
with newly diagnosed colorectal
regardless of age, family
or histology, which has furthe
supported by other organi
including the National Soci
Genetic Counselors (NSGC), a
Collaborative Group of the Amer
Inherited Colorectal Cancer (GA-

When informative, tumor a
can direct appropriate germline
and is very cost effective and th
ferred first-line testing, when po
for any patient being evaluat

Geneticists estimate that 25,000 people in Michigan and 600,000 people throughout the nation have

EXAMPLE OF BRCA HEALTH PLAN POLICY DASHBOARD & UTILIZING MICHIGAN CANCER GENETIC CLINICAL DATA



BREAST CANCER GENOMICS BEST PRACTICES

for Michigan Health Plan Partners

BRCA Policy Dashboard

*This dashboard was created for **Aetna** as an update on progress toward developing written policies related to all four areas of cancer genetic services **(Figure 1)**. For more information on policy development or for technical assistance from MDCH Cancer Genomics Program staff call 1-866-852-1247 or email genetics@michigan.gov. If this scorecard is not accurate, please contact us immediately. We would greatly appreciate up-to-date information from all health plans in Michigan.*

Figure 1. Spectrum of Cancer Genetic Services

Record Family and/or Personal History of Cancer → Cancer Genetic Risk Evaluation Referral and Counseling → BRCA Testing & Interpretation of Results → BRCA related clinical services

👍 = policy is consistent with project standards

👎 = policy is not consistent with project standards

U = policy is unavailable/unknown if consistent with project standards

Your health plan has written policies related to *BRCA* that...	
1. include coverage for the following individuals:	
• Adults with a personal history of breast and/or ovarian cancer.[1]	👍
• Adults with a family history of breast and/or ovarian cancer.[1,2]	👍
2. require or strongly recommend genetic counseling ***prior*** to *BRCA* genetic testing.	👍
3. encourage providers to obtain written informed consent (as is required by Michigan law) ***prior*** to ordering *BRCA* genetic testing.	👍
4. cover *BRCA*-related clinical services for positive patients (policies would contain coverage information for the following services)[1]	
• Mammography	👍
• MRI of the Breast	👍
• Prophylactic Mastectomy	👍
• Prophylactic Oophorectomy	👍
• Breast Reconstruction / Prostheses	👍

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Genetic/Familial Risk Assessment: Breast and Ovarian V.3.2013.© National Comprehensive Cancer Network, Inc 2013. All rights reserved. Accessed July 1, 2013. To view the most recent and complete version of the guideline, go online to www.nccn.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc. 2. U.S. Preventive Services Task Force: Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: recommendation statement. Ann Intern Med 2005; 143: 355-361.

Michigan Department of Community Health — MDCH — Rick Snyder, Governor — James K. Haveman, Director

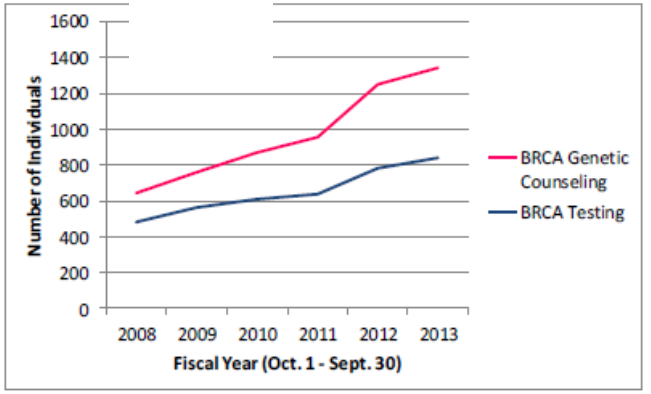
BREAST CANCER GENOMICS BEST PRACTICES

for Michigan Health Plan Partners

Prepared in 2014 by MDCH staff

BRCA Genetic Counseling & Testing Among Members

Figure 1. Members Receiving *BRCA* Counseling and Testing, October 1, 2007—September 30, 2013



Healthy People 2020 includes an objective to increase the proportion of women with a family history of breast and/or ovarian cancer who receive genetic counseling. **Thank you for helping to increase the number of your members receiving this service over the six year period shown in Table 2.**

The MDCH Cancer Genomics Program and the MAHP Foundation are honoring health plans with written *BRCA* counseling and testing policies aligned with the USPSTF and NCCN recommendations. If your health plan has not been honored, please contact the MDCH Cancer Genomics Team at 1-866-852-1247 or email genetics@michigan.gov. Please also contact MDCH Cancer Genomics if you would like further information about newly released and updated USPSTF and NCCN recommendations for *BRCA* counseling and testing and/or information about clinical services and laboratories offering *BRCA* testing.

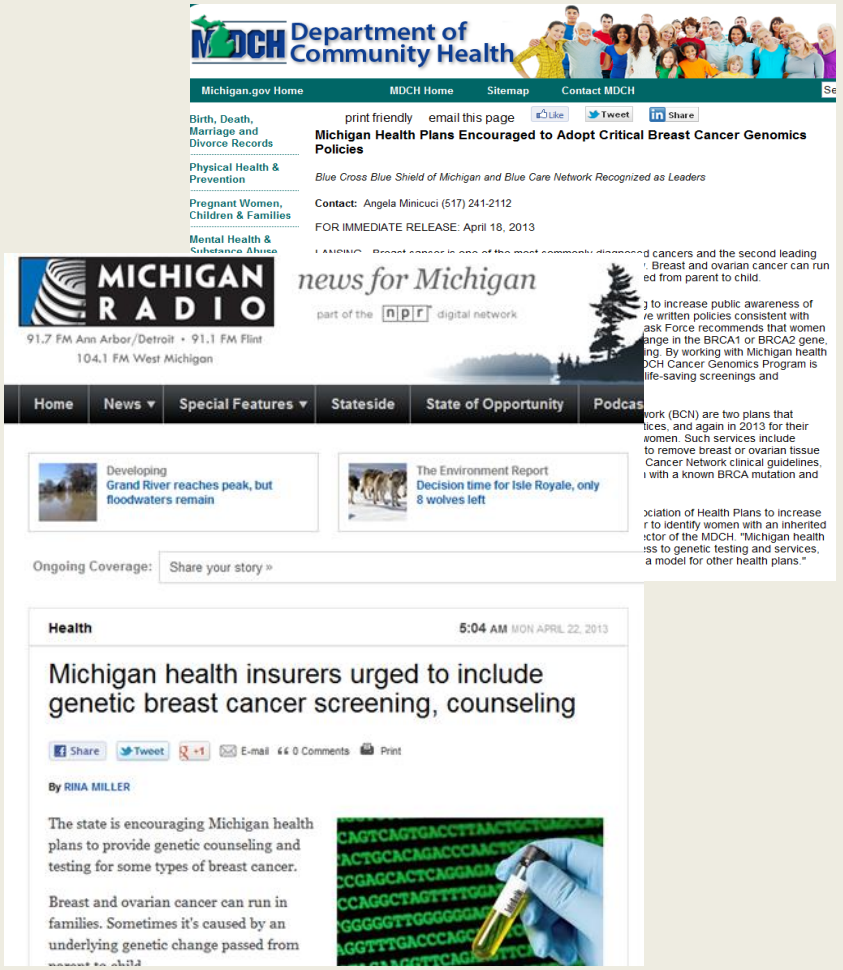
These data include genetic counseling visits as reported to MDCH through a statewide network of board-certified genetics professionals. Special thanks to the following institutions whose de-identified patient information was included in these analyses: Beaumont Cancer Genetics Program, Cancer Genetics Program at St. Joseph Mercy Hospital, Henry Ford Health System, InformedDNA, Karmanos Cancer Genetic Counseling Service, Lacks Cancer Center Genetics Program at Saint Mary's Healthcare, Michigan State University Division of Clinical Genetics, Marquette General Hereditary Cancer Program, Oakwood Healthcare System's Genetic Risk Assessment for Cancer Clinic, Providence Hospital Medical Genetics, Spectrum Health Cancer Genetics, University of Michigan Cancer Genetics Clinic, University of Michigan Breast and Ovarian Cancer Risk and Evaluation Program, and West Michigan Cancer Center.

Patients with a deleterious *BRCA* mutation	*	539 (12.8)
Patients not testing due to inadequate insurance	63	200

Michigan Department of Community Health — MDCH

MDHHS AWARDS HEALTH PLANS FOR WRITTEN POLICIES ALIGNED WITH CANCER GENOMICS BEST PRACTICES, 2010-2015

- Michigan Association of Health Plans (MAHP) Summer Conference held in 2010-2015
- MAHP Pinnacle Awards to honor health plans aligned with BRCA Recommendation in 2010-2013
- Pinnacle Award for best BRCA policy awarded to Priority Health in 2011
- CME Best Practices event to educate health plan directors in 2010-2014
- MAHP *Insight* Magazine
- MAHP and MDCH Press Releases
- Michigan Cancer Consortium Update Newsletters
- Michigan Cancer Genetics Alliance meetings and listserv announcements



MDCH Department of Community Health

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Physical Health & Prevention
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Michigan Health Plans Encouraged to Adopt Critical Breast Cancer Genomics Policies

Blue Cross Blue Shield of Michigan and Blue Care Network Recognized as Leaders

Contact: Angela Minicuci (517) 241-2112

FOR IMMEDIATE RELEASE: April 18, 2013

cancers and the second leading . Breast and ovarian cancer can run ed from parent to child.

to increase public awareness of e written policies consistent with ask Force recommends that women ange in the BRCA1 or BRCA2 gene, ing. By working with Michigan health DCH Cancer Genomics Program is life-saving screenings and

ork (BCN) are two plans that ices, and again in 2013 for their omen. Such services include to remove breast or ovarian tissue Cancer Network clinical guidelines, with a known BRCA mutation and

ociation of Health Plans to increase r to identify women with an inherited ctor of the MDCH. "Michigan health ss to genetic testing and services, a model for other health plans."

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Health 5:04 AM MON APRIL 22, 2013

Michigan health insurers urged to include genetic breast cancer screening, counseling

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By RINA MILLER

The state is encouraging Michigan health plans to provide genetic counseling and testing for some types of breast cancer.

Breast and ovarian cancer can run in families. Sometimes it's caused by an underlying genetic change passed from

EXAMPLES OF MDHHS HEALTH PLAN CANCER GENOMICS BEST PRACTICES POLICY OUTCOMES

- Increased written health plan policies for appropriate BRCA counseling and testing to 16 of 25 health plans (increase from 4 health plans in 2009)
  - Covering over 8 million residents in Michigan
- Awarded 8 of 25 health plans in Michigan with written policies for *BRCA*-related clinical services for women with a known deleterious *BRCA* mutation aligned with NCCN guidelines
- Reduced barriers for appropriate *BRCA* testing with continued decrease in percentage of individuals who had genetic counseling but were not able to pursue *BRCA* testing due to inadequate insurance
  - Reduced to 8.3% of those not testing in 2014 compared to 21.7% in 2008
- Received MCC Spirit of Collaboration, 2014 Award

THANK YOU!

Some of this presented work was supported by the Cooperative Agreement Number 5U58DP003798-03 and 1U58DP005357 from The Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the presenter and do not necessarily represent the official views of the CDC.