

Cancer Genomics Best Practices: Is Testing in Michigan on the Rise?



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MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

**MAHP BEST PRACTICES FORUM
FEBRUARY 27, 2013**

Considerations



Payer Goals:

- What's in the best interest of the plan?
- What's best for the health of the members?
- How do we reduce, or at least control, overall costs?

MDCH Goals:

- What's best for the health of Michigan residents?
- How do we reduce, or at least control, overall costs?
- What can be done by payers to ensure appropriate genetic testing?

Healthy People 2020



- Started in 1979
- 10-year national objectives for promoting health and preventing disease
- HP 2020 marks first time for genomics objectives

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

Close Details ▼

Baseline:	23.3 percent of females with a family history of breast and/or ovarian cancer received genetic counseling in 2005
Target:	25.6 percent
Target-Setting Method:	10 percent improvement
Data Source:	National Health Interview Survey (NHIS), CDC, NCHS

More Information:



[Data from the HHS Health Indicators Warehouse](#)



[Search PubMed for Literature Relating to this Objective](#)

Breast Cancer Genetics in Michigan



- Approximately 1 in 12 (8%) Michigan women have a significant family history of breast or ovarian cancer.¹
- Women with a significant family history of breast and/or ovarian cancer should be referred for genetic counseling and risk assessment.^{2,3,4}
- As many as 35% of Michigan women with a significant family history of breast and/or ovarian cancer are referred for genetic counseling and risk assessment; as many as 65% are not.¹

1. Michigan Behavioral Risk Factor Survey, 2009. **2.** U.S. Preventive Services Task Force: Genetic risk assessment and *BRCA* mutation testing for breast and ovarian cancer susceptibility: recommendation statement. *Ann Intern Med* 2005; 143: 355–361. **3.** National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology “Genetic/Familial Risk Assessment: Breast and Ovarian” version 1.2012, accessed July 2012 from www.nccn.org. **4.** American College of Surgeons Commission on Cancer 2012 Patient Care Standards accessed June 2012 from <http://www.facs.org/cancer/coc/cocprogramstandards2012.pdf>. **5.** Michigan Resident Cancer Incidence File. Updated with cases processed through December 30, 2009. Division for Vital Records & Health Statistics, Michigan Department of Community Health. **6.** *BRCA* Clinical Genetic Counseling Database, Michigan Department of Community Health, Division of Genomics, Perinatal Health, and Chronic Disease Epidemiology, Genomics and Genetic Disorders Section, Cancer Genomics Program, June 2012.

Breast Cancer Genetics in Michigan



- Approximately 7,000 Michigan women are diagnosed with breast cancer each year, with approximately 1,500 being diagnosed under age 50. Approximately 600 Michigan women are diagnosed with ovarian cancer each year.⁵
- 21% of women with ovarian cancer will test positive for a gene change (mutation) in a BRCA (“breast cancer”) gene and 8.7% of women with breast cancer will test positive for a BRCA mutation.⁶

1. Michigan Behavioral Risk Factor Survey, 2009. **2.** U.S. Preventive Services Task Force: Genetic risk assessment and *BRCA* mutation testing for breast and ovarian cancer susceptibility: recommendation statement. *Ann Intern Med* 2005; 143: 355–361. **3.** National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology “Genetic/Familial Risk Assessment: Breast and Ovarian” version 1.2012, accessed July 2012 from www.nccn.org. **4.** American College of Surgeons Commission on Cancer 2012 Patient Care Standards accessed June 2012 from <http://www.facs.org/cancer/coc/cocprogramstandards2012.pdf>. **5.** Michigan Resident Cancer Incidence File. Updated with cases processed through December 30, 2009. Division for Vital Records & Health Statistics, Michigan Department of Community Health. **6.** *BRCA* Clinical Genetic Counseling Database, Michigan Department of Community Health, Division of Genomics, Perinatal Health, and Chronic Disease Epidemiology, Genomics and Genetic Disorders Section, Cancer Genomics Program, June 2012.

USPSTF Grade B Recommendation (women without a personal history)

“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.”

Not recommended for those without significant family and/or without personal history (USPSTF)

<http://www.ahrq.gov/CLINIC/uspstfix.htm>

Annals of Internal Medicine

CLINICAL GUIDELINES

Genetic Risk Assessment and *BRCA* Mutation Testing for Breast and Ovarian Cancer Susceptibility: Recommendation Statement

U.S. Preventive Services Task Force*

This statement summarizes the U.S. Preventive Services Task Force (USPSTF) recommendations on genetic risk assessment and *BRCA* mutation testing for breast and ovarian cancer susceptibility, along with the supporting scientific evidence. The complete information on which this statement is based, including evidence tables and references, is included in the evidence synthesis available through the USPSTF Web site (www.preventiveservices.ahrq.gov). The recommendation is also posted on the Web site of the National Guideline Clearinghouse (www.guideline.gov).

Ann Intern Med. 2005;143:355-361.
For author affiliation, see end of text.

www.annals.org

Individuals who wish to cite this recommendation statement should use the following format: U.S. Preventive Services Task Force. Genetic risk assessment and *BRCA* mutation testing for breast and ovarian cancer susceptibility. Ann Intern Med. 2005;143:355-61.

*For a list of the members of the U.S. Preventive Services Task Force, see the Appendix.

SUMMARY OF RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) recommends against routine referral for genetic counseling or routine breast cancer susceptibility gene (*BRCA*) testing for women whose family history is not associated with an increased risk for deleterious mutations in breast cancer susceptibility gene 1 (*BRCA1*) or breast cancer susceptibility gene 2 (*BRCA2*).

This is a grade D recommendation. (See Appendix Table 1 for a description of the USPSTF classification of recommendations.)

The USPSTF found fair evidence that women without certain specific family history patterns, termed here “increased-risk family history” (see Clinical Considerations for a definition), have a low risk for developing breast or ovarian cancer associated with *BRCA1* or *BRCA2* mutations. Thus, any benefit to routine screening of these women for *BRCA1* or *BRCA2* mutations, or routine referral for genetic counseling, would be small or zero.

The USPSTF found fair evidence regarding important adverse ethical, legal, and social consequences that could result from routine referral and testing of these women. Interventions such as prophylactic surgery, chemoprevention, or intensive screening have known harms. The USPSTF estimated that the magnitude of these potential harms is small or greater.

The USPSTF concluded that the potential harms of routine referral for genetic counseling or *BRCA* testing in these women outweigh the benefits. (See Appendix Table 2 for a description of the USPSTF classification of levels of evidence.)

The USPSTF recommends that women whose family history is associated with an increased risk for dele-

rious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.

This is a grade B recommendation.

The USPSTF found fair evidence that women with certain specific family history patterns (increased-risk family history) have an increased risk for developing breast or ovarian cancer associated with *BRCA1* or *BRCA2* mutations. The USPSTF determined that these women would benefit from genetic counseling that allows informed decision making about testing and further prophylactic treatment. This counseling should be done by suitably trained health care providers. There is insufficient evidence to determine the benefits of chemoprevention or intensive screening in improving health outcomes in these women if they test positive for deleterious *BRCA1* or *BRCA2* mutations. However, there is fair evidence that prophylactic surgery for these women significantly decreases breast and ovarian cancer incidence. Thus, the potential benefits of referral and discussion of testing and prophylactic treatment for these women may be substantial.

The USPSTF also found insufficient evidence regarding important adverse ethical, legal, and social consequences that could result from referral and testing of high-risk women.

See also:

Print	
Editorial comment	388
Related article	362
Summary for Patients	1-47

Web-Only

Conversion of tables into slides

Annals of Internal Medicine

www.annals.org



6 September 2005 | Annals of Internal Medicine | Volume 143 • Number 5 | 355

Affordable Care Act



 February 25, 2013

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22 Covered Preventive Services for Women, Including Pregnant Women

The eight new prevention-related health services marked with an asterisk (*) must be covered with no cost-sharing in plan years starting on or after August 1, 2012.

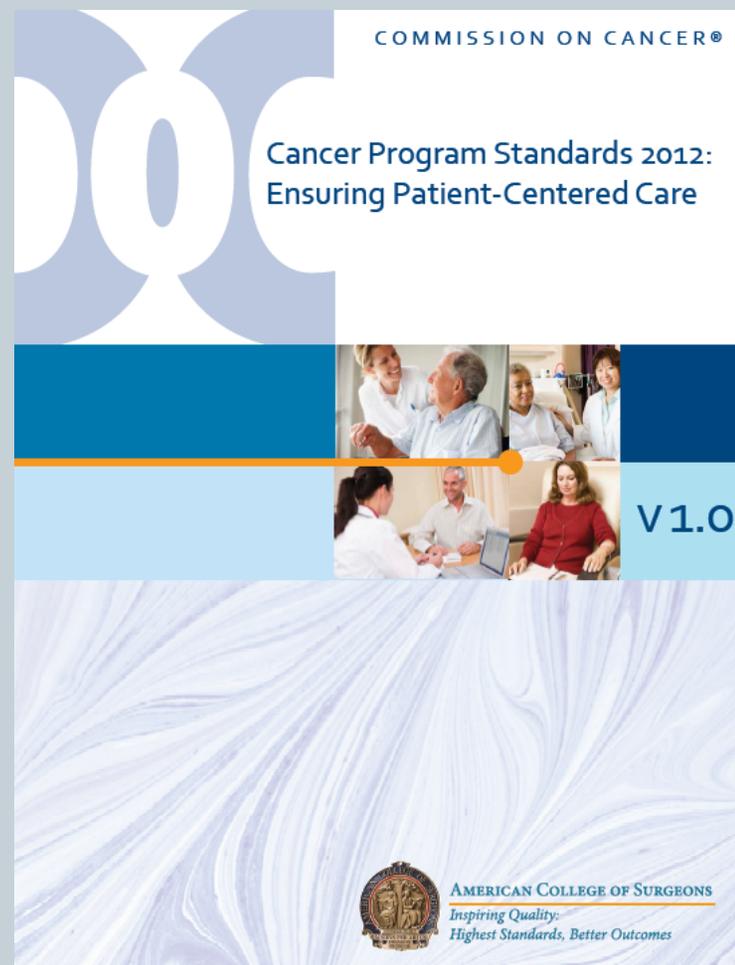
1. **Anemia** screening on a routine basis for pregnant women
2. **Bacteriuria** urinary tract or other infection screening for pregnant women
3. **BRCA** counseling about genetic testing for women at higher risk
4. **Breast Cancer Mammography** screenings every 1 to 2 years for women over 40

American College of Surgeons Commission on Cancer (Coc) Cancer Program Standards 2012

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 genetics professional

<http://www.facs.org/cancer/coc/cocprogramstandards2012.pdf>



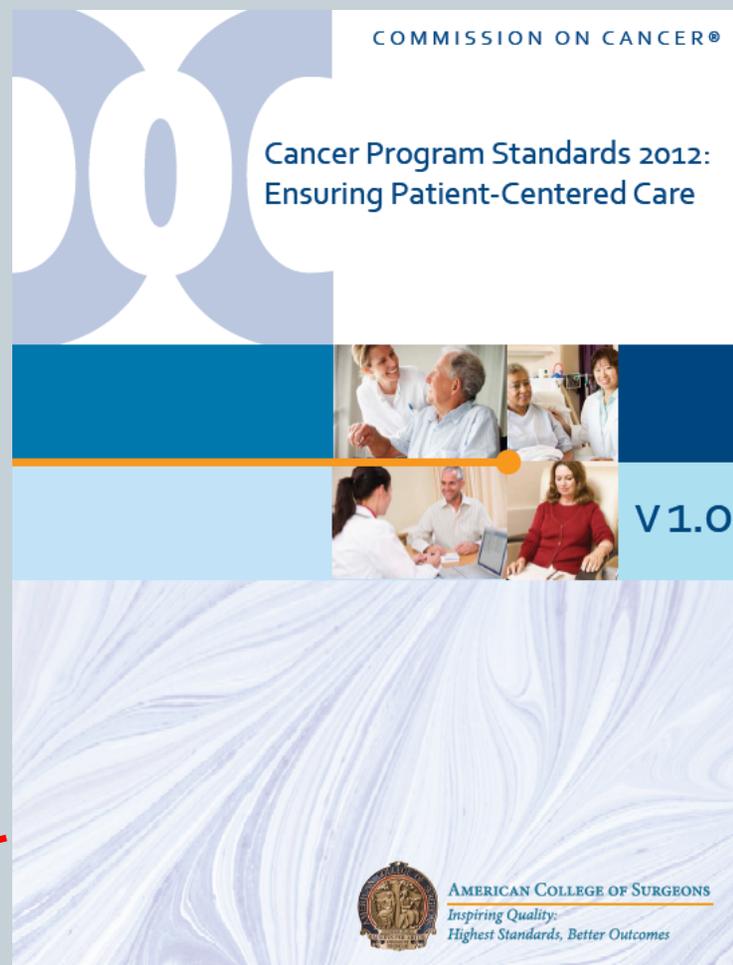
<http://www.facs.org/cancer/coc/programstandards2012.html>

American College of Surgeons Commission on Cancer (Coc) Cancer Program Standards 2012

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 (GCN) or an Advanced Practice Nurse in Genetics (APNG), credentialed through the Genetics Nursing Credentialing Commission (GNCC). Credentialing 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.*



National Comprehensive Cancer Network (NCCN)



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NCCN Guidelines Version 1.2012

Breast and/or Ovarian Cancer Genetic Assessment

[NCCN Guidelines Index](#)
[Genetics Table of Contents](#)
[Discussion](#)

CRITERIA FOR FURTHER GENETIC RISK EVALUATION^a

An affected individual with one or more of the following:

- Early-age-onset breast cancer^b
- Triple negative (ER-, PR-, HER2-) breast cancer
- Two breast cancer primaries^c in a single individual
- Breast cancer at any age, and
 - ▶ ≥ 1 close blood relative^d with breast cancer ≤ 50 y, or
 - ▶ ≥ 1 close blood relative^d with epithelial ovarian^e cancer at any age, or
 - ▶ ≥ 2 close blood relatives^d with breast cancer and/or pancreatic cancer at any age
 - ▶ From a population at increased risk^f
- A combination of breast cancer with one or more of the following: thyroid cancer, sarcoma, adrenocortical carcinoma, endometrial cancer, pancreatic cancer, brain tumors, diffuse gastric cancer,^g dermatologic manifestations^h and/or macrocephaly, or leukemia/lymphoma on the same side of family (especially if early onset)
- Ovarian^e cancer
- Male breast cancer

An unaffected individual with a family history of one or more of the following:^f

- ≥ 2 breast primaries, either in 1 individual or 2 different individuals from the same side of family (maternal or paternal)
- ≥ 1 ovarian^e cancer primary from the same side of family (maternal or paternal)
- First- or second-degree relative with breast cancer ≤ 45 y
- A combination of breast cancer with one or more of the following: thyroid cancer, sarcoma, adrenocortical carcinoma, endometrial cancer, pancreatic cancer, brain tumors, diffuse gastric cancer,^g dermatologic manifestations^h and/or macrocephaly, or leukemia/lymphoma on the same side of family (especially if early onset)
- A known mutation in a breast cancer susceptibility gene within the family
- Male breast cancer

Referral to
cancer genetics
professional
recommendedⁱ

See
[Assessment
\(BR/OV-2\)](#)

^aThe 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.

^bClinically use age ≤ 50 y because studies define early onset as either ≤ 40 or ≤ 50 y.

^cTwo breast primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors either synchronously or asynchronously.

^dClose blood relatives include first-, second-, and third-degree relatives. (See BR/OV-3)

^eFor the purposes of these guidelines, fallopian tube and primary peritoneal cancers are included.

^fFor populations at increased risk, requirements for inclusion may be modified (eg, women of Ashkenazi Jewish descent with breast or ovarian cancer at any age).

^gFor lobular breast cancer with a family history of diffuse gastric cancer, CDH1 gene testing should be considered.

^hFor dermatologic manifestations, see COWD-1.

ⁱGenetic counseling is highly recommended when genetic testing is offered and after results are disclosed. A genetic counselor, medical geneticist, oncologist, surgeon, oncology nurse or other health professional with expertise and experience in cancer genetics should be involved early in counseling patients who potentially meet criteria for an inherited syndrome.

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.

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BR/OV-1

National Comprehensive Cancer Network (NCCN)



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NCCN Guidelines Version 1.2012

Hereditary Breast and/or Ovarian Cancer Syndrome

[NCCN Guidelines Index](#)
[Genetics Table of Contents](#)
[Discussion](#)

HEREDITARY BREAST AND/OR OVARIAN CANCER SYNDROME TESTING CRITERIA^{a,b,c}

- Individual from a family with a known deleterious BRCA1/BRCA2 mutation
- Personal history of breast cancer^d + one or more of the following:
 - ▶ Diagnosed age ≤ 45 y
 - ▶ Diagnosed age ≤ 50 y with ≥ 1 close blood relative^e with breast cancer ≤ 50 y and/or ≥ 1 close blood relative^e with epithelial ovarian^f cancer at any age
 - ▶ Two breast primaries^g when first breast cancer diagnosis occurred ≤ age 50 y
 - ▶ Diagnosed age ≤ 60 y with a triple negative breast cancer
 - ▶ Diagnosed age ≤ 50 y with a limited family history^c
 - ▶ Diagnosed at any age, with ≥ 2 close blood relatives^e with breast and/or epithelial ovarian^f cancer at any age
 - ▶ Diagnosed at any age with ≥ 2 close blood relatives^e with pancreatic cancer at any age
 - ▶ Close male blood relative^e with breast cancer
 - ▶ For an individual of ethnicity associated with higher mutation frequency (eg, Ashkenazi Jewish) no additional family history may be required^h
- Personal history of epithelial ovarian^f cancer
- Personal history of male breast cancer
- Personal history of pancreatic cancer at any age with ≥ 2 close blood relatives^e with breast and/or ovarian^f and/or pancreatic cancer at any age
- Family history only (Testing of unaffected family members should only be considered when no affected family member is available and then the unaffected family member with the highest probability of mutation should be tested. Significant limitations of interpreting test results should be discussed.)
 - ▶ First- or second-degree blood relative meeting any of the above criteria
 - ▶ Third-degree blood relative with breast cancer^d and/or ovarian^f cancer with ≥ 2 close blood relatives^e with breast cancer (at least one with breast cancer ≤ 50 y) and/or ovarian^f cancer

HBOC
criteria
met

→ [See Follow-up
\(HBOC-2\)](#)

HBOC
criteria
not met

→ [See NCCN
Breast Cancer
Screening and
Diagnosis
Guidelines](#)

^a One or more of these criteria is suggestive of hereditary breast/ovarian cancer syndrome that warrants further personalized risk assessment, genetic counseling and management. The maternal and paternal sides should be considered independently. Other malignancies reported in some HBOC families include prostate and melanoma.

^b Patients who have received an allogeneic bone marrow transplant should not have molecular genetic testing via blood or buccal samples due to unreliable test results from contamination by donor DNA. If available, DNA should be extracted from a fibroblast culture. If this source of DNA is not possible, buccal samples can be considered, subject to the risk of donor DNA contamination.

^c Individuals with limited family history, such as fewer than 2 first- or second-degree female relatives or female relatives surviving beyond 45 years in either lineage, may have an underestimated probability of a familial mutation.

^d For the purposes of these guidelines, invasive and ductal carcinoma in situ breast cancers should be included.

^e Close blood relatives include first-, second-, and third-degree relatives. (See BR/OV-3)

^f For the purposes of these guidelines, fallopian tube and primary peritoneal cancers are included. Ovarian/fallopian tube/primary peritoneal cancers are component tumors of hereditary non-polyposis colorectal cancer/ Lynch syndrome; be attentive for clinical evidence of this syndrome. See [NCCN Colorectal Cancer Screening Guidelines](#).

^g Two breast primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors either synchronously or asynchronously.

^h Testing for Ashkenazi Jewish founder-specific mutation(s), should be performed first. Full sequencing may be considered if ancestry also includes non-Ashkenazi Jewish relatives or other HBOC criteria is met. Founder mutations exist in other populations.

Note: All recommendations are category 2A unless otherwise indicated.

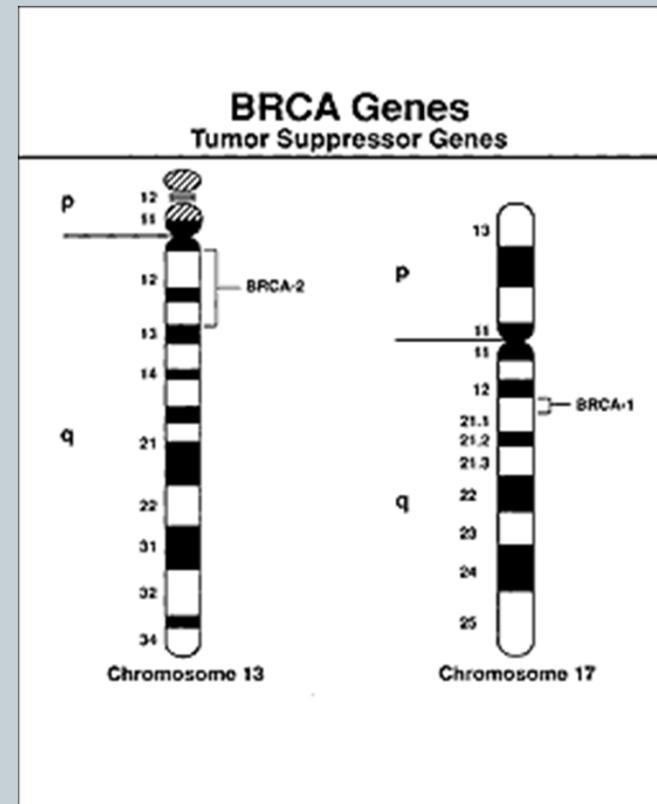
Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

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HBOC-1

Hereditary Breast and/or Ovarian Cancer (HBOC) Syndrome

- Accounts for 5-10% of all breast cancers and 10% of ovarian cancers. And accounts for 20% of breast cancers in women diagnosed under age 45.
- Approximately 1 in 200 people are carriers in the general population.
- Autosomal dominant inheritance – each child/sibling.



Hereditary Breast and/or Ovarian Cancer (HBOC) Syndrome

Cancer	Lifetime Cancer risk	Lifetime Cancer risk	2nd Cancer Risk within 5 yrs	2nd Cancer Risk within 5 yrs
	General Population	BRCA1/2 mutation carrier	General Population	BRCA1/2 mutation carrier
Breast	12%	36-85%	5%	12-20%
Ovary	1.6%	20-45%		
Pancreas		Slightly increased		
Prostate		20% Slightly increased		

** Men with BRCA1 or BRCA2 mutations have a 1.5% to 8% lifetime risk of breast cancer respectively (by age 80)

Breast Cancer Genetics and Saving Lives



- **Women's breast cancer risk is increased to 50-85% (from 12%)**
- **Men's breast cancer risk is increased to 1.5 to 8%**
- **Ovarian cancer risk is increased to 16-50% (from 1%)**
- **Risk of second primary cancer within 10 years following initial breast cancer is as high as 40%**
- **Prophylactic mastectomy may reduce the risk of breast cancer by 90%**
- **Prophylactic oophorectomy reduces the risk of ovarian cancer by 90-95% (peritoneal carcinomatosis may still occur); and reduces breast cancer risk by 50%.**

Michigan Cancer Genomics 2008-2012

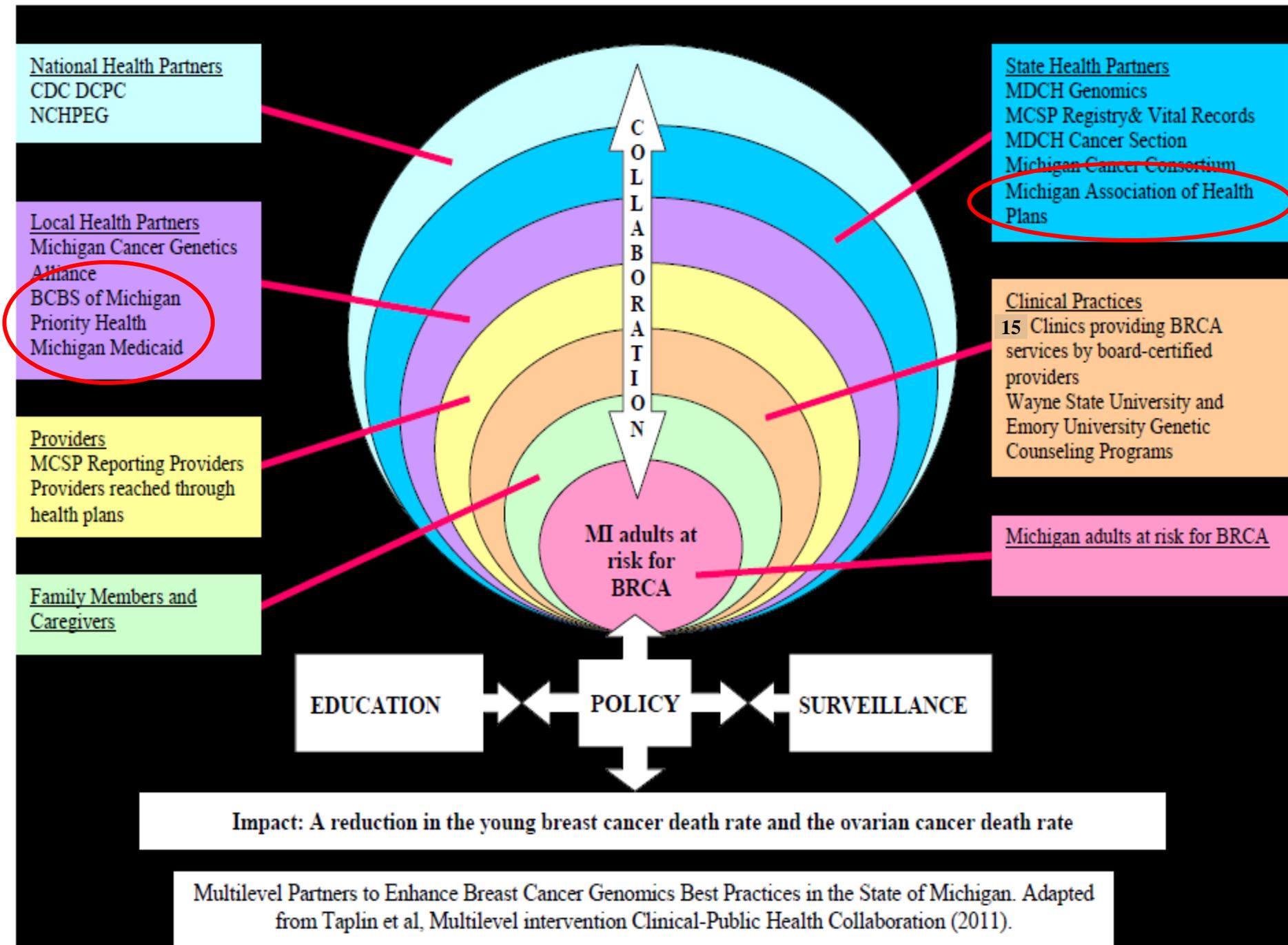


- **Understand current status of Michigan health insurance policies for BRCA1/2 testing with respect to USPSTF guidelines**
 - 16 out of 25 health plans with written policies for BRCA coverage as of 2012
 - 14 in alignment with USPSTF recommendations as of 2012
 - Congratulations to Humana and Health Plus of Michigan for 2012
- **Increase the number of health plans that have policies consistent with USPSTF recommendations**
 - Increased the number from 4 to 14 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**

Michigan Cancer Genomics 2011-2014



- Investigate insurance gaps for *BRCA* Clinical Services among 25 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
- NCCN recommends the following services (when appropriate) for *BRCA* positive patients: breast MRI, mammogram, prophylactic oophorectomy, prophylactic mastectomy, breast reconstruction following mastectomy



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

Michigan Department of Community Health 201 Townsend St. P.O. Box 30195 Lansing, MI 48909 1-866-852-1247 (toll-free)

MDCH
Risk Analysis, Governance
Chief Health Officer

Sample Health Plan

Member Report on BRCA Genetic Counseling & Testing

MDCH Cancer Genetics Database (October 2007-March 2011)

Hereditary Breast and Ovarian Cancer (HBOC) syndrome, caused by a mutation in the BRCA1 or BRCA2 gene, accounts for approximately 5-10% of all breast cancer diagnoses and is associated with increased risk for breast and ovarian cancer. Displayed in the table below are the numbers of patients covered by your health plan who were seen by a board certified genetic counselor/physician from October 2007 to March 2011 for assessment of HBOC and possible BRCA genetic testing. Data on over 5,800 patients includes those with a personal history of cancer and those with a significant family history of cancer as determined by the USPSTF Grade B recommendation statement. In addition, we have outlined the total number of SAMPLE HEALTH PLAN patients who received BRCA testing during this timeframe and the total number of patients not tested reporting "inadequate insurance coverage" as the primary reason not to test.

For questions regarding this report, please contact the MDCH Cancer Genomics Team at 1-866-852-1247 or email genetics@michigan.gov.

	Health Plan	Michigan Clinical Network Total
	Number (%)	Number (%)
Patients counseled	###	###
With personal history of breast/ovarian cancer	### (%)	### (%)
USPSTF family history (no personal history)	### (%)	### (%)
Patients tested after counseling	###	###
With personal history of breast/ovarian cancer	### (%)	### (%)
USPSTF family history (no personal history)	### (%)	### (%)
Patients not testing due to inadequate insurance	###	###

These data include genetic counseling visits from October 1, 2007 – March 31, 2011 as reported to MDCH through a statewide network of board-certified genetics professionals. Special thanks to the following institutions whose de-identified patient information was included in these analyses: Beaumont Health System Cancer Genetics Program, Henry Ford Health System, InfomedDNA, Karmanos Cancer Institute Genetics Service, Michigan State University Division of Clinical Genetics, Oakwood Healthcare System's Genetic Risk Assessment for Cancer Clinic, Providence Hospital Medical Genetics, Spectrum Health Cancer Genetics Program, University of Michigan Cancer Genetics Clinic, and University of Michigan Breast and Ovarian Cancer Risk and Evaluation Program. Without the commitment and effort of these institutions, this work would not be possible.

* Phone counseling service providing data on patients residing in Michigan only

BREAST CANCER GENOMICS BEST PRACTICES

for Michigan Health Plan Partners



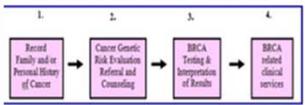
Michigan Department of Community Health
MDCH
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Chief Health Officer

SAMPLE HEALTH PLAN BRCA Policy Dashboard



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

Figure 1. Spectrum of Cancer Genetic Services



✔ = policy is consistent with project standards
✘ = policy is not consistent with project standards
U = policy is unavailable/unknown if consistent with project standards

Your health plan has written policies related to BRCA that...

1. Include coverage for the following individuals:	
• Adults with a personal history of breast and/or ovarian cancer. ¹	✔
• Adults with a family history of breast and/or ovarian cancer. ^{1,2}	✘
2. require or strongly recommend genetic counseling prior to BRCA genetic testing.	✔
3. encourage providers to obtain written informed consent (as is required by Michigan law) prior to ordering BRCA genetic testing.	✔
4. cover BRCA-related clinical services for positive patients (policies would contain coverage information for the following services) ¹	
• Mammography	✔
• MRI of the Breast	✔
• Prophylactic Mastectomy	U
• Prophylactic Oophorectomy	U
• Breast Reconstruction and Prostheses	U
• Genetic Testing for Susceptibility to Breast and Ovarian Cancer	U
• Genetic Counseling	U

1. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology "Genetic/Familial Risk Assessment: Breast and Ovarian" version 1.2012, accessed July 2012 from www.nccn.org; 2. U.S. Preventive Services Task Force. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: recommendation statement. Ann Intern Med 2005; 143: 355-361.



Clinical *BRCA* Testing in Michigan



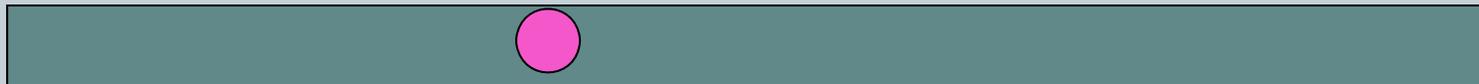
- Carried out by only one lab, Myriad Genetics Inc.
- Four levels of testing:
 - Single site testing for a family mutation
 - Multisite 3 testing for the three common founder mutations in the Ashkenazi Jewish population
 - Comprehensive testing of both *BRCA1* and *BRCA2*
 - *BRCAAnalysis*® Rearrangement Test (BART) testing both *BRCA1* and *BRCA2* for large scale rearrangements

Single Site BRCA*Analysis*[®]



For Individuals with a Known Familial Mutation in *BRCA1* or *BRCA2*

\$475.00



- Performed when there is a known mutation in the family
- Since Single Site BRCA*Analysis*[®] requires knowledge of the specific mutation in the family, it is important for patients to notify family members about their mutation
- It is also important for providers to ask for this information prior to ordering *BRCA* testing
- Knowing if there is a specific mutation in the family prior to testing will result in a more informative test result for family members and lower test costs.

Multisite 3 BRACAnalysis[®]



**For Individuals of Ashkenazi Jewish
Ancestry
\$575.00**

BRCA1



BRCA2



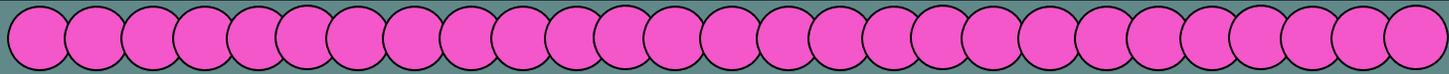
Comprehensive BRCA Analysis[®]

\$3,340.00

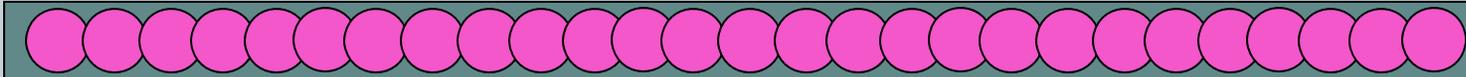


Sequencing

BRCA1



BRCA2



5-Site Rearrangement

BRCA1

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
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1. Dutch Ancestry: deletions in exon 13 and exon 22
2. European (primarily British) ancestry: duplication of exon 13
3. European ancestry: deletion of exons 8 and 9
4. Deletion of exons 14-20

BRCAAnalysis[®] Rearrangement Test (BART)

\$700.00



BRCA1

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
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BRCA2

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
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BART analysis is not necessary for every case and should be considered in very specific clinical situations

All coding exons are examined for duplications and deletions.*

These deletions or duplications are present in approximately 1% of individuals who undergo *BRCA1/2* testing.

*Exon 1 and 4 in BRCA1 are non-coding; exon 1 in BRCA2 is non-coding

Overview of *BRCA* Testing in Michigan



Type of BRCA Test	Clinical Indication	Cost	Description of Test	Number of tests per year ordered in Michigan since 2008
Comprehensive BRCAAnalysis®	Patient with significant family and/or personal history (1, 2)	\$3,340	Full sequencing of BRCA1/2 and five specific large genomic rearrangements analyzed	2,442 in 2008; 4,205 in 2011
Single Site BRCAAnalysis®	Known deleterious mutation in the family	~\$475	Specific single known mutation analyzed	388-434 per year
Multisite3 BRCAAnalysis®	Patient of Ashkenazi Jewish with family and/or personal history of breast and/or ovarian cancer	~\$575	Three specific mutations examined (accounts for >90% of BRCA mutations in Ashkenazi Jewish population)	199-235 per year
BART	Patient with no known mutation detected on Comprehensive BRCAAnalysis with significant family and/or personal history (2,3)	~\$700	Large genomic rearrangements of BRCA1/2	175 in 2008; 824 in 2011

Comparing Data



- From 2008-2011, genetics providers ordered approximately 30% of Comprehensive BRCAAnalysis tests each year
 - In 2008, over 95% of all BART tests were ordered by genetics providers
 - In 2011, only 61.7% of all BART tests were ordered by genetics providers
-
- In 2011 more 50% of both Single Site BRCAAnalysis® and Multisite3 BRCAAnalysis® tests were ordered by genetics providers.

Comparing Data



- *BRCA* testing is increasing among genetics and other providers in Michigan.
- The growth is primarily due to increases in Comprehensive *BRCAAnalysis*® and BART testing.
- Single Site *BRCAAnalysis*® and Multisite3 *BRCAAnalysis*® constitute a diminishing proportion of all tests.
- These cost-saving tests require a more sophisticated knowledge of *BRCA1/2* genetics and are disproportionately ordered by genetics providers.



Genetic Counseling



- **Determination of the most appropriate test for each clinical scenario, which may mean testing an alternative family member or not testing at all**
- **Collaboration with other providers in making management decisions regarding earlier screening and detection, alternating breast MRI with mammogram, prophylactic surgeries, chemoprevention, etc**
- **Summarizes appropriate medical management that can lead to earlier diagnoses, perhaps stage I and II rather than III and IV; or possibly prevent cancer all together with prophylactic oophorectomy or mastectomy**
- **With the goal of preventing cancer or diagnosing it at an earlier stage which can possibly reduce the cost of treatment or end of life hospice care and lead to healthier members overall**

Current Genomics Health Environment



Insufficient access to genetics experts and genetic counseling

- *Payers, providers and patients don't know what they don't know.*

Unrealistic public expectations

- *Perceptions of genetic testing exceed realities of science, policy, expense and clinical utility.*

Laboratory influence on test ordering

- *Have provider education initiatives and marketing campaigns*

Policies in place, but proactive approach needed for full benefit

- *Providers are aware of genetic policies, but often don't change practice. Providers must be engaged to realize full impact of genetic policy.*

Insufficient access to genetics experts and genetic counseling

- *Payers, providers and patients don't know what they don't know.*



- Michigan Cancer Genetics Alliance (MCGA) maintains a directory of board certified genetics professionals, including a telephone counseling service (www.migrc.org)
- Michigan Association of Health Plans (MAHP) has an online, CME module for providers that's available now!
- American College of Surgeons Commission on Cancer (CoC) has accreditation standards for cancer centers which require that genetic counseling be provided onsite or through referral
- MCGA maintains a patient tutorial, appropriate for your members, about inherited breast and ovarian cancer and the genetic counseling process

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MI Genetics Resource Center

Patients & Families Providers Teachers & Students Public Health Directories Resources New!

Michigan Cancer Genetics Alliance

MCGA
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MCGA Leadership
MCGA Directory
MCGA Resources

Home → Providers → MCGA Home

Michigan Cancer Genetics Alliance

News:

Check out our [Directory of Cancer Genetic Service Providers in Michigan!](#)

The MCGA webpage has recently changed. If you need assistance in locating materials or resources, please contact genetics@michigan.gov.

The Michigan Cancer Genetics Alliance (MCGA) is a collaborative network of individuals (including genetics professionals, patient advocates, oncology experts, health plan employees, state and local public health workers, and others) with an interest in cancer genomics. We come together on a biannual basis to discuss the latest issues in cancer genetics and clinical care, research, public health initiatives, genetic counseling and testing, patient needs, advocacy and support availability, and provider education in the state of Michigan. Participation in MCGA is voluntary and there are no fees associated with being a member.

Policies in place, but proactive approach needed for full benefit

- Providers are aware of genetic policies, but often don't change practice. Providers must be engaged to realize full impact of genetic policy.



- NCHPEG Core Competencies → Each health care professional should at a minimum be able to: Appreciate limitations of genomics expertise; Understand social and psychological implications of genetic services; Know how and when to make a referral to a genetics professional (www.nchpeg.org)
- Michigan Informed Consent Law
- Previous MDCH Chart Reviews → showed that most charts (82-92%) show documentation of family history; however greater than 98% of charts are missing age at onset of the affected family member
- Follow up focus groups with providers →
 - Do not believe they see patients with high-risk cancer family history
 - Do not feel confident in ability to identify high-risk family history
 - Uncertain where to refer

THE CORE COMPETENCIES

Note: Throughout this document, the term "clients" includes individuals and their sociological and biological families.

KNOWLEDGE	SKILLS
<p>All health professionals should understand:</p> <p>1.1 basic human genetics/genomics</p> <p>1.2 the basic patterns of biological inheritance and recessive/dominant traits within families and within populations</p> <p>1.3 how identification of disease-associated genetic variants facilitates development of prevention, diagnosis, and treatment options</p> <p>1.4 the importance of family history (includes three generations in assessing predisposition to disease)</p> <p>1.5 the role of genetic factors in maintaining health and preventing disease</p> <p>1.6 the difference between clinical diagnosis of disease and identification of genetic predisposition to disease (genetic variation is an etiology associated with disease manifestation)</p> <p>1.7 the role of behavioral, social, and environmental factors (lifestyle, socioeconomic factors, pollution, etc.) to modify or influence genetic risk in the manifestation of disease</p> <p>1.8 the influence of abnormalities and variants in the production and diagnosis of genetic disease</p> <p>1.9 the influence of culture, values, related health beliefs, and economics in the client's ability to use genetic information and services</p> <p>1.10 the potential physical and/or psychological benefits, limitations, and risks of genetic information for individuals, family members, and communities</p> <p>1.11 the range of genetic approaches to treatment of disease (prevention, pharmacogenomics/precision of drugs to match individual genetic profiles, gene-based drugs, gene therapy)</p> <p>1.12 the resources available to assist clients seeking genetic information or services, including the types of genetic professionals available and their disease specializations</p> <p>1.13 the components of the genetic counseling process and the indications for referrals to genetic specialists</p> <p>1.14 the indications for genetic testing and/or gene-based interventions</p> <p>1.15 the ethical, legal and social issues related to genetic testing and counseling of genetic information (e.g., privacy, the potential for genetic discrimination in health insurance and employment)</p> <p>1.16 the history of misuse of human genetic information (eugenics)</p> <p>1.17 one or more professional roles in the referral to genetic services, or prevention, diagnosis, and quality review of genetic services</p>	<p>All health professionals should be able to:</p> <p>2.1 gather genetic family history information, including an appropriate comprehensive three-generational family history</p> <p>2.2 identify clients who would benefit from genetic services</p> <p>2.3 explain basic concepts of probability and disease susceptibility and the influence of genetic factors in maintenance of health and development of disease and prevention from and active appropriate genetic testing and gene therapy options</p> <p>2.4 assess genetic risk and advise appropriate genetic testing and gene therapy options</p> <p>2.5 explain the role of genetic factors in maintaining health and preventing disease</p> <p>2.6 assess client's social, cultural, and economic factors to determine if genetic information is relevant to their clients' lives</p> <p>2.7 participate in professional and public education about genetics</p> <p>2.8 identify the components of the genetic counseling process and the role of genetic professionals in the process. Genetic health professionals should be able to facilitate the genetic counseling process and prepare clients and families for what to expect, communicate relevant information to the genetic team, and follow up with the client after genetic services have been provided. For those health professionals who choose a genetic genetic counseling service to their clients, all components of the process are delineated in 2.8.2.7 through 2.8.2.17.</p> <p>2.9 educate clients about availability of genetic testing and/or services for conditions such as hypercholesterolemia</p> <p>2.10 provide appropriate information about the potential risks, benefits, and limitations of genetic testing</p> <p>2.11 provide clients with an appropriate informed consent process to facilitate decision making related to genetic testing</p> <p>2.12 provide and encourage use of, culturally appropriate, and disease-specific genetic information to clients and families</p> <p>2.13 identify clients who are at high risk of associated effects from genetic testing</p> <p>2.14 explain potential physical and psychological benefits and limitations of gene-based therapies for clients</p> <p>2.15 identify potential physical and psychological benefits and limitations of gene-based therapies for clients</p> <p>2.16 identify potential physical and psychological risks of using health insurance for payment of genetic services, potential risks of discrimination</p> <p>2.17 understand privacy and confidentiality of genetic information of clients in the genetic counseling process</p> <p>2.18 inform clients of potential limitations to maintaining privacy and confidentiality of genetic information</p>



**So how are providers getting their
information?**

Sources of Information



- State and National Professional Groups
- Professional Meetings and CME Courses
- Internet Searching
- Professional newsletters and e-blasts
- Colleagues
- Presentations from MDCH Cancer Genomics Educator
- Presentations from local genetics services providers
- Myriad Genetics, Inc.
- Others?

MDCH will be disseminating a provider survey through a major Michigan health plan to determine provider knowledge and practices surrounding genetics, as well as where they turn to for information related to genetics. If other health plans would like to disseminate the survey as well, please let us know.



A Look at Laboratory Educational Practices

Conclusion?



- **No information provided about when to order specific test types**
- **Multisite3 testing is not mentioned at all**
- **Single site testing is only discussed in the context of interpreting test results**
- **NO mention of genetic counseling or referral to a genetics specialist**

So what's the bottom line for Michigan?



High testing volume

- There are more than 1200 genetic tests clinically available
- 5,000,000 gene-based tests ordered in 2009
- Make up approximately 1/3 of diagnostic tests

High cost of testing

- In 2008 - \$8,156,280 on comprehensive BRCA, \$184,300 on single site, \$144,425 on multisite, and \$122,500 on BART
- In 2011 - \$14,044,700 on comprehensive and \$576,800 on BART

Inappropriate testing

- Clinical utility varies
- Inappropriate test selection by clinicians
- Underutilization of appropriate testing

Considerations



Payer Goals:

- What's in the best interest of the plan?
- What's best for the health of the members?
- How do we reduce, or at least control, overall costs?

MDCH Goals:

- What's best for the health of Michigan residents?
- How do we reduce, or at least control, overall costs?
- What can be done by payers to ensure appropriate genetic testing?

Reminders



- We are still encouraging plans to have a written policy for *BRCA1/2* genetic testing that includes:
 - Family history criteria consistent with the USPSTF recommendation
 - Strongly recommending or requiring genetic counseling
- Health Plus of Michigan and Humana are being honored with 2012 awards
- We are also encouraging plans to have written policies for *BRCA*-related clinical services for positive patients (i.e. mammogram, breast MRI, prophylactic surgeries, etc.)
- Blue Cross Blue Shield of Michigan, Blue Care Network, and Cigna are being honored with 2012 awards
- Contact Jenna McLosky – mcloskyj@michigan.gov or 517-335-8826 for your specialized health plan packet