Genomic/Genetic Services: Barriers to Access

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Sue Friedman, DVM
National Academies of Science Roundtable
06/26/18

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”

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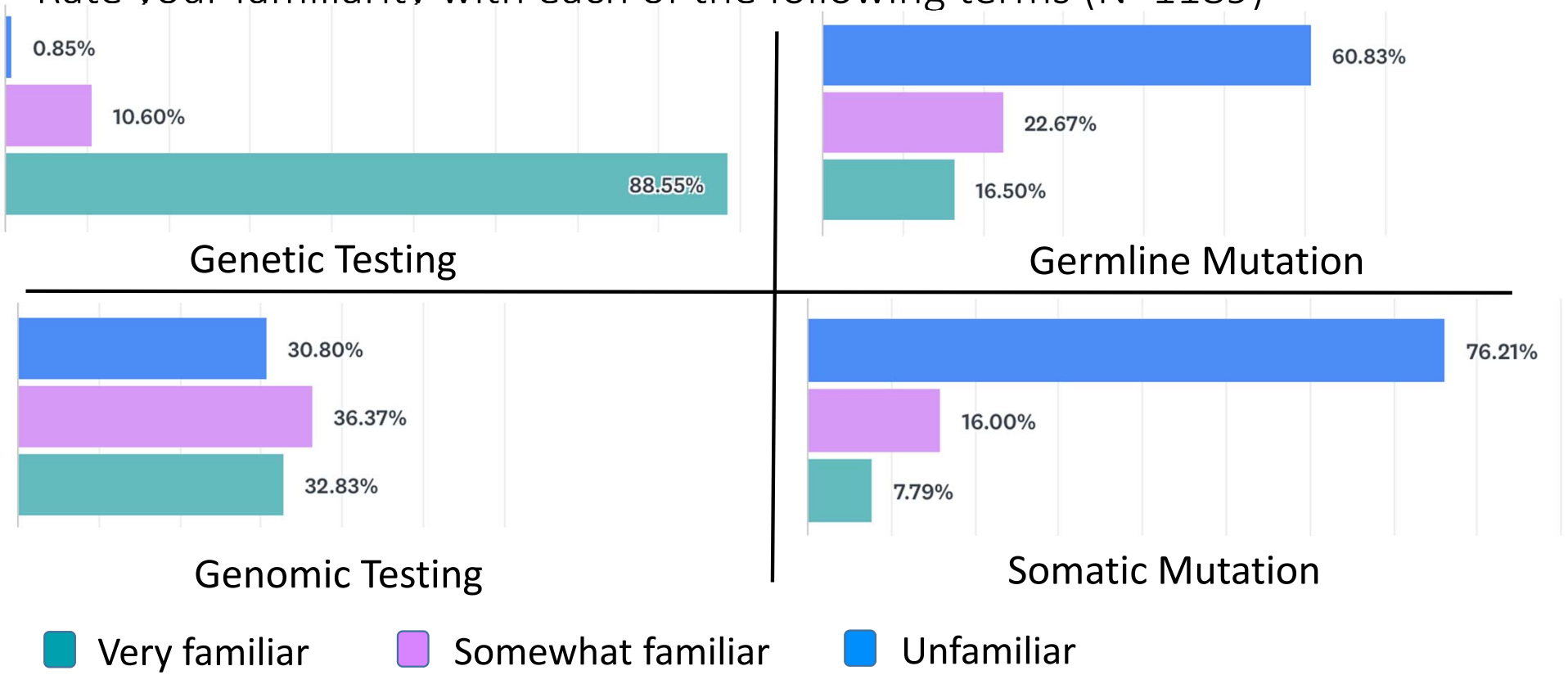
Awareness and Knowledge

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



FORCE Survey: "What Patients Need to Know Before They Decide to Participate in Clinical Research: More Results from the Project IMPACT"

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Awareness and Knowledge

FIRST OPINION

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

By ANNE WOJCICKI / APRIL 9, 2018

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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

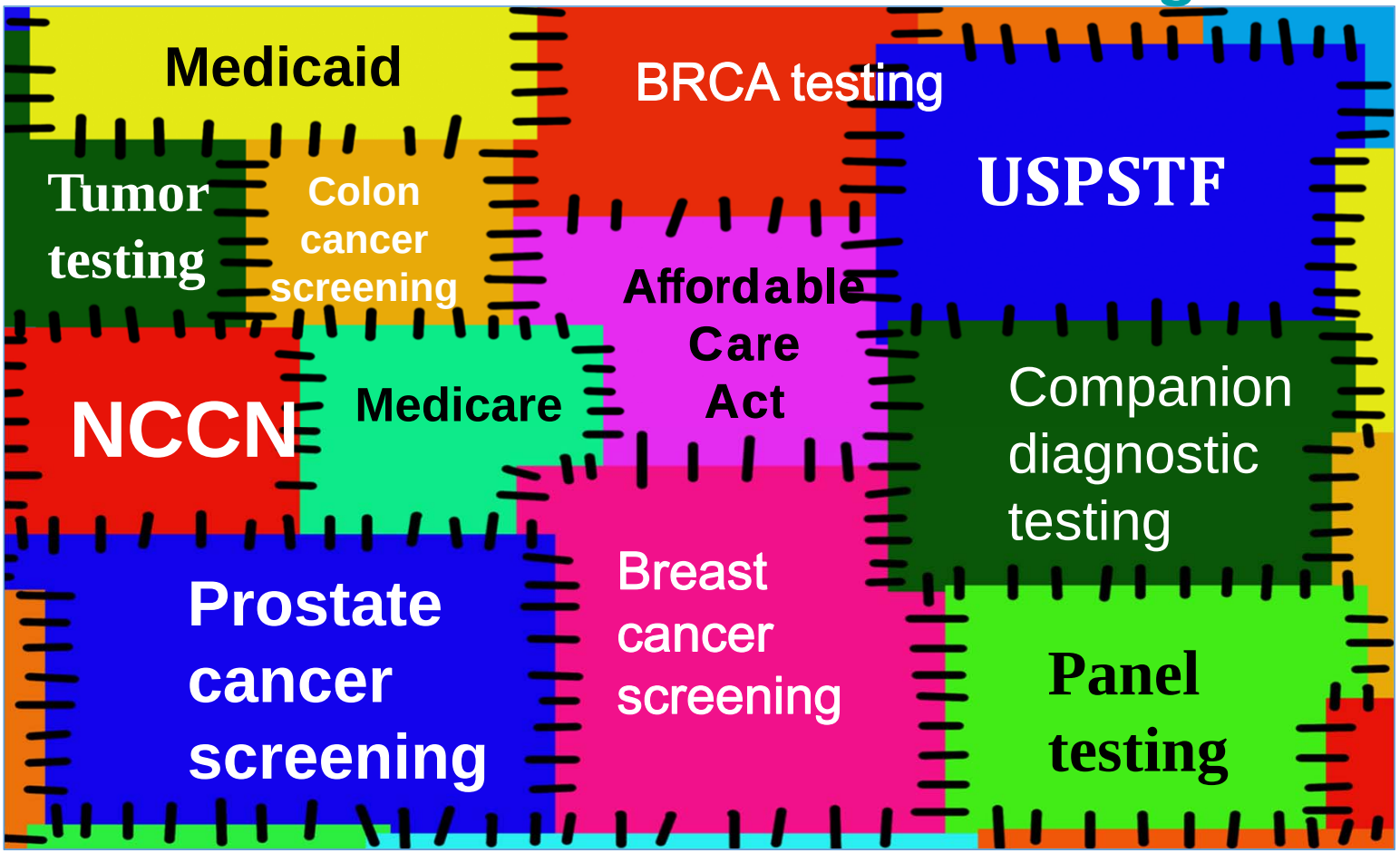
Hi everyone,

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



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USPSTF and Insurance

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

Insurance Coverage

> 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.

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Medicare Coverage

HBOC - Germline testing	Lynch Syndrome 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
	• 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

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Medicare Coverage

Breast Screening and Prevention	Colon Screening

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

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.

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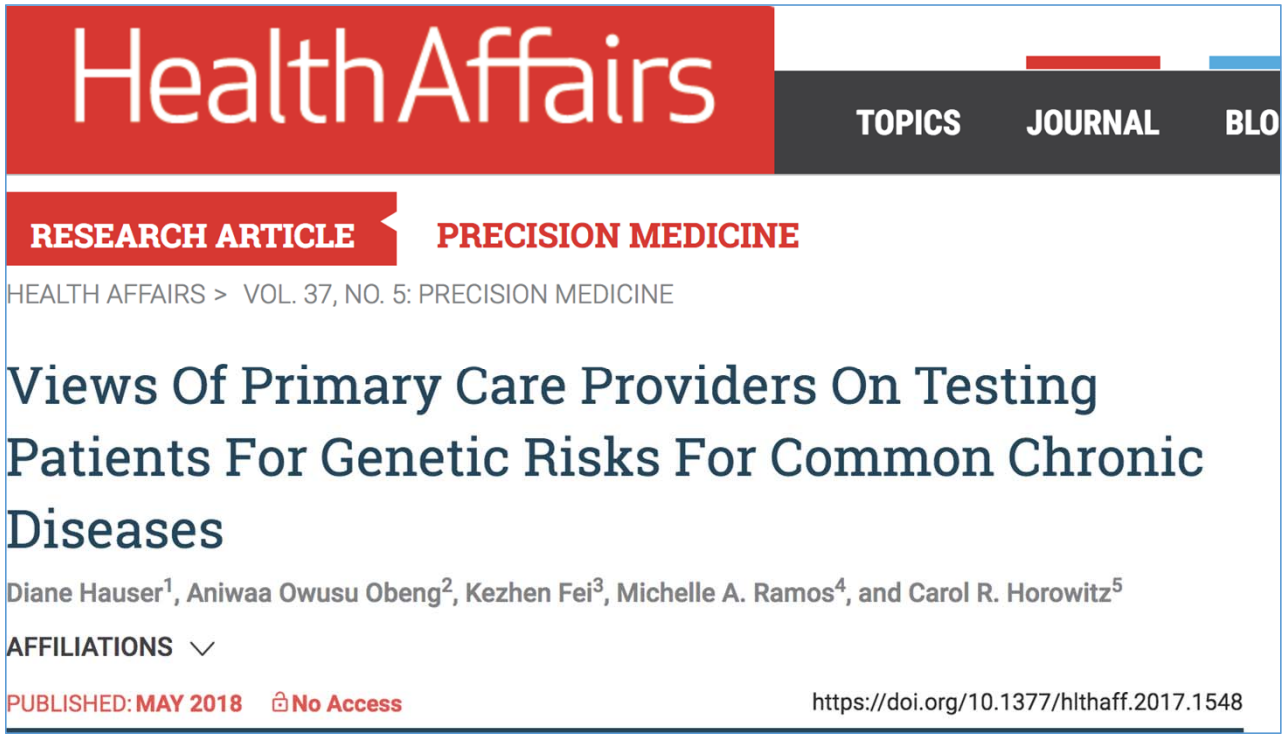
Disparities/Biases/Misperceptions



Health Affairs

TOPICS JOURNAL BLO

RESEARCH ARTICLE PRECISION MEDICINE

HEALTH AFFAIRS > VOL. 37, NO. 5: PRECISION MEDICINE

Views Of Primary Care Providers On Testing Patients For Genetic Risks For Common Chronic Diseases

Diane Hauser[1], Aniwaa Owusu Obeng[2], Kezhen Fei[3], Michelle A. Ramos[4], and Carol R. Horowitz[5]

AFFILIATIONS

PUBLISHED: MAY 2018 No Access https://doi.org/10.1377/hlthaff.2017.1548

Source, Health Affairs, Diane Hauser; Carol R. Horowitz, et. al.Vol. 37, No. 5 Precision Medicine. May, 2018l

> 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

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Disparities/Biases/Misperceptions

> 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.

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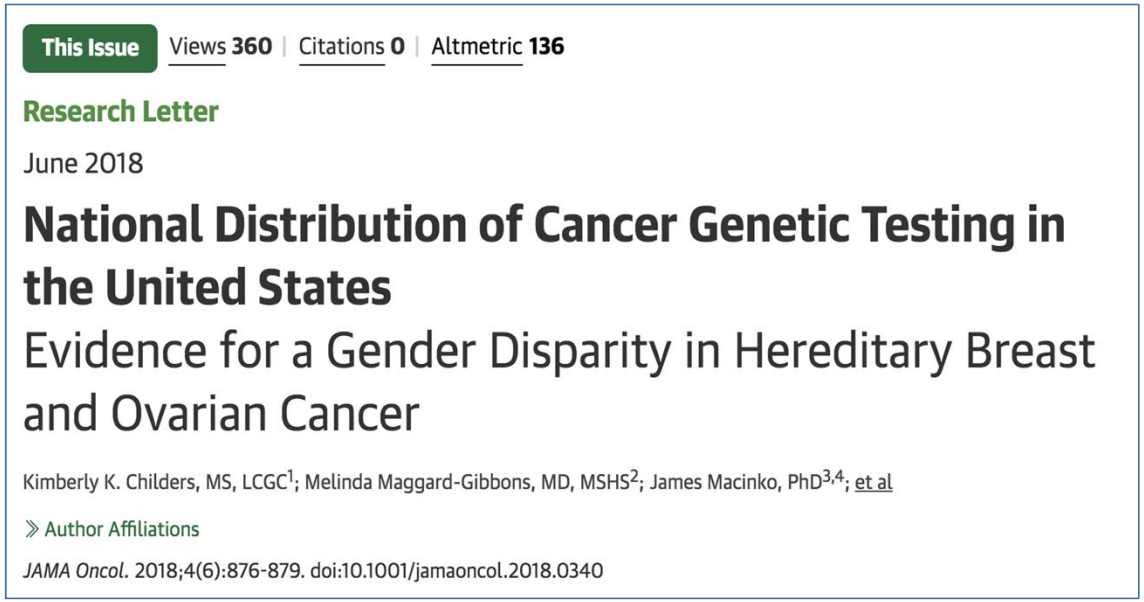
Disparities/Biases/Misperceptions



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Research Letter

June 2018

National Distribution of Cancer Genetic Testing in the United States

Evidence for a Gender Disparity in Hereditary Breast and Ovarian Cancer

Kimberly K. Childers, MS, LCGC[1]; Melinda Maggard-Gibbons, MD, MSHS[2]; James Macinko, PhD[3,4]; et al

» Author Affiliations

JAMA Oncol. 2018;4(6):876-879. doi:10.1001/jamaoncol.2018.0340

> 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.

Source: Childers KK, Maggard-Gibbons M, Macinko J, Childers CP. National Distribution of Cancer Genetic Testing in the United States: Evidence for a Gender Disparity in Hereditary Breast and Ovarian Cancer. *JAMA Oncol.*2018;4(6):876–879. doi:10.1001/jamaoncol.2018.0340

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Disparities/Biases/Misperceptions

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

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

Source: Table created from data from Childers, et.al. *JAMA Oncol.*2018;4(6):876–879. doi:10.1001/jamaoncol.2018.0340

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Disparities/Biases/Misperceptions

> 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.

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Disparities/Biases/Misperceptions

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Health

Angelina Jolie gene testing for all?

By James Gallagher
Health and science correspondent, BBC News

18 January 2018 | Share

'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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Disparities/Biases/Misperceptions

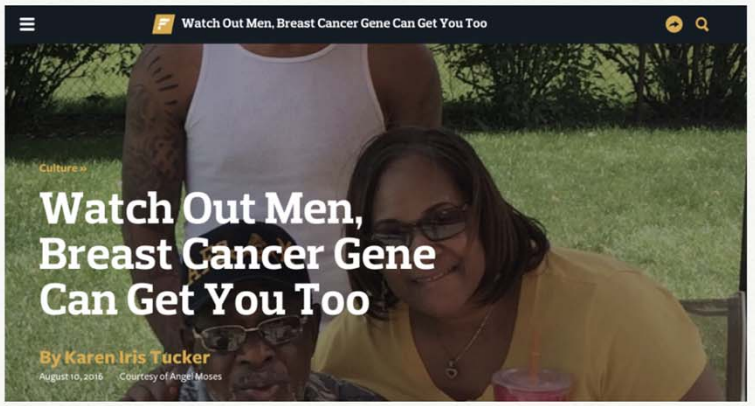
Solving for Y: Reaching Men About Genetic Testing for Hereditary Breast, Ovarian, Pancreatic, Prostate And Related Cancers (HBOC)

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, res
on genetic testing in women.
this disparity in BRCA testing b
Emerging information on the i
reinforces the importance of F
support and advocacy efforts

According to the article by Ch
have BRCA genetic testing at
However, no such disparity in
was seen for Lynch syndrome,
colorectal, uterine, and ovaria



FORCE volunteer, Angel Moses and her father were the subject of a FORWARD article about genetic testing in men

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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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Connect with us

Website:

FacingOurRisk.org

Helpline:

866-288-RISK (7475)

Email:

info@FacingOurRisk.Org

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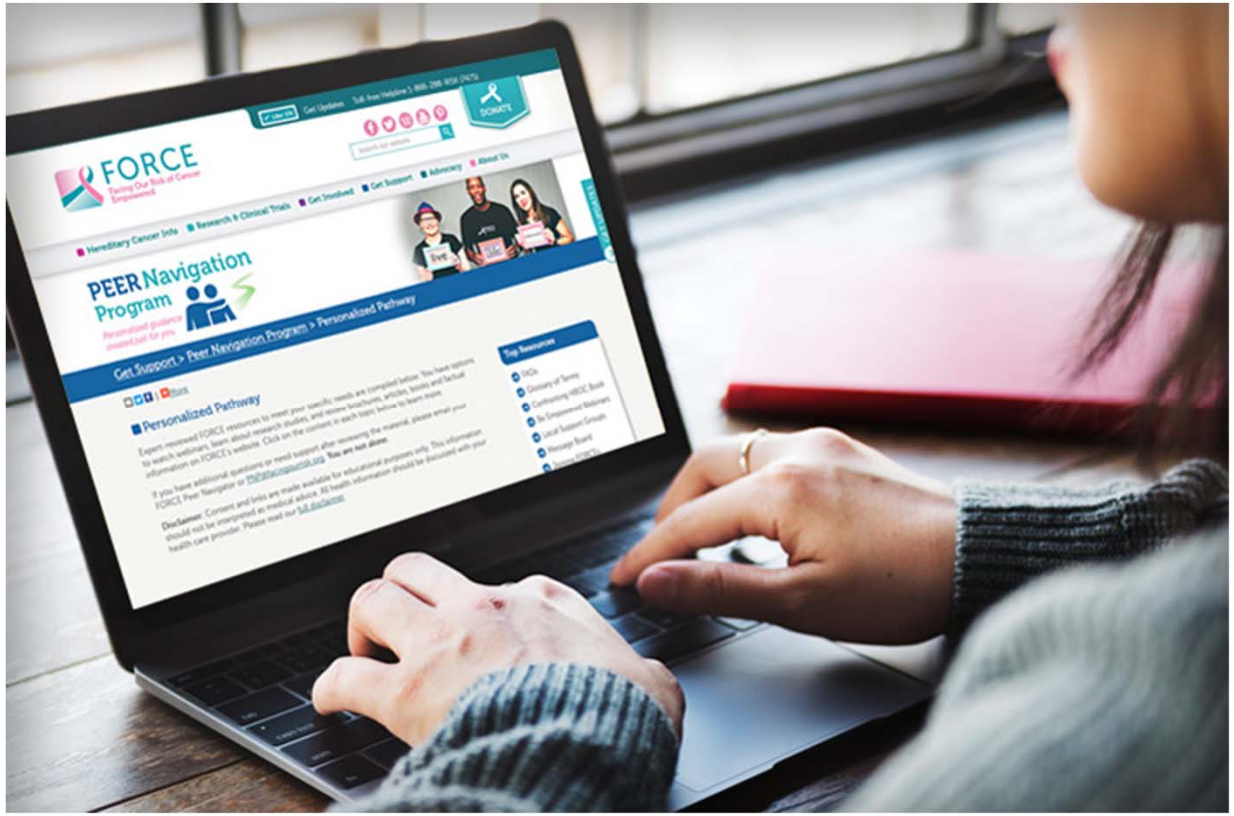

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