Reducing Barriers to Risk Appropriate Cancer Genetic Services: Current Strategies and Barriers

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MCC Annual Meeting

Debra Duquette, MS, CGC
Michigan Department of Community Health
duquetted@michigan.gov;
517.335.8286,
Learning Objectives

- Describe the current status of access to appropriate cancer genomics services in the State of Michigan
- Identify specific strategies employed in Michigan to increase access in underserved populations and limitations of these strategies
Presenters and Topics

- Deb Duquette, MS, CGC, MDCH
  - Overview and Background
- Kara Milliron, MS, CGC, University of Michigan
  - Planned Parenthood
  - Informed Medical Decisions, Inc
- Dana Zakalik, MD, Beaumont Health System
  - Federally Qualified Health Center
- Julie Zenger-Hain, PhD, FACMG, Oakwood Hospital
  - Hispanic Community

Genomics Goal:

Increase availability of cancer-related genetic information to the Michigan public and decrease barriers to risk-appropriate services

http://michigancancer.org/
Healthy People 2020 Genomics Objectives

Genomics New

Overview Objectives Interventions & Resources

Download all Genomics Objectives [PDF – 10 KB]

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

G-2 (Developmental) 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]

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Commission on Cancer (CoC)
Genetic Counseling Standard

STANDARD 2.3
Risk Assessment and Genetic Counseling

Cancer risk assessment, genetic counseling, and testing services are provided to patients either on-site or by referral, by a qualified genetic professional.

DEFINITION AND REQUIREMENTS

Cancer risk assessment and genetic counseling are the processes to identify and counsel patients at risk for familial or hereditary cancer syndromes. The purposes of genetic counseling are to educate patients about their chance of developing cancer, help them obtain personal counseling from cancer genetic information, and empower them to make educated, informed decisions about genetic testing, cancer screening, and cancer prevention. Identifying patients at increased risk of developing cancer because of a family history of cancer or a known hereditary cancer syndrome can have dramatic effects on early detection and cancer outcome. For this reason, cancer risk assessment and genetic counseling are rapidly becoming standards of care for patients with personal and/or family history of cancer who are at high risk of having a hereditary syndrome.

The program provides cancer risk assessment and genetic counseling on-site or by referral to another facility or community-based organization.

Cancer risk assessment and genetic counseling are performed by a cancer genetics professional who has extensive experience and educational background in genetics, cancer genetics, counseling, and hereditary cancer syndromes to provide accurate risk assessment and empathetic genetic counseling to patients with cancer and their families.

Cancer risk assessment and the potential for referral may be discussed as part of the multidisciplinary cancer conference.

Genetics professionals include people with the following:

- An American Board of Genetic Counseling (ABGC) or American Board of Medical Genetics (ABMG) board-certified board eligible or (in some states) a licensed genetic counselor
- An American College of Medical Genetics physician board certified in medical genetics
- A Genetics Clinical Nurse or an Advanced Practice Nurse in Genetics (APNG)
- Certified through the Genetics Nursing Credentialing Commission (GNCC).
- Certification is obtained through successful completion of a professional portfolio review process.
- An advanced practice oncology nurse who is prepared at the graduate level (master or doctorate) with specialized education in cancer genetics and hereditary cancer predisposition syndromes; certification by the Oncology Nursing Certification Corporation is preferred.

- A board-certified physician with experience in cancer genetics (defined as providing cancer risk assessment on a regular basis).

Please note, specialized training in cancer genetics should be ongoing: educational seminars offered by commercial laboratories about how to perform genetic testing are not considered adequate training for cancer risk assessment and genetic counseling.

The Cancer Committee defines the appropriate individuals who provide risk assessment and counseling for major cancer genetic diseases (such as breast and colorectal). In addition, the program must have immediate access to formal genetic counseling services should they identify resources for referral.

Cancer risk assessment and genetic counseling involve pretest and posttest counseling. At a minimum, this counseling includes the following:

Pretest Counseling

- Collecting relevant information needed to assess a patient's personal and family medical history
- A 3- to 4-generation pedigree, including detailed medical information about the patient's first, second, and third-degree relatives should be obtained. Gathering information about paternal and maternal family history, ancestry, and consanguinity, as available, is necessary.

- Evaluating the patient's risk
  - One aspect of risk assessment is discussing the absolute risk that the patient will develop a specific type of cancer or cancers based on the family history. The second aspect is the risk that the patient carries a heritable or germline mutation in a cancer susceptibility gene.
  - Performing a psychosocial assessment
  - Educating the patient about the suspected hereditary cancer syndrome, if appropriate

Posttest Counseling

- Disclosure of the results and posttest counseling include a discussion of the results, significance and impact of the test results, medical management options, informing other relatives, future context, and available resources. The test results and interpretation will be communicated to the provider. The provider and the patient will decide on the best course of action.


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Hereditary Breast and Ovarian Cancer (HBOC)

- Accounts for 5-10% of all breast cancers
- At least 11% of Michigan adult women meet USPSTF and NCCN criteria for referral for BRCA counseling (2011 and 2012 MiBRFS)
- Approximately 1/200-1/500 are carriers in the general population; 1/40 in Ashkenazi Jewish population
- Caused by mutations in BRCA1/BRCA2
- Autosomal dominant inheritance – 50% risk to each child/sibling/parent
- For those women with a deleterious BRCA mutation, the risk of developing breast cancer by age 70 is ~ 35-84% and the risk of developing ovarian cancer by age 70 is ~ 10-63%
- For men with a deleterious BRCA mutation breast cancer risk increased to 6%
- Management by risk-reducing surgery, enhanced screening regimen and chemoprevention


http://abcnews.go.com/blogs/health/2013/05/14/angelina-jolies-choice-should-you-get-brca-gene-testing/

2013 U.S. Preventive Services Task Force
BRCA Recommendation (updated from 2005)

Primary care providers should screen women with a family history of breast, ovarian, fallopian tube or peritoneal cancer to identify those potentially at increased risk for a BRCA mutation. Women with a significant family history receive genetic counseling, and, if indicated, they be offered genetic 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/uspstf/uspsbrgen.htm
NCCN Guidelines Version 1.2014
Breast and/or Ovarian Cancer Genetic Assessment

CRITERIA FOR FURTHER GENETIC RISK EVALUATION
An affected individual with one or more of the following:
- A known mutation in a breast cancer susceptibility gene within the family
- Early-onset breast cancer
- Triple negative (ER-, PR-, HER2-) breast cancer
- Two breast cancer primaries in a single individual
- Breast cancer at any age, and
  - ≥1 close blood relative with breast cancer <50 y, or
  - ≥1 close blood relative with epithelial ovarian cancer at any age, or
  - ≥2 close blood relatives with breast cancer and/or pancreatic cancer at any age
- From a population at increased risk
  - ≥1 family member on the same side of family with a combination of breast cancer and ≥1 of the following (especially if early onset): pancreatic cancer, prostate cancer (Gleason ≥7), sarcoma, adrenocortical carcinoma, brain tumors, endometrial cancer, leukemia/lymphoma; thyroid cancer, dermatologic manifestations and/or macrocephaly, hamartomatous polyps of GI tract; diffuse gastric cancer
- Ovarian cancer
  - Male breast cancer

Male breast cancer
- Criteria for further risk evaluation and genetic testing are not identical. For the purposes of these guidelines, invasive and ductal carcinoma in situ breast cancers should be included. The maternal and paternal sides of the family should be considered independently for familial patterns of cancer.
- Clinically use age <50 y because studies define early onset as either ≤40 or ≤50 y.
- Two breast primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors either synchronously or asynchronously.
- Close blood relatives include first-, second-, and third-degree relatives. (See BR/OV-3)
- For the purposes of these guidelines, fallopian tube and primary peritoneal cancers are included. Ovarian/fallopian tube/primary peritoneal cancers are component tumors of Lynch syndrome/hereditary non-polyposis colorectal cancer; be attentive for clinical evidence of this syndrome. See NCCN Guidelines for Genetic/Familial High-Risk Assessment: Colorectal.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.
Continual growth of appropriate cancer genetic counseling and BRCA testing of individuals with a personal and/or family history of breast and/or ovarian cancer.

Extraordinary increase in number of cancer genetic clinics with board-certified genetic professionals in Michigan including new clinics in previously underserved areas.

- 17 clinics in 2014 compared to 8 clinics in 2010

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.

- 8.3% in 2014 compared to 21.7% in 2008
Populations in Need of Greater Cancer Genetic Services in Michigan

- All women with a significant family history of breast and ovarian cancer
  - ~11% of adult Michigan women met USPSTF family history criteria for BRCA counseling and testing (MiBRFS 2011 and 2012)
  - Of these, 8.8% have had cancer genetic counseling
  - Of these 22.4% had at least one family member who had cancer genetic counseling

- Individuals of a relative with a known deleterious mutation
  - 50% risk to inherit known deleterious mutation for first degree relatives
  - Single site testing is extremely informative and much less expensive
  - Rate of single site testing has remained relatively low and steady in Michigan (BRCA Clinical Network database, Myriad data)
Populations in Need of Greater Cancer Genetic Services in Michigan (continued)

- **Ovarian cancer patients**
  - Of 137 ovarian cancer charts reviewed by Michigan Cancer Surveillance Program, only 3.6% of ovarian cancer cases in 2006-2010 had received cancer genetic counseling (MCSP data)
  - 29.4% of patients with a history of both breast and ovarian cancer; and 14.0% of patients with ovarian cancer found to have deleterious BRCA mutation (BRCA Clinical Database)
  - 50.0% of women with both breast and ovarian cancer and 30.6% with ovarian cancer alone had to decline testing due to inadequate insurance coverage or high co-pay (BRCA Clinical Database)

- **African American adults with a significant personal or family history** (BRCA Clinical Database)
  - 9.4% of all patients receiving BRCA genetic counseling were African American
  - 56.1% of African American patients had BRCA testing (lowest of all race/ethnicity groups) vs. 67.6% of white patients
  - Only 3.3% of African Americans referred with a known family mutation vs. 13.4% of whites
Use of Cancer Genetic Services among Michigan Young Breast Cancer Survivors (YBCS)

<table>
<thead>
<tr>
<th>Use of cancer genetic services</th>
<th>Total (n=828)</th>
<th>Black (n=317)</th>
<th>Other (n=511)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had genetic counseling*</td>
<td>32.9%</td>
<td>26.6%</td>
<td>37.1%</td>
</tr>
<tr>
<td>Had genetic testing*</td>
<td>28.5%</td>
<td>19.9%</td>
<td>33.7%</td>
</tr>
<tr>
<td>Had genetic counseling and testing*</td>
<td>27.5%</td>
<td>18.3%</td>
<td>32.9%</td>
</tr>
</tbody>
</table>

* Significant at the 0.001 level for Black vs. Other

Black YBCS were less likely than White/Other YBCS to use cancer genetic services

Study conducted by University of Michigan School of Nursing, MDCH Cancer Genomics, MCSP and Prevention Research Center of Michigan with funding from CDC in 2011-2014
**Reasons for not seeking genetic services among Michigan YBCS**

<table>
<thead>
<tr>
<th>Most common reasons for not seeking genetic services*</th>
<th>Total (n=547)</th>
<th>Black (n=228)</th>
<th>Other (n=319)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No one ever suggested</td>
<td>67.8%</td>
<td>74.6%</td>
<td>63.0%</td>
</tr>
<tr>
<td>Out-pocket expense/Not covered</td>
<td>13.0%</td>
<td>6.6%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Unknown benefit</td>
<td>2.9%</td>
<td>1.3%</td>
<td>4.1%</td>
</tr>
</tbody>
</table>

* Significant at the 0.001 level for Black vs. Other

**The most common self-reported reason among all groups for not seeking genetic services was that no one ever suggested**

Study conducted by University of Michigan School of Nursing, MDCH Cancer Genomics, MCSP and Prevention Research Center of Michigan with funding from CDC in 2011-2014
Patient-Powered Network for Hereditary Breast and Ovarian Cancer

- Established in 2014 under the Affordable Care Act
- Goal is patient-centered, representative, large-scale, rapid comparative effectiveness research studies by collecting, sharing and integrating health data
  - 11 health system networks – each includes >7 million patients
  - 18 condition-focused patient-powered networks – each targeting enrollment of 0.5% of U.S. population with the condition
  - Integrate EHR, health claims and/or patient-reported outcomes data on 70 million Americans by September 2015
One of PCORnet’s 18 patient-powered, condition-focused networks
- Hereditary breast, ovarian and related cancer risks
- Goal: to improve informed decision-making and health outcomes by answering important questions high-risk patients and their providers face every day
- Led by patients, public health professionals and researchers
  - Patients driving governance and research – identifying the research questions, priorities, design, recruitment, analysis and dissemination
- Representativeness is key – across geographic, socioeconomic, clinical severity, racial, ethnic, age groups
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*
What is Lynch Syndrome (LS)?

- Autosomal dominant hereditary cancer syndrome
  - Most common hereditary colorectal (CRC) and uterine cancer syndrome
  - 20-80% lifetime risk for CRC cancer ~3% of CRCs with LS
  - Mean age of onset of CRC is ~45 years old
  - Increased risk of endometrial, ovarian, urinary tract, gastric tract, small bowel, pancreas, sebaceous cancers
**LS Screening & Management**

- Screening is complex
  - Multiple approaches including IHC and/or MSI testing on tumor with DNA testing
  - Different genes involved in LS
    - MSH2, MSH6, MLH1, PMS2
- Cancer surveillance & prophylactic survey options
  - Colonoscopy every 1-2 years beginning at ~20-25 years old or 10 years earlier that youngest case in family
  - Annual endometrial sampling and transvaginal ultrasound beginning at 30 years old
  - History and exam annually begin at 21 years
  - Annual urinalysis
  - Prophylactic surgery including subtotal colectomy, total abdominal hysterectomy and bilateral salpingo-oophorectomy
Michigan & National Data on Lynch Syndrome Screening

- No source of national data
  - HP2020 objective is developmental
  - MSI included in cancer registry reporting since 2010

- Michigan surveillance efforts
  - In 2006-2009 Michigan Colorectal Cancer Screening Program provided screening for low income, uninsured in three counties with high mortality rates
    - Of 1500 adults screened, 177 referred to genetic counselor
  - 2010 MiBRFS indicates nearly 80% of individual at risk for familial CRC syndrome report no knowledge of genetic test
    - Only 3% at risk for familial CRC syndrome had genetic test
  - Of 610 CRC charts reviewed from 2006-2010 diagnoses, less than 2% had Lynch syndrome screening
    - 119 cases aligned with NCCN guidelines
    - 6 had MSI testing; 11 had IHC; 0 had BRAF; 5 had MMR; 6 had genetic counseling
CDC Funding Announcement


- **5 year** cooperative agreement awarded to four projects
  - Authorized from Affordable Care Act
  - State health departments and Tribal governments eligible

**Purpose:** Enhance state health department’s 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 HBOC *but may also include* Lynch syndrome
- May identify target populations disproportionately affected by HBOC and lack genetic services
For More Information

www.migrc.org
www.michigan.gov/genomics
www.michigan.gov/cge

Or call 1-866-852-1247

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