Promoting Policy Changes for Appropriate Cancer Genetic Services for High Risk Women in Three States

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**CDC Funding Announcement**

**Enhancing Breast Cancer Genomic Best Practices through Education, Surveillance and Policy**

- 3 year cooperative agreement (2011-2014) awarded to three projects
  - Authorized from Affordable Care Act
  - State health departments and Tribal governments eligible
- **Purpose:** develop or enhance activities related to breast cancer genomics
  - Promote use of BRCA1/2 clinical practices as recommended by USPSTF and NCCN
- **Must conduct programs in policy plus surveillance and/or health education**
- **Expected policy performance measures:**
  - increase use of family history, counseling, and BRCA1/2 tests as recommended by USPSTF and NCCN
  - Identify existing model policy implementation programs used in state

![Figure 1: BRCA Counseling, Testing and Clinical Services](image-url)
Policy Objectives for States

**Georgia**
- Increase coverage for genetic services by 13 private health plans
- Increase coverage for genetic services by state health plans
- Establish alternative payments methods for cancer services
- Include breast cancer genomics and coverage screening as priority in state plan

**Michigan**
- Investigate insurance gaps for BRCA Clinical Services among 24 health plans
- Enhance payers’ awareness, knowledge and use of BRCA Clinical Services with respect to USPSTF and NCCN
- Increase number of health plans that have written policies for BRCA Clinical Services consistent with USPSTF and NCCN recommended practices

**Oregon**
- Among 10 private insurance plans, increase number that cover USPSTF and NCCN recommended genomic services for women with or at risk for hereditary breast cancer
- Increase evidence-based genomic application for BRCA counseling, testing and treatment through legislation requiring licensing for genetic counselors
- Chair/facilitate Genetic Advisory Committee to Oregon Health Services Commission
Importance of Partners for States and Policy

• State Medicaid Partners
• Key legislative representatives?
• Health Association Plans
  – Georgia Association of Health Plans
  – Michigan Association of Health Plans
  – Michigan ‘Health Plan Champion’
Michigan Informed Consent Law for Genetic Testing, 2000

- Michigan law states that a provider shall not order “a presymptomatic or predictive genetic test without first obtaining the written, informed consent”
- Nature and purpose of the test
- Effectiveness and limitations
- Implications of taking the test, including, but not limited to, the medical risks and benefits.
- The future uses of the sample taken and the information gained from the test.
- The meaning of the test results and how results will be disclosed
- Who will have access to the patient’s sample and result and the right to confidentiality

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, improve genetic health care financing and access to testing and support services

http://michigancancer.org/
Genomics Integration in State Cancer Plans, 2005-2010

• 2005 review¹ of 30 existing comprehensive cancer control plans:
  – 18 plans (60%) with specific terms related to genomics

• 2010 review² of 50 existing comprehensive cancer state plans:
  – 47 plans (94%) with specific terms related to genomics
    • Most common genomics term found ‘family history’ (43/47 plans)
    • Specific genetic tests less commonly mentioned
      – BRCA (18/47 plans)
      – Lynch syndrome (6/47 plans)

Genomics Integration in State Cancer Plans, 2005-2010 (continued)

– 32 plans (64%) with at least one genomics goal, strategy or objective
  • Most common goal/theme identified (24/32 plans) related to:
    – Increase access to genetic risk assessment services such as genetic counseling or genetic testing including reimbursement for genetic risk assessment services
  • Second most common goal/theme (18/32 plans) related to:
    – Educating public and providers about family history or developing family history tool
  • Six states had goals, strategies or objectives related to assurance, assessment and policy (Michigan, Minnesota, Mississippi, New Mexico, Oregon, Washington)
    – Michigan, Minnesota and Oregon funded from CDC OPHG, 2003-2008
  • Online survey to 47 comprehensive cancer state programs with at least one genomic term, April-May 2011 (response rate 40.4%)
    – Barriers to implementation identified:
      • low priority of genomics; time constraints; lack of sufficient staff/leadership; lack of funding
    – Possible facilitators to implementation of genomics goal, strategy or objective identified:
      • increased funding; stronger partnerships with health insurance companies
2005 U.S. Preventive Services Task Force
BRCA Recommendation

Women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes should be referred for genetic counseling and evaluation for BRCA testing

(Grade B Recommendation)

USPSTF also recommends against routine referral or routine BRCA testing for women whose family history is not associated with increased risk

(Grade D Recommendation)

http://www.uspreventiveservicestaskforce.org/uspstf05/brcagen/brcagenrs.htm
MDCH-CDC Cooperative Agreements for Cancer Genomics Surveillance, Education, and Policy

Promoting Cancer Genomics Best Practices through Surveillance, Education, and Policy Change in the State of Michigan (CDC-RFA-GD08-801)
- Awarded from CDC Office of Public Health Genomics, 2008-2011
- Supplemental Funding from CDC Division of Cancer Prevention and Control (DCPC) in 2010/2011
- One-year no-cost extension in 2011/2012

- Awarded from CDC DCPC to MDCH, 2011-2014
- Authorized from Affordable Care Act
Multi-faceted, state-wide comprehensive program

Translation of evidence-based recommendations for genetic tests into practice

- USPSTF BRCA recommendations
- EGAPP recommendations on Lynch syndrome
- EGAPP recommendation on breast cancer gene expression profiling

Evaluate effectiveness in changing provider knowledge, test use, insurance coverage
Honoring Health Plans Aligned with USPSTF Grade B Recommendation

- Michigan Association of Health Plans (MAHP) Summer Conference held in 2010-2012
- Announcement regarding regulations requiring new health insurance plans to cover preventive care for USPSTF Grade A & B Recommendations on July 14, 2010
- Pinnacle Awards to honor health plans aligned with USPSTF Grade B BRCA Recommendation in 2010-2012
- Pinnacle Award for best BRCA policy awarded to Priority Health in 2011
- CME Best Practices event to educate health plan directors in 2010-2012
- MAHP Insight Magazine
- MAHP and MDCH Press Releases
- Michigan Cancer Consortium Update Newsletters
- Michigan Cancer Genetics Alliance meetings and listserv announcements
Promoting USPSTF Grade B BRCA Recommendation to Health Plans

- Educate health plans about USPSTF Grade B BRCA Recommendation and Best Practices
  - Health plan conferences
  - CME events
  - Displays
  - Provider tools
  - Articles in newsletters
Notification to Health Plans Not Aligned with USPSTF

- MDCH staff provided individualized packets to Michigan health plans at key events
  - Discuss in person with key health plan administrators
  - Emphasize USPSTF Grade B Recommendation
  - Provide summary of project and partnership with CDC and MAHP
  - Highlight three criteria required to receive honors
  - Report individualized information for each health plan regarding their assessment
  - Encourage to contact MDCH or MAHP for technical assistance
Packet of educational materials includes:

- 2005 USPSTF BRCA Recommendation
- Michigan Informed Consent Law for Pre-symptomatic and Predictive Genetic testing
- Cancer Family History Guide©
- Directory of Michigan Cancer Genetic Counseling Services
- Model BRCA Policies with permission from:
  - Aetna
  - Priority Health
  - UnitedHealthcare
For More Information

www.migeneticsconnection.org

www.michigan.gov/genomics

www.michigancancer.org

Or call 1-866-852-1247

www.michigancancer.org
**Additional Activities with Michigan Association of Health Plans (MAHP)**

- Brief survey to identify barriers and facilitators to BRCA policies at MAHP Annual Conference in July 2011
  - Top 2 barriers
    - inefficient access to cancer genetic experts
    - lack of coding transparency
  - Top 2 facilitators
    - frequent requests for written policy by providers
    - cancer genetic expertise among health plan staff
- **BRCA educational workshop to key health plan administrators at MAHP CME Best Practices annually since December 2010**
  - Pre-survey
    - 41% of attendees aware of USPSTF BRCA recommendation
  - Post-survey and 6 month follow-up
    - 100% of attendees aware of USPSTF BRCA recommendation
Summary

- Understand current status of Michigan health insurance policies for BRCA1/2 testing with respect to USPSTF guidelines
  - 15 out of 24 health plans with written policies for BRCA coverage as of 2012
  - 12 in alignment with USPSTF recommendations as of 2012
- Increase the number of health plans that have policies consistent with USPSTF guidelines
  - Increased the number of health plans that have policies consistent with USPSTF recommendations from 4 to 12 out of 24 Michigan plans as of 2012
- CDC Division of Cancer Prevention & Control used process as a model to investigate BRCA health plan policies in most states in 2011
- Georgia, Michigan and Oregon received CDC cooperative agreements from 2011-2013; foci on health plans and policy
- Ohio Cancer Genetics Network currently replicating surveillance and education with their health plans
**Examples of 2012 Health Plan Policy Enhancements**

- Promote USPSTF and NCCN guidelines
- **New** ‘BRCA Policy Dashboard’ for each health plan
- **New** BRCA Genetic Counseling & Testing report for each health plan
- **New** education resource packet contains:
  - Same resources as previous educational packet **plus**
  - NCCN guidelines for referral and testing for those with personal and/or family history **plus**
  - NCCN guidelines for management for women with known deleterious mutation **plus**
  - Model policies from Cigna and BCBSM of above
Enhancing Breast Cancer Genomics Best Practices and Policies in the State of Michigan

**Inputs**
- Partners & Resources
- Michigan Department of Community Health Genomics, Cancer Registry/Vital Records, Cancer Section
- Centers for Disease Control & Prevention
- Michigan Cancer Genetics Alliance (MCGA)
- Michigan Cancer Consortium (MCC)
- Board-Certified BRCA Clinical Providers
- Michigan Health Plans
- Michigan Association of Health Plans
- MCSP Reporting Provider
- National Coalition for Health Professional Education in Genetics (NCHPEG)
- USPSTF BRCA Counseling Grade B Recommendation
- NCCN Guidelines 2011 Breast and Ovarian Genetic/Familial High-Risk Assessment Guidelines
- MGSA/MCC Position Paper for Providers
- Michigan Informed Consent Law for Genomic Testing
- Cancer Family History Guide

**Outputs**
- Activities/Interventions
- Policy
  - Assess Michigan health plan policies to determine consistency with national guidelines
  - Educate payers about guidelines using multiple methods
  - Provide technical assistance to promote development of health plan policies consistent with guidelines
  - Recognize Michigan health plans that comply with recommended BRCA practices
- Education
  - Partner with health plans to disseminate BRCA provider tools and resources
  - Partner with health plans to explore feasibility of creating provider incentive programs for BRCA best practices
  - Provide targeted BRCA educational materials to the physicians of patients with early breast & ovarian cancer reported to MCSP
- Surveillance
  - Expand network of sites to include all board-certified Michigan cancer genetics clinical providers
  - Explore quality assurance measures to ensure accurate family history reporting to MCSP
  - Monitor BRCA related cancers using MCSP and vital records data; examine usefulness of cancer stage in surveillance
  - Analyze health plan claims data to evaluate impact of BRCA testing on related clinical services
  - Analyze population-based survey data (i.e. BRF5) to measure progress toward HP2020 BRCA objectives
- Evaluation and Dissemination
  - Develop an evaluation plan
  - Complete a dissemination plan

**Public Health & Clinical Relevance**

**Goal #1**
- Increased understanding of insurance coverage gaps for BRCA Clinical Services
- Increased payers’ awareness, knowledge and use of BRCA clinical practice guidelines
- Increased number of health plans that have policies consistent with USPSTF and NCCN recommended practices
- Promote adoption of health plan policies to increase coverage of BRCA clinical services for high risk women

**Goal #2**
- Increased provider knowledge about validity, utility, and harms of BRCA counseling and testing
- Increased appropriate referrals for BRCA counseling
- Increased appropriate BRCA tests ordered and related clinical services
- Increase health care provider knowledge and use of BRCA clinical practices recommended by USPSTF and NCCN

**Goal #3**
- A comprehensive surveillance system for tracking use of BRCA Clinical Services through board certified genetics providers
- Understanding of statewide trends regarding family history collection for appropriate BRCA genetic referrals
- Understanding of statewide incidence, trends and mortality of BRCA-related cancers
- Increased understanding of the patient/provider practices before and after receiving a BRCA genetic test
- Increased understanding of Michigan HP2020 BRCA progress
- Expand surveillance of BRCA clinical practices

**Goal #4**
- Increased understanding of the strengths, impact and needs of the program
- Dissemination of model policies, educational resources, surveillance findings and strategies for payers and providers
- Utilize data to inform best practices, promote policy change, conduct program evaluation, and disseminate findings

**Ultimate Impact:** A reduction in breast cancer deaths at a young age and ovarian cancer deaths in Michigan
1. Documentation of key cancer family history and personal history elements to conduct risk assessment
2. Referrals to genetic counseling services of patients at high risk for deleterious BRCA mutations based on personal and/or family history of cancer
3. Appropriate BRCA testing with prior written informed consent explaining risks, benefits and limitations of BRCA testing and appropriate interpretation of test results
4. Provision of related clinical services/interventions for patients with a known deleterious BRCA mutation.
Michigan Cancer Surveillance Program (MCSP)

- Statewide reporting since 1985
- Registry established by law (Act 82 of 1984)
- Includes in situ or invasive malignancies other than basal or squamous nongenital skin; benign brain and CNS tumors since 2004
- ~64,000 new reportable cases per year
- Reported through 2 sources:
  - National Program of Cancer Registries (NPCR)
  - National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program
- Collects data on the occurrence of cancer; the type, extent, and location of the cancer; and the type of initial treatment
**Single Primary Cancers**

- Number of cancer cases in 2006-2007 with a diagnosis at any age for the following:
  - Colorectal (Lynch)
  - Male Breast (*BRCA*)
  - Ovarian (*BRCA* & Lynch)
- Number of cancer cases in 2006-2007 with a diagnosis between 18-49 years for the following:
  - Female Breast (*BRCA*)
  - Endometrial (Lynch)
Multiple Primaries Methods

• 1990-2007 cancer registry data, with at least one diagnosis in 2006 or 2007
• Multiple primaries defined as two or more BRCA1/2 or HNPCC- potentially related cancers that were classified as separate primary tumors
• Examples of multiple primaries: breast-breast, breast-ovarian, colorectal-endometrial, and colorectal-colorectal
• Oregon has also examined cancer registry data using similar methods
Facility-specific Profiles

A Cancer Genetics Profile: Prepared for Sample Hospital

Focusing on Your Patients’ Hereditary Cancer Risk

March 1, 2010

Michigan healthcare facilities are required to report all cancer diagnoses to the Michigan Cancer Surveillance Program (MCSP) within the Michigan Department of Community Health (MDCH). MDCH has compiled state-wide registry data as well as facility-specific data in order to provide you with the number of patients at your facility who may be at risk for HBOC syndrome or Lynch syndrome, also called Hereditary Non-Polyposis Colorectal Cancer (HNPCC). These patients should have a formal risk assessment by a suitably trained health care provider to discuss the appropriate indications for genetic testing. HBOC accounts for approximately 5-10% of all breast cancer diagnoses and is associated with increased risk for ovarian cancer. Approximately 3-5% of all individuals with colorectal cancer will have Lynch syndrome, which is associated with an increased risk for endometrial and ovarian cancers. Proper documentation and discussion of the above and related cancers, along with demographic features suggestive of a hereditary cancer syndrome, is critical. Individuals diagnosed with early onset cancers, multiple primary diagnoses, or rare cancers are at risk for hereditary cancer syndromes and may benefit from increased cancer surveillance, genetic testing, or specialist medical management.

Table 1. Age 15-49 at diagnosis

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Breast (female)</td>
<td>199</td>
<td>3,026</td>
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<tr>
<td>Endometrial</td>
<td>30</td>
<td>459</td>
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Table 2. All ages

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<tbody>
<tr>
<td>Colorectal</td>
<td>476</td>
<td>10,340</td>
</tr>
<tr>
<td>Ovarian*</td>
<td>127</td>
<td>1,544</td>
</tr>
<tr>
<td>Breast (male)</td>
<td>12</td>
<td>147</td>
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Table 3. All ages

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<tr>
<td>Multiple primary cancer diagnoses</td>
<td>106</td>
<td>1,985</td>
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* All ovarian cancer data also include those cases diagnosed with cancer of the fallopian tube.

Patient names associated with the reported diagnoses can be sent to a designated person in your facility upon request. If requested, the names will be disclosed to your facility using current confidentiality rules.

Prepared in 2010 by MDCH staff
Contents

• Introductory letter
• Guidelines
  – USPSTF BRCA
  – EGAPP Lynch syndrome
• Data Report
• MCGA Directory of Cancer Genetics Services
• Resources: informed consent brochure, newsletters, fact sheets
• Front cover: Resource CD, MDCH fact cards, and our new pocket guide
• Assist facility to meet ACOS Cancer Program Patient Care Improvement Standards 6.2 or 8.2
  • Since November 2011 also highlight New Commission Cancer Genetic Counseling Standards

Since November 2011 also highlight New Commission Cancer Genetic Counseling Standards
Acknowledgements

Clinical Sites
Beaumont Hospital
Henry Ford Health System
Karmanos Cancer Institute
Oakwood Hospital
University of Michigan, Breast Cancer Risk Assessment Clinic
University of Michigan, Cancer Genetics Clinic
Informed Medical Decisions, Inc
Michigan State University
St. John-Providence West Spectrum Health
St. Mary’s Hospital
St. Joseph’s Hospital
Marquette General Hospital
Mid Michigan Cancer Center
West Michigan Cancer Center

Michigan Association of Health Plans (MAHP)
Priority Health
Blue Cross/Blue Shield of Michigan
Office of Public Health Genomics, CDC
Division of Cancer Prevention and Control, CDC
Michigan Department of Community Health (MDCH) Genomics Program
Michigan Cancer Surveillance Program
MDCH Cancer Prevention and Control Section
Wayne State University
Emory University
National Coalition for Health Professional Education in Genetics (NCHPEG)
New 2012 Important Cancer Genomics Resources

- Cancer Resource Foundation, Inc. provides Genetic Testing Co-Pay Assistance Program
  - 2012 pilot in Massachusetts, Michigan, Ohio, Indiana and Illinois
    - Since January 2012, Michigan has had 47 health care providers enroll
    - Co-pay assistance provided to 15 Michigan residents for 18 cancer genetic tests
  - Now being introduced to all states
  - Provides co-pay assistance for genetic testing for hereditary cancer syndromes (up to approximately $520)
  - Eligible patients must have insurance; meet specific income criteria (<250% Federal Poverty Threshold); meet NCCN guidelines for testing
Thank you!

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