A State Health Department Approach to Promoting Cancer Genomics Through Surveillance, Education and Policy

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What is Public Health Genomics? 
(Bellagio Statement, 2006)

- A multidisciplinary field concerned with the effective and responsible translation of genome-based knowledge and technologies to improve population health.
*Assessment*: The regular systematic collection, assembly, analysis, and dissemination of information, including genetic epidemiologic information, on the health of the community.
Policy Development: The formulation of standards and guidelines, in collaboration with stakeholders, which promote the appropriate use of genomic information and the effectiveness, accessibility, and quality of genetic tests and services.
Three Core Public Health Functions and Ten Essential Services

- **Assurance**: That genomic information is used appropriately and that genetic tests and services meet agreed upon goals for effectiveness, accessibility, and quality.
MDCH Cancer Genomics Program
Michigan’s Timeline

1990s
- Genetics Program “discovers” Comprehensive Cancer Control Program
- BRCA 1/2 and Lynch Syndrome genetic testing moves into clinical practice

2000
- Genetics Program participates in genetics needs assessment and state plan process
- Informed Consent Law for Genetic Testing Begins
- Genetics staff participates in Michigan Cancer Consortium

2002
- Michigan Cancer registry (MCSP) family history chart reviews
- Cancer objectives in state genetics plan

2003
- Cancer Program participates in Michigan Cancer Consortium
- Cancer Genetics Clinic Network for Data Collection begins
- MI Informed Consent Law for Genetic Testing Begins

2005
- “Cancer Genomics for Public Health” seminar series
- MCSP Mandatory family History fields for Reportable cancers

2007
- MCSP

2008
- Genomics goal and objectives in state cancer plan, 2009-2015
- Michigan Cancer registry (MCSP) family history chart reviews

2010
- Work with Michigan health plans begins
- LSSN formed

2011
- CDC Prevention Research Center-Special Interest Project: Potential for Cancer Screening Interventions for Cancer Survivors Delivered Through Central Cancer Registries, 2011-2013

2012
- CDC Cooperative Agreement: Genomics Applications in Practice and Prevention, 2008-2012
- CDC Cooperative Agreement: Genomics Integration in Public Health Programs, 2003-2008

2013
- DCPC supplemental funding for young breast cancer survivors activities, 2010
Cancer Genomics & the 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.
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 review\(^1\) of 30 existing comprehensive cancer control plans:
  – 18 plans (60%) with specific terms related to genomics

• 2010 review\(^2\) 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
• “…efforts are needed not only to implement what is known in genomics to improve health but also to reduce potential harm and create the infrastructure needed to derive health benefits in the future.”

Three-Tier Classification of Recommendations on Genomic Applications

- **Tier 1: Ready for implementation** (per evidence-based recommendation on clinical utility)
  - Encourage use; can save lives
  - Examples: *BRCA*, *Lynch syndrome*, familial hypercholesterolemia, newborn screening

- **Tier 2: Informed decision making** (adequate information on analytic and clinical validity, promising but not definitive information on clinical utility)
  - Provide information for shared decision making
  - Examples: *Gene expression profiles in breast cancer*, family history assessment in primary care

- **Tier 3: Discourage use** (no or little information on analytic, clinical validity or clinical utility; or evidence of harm)
  - Discourage use; reduce potential harms and save unnecessary healthcare costs
  - Examples: Population screening for hereditary hemochromatosis, personal genomic tests sold directly to consumers

Healthy People 2020 Genomics Objectives

1. Increase the proportion of women with a family history of breast and/or ovarian cancer who receive genetic counseling.

2. Increase the proportion of persons with newly diagnosed colorectal cancer who receive genetic testing to identify Lynch syndrome (or familial colorectal cancer syndromes).

Download all Genomics Objectives [PDF – 10 KB]
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
Evaluation of Genomic Applications in Practice and Prevention (EGAPP)

www.egappreviews.org
**EGAPP Recommendation on Genetic Testing for Lynch Syndrome**

- Sufficient evidence to offer counseling & genetic testing for Lynch syndrome to patients newly diagnosed with colorectal cancer to reduce morbidity & mortality in relatives

- Relatives of patients who test positive for Lynch could be offered counseling, testing & if positive, increased colonoscopy

- Evidence of benefit to the patient’s relatives

*Gen Med* 2009;11:35-41 & 42-65
CDC Funding Announcement

Genomics Applications in Practice and Prevention (GAPP): Translation Programs in Education, Surveillance, and Policy

• 3 year cooperative agreement (2008-2011) awarded to four projects
  – Large, well-defined populations in US (greater than 100,000)
• Goal: move human genome applications into health practice to maximize health benefits and minimize harm through non-research activities

• Expected measurable outcomes:
  – **Surveillance**: measure use of counseling and testing for BRCA1/2; knowledge of providers or public on use of BRCA1/2 or EGAPP-identified genetic test(s); use of EGAPP genetic test(s); use of family history tools
  – **Provider Education**: increase knowledge of validity, utility, harms and benefits of EGAPP-identified genetic test(s); increase use of family history, counseling and BRCA1/2 tests as recommended by USPSTF
  – **Policy**: increase use of family history, counseling, and BRCA1/2 tests as recommended by USPSTF
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

A reduction in early cancer deaths (before age 50) through statewide surveillance and implementation of systems of care for inherited breast, ovarian, colorectal and other Lynch syndrome (HNPCC) related cancers that use best practice recommendations for family history assessment, cancer genetic counseling and testing
Our Program’s Goals
2008-2012

- Develop and implement a model for surveillance of inherited cancers and use of relevant genetic tests; and share with other cancer registries and national programs
- Identify model provider education programs to increase use of appropriate screening, counseling and evidence-based genetic tests; and share with public health and/or clinical practice organizations
- Identify a model health insurance policy for BRCA1 & 2 cancer genetic testing; and share with health plans in Michigan and other states

Funding for this project was made possible by Cooperative Agreement #5U38GD000054 from the Centers for Disease Control and Prevention. The contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.
State of Michigan

♦ **Public**
  - ~10 million residents
  - ~6.9 million under age 50

♦ **Health systems and providers**
  - ~200 facilities reporting to the Michigan Cancer Surveillance Program (excludes labs, dermatology and dental offices)
  - ~64,000 new reportable cancer cases per year

♦ **Health insurance plans**
  - 24 health plans
**Policy Objectives**

- Understand current status of Michigan health insurance policies for BRCA1/2 counseling and testing with respect to USPSTF guidelines and related clinical services for BRCA1/2 mutation carriers
- Understand current status of Michigan health insurance policies for Lynch syndrome genetic testing with respect to EGAPP recommendations
  - No known health plans with written policies for Lynch syndrome testing in alignment with EGAPP recommendations
- Increase the number of health plans that have policies consistent with USPSTF guidelines
Activities

- Review Michigan health plan policies for consistency with USPSTF BRCA recommendation, coverage for clinical services for BRCA positive members, and consistency with EGAPP Lynch recommendation
- Disseminate USPSTF guidelines and need for related clinical services for BRCA 1/2 mutation carriers to health plans through multiple venues
- Track BRCA counseling and testing at 10 clinical cancer genetics clinics for members with and without health plan policies consistent with USPSTF
- Recognize health plans consistent with USPSTF
- Provide technical assistance to health plans
- Conduct a workshop for health plans and cancer genomics experts

Resources

- USPSTF BRCA Recommendations
- EGAPP Lynch Syndrome Recommendations
- Health Plan Champion
- Michigan Cancer Consortium
- Michigan Cancer Genetics Alliance
- MDCH Genomics Program

Policy

Performance Measure

★ Use of family history, genetic counseling and BRCA 1/2 testing (as recommended by USPSTF) and related clinical services increases from baseline

Promote Use of Identified Health Insurance Policy Model
Surveillance of Health Plan BRCA 1/2 Policies

Methods:

- Contracted with “health plan champion” and Michigan Association of Health Plans (MAHP)
- Identified total of 24 Michigan health plans
- Using multiple search types (i.e. websites, key administration contacts, list servs, newsletters, conferences) request and/or identify policies

Conduct ongoing surveillance to determine:

1. Does the health plan have a written BRCA counseling and testing policy?
2. If written policy, does it include coverage for female members with a significant family history of breast and/or ovarian cancer without a personal history (aligned with USPSTF)?
3. Does the policy ‘require’ or ‘strongly recommend’ counseling by a qualified health care professional or genetic counselor prior to BRCA testing?

Consider aligned with USPSTF if all three criteria are fulfilled
<table>
<thead>
<tr>
<th>Health Plan</th>
<th>BRCA1/2 written policy (Y/N)</th>
<th>Consistent with USPSTF</th>
<th>Distribution (%) of Visits Covered at Cancer Genetic Counseling Sites (n=9,851)*</th>
<th>Number of Michigan Health Plan Members*</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Health Plans</td>
<td>Y</td>
<td>Y</td>
<td>8,036 (83.8%)</td>
<td>~7.5 million</td>
</tr>
<tr>
<td>9 Health Plans</td>
<td>N</td>
<td>N</td>
<td>166 (1.6%)</td>
<td>~1 million</td>
</tr>
<tr>
<td>1 Health Plan</td>
<td>Y</td>
<td>N</td>
<td>4 (0.0%)</td>
<td>187,000</td>
</tr>
<tr>
<td>Medicaid</td>
<td>Y</td>
<td>N</td>
<td>279 (2.8%)</td>
<td>500,000+</td>
</tr>
<tr>
<td>Medicare</td>
<td>Y</td>
<td>N</td>
<td>1,257 (12.8%)</td>
<td>~1.5 million</td>
</tr>
</tbody>
</table>
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
Educational Materials for Health Plans

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

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
  - MCSP/MCC Position Paper for Providers
  - Michigan Informed Consent Law for Genetic 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 &/or 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. BRF3) to measure progress toward HP2020 BRCA objectives
  - Evaluation and Dissemination
    - Develop an evaluation plan
    - Complete a dissemination plan

**Public Health & Clinical Relevance**
- Outcomes
  - Goal #1
    - Promote adoption of health plan policies to increase coverage of BRCA clinical services for high risk women
    - 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
  - Goal #2
    - Increase health care provider knowledge and use of BRCA clinical practices recommended by USPSTF and NCCN
    - 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
  - Goal #3
    - Expand surveillance of BRCA clinical practices
    - 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
  - Goal #4
    - Utilize data to inform best practices, promote policy change, conduct program evaluation, and disseminate findings
    - 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

**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.

Ensure Appropriate Translation of “BRCA Clinical Services”
A reduction in breast cancer deaths at a young age and ovarian cancer deaths in Michigan

Michigan Cancer Surveillance Program (MCSP); Local Cancer Registrars; Local Cancer Genomics Champion

Health Plan Champion; Michigan Association of Health Plans (MAHP); Blue Cross Blue Shield of Michigan

Michigan Cancer Consortium; FORCE

Michigan Cancer Genetics Alliance

15 Clinical Cancer Genetics Sites

Priority Health

NCHPEG; Wayne State; Emory

CDC Division of Cancer Prevention and Control

CDC Office of Public Health Genomics

Surveillance

Education
Impact: A reduction in the young breast cancer death rate and the ovarian cancer death rate

Surveillance Objectives

• To examine the epidemiology of multiple primaries, early onset breast, male breast, ovarian and Lynch syndrome cancers

• To evaluate the use of genetic counseling and tests:
  – Who is accessing genetic counseling? and testing?
  – What providers are referring for genetic counseling?
  – Is referral for counseling appropriate using USPSTF family history guidelines?
  – For patients having BRCA testing, what are their test results?
  – Do health plan policies that are consistent with USPSTF guidelines influence visits?
  – Is the number of women with a family history of breast and/or ovarian cancer receiving genetic counseling increasing?

• To assess barriers/facilitators to cancer survivors knowledge and attitudes about family health history, genetic counseling and testing

• To provide data that will reinforce educational messages to health care providers
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

Table 1. Number of early onset female breast and endometrial diagnoses within your health system and within Michigan.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast (female)</td>
<td>199</td>
<td>3,025</td>
</tr>
<tr>
<td>Endometrial</td>
<td>30</td>
<td>459</td>
</tr>
</tbody>
</table>

Table 2. Number of colorectal, ovarian, and male breast diagnoses within your health system and within Michigan.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>476</td>
<td>10,340</td>
</tr>
<tr>
<td>Ovarian*</td>
<td>137</td>
<td>1,644</td>
</tr>
<tr>
<td>Breast (male)</td>
<td>12</td>
<td>147</td>
</tr>
</tbody>
</table>


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**
Who received the report?

- 107 NPCR facilities in 2010-2011
- 38 SEER facilities in 2011
- For each facility, multiple key administrators sent report including:
  - Cancer Registrar
  - President and CEO
  - Medical/Clinical Affairs
  - Medical Director
  - Quality Assurance/Risk Management
  - Patient Care
  - Legal Affairs
  - Nursing
  - Oncology
  - OB/GYN
In-Services Offered

- Real-life clinical scenarios
- Critical decision-making skills
- Uses interactive audience response system
- Promotes USPSTF guidelines for Hereditary Breast and Ovarian Cancer syndrome
- Promotes EGAPP Recommendation for Lynch syndrome
2012 Bidirectional Process Updates

- Seven Michigan facilities requested names from cases reported to provide appropriate follow-up.
- MDCH piloting process of reporting ~200 cases diagnosed in 2008-2009 from 4-5 NPCR Michigan facilities affiliated with newly established cancer genetics clinics and providing materials directly to physician.
- Connecticut successfully replicated process in 2012:
  - Received HP2020 funds to implement similar bidirectional process with dissemination of educational materials and provide cancer genomic in-services.
  - Utilized select board-certified genetic counselors to provide in-services.
  - Greater success than Michigan in percentage of in-services provided.
Network of Michigan Clinical Cancer Genetics Clinics

Collected all BRCA counseling cases from October 2007-March 2011 seen by a Michigan board certified/eligible genetics professional

Currently collecting data on April 2011-October 2013 with new online database

New online database also identifies if NCCN counseling and/or testing criteria met

Utilizing data in health plan policy work in 2012-2013
Indications for Referral: Personal Cancer History versus Family History only

Referring provider of patients receiving BRCA counseling

Age at first visit in those with and without a personal history of breast and/or ovarian cancer

Number of BRCA counseling visits and tests per fiscal year quarter, October 2007 through March 2011

Number of BRCA tests and known deleterious mutations per fiscal year quarter, October 2007 through March 2011
<table>
<thead>
<tr>
<th></th>
<th>Personal Cancer History</th>
<th>No Personal History</th>
<th>Known Familial Mutation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ovarian cancer</td>
<td>Breast cancer at ≤ 50 years</td>
<td>Breast cancer at &gt; 50 years</td>
</tr>
<tr>
<td>Negative</td>
<td>153 (73.6)</td>
<td>1,352 (86.8)</td>
<td>676 (90.1)</td>
</tr>
<tr>
<td>Positive</td>
<td>44 (21.2)</td>
<td>135 (8.7)</td>
<td>29 (3.9)</td>
</tr>
<tr>
<td>Variant</td>
<td>11 (5.3)</td>
<td>71 (4.6)</td>
<td>45 (6.0)</td>
</tr>
<tr>
<td>Total</td>
<td>208</td>
<td>1,558</td>
<td>750</td>
</tr>
</tbody>
</table>
### Reasons for declining BRCA genetic testing after receiving genetic counseling

<table>
<thead>
<tr>
<th>Reason</th>
<th>Patients Number</th>
<th>(%   )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not the best test candidate</td>
<td>477</td>
<td>29.2</td>
</tr>
<tr>
<td>Not clinically indicated</td>
<td>436</td>
<td>26.7</td>
</tr>
<tr>
<td>Inadequate insurance coverage</td>
<td>243</td>
<td>14.9</td>
</tr>
<tr>
<td>Other</td>
<td>116</td>
<td>7.1</td>
</tr>
<tr>
<td>Discuss options with relatives</td>
<td>80</td>
<td>4.9</td>
</tr>
<tr>
<td>Not a good time</td>
<td>71</td>
<td>4.4</td>
</tr>
<tr>
<td>Reassured by risk assessment</td>
<td>50</td>
<td>3.1</td>
</tr>
<tr>
<td>Does not meet Medicare criteria</td>
<td>45</td>
<td>2.8</td>
</tr>
<tr>
<td>Does not want to know</td>
<td>45</td>
<td>2.8</td>
</tr>
<tr>
<td>Test co-pay too costly</td>
<td>30</td>
<td>1.8</td>
</tr>
<tr>
<td>Patient sees no benefit</td>
<td>20</td>
<td>1.2</td>
</tr>
<tr>
<td>Arrange life/disability insurance</td>
<td>19</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,632</strong></td>
<td></td>
</tr>
</tbody>
</table>

**913 patients found to be inappropriate for testing at time of counseling** (potential cost savings of Over $3 million)

**Interesting Trend:**
- In Oct 2007-2008 and Oct 2008-2009, 16.7% of patients who received genetic counseling did not proceed with BRCA testing due to inadequate insurance coverage.
- In Oct 2010-2011 (MDCH provider and policy work began in 2010), number dropped to 10.7%.
- In Oct 2010-March 2011, number dropped again to 9.7%.
### Surveillance Data Reinforces Key Messages to Referring Providers:

- Test Affected First
- Remember to ask about Ashkenazi Jewish ancestry
- Document prior BRCA testing results in family if possible
- Males are important too
- Consider racial/ethnic/cultural differences when counseling
- Personal history of ovarian cancer is especially important

### Characteristics of patients who had and did not have BRCA genetic testing after counseling

<table>
<thead>
<tr>
<th></th>
<th>Tested</th>
<th>Did Not Test</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (%)</td>
<td>(%)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>3,808 (94.6)</td>
<td>1,655 (96.2)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Male</td>
<td>219 (5.5)</td>
<td>65 (3.8)</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td>&lt; 0.01*</td>
</tr>
<tr>
<td>White</td>
<td>3,333 (82.9)</td>
<td>1,277 (74.2)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>244 (6.1)</td>
<td>183 (10.6)</td>
<td></td>
</tr>
<tr>
<td>Multi-racial</td>
<td>243 (6.0)</td>
<td>153 (8.9)</td>
<td></td>
</tr>
<tr>
<td>Asian / Pacific Islander</td>
<td>76 (1.9)</td>
<td>31 (1.8)</td>
<td></td>
</tr>
<tr>
<td>Arabic</td>
<td>63 (1.6)</td>
<td>36 (2.1)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>33 (0.8)</td>
<td>23 (1.3)</td>
<td></td>
</tr>
<tr>
<td>Native American</td>
<td>2 (0.1)</td>
<td>6 (0.4)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>10 (0.3)</td>
<td>1 (0.1)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>17 (0.4)</td>
<td>11 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Ashkenazi Jewish Heritage</td>
<td></td>
<td></td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>No</td>
<td>3,524 (87.6)</td>
<td>1,653 (96.0)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>498 (12.4)</td>
<td>69 (4.0)</td>
<td></td>
</tr>
<tr>
<td>Known Familial Mutation</td>
<td></td>
<td></td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>No</td>
<td>3,386 (84.2)</td>
<td>1,670 (97.0)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>636 (15.8)</td>
<td>52 (3.0)</td>
<td></td>
</tr>
<tr>
<td>Family History Defined by USPSTF</td>
<td></td>
<td></td>
<td>0.04</td>
</tr>
<tr>
<td>No</td>
<td>2,303 (57.3)</td>
<td>1,035 (60.1)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1,719 (42.7)</td>
<td>687 (39.9)</td>
<td></td>
</tr>
<tr>
<td>Personal Cancer History</td>
<td></td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>No</td>
<td>1,396 (34.7)</td>
<td>1,132 (65.7)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2,626 (65.3)</td>
<td>590 (34.3)</td>
<td></td>
</tr>
</tbody>
</table>
Young Breast Cancer Survivors (YBCS) Mail Survey

- 500 YBCS (diagnosed between 18-49 years of age in 2006-2007) identified through MCSP
- 12 page mail survey sent (up to three attempts)
  - to assess barriers and facilitators to YBCS knowledge, attitudes and use of family history, genetic counseling and testing in regards to BRCA1/2
- YBCS who completed survey received gift certificate
- Notified reporting cancer registrars and physician on record for each YBCS prior to sending survey
YBCS Survey Results

- 289 YBCS responded (59.2%)
- 122 YBCS (42.2%) reported having received cancer genetic services
  - Most frequent reason to benefit family’s future
  - 121 reported BRCA testing
    - 13.2% reported known deleterious mutation
    - 4.1% reported variant of uncertain clinical significance
    - 74.4% reported no BRCA mutation found
  - 116 (95.9%) shared results with relatives

### Table 8. Facilitators of BRCA Genetic Counseling & Risk Assessment in YBCS

<table>
<thead>
<tr>
<th>Facilitators</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit my family’s future</td>
<td>105 (86.1%)</td>
</tr>
<tr>
<td>Wanted to know my future risk of cancer</td>
<td>62 (50.8%)</td>
</tr>
<tr>
<td>My doctor recommended that I go</td>
<td>50 (41.0%)</td>
</tr>
<tr>
<td>May alter my cancer treatment</td>
<td>48 (39.3%)</td>
</tr>
<tr>
<td>Going seemed very important</td>
<td>41 (33.6%)</td>
</tr>
<tr>
<td>Family members wanted me to go</td>
<td>21 (17.2%)</td>
</tr>
<tr>
<td>Already knew of a familial mutation</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>My medical insurance covered the visit</td>
<td>83 (68.0%)</td>
</tr>
<tr>
<td>Clinic was close to home</td>
<td>49 (40.2%)</td>
</tr>
<tr>
<td>Have available transportation</td>
<td>49 (40.2%)</td>
</tr>
<tr>
<td>Clinic hours were flexible and fit my schedule</td>
<td>30 (24.6%)</td>
</tr>
<tr>
<td>Have available childcare</td>
<td>11 (9.0%)</td>
</tr>
<tr>
<td>I was able to obtain these services by phone</td>
<td>2 (1.6%)</td>
</tr>
</tbody>
</table>
158 (54.7%) YBCS did not receive genetic services
- Top three reasons:
  - No one recommended (58.2%)
  - Health insurance coverage issues (23.4%)
  - Did not know existed (10.8%)

Table 9. Barriers to Receiving Genetic Services Among YBCS

<table>
<thead>
<tr>
<th>Reason</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No one ever recommended it</td>
<td>92</td>
<td>58.2%</td>
</tr>
<tr>
<td>Medical insurance coverage issues</td>
<td>37</td>
<td>23.4%</td>
</tr>
<tr>
<td>Did not know they existed</td>
<td>17</td>
<td>10.8%</td>
</tr>
<tr>
<td>Worried a genetic test could be used against me</td>
<td>15</td>
<td>9.5%</td>
</tr>
<tr>
<td>Too nervous</td>
<td>6</td>
<td>3.8%</td>
</tr>
<tr>
<td>A doctor told me not to go</td>
<td>5</td>
<td>3.2%</td>
</tr>
<tr>
<td>Lack of transportation</td>
<td>4</td>
<td>2.5%</td>
</tr>
<tr>
<td>Other life arise that are more important</td>
<td>4</td>
<td>2.5%</td>
</tr>
<tr>
<td>Too busy</td>
<td>3</td>
<td>1.9%</td>
</tr>
<tr>
<td>Disability makes it difficult to carry out daily activities</td>
<td>2</td>
<td>1.3%</td>
</tr>
<tr>
<td>Family members wouldn’t want me to go</td>
<td>2</td>
<td>1.3%</td>
</tr>
</tbody>
</table>
YBCS Survey Expanded in 2011-2013: Recruiting Young Breast Cancer Survivors and High-Risk Relatives to a Randomized Trial using a State Cancer Registry

Aim 1: Identify and survey 3,000 YBCS (diagnosed at 20-45 y.o.) to determine breast cancer surveillance utilization and perceived barriers and facilitators to surveillance

Aim 2: Identify and survey up to 2 unaffected female relatives (first and/or second degree) per YBCS to determine breast cancer screening utilization and perceived barriers and facilitators to screening

Aim 3: Test the efficacy of two versions (targeted vs. enhanced tailored) of an evidence-based intervention among YBCS and their female relatives to increase breast cancer surveillance/screening utilization
Using Michigan BRFS to Measure HP2020 BRCA Objective

- 2008 Michigan Behavioral Risk Factor Survey (MiBRFS)
  - 8.7% of Michigan adult women had significant family history of breast and/or ovarian cancer
  - Only 18% (11.8-26.4) of these women had received genetic counseling due to this family history

- 2009 MiBRFS
  - 7.9% of Michigan adult women had significant family history of breast and/or ovarian cancer
  - 35.7% (24.8-48.2) of these women had received genetic counseling due to this family history
  - Please be cautious in evaluating this trend since small numbers (n=136) and confidence intervals overlap slightly

- 2011 MiBRFS results pending
- 2012 MiBRFS currently being conducted
Partners, Partners, Partners...!

“…no important health problem will be solved by clinical care alone, or research alone, or by public health alone- But rather by all public and private sectors working together…..”

J S Marks. Managed Care 2005;14:p11
Supplement on “The Future of Public Health”
Acknowledgements

Clinical Sites
Beaumont Hospital
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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
Lynch Syndrome Screening Network (LSSN)

- Created in September 2011 with one-time funding from CDC OPHG
- Founding Board of Directors from MDCH, Emory University, Huntsman Cancer Institute, The Ohio State University
- Institutional membership with 92 institution applications to date
  - Up to 2 individuals/institution
- 52 institutions currently providing routine tumor screening for Lynch syndrome on all or subset of cancers
- 10 additional institutions planning to implement within 6-12 months

http://www.lynchscreening.net
LSSN Vision and Mission

• LSSN Vision:
  – to reduce the cancer burden associated with Lynch syndrome.

• LSSN Mission:
  – to promote universal Lynch syndrome screening on all newly diagnosed colorectal and endometrial cancers; to facilitate the ability of institutions to implement appropriate screening by sharing resources, protocols and data through network collaboration; and to investigate universal screening for other Lynch syndrome related malignancies
LSSN Activities

- Two in-person meetings held; next in-person meeting on Oct 27, 2012 in Boston
- Creation of active listserv
- Creation of website and educational materials
- Creation of database
- Multiple research proposals in development
- Creation of CDC OPHG Blog in March 2012
- Creation of bylaws
- Creation of membership application
- Four active workgroups (data, research, education, membership) meet regularly by conference call
LSSN Membership Application Data

- Impact of 2009 EGAPP Lynch syndrome recommendation
  - 58/62 institutions reported that EGAPP impacted their institutions
  - 24/62 institutions reported EGAPP supported/justified existing screening protocols
  - 23/62 institutions reported EGAPP provided basis for initiating Lynch screening protocol at their institution
Thank you!

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