Local Cancer Registrars & Cancer Genomics Best Practices

September 12, 2014
MCSP Educational Workshop

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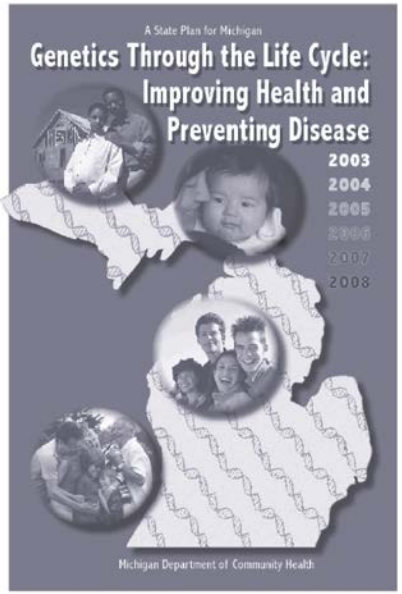
Learning Objectives

- Describe importance of local cancer registrars to cancer genomics best practices surveillance and education
- Identify two hereditary cancer syndromes that are important for public health surveillance
- Provide at least two examples of activities to promote cancer genomics best practices

Michigan Genetics Plan: A Vision for the Role of Genetics in Public Health

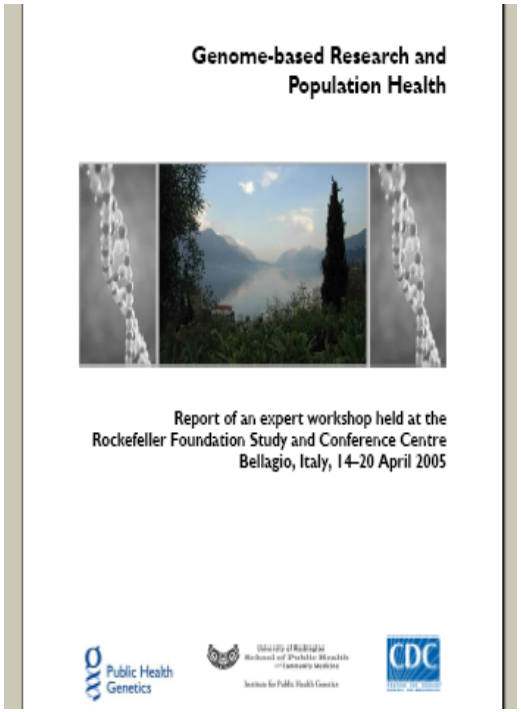


Improved health outcomes and an enhanced quality of life for the people of Michigan through appropriate use of genetic information, technology, and services

www.michigan.gov/genomics

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



Hereditary Breast and Ovarian Cancer (HBOC)

- Accounts for 5-10% of all breast cancers.
- Approximately 1/200-1/500 are carriers in the general population; 1/40 in Ashkenazi Jewish population
- Caused by mutations in *BRCA1/BRCA2* genes.
- Autosomal dominant inheritance – 50% risk to each child/sibling/parent
- For those women with a deleterious mutation in BRCA1 or BRCA2, 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 mutation in BRCA1 or BRCA2 breast cancer risk increased to 6%
- Management by risk-reducing surgery, enhanced screening regimen and chemoprevention

http://forward.com/articles/185563/angelina-jolies-jewish-gene-breast-cancer-surgery/

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

Questions to Consider:

- Was it appropriate to offer Angelina Jolie BRCA testing? Was there another more effective genetic testing strategy that could have been used (which would have utilized a local cancer registrar)?
- Did Angelina Jolie make the ‘right’ decision by having a prophylactic mastectomy? What other options did Angelina have?
- What are the risks of her children inheriting BRCA mutation? What are their options?
- What was the impact of her public announcement (May 14, 2013)?

June 13, 2013

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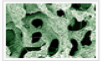
Think Bone Health in Cancer Patients: IOF Position Paper

VTEs With Ch 'Much Higher World Than ir

Medscape Medical News > Oncology

Myriad *BRCA* Patents Ruled Invalid by US Supreme Court

Roxanne Nelson
June 13, 2013

36 comments | Print

EDITORS' RECOMMENDATIONS

Supreme Court to Hear Challenge to BRCA Gene Patents Again

Cancer Gene Patents Upheld by Court -- At Least for Now

Breast Cancer News & Perspectives

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Mammography in Breast Cancer

In an highly anticipated decision, the Supreme Court has effectively invalidated the patents held by Myriad Genetics for the *BRCA1* and *BRCA2* genes.

However, the ruling is not all bad news for Myriad.

The Court unanimously ruled that although naturally isolated DNA is not patentable, synthetically created exon-only strands of nucleotides — complementary (c)DNA — is patentable.

In essence, the Court ruled that 5 of Myriad's claims covering isolated DNA are not eligible for patents. But according to Myriad, the company holds more than "500 valid and enforceable claims in 24 different patents conferring strong patent protection for its BRACAnalysis test."

The ruling was written by Justice Thomas, who was joined by Chief Justice Roberts and Justices Kennedy, Ginsberg, Breyer, Alito, Sotomayor, and Kagan; Justice Scalia concurred in part. The Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring."

http://www.medscape.com/viewarticle/805756

September 3, 2014

Medscape Medical News from the
2014 Breast Cancer Symposium (BCS)

Medscape Medical News > Conference News

'Angelina Jolie Effect': BRCA Testing Doubles

Zosia Chustecka
September 03, 2014

5 comments Print

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DRUG & REFERENCE INFORMATION

Mammography in Breast Cancer

Male Breast Cancer Imaging

Breast Cancer and HER2

Twice as many women were tested for *BRCA1/2* mutations in a North American clinic in the 6 months after the revelation by actress Angelina Jolie that she had undergone a prophylactic mastectomy after finding out that she was a carrier.

Importantly, the increase in genetic testing was appropriate, as the proportion of women found to be carriers remained constant, the researchers note.

The finding illustrates "the profound impact that prominent figures like Jolie can have on public awareness of health issues," commented lead author Jacques Raphael, MD, clinical fellow at Sunnybrook Odette Cancer Center in Toronto.

He was speaking at a presscast held by the American Society of Clinical Oncology ahead of the 2014 Breast Cancer Symposium in

http://www.medscape.com/viewarticle/831010

Three-Tier Classification of Recommendations on Genomic Applications

- **Tier 1: Ready for implementation**
  - Demonstrated analytic validity, clinical validity, clinical utility and evidence-based recommendations
  - Health professionals: encourage use; can save lives!
    - Examples: ***BRCA (Grade B),*** **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; no evidence-based guidelines recommending clinical use
  - Health professionals: 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
  - Health professionals: discourage use; may be considered for research in select instances; reduce potential harms and save unnecessary healthcare costs
    - Examples: ***BRCA (Grade D),*** Population screening for hereditary hemochromatosis, personal genomic tests sold directly to consumers

Khoury MJ et al. Am J Prev Med 2011;
Bowen MS et al Public Health Genomics 2012

Three-Tier Classification

Green

- FDA label requires use of test to inform choice or dose of a drug
- CMS covers testing
- Clinical practice guidelines based on systematic review supports testing

Yellow

- FDA label mentiones biomarkers*
- CMS coverage with evidence development
- Clinical practice guideline, not based on systematic review, supports use of test
- Clinical practice guideline finds insufficient evidence but does not discourage use of test
- Systematic review, without clinical practice guideline, supports use of test
- Systematic review finds insufficient evidence but does not discourage use of test
- Clincial practice guideline recommends dosage adjustment, but does not address testing

Red

- FDA label cautions against use
- CMS decision against coverage
- Clincial practice guideline recommends against use of test
- Clinical practice guideline finds insufficient evidence and discourages use of test
- Systematic review recommends against use
- Systematic review finds insufficient evidence and discourages use
- Evidence available only from published studies without systematic reviews, clinical practice guidelines, FDA label or CMS labels coverage decision

*Can be reassigned to Green of Red of one or more conditions in these categories apply

http://www.cdc.gov/genomics/gtesting/tier.htm

Tier 1/Green category: represents genomic and family health history applications which have a base of synthesized evidence supporting implementation into practice.

Gene, Gene/Drug Test, or Family History	Disorder/Indication	Use*	Synthesized Evidence Sources
Cancer—Breast/Ovarian			
family history of breast/ovarian or other types of BRCA-related cancer	hereditary breast and ovarian cancer in women	risk prediction for referral for BRCA genetic counseling	USPSTF (2013) NCCN Guideline [PDF 836.97 KB] (2013) NCCN Task Force (2011)
first-degree family history of breast cancer	chemoprevention of breast cancer	risk prediction	USPSTF (2013)
family history of known breast/ovarian cancer with deleterious BRCA mutation	hereditary breast and ovarian cancer in women	risk prediction; referral to counseling for BRCA genetic testing	USPSTF (2013)
HER2/trastuzumab	invasive breast cancer	PGx	NICE [PDF 2.00 MB] (2009) ASCO (2007) FDA-Device (2013) FDA-PGx Drug Information (2013)
HER2/pertuzumab	invasive breast cancer	PGx	FDA-Device (2013) FDA-PGx Drug Information (2013)
HER2/ado-trastuzumab emtansine	metastatic breast cancer	PGx	FDA-PGx Drug Information (2013)
HER2/everolimus	advanced HR+ HER2- breast cancer	PGx	FDA-PGx Drug Information (2013)
HER2/lapatinib (in combination with capecitabine or letrozole)	advanced or metastatic breast cancer	PGx	FDA-PGx Drug Information (2013)
HER2	invasive breast cancer	PGx	ASCO/CAP (2007) NICE [PDF 178.88 KB] (2009)
ER /fulvestrant	metastatic breast cancer	PGx	FDA-PGx Drug Information (2012)
ER/exemestane	ER+ early breast cancer	PGx	FDA-PGx Drug Information (2013) NICE [PDF 178.88 KB] (2009)
ER/anastrozole or letrozole	ER+ early invasive breast cancer	PGx	NICE [PDF 178.88 KB] (2009) FDA-PGx Drug Information [anastrozole] (2013) FDA-PGx Drug Information [letrozole] (2011)
ER and PgR	invasive breast cancer, breast cancer recurrences	PGx	ASCO/CAP (2010) NCCN Task Force (2011)
Oncotype DX® adjuvant chemotherapy	ER+/LN-/HER2- breast cancer, intermediate risk of recurrence	prognostic; guiding decision-making: adjuvant chemotherapy	NICE (2013) NCCN Task Force (2011)
Cancer—Colorectal			
Testing for Lynch syndrome	newly diagnosed colorectal cancer	screening, cascade testing of relatives	EGAPP (2009)
Testing for Lynch syndrome	known Lynch syndrome in family	diagnostic, screening	EGAPP (2009) NCCN: Genetic/Familial High Risk Assessment - Colorectal (2014)
KRAS/cetuximab, panitumumab	metastatic colorectal cancer	PGx	EGAPP [PDF 456.16 KB] (2013) NCCN (2011) ASCO (2009)

Carcinoembryonic antigen-related cell adhesion molecule 5 (CEACAM5 or CEA)	invasive colorectal cancer	prognostic	ASCO/CAP (2006) NCCN [PDF 1.27 MB] (2013) NCCN Task Force (2011)
Cancer—Gastric			
HER2/trastuzumab	gastric or gastroesophageal junction adenocarcinoma	PGx	FDA-Device (2013) FDA-PGx Drug Information (2013)
c-Kit protein (CD 117)/imatinib	gastrointestinal stromal tumors	PGx	FDA-Device (2013) FDA-PGx Drug Information (2013)
Cancer—Leukemia/lymphoma			
Philadelphia chromosome, T315I mutation/dasatinib	chronic myeloid leukemia, acute lymphoblastic leukemia	PGx; diagnostic	FDA-PGx Drug Information (2013)
Philadelphia chromosome/imatinib	chronic myeloid leukemia, acute lymphoblastic leukemia	PGx; diagnostic	FDA-PGx Drug Information (2013)
Philadelphia chromosome/bosutinib	chronic myelogenous leukemia	PGx; diagnostic	FDA-PGx Drug Information (2013)
Philadelphia chromosome/nilotinib	chronic myeloid leukemia	PGx; diagnostic	FDA-PGx Drug Information (2013)
PML/RARα/tretinoin	acute promyelocytic leukemia	PGx	FDA-PGx Drug Information (2004)
PML/RARα/arsenic trioxide	acute promyelocytic leukemia	PGx	FDA-PGx Drug Information (2010)
PDGFRB/imatinib	myelodysplastic/ myeloproliferative diseases	PGx	FDA-PGx Drug Information (2013)
CD25/denileukin diftitox	persistent or recurrent cutaneous T-cell lymphoma	PGx	FDA-PGx Drug Information (2011)
CD20/tositumomab	Non-Hodgkin's lymphoma	PGx	FDA-PGx Drug Information (2012) Alberta Health Services [PDF 792.34 KB] (2013)

G6PD/rasburicase	leukemia, lymphoma, solid tumor malignancies	PGx, pretreatment screening in patients at higher risk for G6PD deficiency (e.g., African or Mediterranean ancestry)	FDA-PGx Drug Information (2009) CPIC (2014)
Chromosome 5q deletion/lenalidomide	transfusion-dependent anemia due to low-or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q	PGx	FDA-PGx Drug Information (2013)
Cancer—Lung			
EGFR (exon 19 deletions and exon 21 (L858R) substitution mutations)/ afatinib	metastatic non-small -cell lung cancer	PGx	FDA-Device (2013) FDA-PGx Drug Information (2013)
EGFR (exon 19 deletions and exon 21 (L858R) substitution mutations) /erlotinib	locally advanced or metastatic non-small -cell lung cancer	PGx	NICE [PDF 189.11 KB] (2012) NCCN Task Force (2011) FDA-Device (2013) FDA-PGx Drug Information (2013)
ALK gene rearrangement/crizotinib	non-small cell lung cancer	PGx	FDA-Device (2013) FDA-PGx Drug Information (2013) NCCN Task Force (2011) NCCN Guideline [PDF 1.61 MB] (2013)
Cancer—Melanoma			
BRAF V600E/K /trametinib	unresectable or metastatic melanoma	PGx	FDA-PGx Drug Information (2013) FDA-Device (2013)
BRAF V600E/dabrafenib	unresectable or metastatic melanoma	PGx	FDA-PGx Drug Information (2013) FDA-Device (2013)

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CRITERIA FOR FURTHER GENETIC RISK EVALUATION[a]

An affected individual with one or more of the following:

- A known mutation in a breast cancer susceptibility gene within the family
- 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]
- ≥1 family member on same side of family with a combination of breast cancer and ≥1 of the following (especially if early onset): pancreatic cancer, prostate cancer (Gleason score ≥7), sarcoma, adrenocortical carcinoma, brain tumors, endometrial cancer, leukemia/lymphoma; thyroid cancer, dermatologic manifestations[g,h] and/or macrocephaly, hamartomatous polyps of GI tract;[h] diffuse gastric cancer[i]
- Ovarian[e] cancer
- Male breast cancer

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

- A known mutation in a breast cancer susceptibility gene within the family
- ≥2 breast primaries in single individual[d]
- ≥2 individuals with breast primaries on the same side of family[d]
- ≥1 ovarian[e] cancer primary from the same side of family
- First- or second-degree relative with breast cancer ≤45 y
- ≥1 family member on same side of family with a combination of breast cancer and ≥1 of the following (especially if early onset): pancreatic cancer, prostate cancer (Gleason score ≥7), sarcoma, adrenocortical carcinoma, brain tumors, endometrial cancer, leukemia/lymphoma; thyroid cancer, dermatologic manifestations[g,h] and/or macrocephaly, hamartomatous polyps of GI tract;[h] diffuse gastric cancer[i]
- Male breast cancer

→ Referral to cancer genetics professional recommended[j] → See Assessment (BR/OV-2)

[a] The 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.

[b] Clinically use age ≤50 y because studies define early-onset as either ≤40 or ≤50 y.

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

[d] Close blood relatives include first-, second-, and third-degree relatives. (See BR/OV-3)

[e] 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.

[f] For populations at increased risk, requirements for inclusion may be modified (eg, women of Ashkenazi Jewish descent with breast or ovarian or pancreatic cancer at any age).

[g] For dermatologic manifestations, see COWD-1.

[h] For hamartomatous colon polyps in conjunction with breast cancer and hyperpigmented macules of the lips and oral mucosa, STK11 testing should be considered. See NCCN Guidelines for Genetic/Familial High-Risk Assessment: Colorectal- Peutz-Jeghers syndrome. Melanoma has been reported in some HBOC families.

[i] For lobular breast cancer with a family history of diffuse gastric cancer, *CDH1* gene testing should be considered.

[j] Genetic 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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Evaluation of Genomic Applications in Practice and Prevention (EGAPP)

- Launched by CDC in 2004
- Aims: Establish systematic evidence-based process for assessing genetic tests and genetic technology in transition from research to clinical and public health practice
- Process:
  - Develop process for evaluation
  - Independent multidisciplinary workgroup of non-federal experts to develop methods, make recommendations
  - Steering Committee of federal agencies
  - Stakeholder Group for consultation, evaluation

http://egappreviews.org/

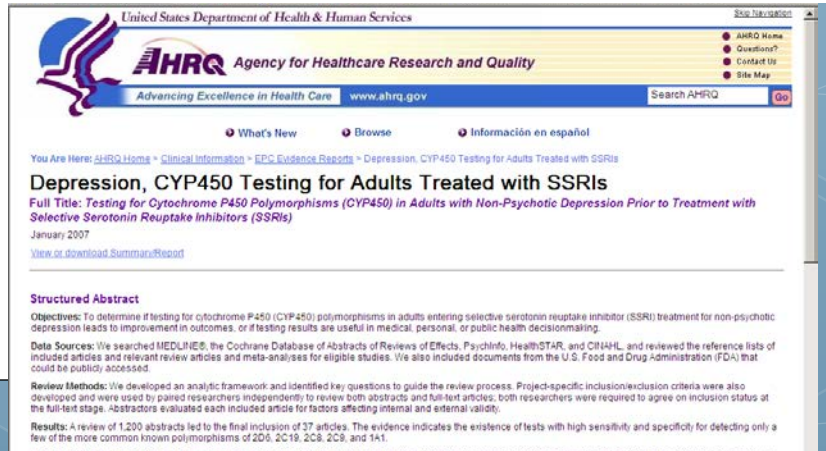
Recommendations from the EGAPP Working Group: genetic testing strategies in newly diagnosed individuals with colorectal cancer aimed at reducing morbidity and mortality from Lynch syndrome in relatives

*Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group**

EGAPP Recommendation Statement

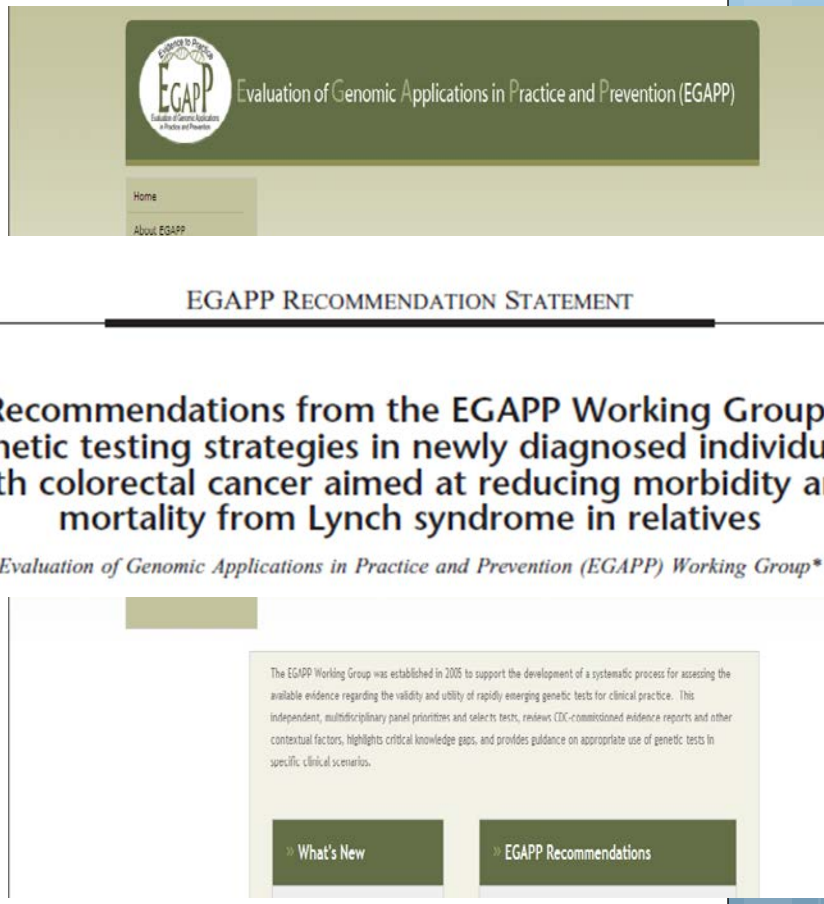
Recommendations from the EGAPP Working Group: can tumor gene expression profiling improve outcomes in patients with breast cancer?

*Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group**



EGAPP Recommendation on Genetic Testing for Lynch Syndrome

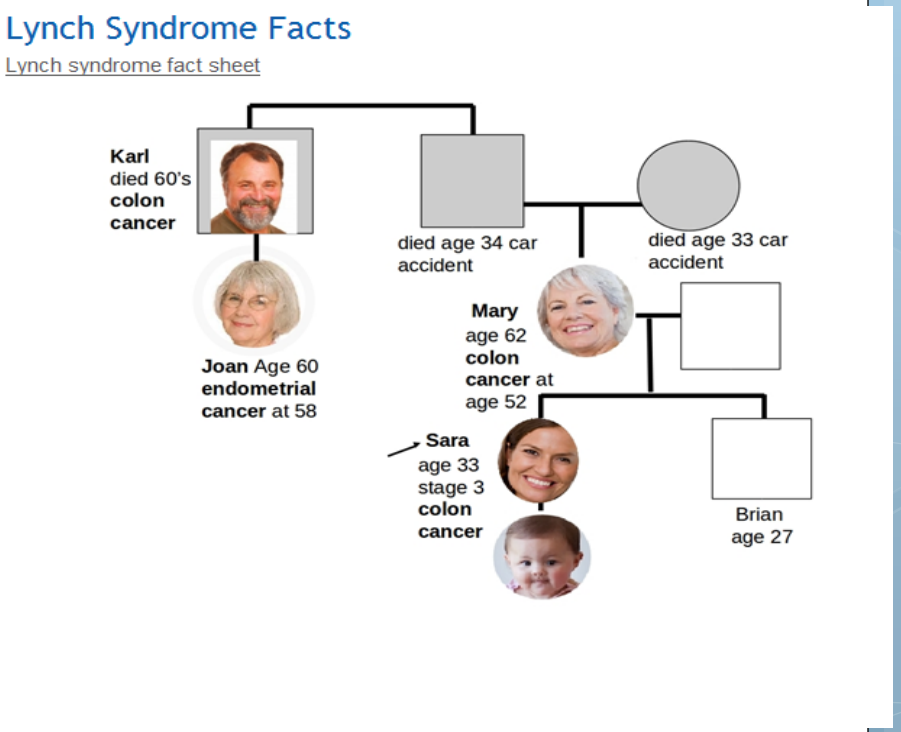
- Sufficient evidence to offer counseling & genetic testing for Lynch syndrome to patients newly diagnosed with colorectal cancer to reduce morbidity & mortality in relatives
- Relatives of patients who test positive for Lynch could be offered counseling, testing &, if positive, increased colonoscopy
- Evidence of benefit to the patient's relatives



Gen Med 2009;11:35-41&42-65

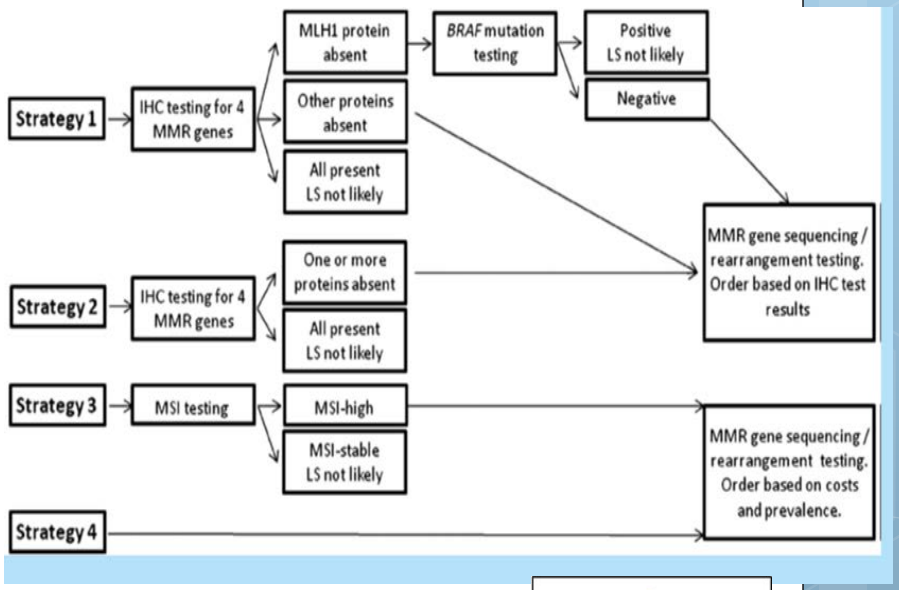
What is Lynch Syndrome (LS)?

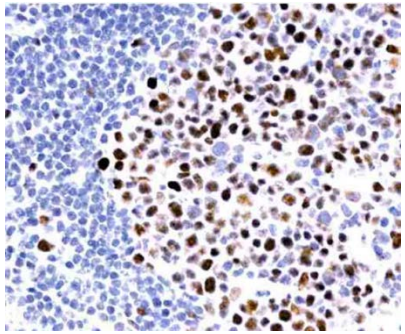
- Autosomal dominant hereditary cancer syndrome
  - Most common hereditary colorectal (CRC) and uterine cancer syndrome
  - 20-80% lifetime risk for CRC cancer ~3% of CRCs with LS
  - Mean age of onset of CRC is ~45 years old
  - Increased risk of endometrial, ovarian, urinary tract, gastric tract, small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

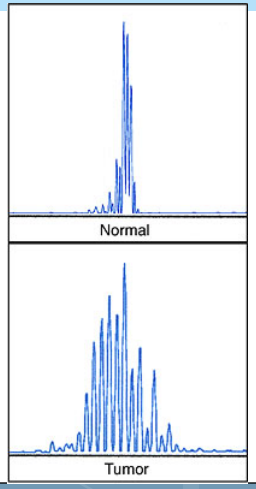


LS Screening & Management

- 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

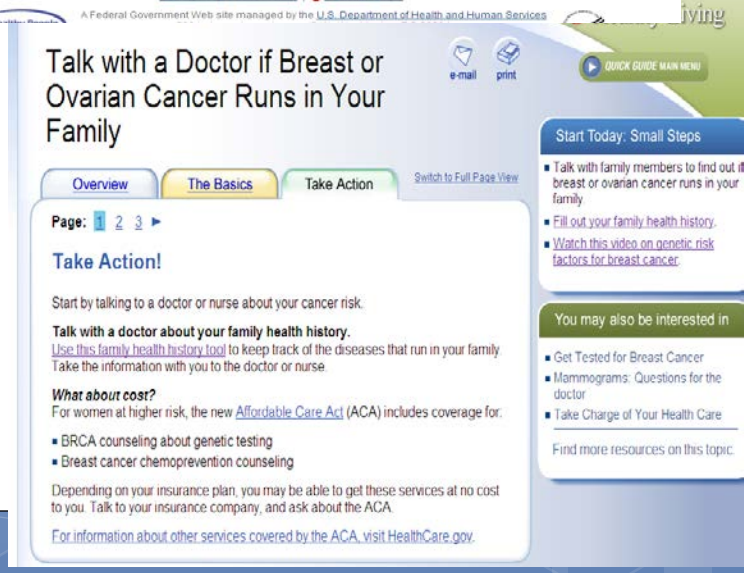






Healthy People 2020 (HP 2020)

- Started in 1979
- 10-year national objectives for promoting health and preventing disease
- HP 2020 marks first time for genomics objectives
- Encourage collaborations across sectors, guide individuals toward making informed health decisions, and measure the impact of prevention activities
- Works to achieve increased quality and years of healthy life and the elimination of health disparities.



Comprehensive Cancer Control Plan for Michigan 2009-2015

Genomics Goal:

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

http://michigancancer.org/

CDC Funding Announcement

Enhancing Breast Cancer Genomic Best Practices through Education, Surveillance and Policy, 2011-2014

- 3 year cooperative agreement (2011-2014) awarded to three projects
  - Authorized from Affordable Care Act
  - State health departments and Tribal governments eligible
- **Purpose:** develop or enhance activities related to breast cancer genomics
  - Promote use of BRCA1/2 clinical practices as recommended by USPSTF and NCCN
- Must conduct programs in policy plus surveillance and/or health education
  - Cannot use funds for research, clinical practice or lobbying

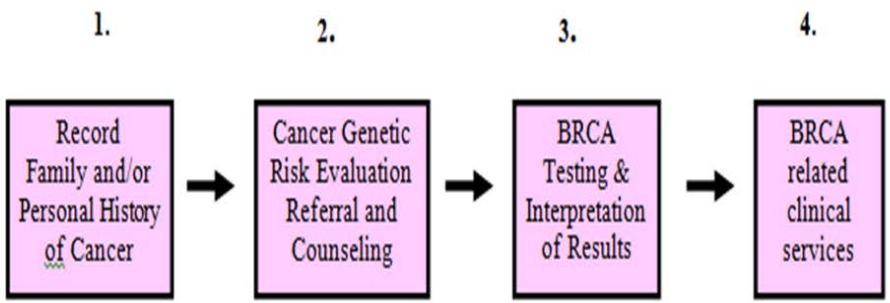


Figure 1: BRCA Counseling, Testing and Clinical Services

Example of Cancer Genomics & MCSP Activities

- Utilized statewide cancer registry and mortality data to conduct cancer genomics surveillance since 2003
  - Existing data analyzed through ‘genomics lens’
  - Identify cases at high risk by age, gender, cancer type and with disparities based on race and county
    - Young women with breast cancer
    - Men with breast cancer
    - Women with ovarian cancer
    - Multiple primary cancers (i.e. breast-ovarian; colorectal-endometrial)
    - Individuals with colorectal cancer
  - Able to then utilize data for:
    - Health system and provider education
    - Patient education
    - Survey cancer patients and at-risk relatives
    - Monitor trends over time

Cancer Incidence in Michigan

1990-2010

Breast Cancer Under age 50

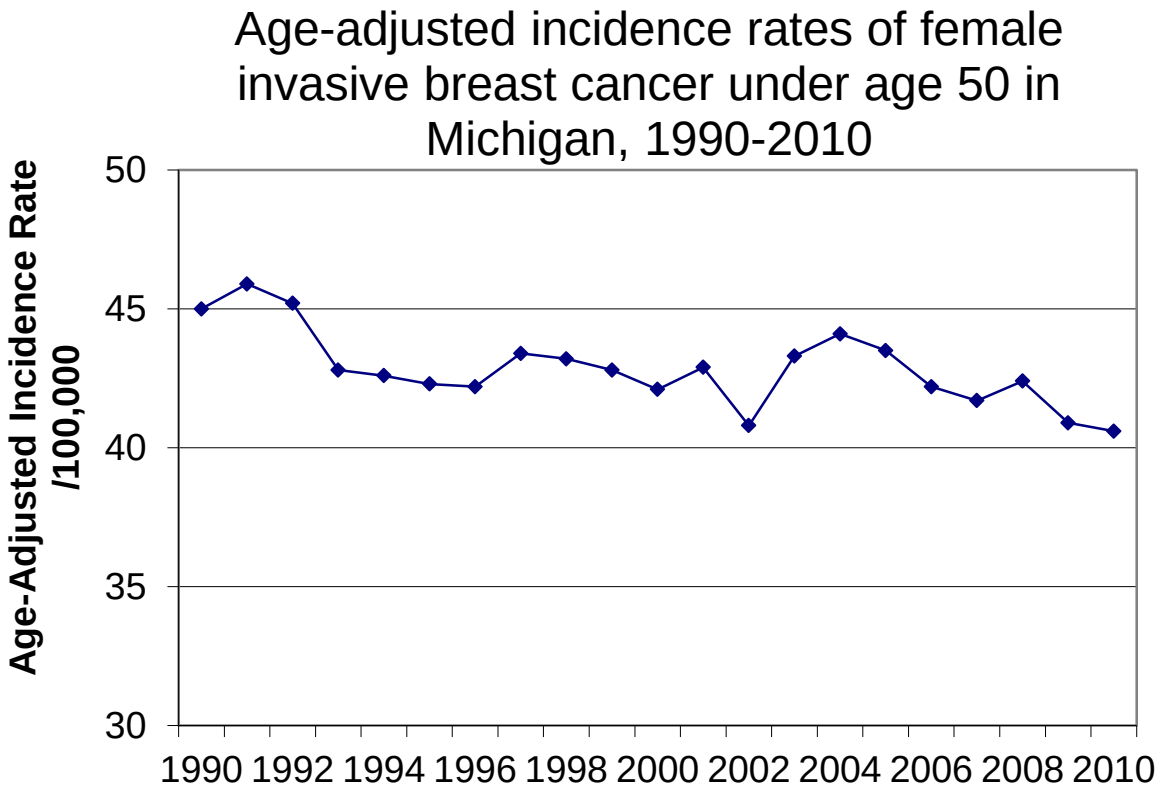
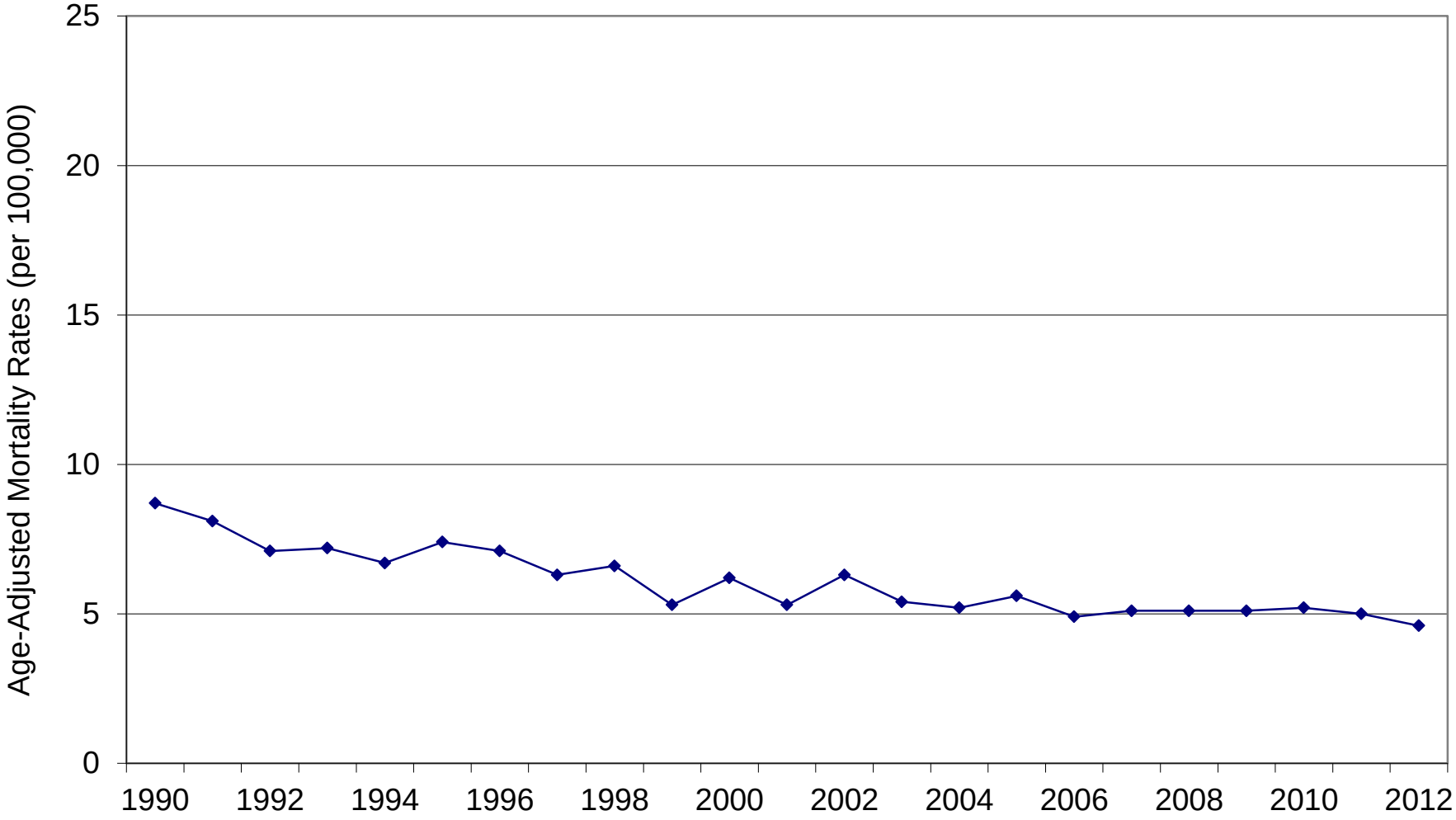


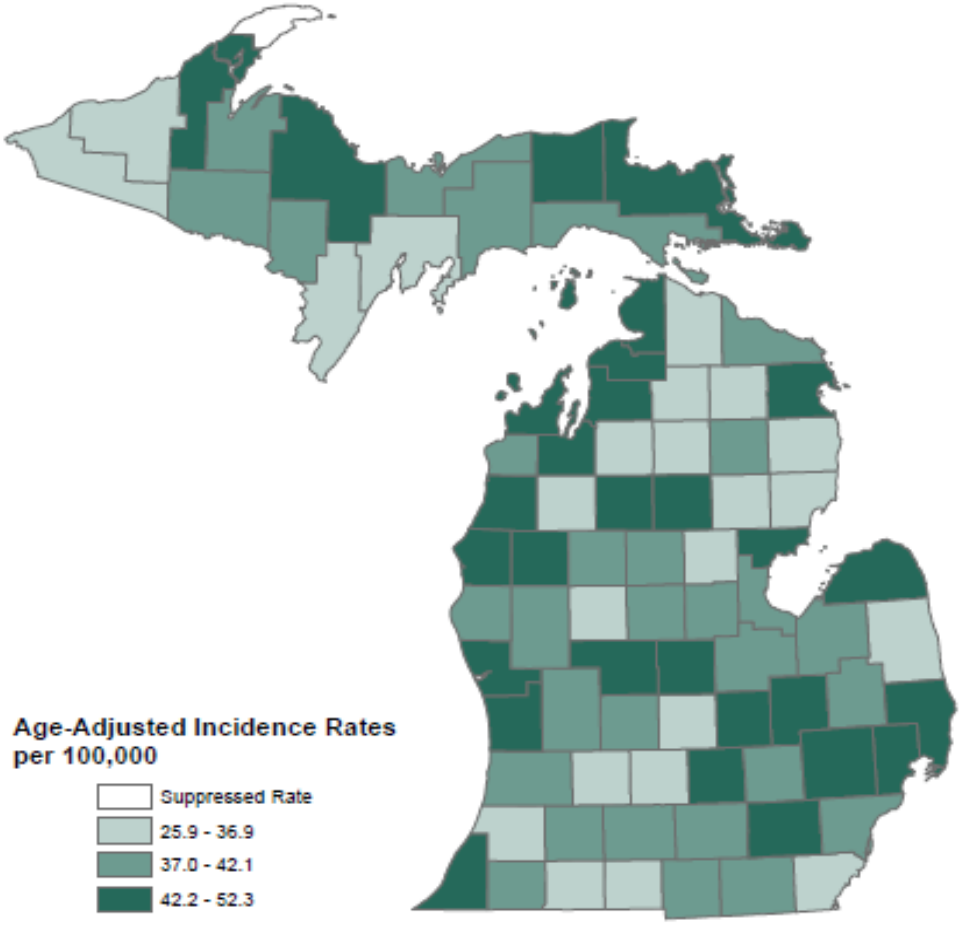
Table 2. Frequency of Triple Negative Breast Cancer Among Females under age 50 in Michigan

SSF 16	2010
Triple Negative	183 (12.29%)
Positive for at least one receptor	940 (63.73%)
Unknown/Info not complete	357 (23.98%)

Age-adjusted mortality rates of invasive female breast cancer under age 50 in Michigan,1990 - 2012

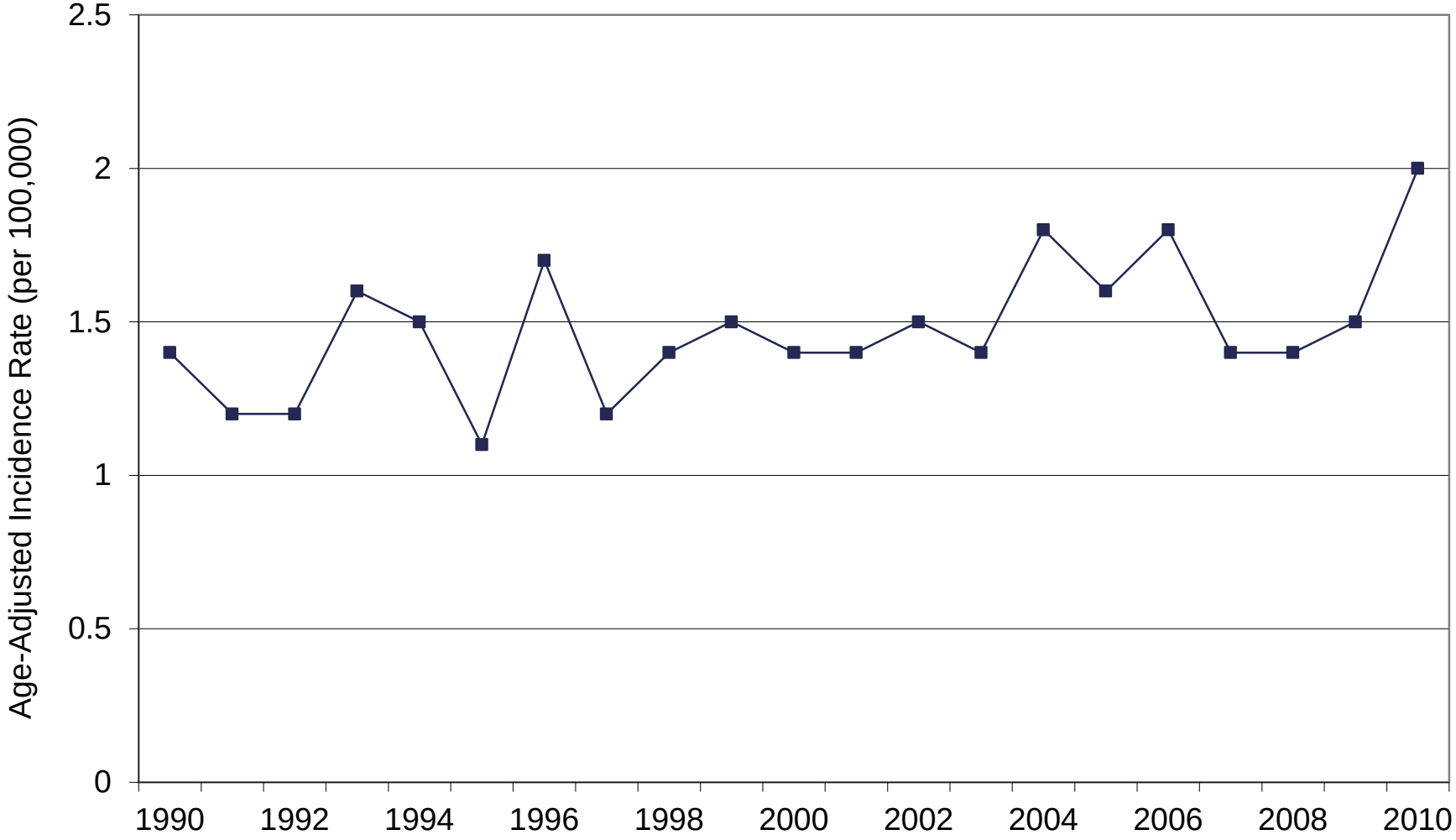


Age-Adjusted Ten-Year Incidence Rates for Breast Cancer by County among Women in Michigan, under age 50, 1998-2007

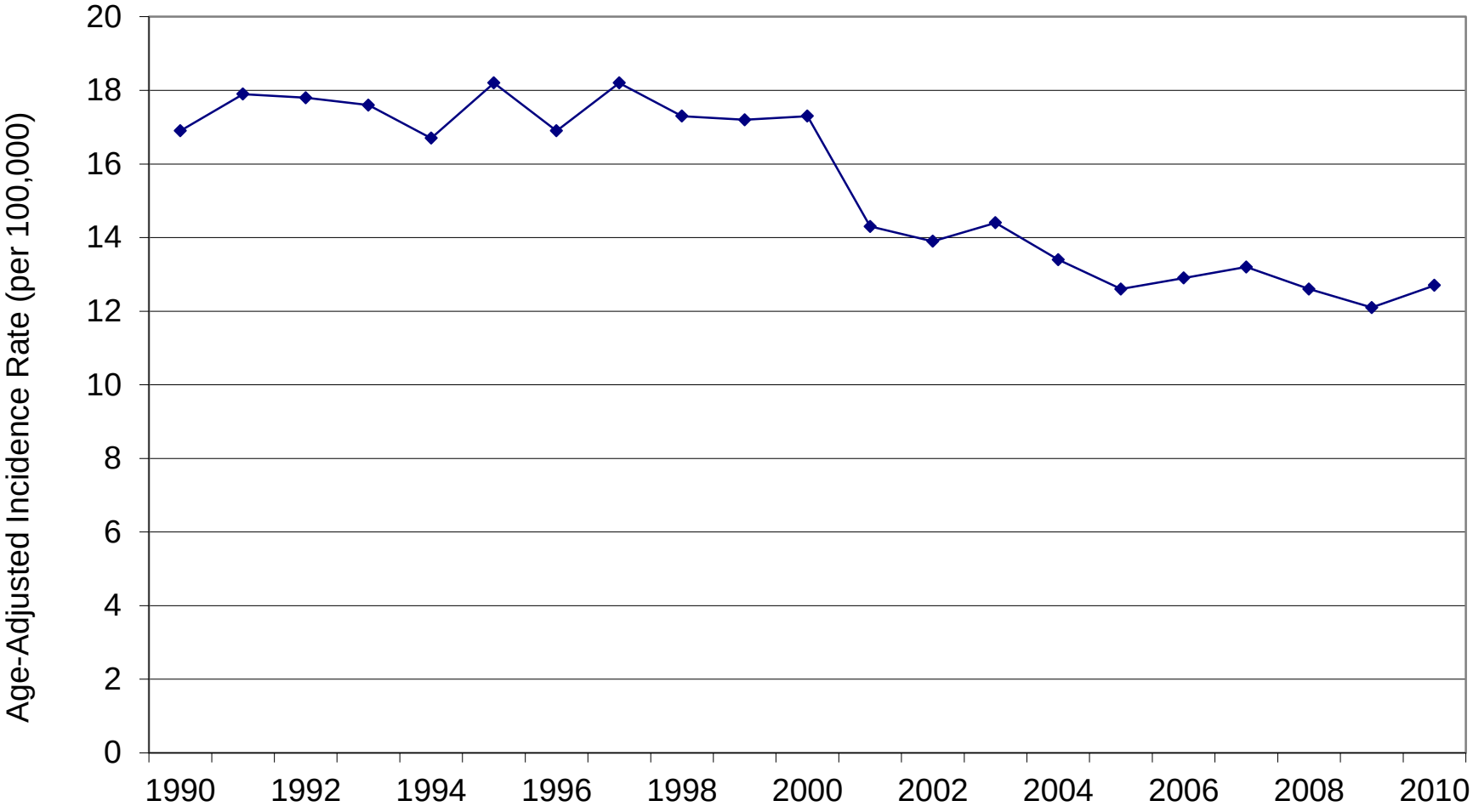


Rates were supressed in counties with fewer than 5 cases in the ten-year period.
The state rate was 42.1 per 100,000 women.

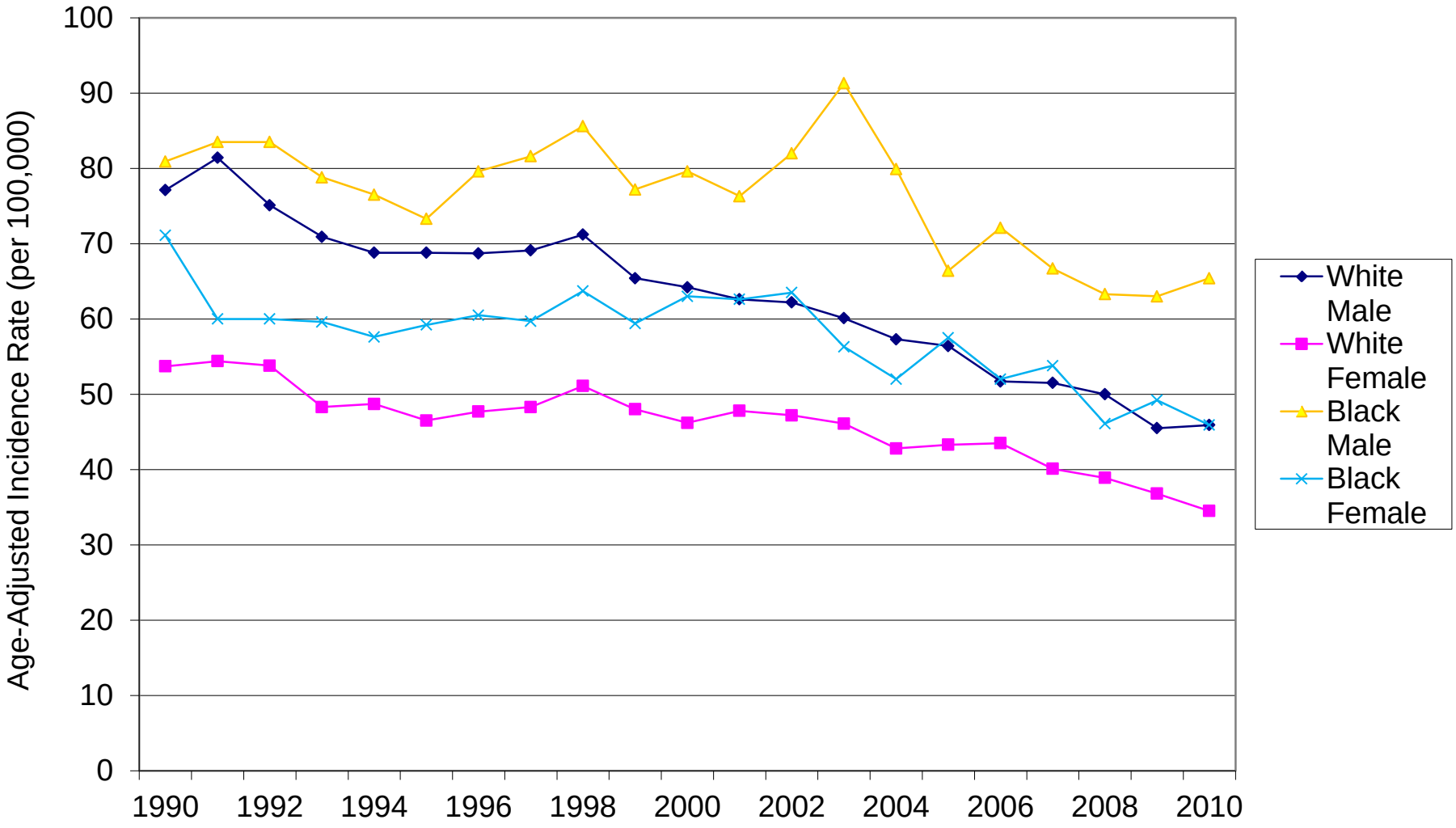
Age-adjusted incidence rates of male breast cancer all ages in Michigan, 1990-2010.



Age-adjusted incidence rates of ovarian cancer in females of all ages in Michigan,1990-2010.



Age-adjusted incidence rates of colorectal cancer by all ages in Michigan, 1990 - 2010



Cancer Family History Reporting

- Beginning in 2007, the Michigan Cancer Surveillance Program (MCSP) became the first state cancer registry to mandate collection of three family history fields for reportable cancer cases.
- This information helps identify individuals at risk for hereditary cancer syndromes.

The three required family history fields are:

1) Is there a family history of cancer?
2) Is the cancer in an immediate relative?
3) Is the relative's cancer in the same site?

“Family history is still the cheapest, most accessible, most time-tested way to get a rough estimate of the genetic component of disease risk.”

- W. Gregory Feero, M.D., Ph.D.

Certificates of Appreciation

MCSP Family History, 2007-2009

Family history among young female breast cancer (≤50 years old), male breast cancer and ovarian cancer cases

Table 1. Coding schema for MCSP family history variables

Code	Family History	Immediate Relative	Same Site
0	No	No	No
1	Yes	Yes	Yes
2	Yes	Yes	No
3	Yes	No	Yes
4	Yes	No	No
5	Yes	Yes	Blank
6	Yes	Blank	Yes
7	Yes	Blank	No
8	Yes	Blank	Blank
9	Blank	Blank	Blank
A	Yes	No	Blank

Table 2. Reporting patterns

Code	Frequency	Percentage
0	573	14.6
1	1,369	34.9
2	64	1.6
3	13	0.3
4	7	0.2
5	1	0.0
6	1	0.0
7	0	0.0
8	397	10.1
9	1,502	38.3
A	0	0.0

Cancer Family History Next Steps

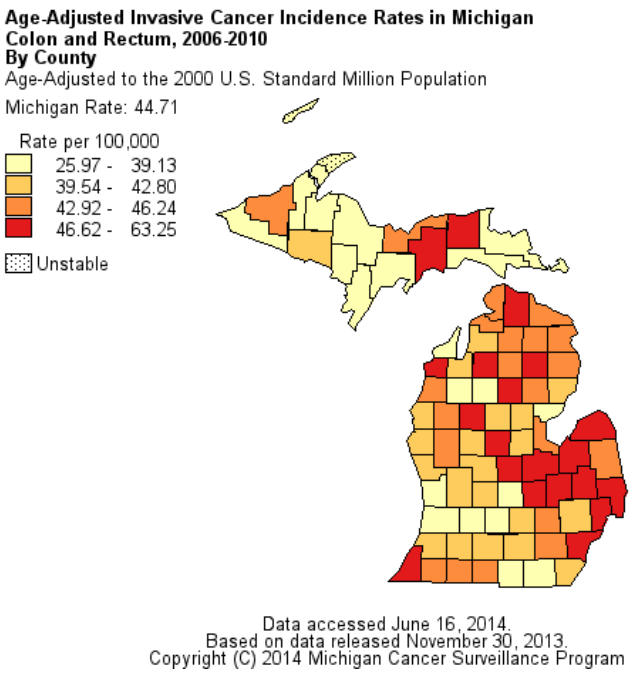
- ~ half of cases contained at least one blank field for family history
- Metriq vs. Abstract Plus software packages

	Metriq	Abstract Plus
Supplier:	2 private vendors	Centers for Disease Control and Prevention
Users:	American College of Surgeon certified facilities	Small facilities/labs
Variables:	Family history & relationship optional; no collection of relative's cancer site	All three fields required

- Chart reviews to determine whether family history is documented in charts

New Cooperative Agreement, 2014-2019

- Geographic focus
  - Young breast cancer: highest in northwest portion of lower peninsula
  - Ovarian cancer: northwest, southwest and thumb region
  - Colorectal cancer: thumb, northern portion of lower peninsula



Next Steps: Activities

- Continue to examine cancer registry data to monitor incidence rates and trends of cases most likely to have an underlying genetic predisposition for HBOC and Lynch syndrome
  - Will disseminate county/regional data profiles highlighting these cancers
- Conduct hard copy and EHR chart reviews with MCSP
  - Family history documentation
  - Referral for cancer genetic counseling
  - Lynch syndrome screening
  - *BRCA* genetic testing

Chart Reviews Example

- http://www.nytimes.com/2014/08/28/opinion/a-plea-to-use-gene-testing.html, published 8/28/2014
- Letter to the NY Times editor cited MDCH chart reviews finding that only 7% of ovarian cancer patients underwent *BRCA* genetic testing
- Room for improvement: reduce barriers to established beneficial services

The Opinion Pages | A Plea to Use Gene Testing

A Plea to Use Gene Testing

AUG. 27, 2014

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To the Editor:

I appreciate Theodora Ross's careful delineation of the promise of and barriers to the use of genetic sequencing in cancer patients ("Cancer and the Secrets of Your Genes," Sunday Review, Aug. 17). Unfortunately, these barriers aren't restricted to the decoding of a person's entire genetic blueprint.

Even simple genetic tests that look at a handful of the usual suspects are dramatically underused in cancer. For example, a study of women with ovarian cancer found that only 7 percent underwent BRCA gene testing, despite its being recommended by experts. A recent study of Harvard doctors found that they are unlikely to order genetic testing, citing their own lack of education as the culprit.

Personalized medicine has great promise for cancer treatment, especially for women at high risk of ovarian cancer, one of the deadliest cancers for women. If we are to fully realize this promise, both physicians and payers must embrace genetics for the benefit of patients' health and well-being.

LAURA M. KOONTZ
Washington, Aug. 19, 2014

The writer is director of policy for the Ovarian Cancer National Alliance.

2014 Video Highlights Bidirectional Michigan Cancer Genomics and Bidirectional Reporting

Michigan Department of Community Health
MDCH
Jennifer M. Granholm, Governor
Janet Olszewski, Director

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

Sample Hospital and Medical Center Cancer Genetics Data Report (2006-2007)

on Hereditary Breast and Ovarian Cancer Syndrome (HBOC) and Lynch Syndrome

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

Table 1. Age 18-49 at diagnosis	*Sample 2006 - 2007*	*Michigan 2006 - 2007*
Breast (female)		3,025
Endometrial		459

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

Table 2. All ages	*Sample 2006 - 2007*	*Michigan 2006 - 2007*
Colorectal		10,340
*Ovarian**		1,544
Breast (male)		147

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

Table 3. All ages	*Sample 2006 - 2007*	*Michigan 2006 - 2007*
Multiple primary cancer diagnoses		1,985

***Table 3.** Number of people with multiple cancer diagnoses between 1990 to 2007 with a cancer diagnosis in 2006-2007 including: breast-breast, breast-ovarian*, ovarian*-ovarian*, colorectal-colorectal, colorectal-endometrial, colorectal-ovarian*, endometrial-endometrial, ovarian*-endometrial.*

* All ovarian cancer data also include those cases diagnosed with cancer of the fallopian tube.

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

Prepared in 2010 by MDCH staff

Michigan Department of Community Health
MDCH
Jennifer M. Granholm, Governor
Janet Olszewski, Director

Public Health Genomics

A Cancer Genetics Profile: Prepared for Sample Hospital

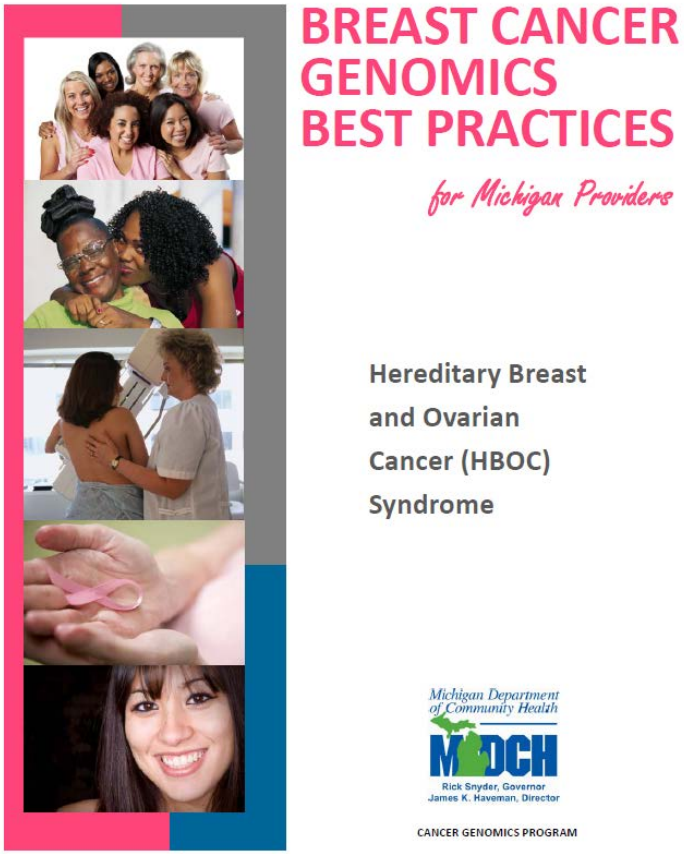
Focusing on Your Patients' Hereditary Cancer Risk

March 1, 2010

First Bidirectional Cancer Genomics Reporting in Michigan

- From 2010-2011, key administrators and local cancer registrars at ~150 facilities (excluded labs, dermatology and dental offices) received cancer genomics reports
- Over 15,000 cases reported from 2006-2007 to MCSP that would be appropriate for cancer genetic services
- Highlighted specific number of cases for each facility
- Included national evidence-based recommendations, CoC genetic counseling standard, Michigan cancer genetic services directory, Michigan Informed Consent Law, and other educational resources

2013 Bidirectional Reporting to Diagnosing Provider

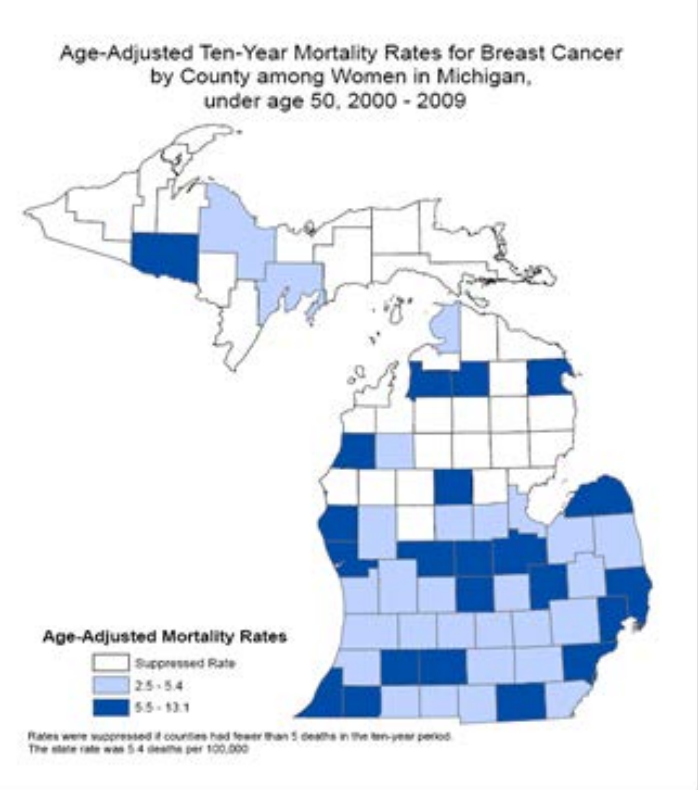


- 4 health systems with new cancer genetics clinics selected in 2011 to pilot bidirectional reporting to diagnosing providers
- Over 5,000 cases of young breast cancer, ovarian cancer, male breast cancer diagnosed in 2008-2009 statewide
- Individualized reports sent to 69 diagnosing providers of 353 young breast cancer, 118 ovarian cancer, 4 male breast cancer cases in Sept/Oct 2013
- Requested feedback from providers; given options of in-person, phone, survey
  - 11 lost to follow-up
  - Only 4 provided feedback
    - Time lag of diagnosis to report
    - Length of booklet
    - Already sufficient knowledge

Interventions to increase screening utilization by young breast cancer survivors (YBCS) and their high risk female relatives

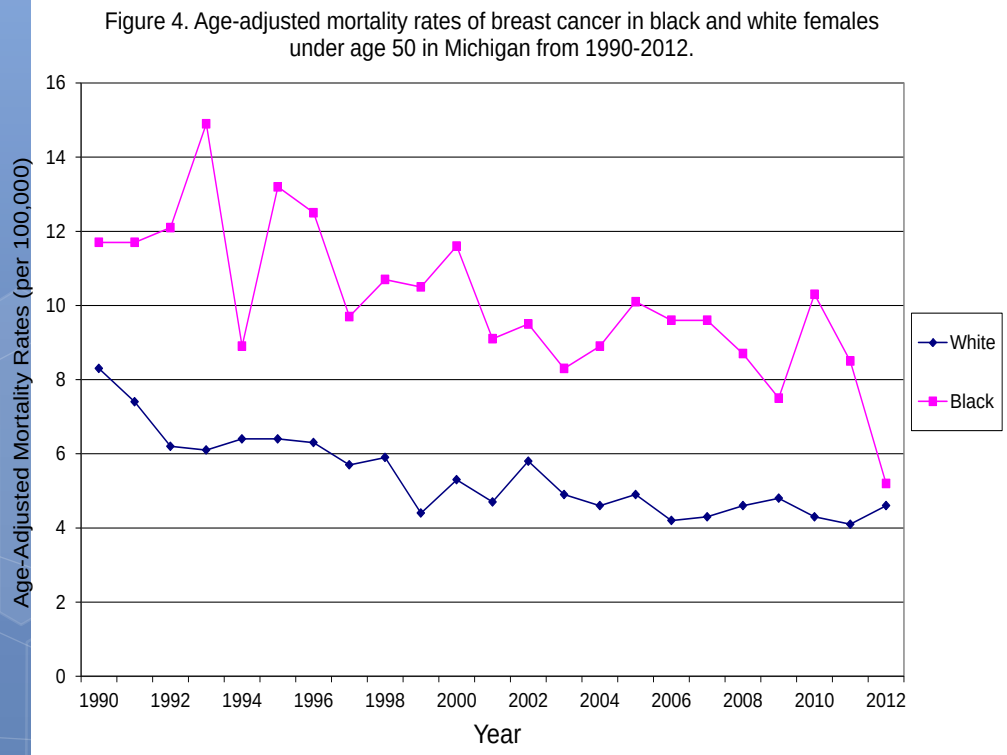
- 1990-2009 mortality data utilized in 2011 CDC Prevention Research Center Special Interest Project (SIP) proposal
- Awarded to Prevention Research Center of Michigan, University of Michigan, MDCH (SIP11-044, 5U48DP001901)
- Specific Aims:
  - **Identify and survey 3,000 YBCS (1,500 black)**
  - **Identify and survey up to 2 unaffected first degree and/or second degree female relatives per YBCS**
  - **Test the efficacy of two versions (targeted vs. enhanced tailored) of an evidence-based intervention among YBCS and their female relatives**

Michigan Mortality Data for Breast Cancer in Young Women



- Healthy People 2020 objective and Michigan Comprehensive Cancer Control Plan, 2009-2015, objective:
  - "Reduce the female breast cancer death rate"
- In 2008, 5.7 per 100,000 Michigan white women died of breast cancer at a young age compared to 11.3 per 100,000 black women.
- 22 of Michigan's 83 counties were above the state age-adjusted breast cancer mortality rate for young women

Michigan Mortality Rates for Breast Cancer in Young Women, Black and White, 1990-2012



- In Michigan, 2012 marked the first year since 1990 that there was not a statistical difference in black/white mortality
  - 5.2 deaths per 100,000 for young black women vs. 4.6 per 100,000 for young white women

Data on Recruitment of YBCS & Relatives, Black and White/Other

- Of 3,000 YBCS identified, 883 contacted by mail and accepted to participate in study (33.2% acceptance rate)
  - Most common reason for non-participation was no or bad address
    - 252 YBCS had no or bad address
    - Black YBCS having higher percentage
- Of 851 unaffected relatives invited to participate by YBCS, 442 accepted (51.6%)
  - Fewer Black relatives accepted participation in the study
- Enrolled Black YBCS and relatives were significantly less likely to be married, have insurance coverage, and less education and income compared to White/Other YBCS and relatives

Data on Use of Cancer Genetic Services among YBCS

Use of cancer genetic services	Total (n=828)	Black (n=317)	Other (n=511)
Had genetic counseling*	32.9%	26.6%	37.1%
Had genetic testing*	28.5%	19.9%	33.7%
Had genetic counseling and testing*	27.5%	18.3%	32.9%

* Significant at the 0.001 level for Black vs. Other

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

Reasons for not seeking genetic services among YBCS

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

* 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

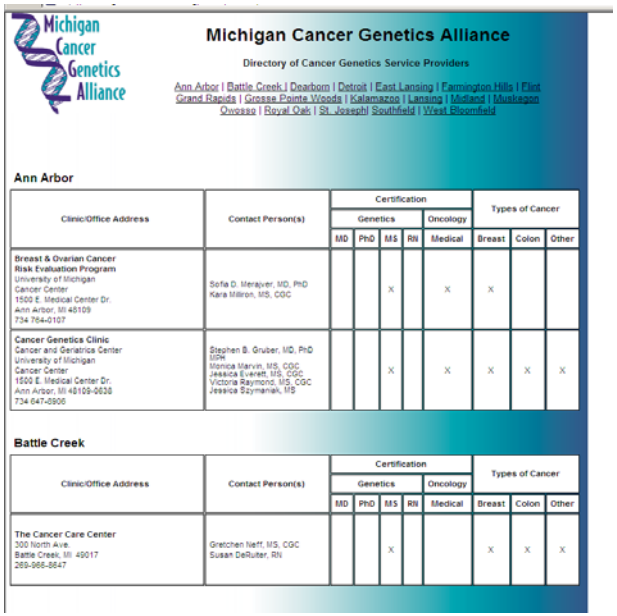
Reasons for genetic testing among YBCS

Most common reasons for getting genetic testing*	Total (n=230)	Black (n=60)	Other (n=170)
Results will benefit my family	81.7%	70.0%	85.9%
Wanted to know if I have a mutation	69.1%	58.3%	72.9%
Learn more about future cancer risk	63.5%	63.3%	63.5%
Provider suggested that I do	50.0%	48.3%	50.6%

* Significant at the 0.001 level for Black vs. Other

Reasons for getting genetic testing varied by race; benefiting family was the most common reason for YBCS

For More Information



Michigan Cancer Genetics Alliance

Directory of Cancer Genetics Service Providers

Ann Arbor | Battle Creek | Dearborn | Detroit | East Lansing | Farmington Hills | Flint | Grand Rapids | Grosse Pointe Woods | Kalamazoo | Lansing | Midland | Muskegon | Owosso | Royal Oak | St. Joseph| Southfield | West Bloomfield

Ann Arbor

Clinic/Office Address	Contact Person(s)	Certification					Types of Cancer		
		Genetics				Oncology			
		MD	PhD	MS	RN	Medical	Breast	Colon	Other
Breast & Ovarian Cancer Risk Evaluation Program University of Michigan Cancer Center 1500 E. Medical Center Dr. Ann Arbor, MI 48109 734 764-0107	Sofia D. Merajver, MD, PhD Kara Milron, MS, CGC			X		X	X		
Cancer Genetics Clinic Cancer and Geriatrics Center University of Michigan Cancer Center 1500 E. Medical Center Dr. Ann Arbor, MI 48109-0638 734 647-0906	Stephen B. Gruber, MD, PhD MPH Monica Marvin, MS, CGC Jessica Everett, MS, CGC Victoria Raymond, MS, CGC Jessica Szymaniak, MS			X		X	X	X	X

Battle Creek

Clinic/Office Address	Contact Person(s)	Certification					Types of Cancer		
		Genetics				Oncology			
		MD	PhD	MS	RN	Medical	Breast	Colon	Other
The Cancer Care Center 300 North Ave. Battle Creek, MI 49017 269-966-8647	Gretchen Neff, MS, CGC Susan DeRuiter, RN			X			X	X	X

MDCH Department of Community Health

Michigan.gov The Official State of Michigan Website

Promoting Cancer Genomics Best Practices through Surveillance, Education and Policy Change in the State of Michigan, 2008-2011

The MDCH Genomics Program, in collaboration with the CDC Office of Public Health Genomics, is identifying and promoting cancer genomics best practices for appropriate translation of cancer genetic tests and gene profiling tests into clinical and public health practice. Project goals include:

1) Developing and implementing a model for surveillance of inherited cancers and use of relevant genetic tests
2) Identifying model provider education programs to increase use of appropriate screening, counseling and evidence-based genetic tests
3) Identifying a model health insurance policy for BRCA1 & 2 cancer genetic testing

Methods:

The core MDCH team includes a project director, coordinator, cancer genomics educator and epidemiologist. In addition, we have identified the partners needed to 1) develop a surveillance system to monitor the use of genetic counseling and testing for BRCA1/2, and the use of genetic tests for colorectal cancer (Lynch Syndrome); 2) implement educational activities; and 3) identify the need for health plan policy changes in relation to the US Preventive Services Task Force Guidelines for the use of BRCA testing. Multiple different activities will address each of these objectives. For further details, please see our logic model

www.migrc.org

Or call 1-866-852-1247

www.michigan.gov/genomics
www.michigan.gov/cge

Research Opportunity

- Researchers from Northeastern University have an NIH-funded grant to study the integration of genomics into state public health programs.
- Their interests include how genomics programs have developed over time, how they benefit population health, and the barriers in implementing these programs.
- One of the projects they wish to explore further is the bidirectional reporting occurring between state hospitals and the state cancer registry. They would greatly enjoy speaking with local cancer registrars who have submitted information to the state registry and have received the Facility Specific Cancer-Genetics Profiles.
- If you are interested in participating in a 30-minute interview to offer your perspective on this project, please contact Dr. Laura Senier, Ph.D., MPH by email at l.senier@neu.edu.
- All information will remain confidential and no identifying information will be utilized in their final reports.

Patient-Powered Network for Hereditary Breast and Ovarian Cancer

pcornet | The National Patient-Centered Clinical Research Network

- 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
- Will integrate EHR, health claims and/or patient-reported outcomes data on 70 million Americans by September 2015.

It's ABOUT Time

ABOUT

American BRCA Outcomes & Utilization of Testing Network

ABOUTnetwork.org

- 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

THANK YOU!