

# Public Health Surveillance of BRCA Counseling and Testing Using Clinical Cancer Genetics Data

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# Outline

## 1. Background

- Cancer genomics project overview
- BRCA1/2 background
- U.S. Preventive Services Task Force recommendation

## 2. Data collection

- Clinical genetics partners

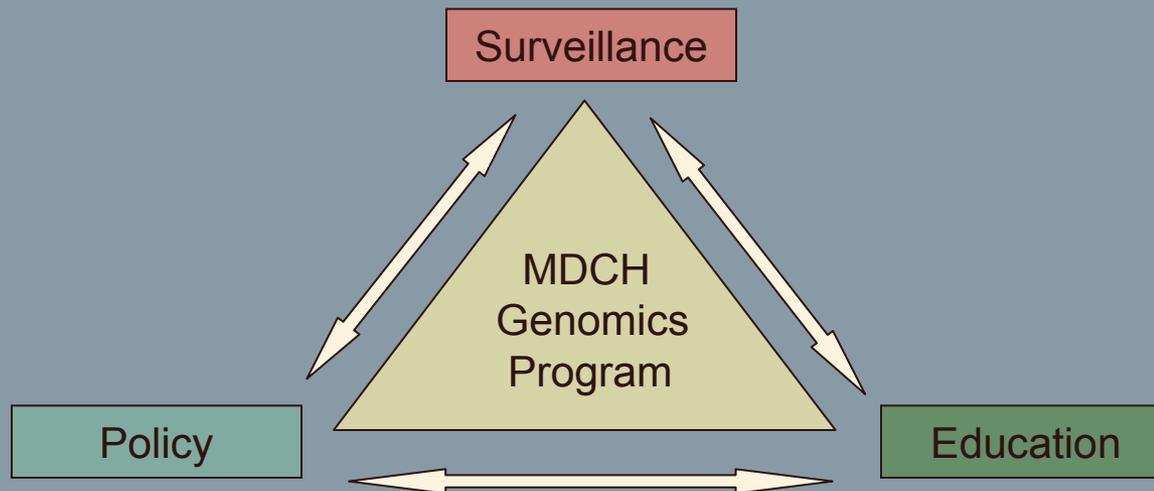
## 3. Data

- Demographics
- Insurance coverage
- Testing results
- Reasons for not testing

## 4. Next Steps



# Promoting Cancer Genomics Best Practices Through Surveillance



Objective: Implement a model for **surveillance** of inherited cancers by developing methods for collecting and sharing data on the clinical use of BRCA1/2 genetic testing through a network of sentinel sites, including health systems.

# BRCA1/2 Overview

## BReast CAncer

- 2 genes on separate chromosomes
- Autosomal dominant inheritance
- May be responsible for 5-7% of all breast and ovarian cancers<sup>1</sup>
- Estimated 35 – 84% chance of breast cancer and 10 – 50% chance of ovarian cancer by age 70 in women<sup>2</sup>



# USPSTF Recommendation, 2005

## **U.S. Preventive Services Task Force BRCA Grade B Recommendation**

“Women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes should be referred for genetic counseling and evaluation for BRCA testing.”



# USPSTF Family History Guidelines

Common examples of family histories that meet guidelines:

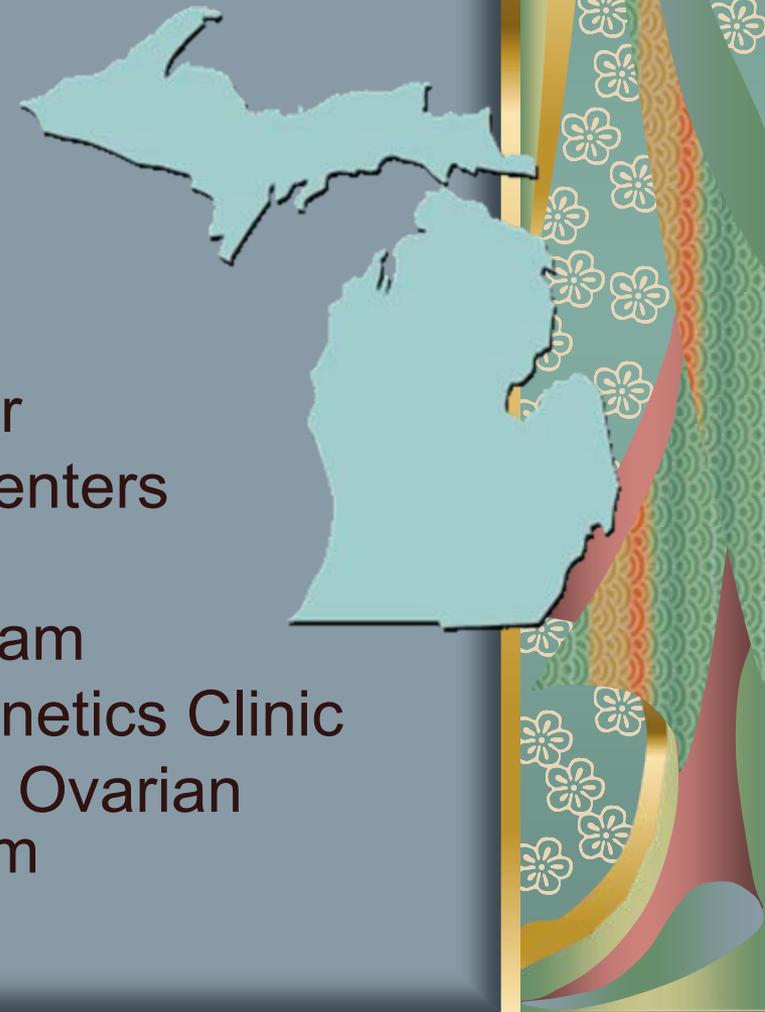
- Two 1° relatives with breast cancer, one  $\leq$  50 yrs of age
- Three or more 1° or 2° relatives with breast cancer
- Breast and ovarian cancer among 1° and 2° relatives
- Two 1° or 2° relatives with ovarian cancer
- A male relative with breast cancer

Example: A sister had ovarian cancer, a paternal aunt had breast cancer



# Cancer Genetics Clinic Partners

- Battle Creek Health System
- Beaumont Hospital
- Henry Ford Health System
- Informed Medical Decisions, Inc.
- Karmanos Cancer Institute
- Michigan State University
- Oakwood Hospital & Medical Center
- Providence Hospital and Medical Centers
- Spectrum Health System
- St. Johns Health Breast Care Program
- University of Michigan – Cancer Genetics Clinic
- University of Michigan – Breast and Ovarian Cancer Risk and Evaluation program



# Data Collection Tool

Find Patient:

Add Patient

Patient Code:

Gender:

Birth Year:

Zip Code:

Race:

Ashkenazi Jewish

Location:

Race 2:

Known Familial Mutation

Referring Physician Type:

Other Race:

Num of 3rd Deg. Relatives with Cancer:

USPSTF:

Visits

Risk Assessment

Tests

Patient History

Relatives

Date:

Visit Type:

Insurance:

Other Insurance:

No Change In Personal History

No Change In Family History

Medicaid

Medicare

If testing not pursued, what was the reason:

Other reason (please specify):



1 of 0 visit(s)

# Demographics by Clinical Site

Table 1.  
Demographics  
by clinic,  
October 2007 –  
September  
2010\*

|                       | Clinic A<br>Num. (%) | Clinic B<br>Num. (%) | Clinic C<br>Num. (%) | Clinic D<br>Num. (%) | Clinic E<br>Num. (%) | Clinic F<br>Num. (%) |
|-----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <b>Total Patients</b> | 217                  | 364                  | 273                  | 1577                 | 583                  | 177                  |
| <b>Gender</b>         |                      |                      |                      |                      |                      |                      |
| Male                  | 5 (2.3)              | 10 (2.8)             | 33 (12.1)            | 84 (5.3)             | 23 (4.0)             | 8 (4.5)              |
| Female                | 212 (97.7)           | 354 (97.3)           | 240 (87.9)           | 1493 (94.7)          | 560 (96.1)           | 169 (95.5)           |
| <b>Race</b>           |                      |                      |                      |                      |                      |                      |
| White                 | 179 (82.5)           | 280 (76.9)           | 256 (93.8)           | 1377 (87.4)          | 460 (78.9)           | 165 (93.2)           |
| Black                 | 11 (5.1)             | 30 (8.2)             | 8 (2.9)              | 87 (5.5)             | 99 (17.0)            | 11 (6.2)             |
| Other                 | 27 (12.4)            | 54 (14.8)            | 9 (3.3)              | 113 (7.2)            | 24 (4.1)             | 1 (0.6)              |

|                       | Clinic G<br>Num. (%) | Clinic H<br>Num. (%) | Clinic I<br>Num. (%) | Clinic J<br>Num. (%) | <b>Total<br/>Num. (%)</b> |
|-----------------------|----------------------|----------------------|----------------------|----------------------|---------------------------|
| <b>Total Patients</b> | 398                  | 67                   | 599                  | 171                  | <b>4426</b>               |
| <b>Gender</b>         |                      |                      |                      |                      |                           |
| Male                  | 9 (2.3)              | 1 (1.5)              | 22 (3.7)             | 3 (1.8)              | <b>198 (4.5)</b>          |
| Female                | 387 (97.2)           | 66 (98.5)            | 577 (96.3)           | 168 (98.3)           | <b>4226 (95.5)</b>        |
| <b>Race</b>           |                      |                      |                      |                      |                           |
| White                 | 358 (90.4)           | 64 (95.5)            | 440 (73.8)           | 117 (70.1)           | <b>3696 (83.7)</b>        |
| Black                 | 12 (3.0)             | 1 (1.5)              | 129 (21.6)           | 42 (25.2)            | <b>430 (9.7)</b>          |
| Other                 | 28 (7.0)             | 2 (3.0)              | 30 (5.0)             | 12 (7.0)             | <b>300 (6.8)</b>          |

\*End date varies by clinic. Chart does not include two clinical sites in the process of data collection

# Total Database, 2007 - 2010

## Demographics

- Total of 4,426 patients
- Mean age = 50 years old at initial visit
- 56.3% have a personal history of cancer

## Risk Factors

- 10.6% Ashkenazi Jewish ancestry
- 11.5% have a known mutation in their family
- 41.2% have a family history that meets USPSTF guidelines for referral

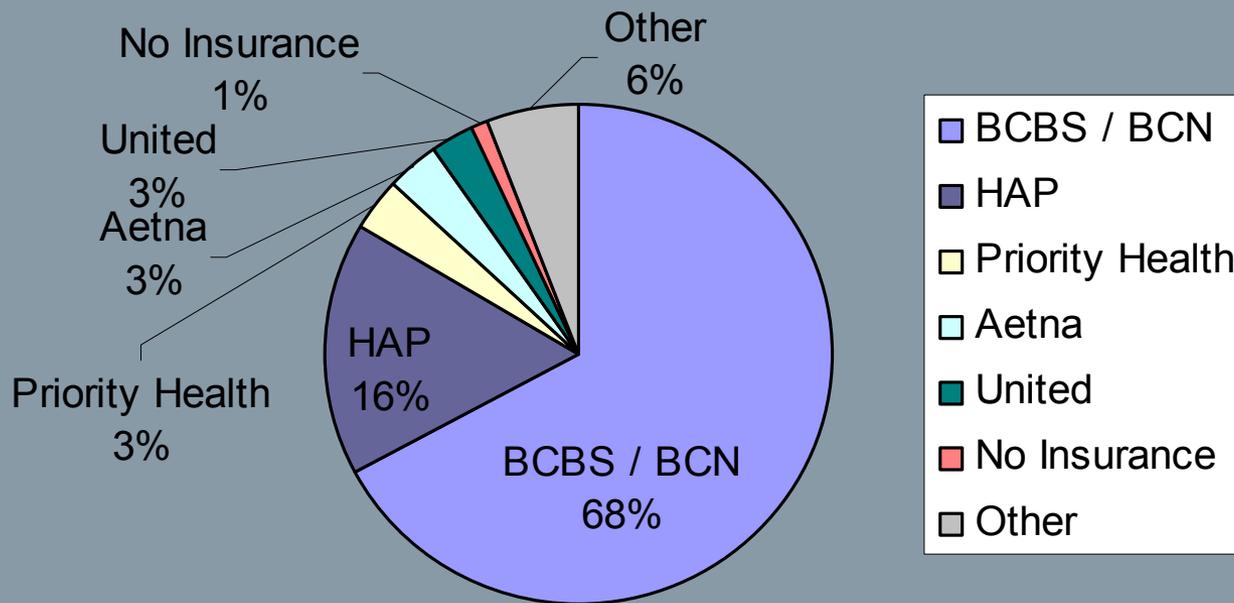
## Room for Improvement

- Only 38.5% of female relatives with a reported cancer history were from the paternal side of the family



# Insurance Coverage

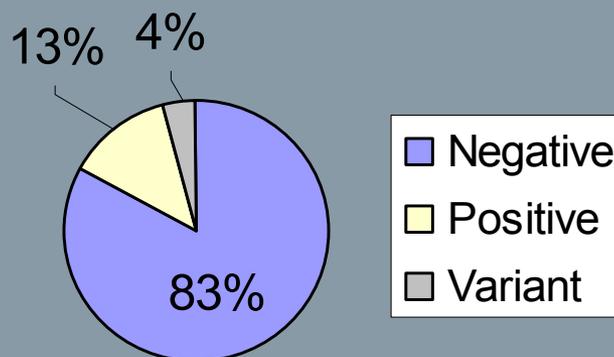
Figure 2. Reported insurer at BRCA counseling visits, 2007-2010



- Likely more uninsured patients – 20% missing insurance information
- 2.4% of patient visits are covered by Medicaid
- 11.7% of patient visits are covered by Medicare

# Patient Results

Figure 1. Results in clinical sites patients with BRCA testing and results, 2007-2010



□ 13% of all patients tested were positive

- Personal history of cancer: 10% positive
- No personal history of cancer, did not meet USPSTF guidelines: 13% positive
- No personal history of cancer, met USPSTF guidelines: 22% positive

# USPSTF guidelines – how do they measure up?

Table 2. USPSTF family history and test results in clinical site patients without a personal history of cancer, 2007-2010

|          | Does not meet USPSTF | Meets USPSTF         |
|----------|----------------------|----------------------|
| Negative | 318 – true negatives | 544 – false positive |
| Positive | 51 – false negative  | 156 – true positive  |

Positive predictive value = 0.23

Proportion of those who meet USPSTF guidelines who are actually positive

Negative predictive value = 0.87

Proportion of those who do not meet USPSTF guidelines who are actually negative



# Test Results by Clinical Site

## *Positive*

% at each clinical site ranged from 3.1 to 15.8

Patient is more likely positive if they have:

- A known family mutation
- Family history of cancer
- Early-onset cancer

Need additional management

## *True Negative*

% at each clinical site ranged from 2.6 to 12.6

Patients are true negatives if:

- Someone in the family has a BRCA mutation, and ...
- The patient tests negative

Same risk and screening recommendations as the general population



# Reasons For Not Testing

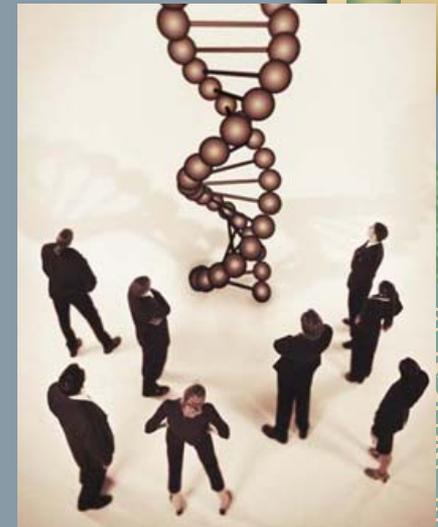
All initial visits in patients who never had testing (1,283 patients)

- Not the best test candidate - 314 (24.5%)
- Not clinically indicated – 239 (18.6%)
- Inadequate insurance – 188 (14.7%)

In the subset with cancer (462 patients)

- Inadequate insurance – 118 (25.5%)
- Not clinically indicated – 78 (16.9%)

Other reasons given for not testing include ‘not a good time,’ ‘don’t want to know,’ and ‘need to discuss options with relatives’



# Next Steps – Phone Survey

□ Phone survey of BRCA positive and true negative women

- 9 clinical sites participating
- Clinical sites contact their own patients
- ~ 160 positive, 110 true negative

□ Goals:

- Show how results influence follow-up care
- Describe experiences with insurance coverage for BRCA-related services
- Collect information on family notification and screening

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Assessment of Follow-Up Decisions and Care After BRCA Genetic Testing

Call Introduction:

Hello, may I please speak with ~first and last name of potential participant~? (IF NOT AVAILABLE, FIND OUT A GOOD TIME TO CALL BACK)

My name is ~name~ and I am calling from ~caller's institution~. We are administering a survey on behalf of the Michigan Department of Community Health Genomics Program. The survey is about the actions women take after receiving results from genetic testing for BRCA1 and 2.

You were selected to participate in this survey because you had BRCA 1 and 2 genetic counseling at our cancer genetics clinic between October 2007 and October 2009. We would like to ask you questions about your genetic test results and your follow-up care and decisions. Some questions about cancer screening and care may not apply to your situation. We are asking the same questions to all participants regardless of BRCA results.

If you choose to participate, any information we gather during this study will be treated in a confidential manner. Your personal identifying information has not been shared with anyone outside of ~institution~, and your responses from this survey will be kept separate from your identity. The Michigan Department of Community Health genomics staff will not be able to link your identity with your survey answers.

We hope that the findings from this survey will help improve services for genetics patients. This survey is voluntary and may cover sensitive information. If you choose not to participate, it will not affect you in any way. If you do choose to participate, you may stop any survey questions you do not want to answer and you may stop the survey at any time.

The survey takes about 20 minutes to complete.

Do you have any questions about the survey?

Are you able to participate at this time?

[IF INTERESTED BUT NOT AVAILABLE AT THIS TIME, FIND OUT A GOOD TIME TO RE-CONTACT AND A PREFERRED NUMBER]

This subject was provided the information in this script and orally expressed the desire to participate.

Signature of interviewer: \_\_\_\_\_

Attempted Contact

Attempt 1 Date: \_\_\_\_\_

Attempt 2 Date: \_\_\_\_\_

Attempt 3 Date: \_\_\_\_\_

Attempt 4 Date: \_\_\_\_\_

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GENETIC AND CANCER HISTORY

Thank you for participating! I will now begin the initial portion of the survey, which covers BRCA testing and your BRCA test results. Although we have some of your information in our records, we would like to ask questions that verify your information for the purposes of this survey.

1. In what year were you born?

2. Prior to your test, approximately how many people in your family had been tested for changes in the BRCA 1 and 2 genes? [If none, go to Q4.1]

3. Prior to your test, was there a known BRCA mutation in your family?

Yes

No

Not sure

Refused

4.1 Did you tell any family members that you were having BRCA testing?

Yes

No [Go to Q5.1]

Not sure [Go to Q5.1]

Refused [Go to Q5.1]

4.2 Approximately how many family members did you tell?

5.1 Did you share your BRCA test result with any family members?

Yes

No [Go to Q7]

Not sure [Go to Q7]

Refused [Go to Q7]

5.2 Approximately how many family members did you share your results with?

# Acknowledgements

## **Clinical Sites**

*Battle Creek Health System:* Sue DeRuiter

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# Thank you!

## Questions?

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1. Aetna Clinical Policy Bulletin: BRCA Testing, Prophylactic Mastectomy, and Prophylactic Oophorectomy. Downloaded on 3/21/11 from [www.aetna.com/cpb/medical/data/200\\_299/0227.html](http://www.aetna.com/cpb/medical/data/200_299/0227.html)
2. U.S. Preventive Services Task Force. Task force recommends against routine testing for genetic risk of breast or ovarian cancer in the general population. Press Release. Rockville, MD: Agency for Healthcare Research and Quality; September 5, 2005. Available at: <http://www.ahrq.gov/news/press/pr2005/brcagenpr.htm>.

