Disclosure

- No conflicts to disclose
Overview

- Awareness and knowledge
- Insurance coverage
- Biases, assumptions and language barriers
- Recommendations
Awareness and Knowledge

- Survey questions: “Did you have genetic testing for hereditary cancer?” And “What were the results of your hereditary cancer test?”

- Not sure. 70% of the cells in my tumor were dividing so had to have chemo

- MammaPrint in 2011, CancerPlex in 2016

- Negative K-ras variation

- OncotypeDX
Survey on clinical research participation
Rate your familiarity with each of the following terms (N=1189)

- Genetic Testing:
  - Very familiar: 88.55%
  - Somewhat familiar: 3.67%
  - Unfamiliar: 10.60%

- Germline Mutation:
  - Very familiar: 60.83%
  - Somewhat familiar: 22.67%
  - Unfamiliar: 16.50%

- Genomic Testing:
  - Very familiar: 16.00%
  - Somewhat familiar: 36.37%
  - Unfamiliar: 32.83%

- Somatic Mutation:
  - Very familiar: 7.79%
  - Somewhat familiar: 16.00%
  - Unfamiliar: 76.21%

FORCE Survey: “What Patients Need to Know Before They Decide to Participate in Clinical Research: More Results from the Project IMPACT”
Awareness and Knowledge

FIRST OPINION

Consumers don’t need experts to interpret 23andMe genetic risk reports

By ANNE WOJCICKI / APRIL 9, 2018
Awareness and Knowledge

- People have broad, instant access to information via the Internet but may have to wait for access to genetics experts for interpretation and clinical context.

Hi everyone,

My 23andme/promethease testing indicated a BRCA2 mutation and my mom was diagnosed with ovarian cancer at age 48. I am 37. She has direct relatives who have had breast, endometrial, and uterine cancers. I have an appointment with a genetic counselor on 11/29 (waiting is hard!).

I saw my obgyn yesterday and brought him all this information. I feel like he really blew me off. I had to talk him into a mammogram (he said he’d order it just so we have a baseline). When I asked him about ovarian ultrasounds, CA125 testing, etc, he said no. Basically said that since those tests have a high rate of inaccuracy, he doesn’t like them. So he wants to do nothing and said if the genetic testing comes back without a mutation, I will pretty much never have those tests.

Post on FORCE Message Boards
Guidelines and Insurance Coverage

USPSTF

NCCN

Medicaid

BRCA testing

Affordable Care Act

Medicare

Companion diagnostic testing

Prostate cancer screening

Tumor testing

Colon cancer screening

Breast cancer screening

Panel testing
**USPSTF and Insurance**

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Details</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic counseling/testing for BRCA</td>
<td>• Genetic counseling and BRCA testing for women with family history of breast or ovarian cancer or a known BRCA mutation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Excludes women with active disease</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>• Excludes men</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Excludes other genes or syndromes – PALB2, ATM, Lynch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Letter grade does not extend to risk-management interventions like MRI or surgery</td>
<td></td>
</tr>
<tr>
<td>Breast screening</td>
<td>• Breast screening recommendations for women of average risk</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>• Biennial mammogram from age 50 - 74</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Letter grade C for screening women ages 40-49 – however covered under PALS Act</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No risk-based breast screening included in guidelines (MRI, mammogram before 50, etc)</td>
<td></td>
</tr>
<tr>
<td>Colon cancer screening</td>
<td>• The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years.</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>• No risk-based breast screening recommendation included in letter grade</td>
<td></td>
</tr>
<tr>
<td>Prostate cancer screening</td>
<td>• For men aged 55 to 69 years of average risk, discuss the potential benefits and harms of screening with doctor</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>• Letter grade D for men 70 years and older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No risk-based recommendation included in guidelines</td>
<td></td>
</tr>
</tbody>
</table>

Guidelines with letter grades “A” or “B” require insurance coverage with no out of pocket costs under the PPACA.
I am 29 years old and tested positive for the BRCA2 gene a couple of months ago. My mother had breast cancer at age 40. I just had my first MRI last month, and am fighting with my insurance company and the imaging center to get this covered...my bill is expensive-- close to $1000 for this one test.
### Medicare Coverage

#### HBOC - Germline testing
- Ovarian cancer
- Breast cancer with additional criteria (young onset, bilateral, family history, Jewish)
- Male breast cancer
- Expanded coverage in 19 states to include:
  - Men with prostate cancer
  - People with pancreatic cancer
  - Panel testing if family history is consistent w/more than one mutation
- Companion diagnostic for advanced ovarian or metastatic breast cancer in people who qualify for Lynparza

#### Lynch Syndrome testing
- Tumor IHC/MSI testing for colorectal & endometrial cancer
- Germline testing
  - Based on tumor results
  - Or if diagnosed w/another LS cancer and family member has tested positive
  - Or if tumor unavailable in patient with CRC or endometrial cancer
  - Or if CRC or endometrial cancer diagnosis prior to Medicare eligibility AND tumor sample no longer available
- Companion diagnostic for treatment
## Medicare Coverage

<table>
<thead>
<tr>
<th>Breast Screening and Prevention</th>
<th>Colon Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average risk:</strong></td>
<td><strong>Average risk:</strong></td>
</tr>
<tr>
<td>• Baseline mammogram at age 35-40</td>
<td>• Fecal occult blood every 12 months</td>
</tr>
<tr>
<td>• Annual mammogram age 45 and older</td>
<td>• Flexible sigmoidoscopy every 4 years, or colonoscopy every 10 years</td>
</tr>
<tr>
<td><strong>High risk:</strong></td>
<td>• Barium enema every 4 years</td>
</tr>
<tr>
<td>• No consistent coverage for breast screening MRI (diagnostic MRI is often covered)</td>
<td>• Cologuard® stool DNA test every 3 years</td>
</tr>
<tr>
<td>• Inconsistent coverage for risk-reducing surgery</td>
<td><strong>High risk:</strong></td>
</tr>
<tr>
<td></td>
<td>• Colonoscopy once every 2 years (with no minimum age listed)</td>
</tr>
<tr>
<td></td>
<td>• Barium enema once every 2 years (if done instead of colonoscopy or flexible sigmoidoscopy)</td>
</tr>
</tbody>
</table>
Medicare Coverage

A FORCE member’s daughter is in her 30s and on disability with Medicare as her insurance. Medicare will not pay for a prophylactic oophorectomy. There is early-onset ovarian cancer in the family, her aunt was diagnosed with ovarian cancer and died in her mid-30s.
Four in five doctors said they didn't expect insurance to cover genetic tests within the next five years. And, half of physicians worried that insurers might use genetic test results to deny coverage or charge higher premiums to patients.

Source, Medscape: Doctors Have Cost Concerns About Genetic Tests for Disease Risk. June 16, 2018
It’s my understanding that woman are protected if BRCA positive for insurance however men are not. This is concerning for my boys.

Insurance often does not pay for it and many doctors still seem hesitant to recommend it.

My doctor said testing was too expensive. They haven't returned my calls about it the last two times I've called.
Cancer genetic testing seems to reach a broad geographic and sociodemographic population...there remain underrepresented groups, including Hispanics, the uninsured, noncitizens, and those with less education.

## Disparities/Biases/Misperceptions

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Breast/Ovarian</th>
<th>Colorectal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>230</td>
<td>101</td>
</tr>
<tr>
<td>Stratification by cancer status (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affected</td>
<td>47</td>
<td>32</td>
</tr>
<tr>
<td>Unaffected</td>
<td>53</td>
<td>68</td>
</tr>
<tr>
<td>Stratification by gender (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>8</td>
<td>50</td>
</tr>
<tr>
<td>Women</td>
<td>92</td>
<td>50</td>
</tr>
<tr>
<td>Stratification by cancer status and gender (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affected men</td>
<td>Too small to estimate</td>
<td>16</td>
</tr>
<tr>
<td>Unaffected men</td>
<td>5</td>
<td>34</td>
</tr>
<tr>
<td>Affected women</td>
<td>43</td>
<td>16</td>
</tr>
<tr>
<td>Unaffected women</td>
<td>49</td>
<td>34</td>
</tr>
<tr>
<td>Rate Ratios (Ratio)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men vs. women</td>
<td>.10</td>
<td>1.06</td>
</tr>
<tr>
<td>Unaffected men vs. women</td>
<td>.10</td>
<td>1.04</td>
</tr>
</tbody>
</table>

Most strikingly, unaffected men underwent genetic testing at half the rate of unaffected women, owing to a 10 to 1 disparity in HBOC testing.

Conclusion: Previous theories for underutilization of HBOC testing in men include lack of patient and clinician awareness on the importance of HBOC mutation status—despite the risks of male breast, pancreatic, melanoma, and aggressive prostate cancers, and social roles of men vs women in health. The latter argument seems less likely given the lack of gender disparity in colorectal/other cancer testing.
Disparities/Biases/Misperceptions

BBC NEWS

Health

Angelina Jolie gene testing for all?

By James Gallagher
Health and science correspondent, BBC News

18 January 2018

'Angelina Jolie gene' may be linked to Alzheimer's, researchers say

Scientists at the University of California, San Francisco found low levels of BRCA1, the DNA repair gene, in the brains of patients who had died from Alzheimer's.

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FORC3
Facing Our Risk of Cancer Empowered
Solving for Y: Reaching Men About Genetic Testing for Hereditary Breast, Ovarian, Pancreatic, Prostate And Related Cancers (HBOC)

June 17, 2018

by Sue Friedman

Half of all people with an inherited BRCA, ATM, CHEK2, PALB2 or other mutation associated with HBOC are men. Nevertheless, the majority of awareness, resources, and attention on genetic testing in women. However, this disparity in BRCA testing between genders persists. Emerging information on the importance of Lynch syndrome reinforces the importance of support and advocacy efforts.

According to the article by Chetan, approximately 20% of men have BRCA genetic testing at some point in their lives. However, no such disparity in testing exists for Lynch syndrome, colorectal, uterine, and ovarian cancers.
Recommendations

- Alignment of guidelines, regulations and coverage
- Review guidelines annually and update as necessary
- Reimbursement for actual interventions, not only tests
- More coordination of tumor/genetic testing
- Better education of providers, patients and public
- Address disparities
- Adapt language and public messaging that is sensitive, inclusive, and consistent
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