APPLYING AN IMPLEMENTATION SCIENCE APPROACH TO GENOMIC MEDICINE: A WORKSHOP

November 19, 2015
Session III: Population Health and Genomics:
Incremental Implementation or Radical Reform?

Debra Duquette, MS, CGC
Michigan Department of Health and Human Services (MDHHS)
duquetted@michigan.gov
517.335.8286
- 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

State Genetics Plan Stakeholder Needs Assessment

MDHHS Cancer Prevention and Control Section Request

MDHHS Genomics Program created (full-time genomics coordinator; part-time cancer genetics staff)
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.
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.
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/
HEALTHY PEOPLE 2020 (HP 2020) CANCER GENOMICS OBJECTIVES, 2010-2020

- 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)

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

- Identify health plan ‘champions’; identify model plans if exist
- Create and assess key metrics for written cancer genomics health plan policies
- Build relationships at all health plans; request and review written health plan policies
- Honor health plans for cancer genomics best practices at key events and press releases
- Attend key health plan events to build relationships and disseminate educational packets
- Create individualized educational packets and utilize data to motivate
EXAMPLES OF MDHHS AND MAHP PARTNERSHIP ACTIVITIES

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:

- Hereditary 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 Syndrome 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. 24 - Oct. 3 is National Hereditary Breast and Ovarian Cancer (HBOC) Week. Genetic Assessment for All Ovarian Cancer Patients and their Relatives is Approaching.

Exp and each y been t mend the in

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 21st Century. The sequencing of DNA and RNA is now occurring in all major scientific institutions across the globe. This trend is expected to accelerate in the next several years.

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 genetic mutation.

It is well established that the vast majority of colorectal/diagnostic tumors from individuals with Lynch syndrome exhibit microsatellite instability (MSI) as well as abnormal nuclear histone-histone staining (HIC) 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 recommend offering Lynch syndrome screening consisting of MSI and/or HIC testing to all individuals with newly diagnosed colorectal cancer, regardless of age, family history, or histology, which has further been supported by other organizations including the National Society of Genetic Counselors (NSGC), the Collaborative Group of the Americas Inherited Colon Cancer (CGA) and the National Comprehensive Cancer Network (NCCN).

When a genetic mutation is found in one family member, it can assist in determining the genetic risk of other relatives. This information is important when considering treatment options and genetic counseling.

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 Plus Partners
BRCA Policy Dashboard

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.
   - Adults with a family history of breast and/or ovarian cancer.

2. Require or strongly recommend genetic counseling prior to BRCA genetic testing.

3. Encourage providers to obtain written informed consent as required by Michigan law prior to ordering BRCA genetic testing.

4. Cover BRCA-related clinical services for specific patients (policies would contain coverage information for the following services):
   - Mammography
   - MRI of the Breast
   - Prophylactic Mastectomy
   - Prophylactic Oophorectomy
   - Breast Reconstruction / Prosthesis

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 MHPP Foundation are honoring health plans with written BRCA counseling and testing policies that align with the USPSTF and NCCN recommendations. If your health plan has not been honored, please contact the MDCH Cancer Genomics Team at 1-866-852-2247 or email genetic@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: Reassure Cancer Genetics Program, Cancer Genetics Program at St. Joseph Mercy Hospital, Henry Ford Health System, InformedDNA, Kaiser Cancer Genetics Counseling Service, Lacks Cancer Center Genetics Program at St. Mary’s Healthcare, Michigan State University Division of Clinical Genetics, Marquess General Medical Center, Marquess Medical Center, Spectrum Health Cancer Genetics, University of Michigan Cancer Genetics, and University of Michigan Breast and Ovarian Cancer Risk Evaluation Program, and West Michigan Cancer Center.

Patients with a deleterious BRCA mutation

Patients not testing due to inadequate insurance
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
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.