



SESSION 1: Overview of Multicancer Detection Testing

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FORCE

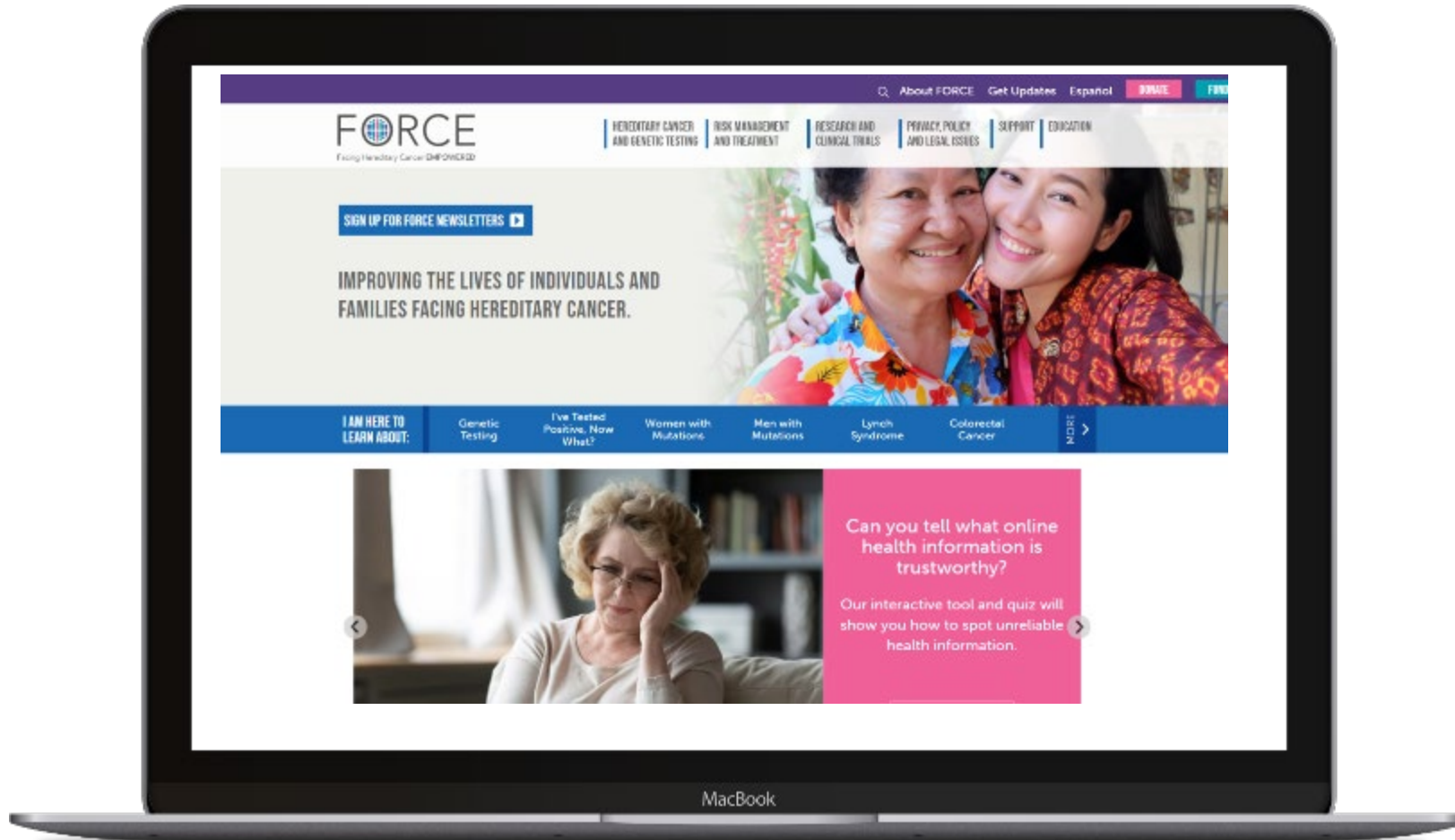
Facing Hereditary Cancer **EMPOWERED**

Disclosure

I have no conflicts to disclose

Note: opinions expressed in this presentation are my own.

ABOUT FORCE



FORCE serves people and families affected by Lynch syndrome or an inherited mutation in BRCA, ATM, CHEK2, PALB2,, PTEN or other gene linked to cancer. We accomplish this through our education, support, advocacy and research efforts.



The Burden of Hereditary Cancers

- Increased lifetime risk for cancer
- Younger-onset cancer risks.
- Risks for multiple primary cancer diagnoses.
- Risks run in families and are shared with blood relatives.



Risk for Multiple Types of Cancer

Lynch Syndrome

- colorectal
- endometrial
- ovarian
- pancreatic
- other

BRCA1/BRCA2

- breast
- ovarian
- pancreatic
- prostate

Intensive Risk-Management Recommendations

Lynch Syndrome



National Comprehensive
Cancer Network®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

**Genetic/Familial High-Risk Assessment:
Colorectal, Endometrial, and Gastric**

Version 2.2024 — October 3, 2024

NCCN.org

NCCN recognizes the importance of clinical trials and encourages participation when applicable and available.
Trials should be designed to maximize inclusiveness and broad representative enrollment.

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BRCA1/BRCA2



National Comprehensive
Cancer Network®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

**Genetic/Familial High-Risk Assessment:
Breast, Ovarian, and Pancreatic**

Version 1.2025 — September 11, 2024

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Burden of High-Risk Screening

... Last colonoscopy I had was when I could use my insurance and my parents as a secondary. Can't do \$4000 every year. Just not doable.

I need support leading up to my colonoscopy every year as I am terrified of the prep.

I'm an under 50 Lynchie and haven't had a colonoscopy yet because I was told it would cost me \$3,000-\$5,000.

I'm 40 and I've never been able to get my insurance to cover colonoscopy as preventive, so I pay about \$2500 before I hit my deductible.

Burden of High-Risk Screening

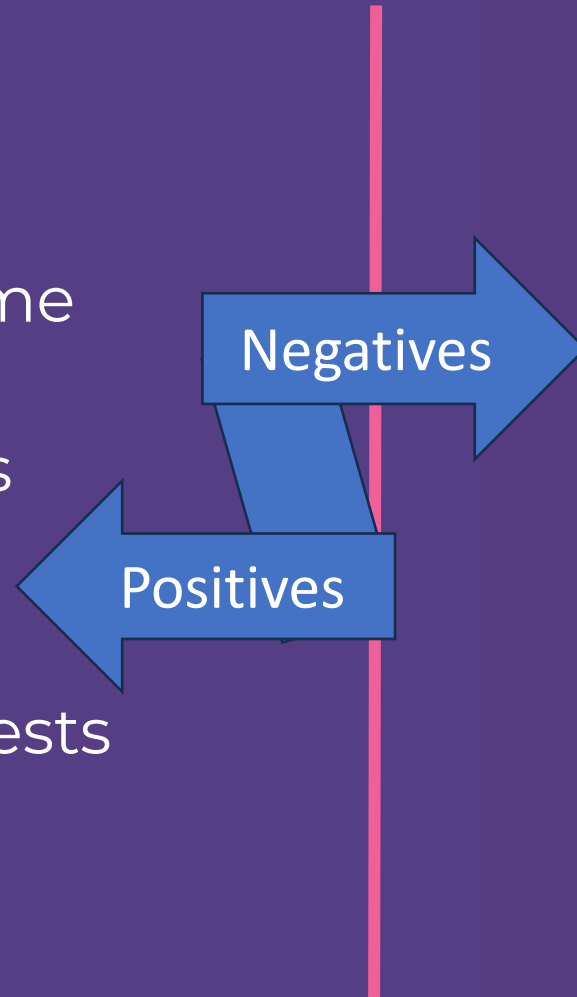
The financial burden of breast MRIs deters me from the additional screenings that are recommended.

I live in a services desert. The nearest breast MRI is a 3 ½ hour drive...
ONE WAY.

Lack of resources in the region plus changes by my provider from one system to another have cut me off from recommended screenings for the past five years.

Balancing Test Benefits vs. Risks, Costs and Limitations

- Lower cost than currently available high-risk screening
- Less preparation time
- Fewer stressful, invasive procedures
- Less travel
- Could reserve more invasive/intensive tests as follow-up for abnormal results



- Clinical validity/utility need to be established, especially for diverse groups & rare cancers.
- People may forego guideline-recommended interventions in favor of a blood test.
- False positives means more invasive procedures.
- Limited dollars for preventive care can exacerbate disparities for high-risk screening.

Media Hype

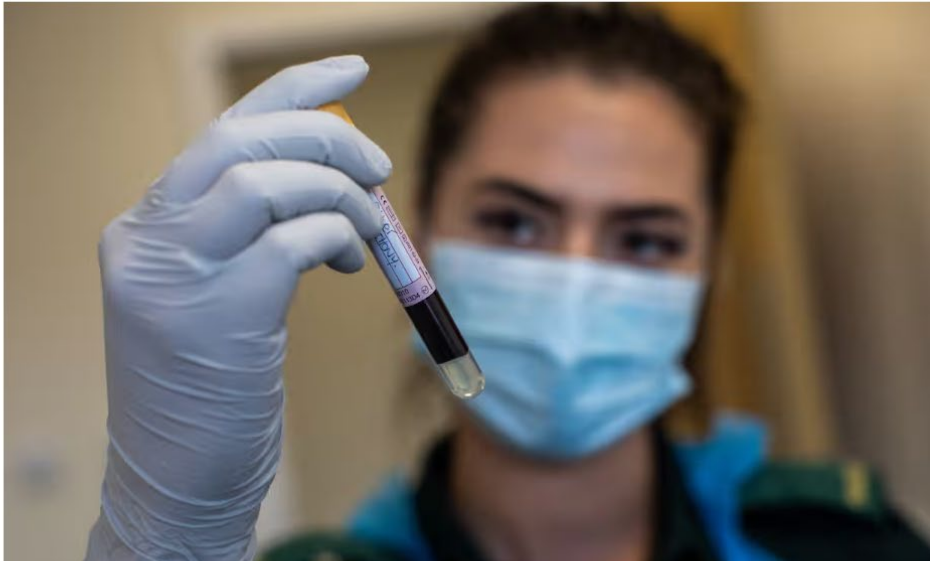
Blood test that finds 50 types of cancer is accurate enough to be rolled out

Diagnostic tool being piloted by NHS England shows 'impressive results' in spotting tumours in early stages

Nadeem
Badshah and
agency

Fri 25 Jun 2021 01:00
EDT

Share



The blood tests are accurate enough to be rolled out as a screening test, scientists say.
Photograph: Getty Images

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Health Headlines: Holy Grail of cancer screening

BREAST CANCER
CERVICAL CANCER
COLON CANCER
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HEALTH HEADLINES

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6:12 66°

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- Nadine Badshaw and Agency, "Blood test that finds 50 types of cancer is accurate enough to be rolled out." *The Guardian*. June 25, 2021.
- Rhonda Kitchens. "Health Headlines: Holy Grail of cancer screening." *WKPLC, Channel 7*. October 15, 2024.

Social Media Amplification

**Aria Integrative Medicine**
February 26 · 🌐

Cancer Hides and Galleri knows how to find it! Today is the last day to sign up for our Cancer screening event which can detect over 50+ cancers in one blood draw!
[#earlycancerdetetion](#) [#galleri](#) [#ariaintegrative](#) [#aimaccess](#)

ATTENTION!

Last Chance to sign up for
our Cancer Screening event
2/27/24
1-5pm
DM for more info
@ariaintegrative

 2

1 comment

 3 days ago · 🌐

Thank you Jesus! I just got back my GRAIL Galleri test! It's a early detection multi cancer screening test that test for 50 different types of cancers.

Negative for cancer! Thank you Jesus!

So glad that my life insurance cares about my health and my longevity that they gift their policy holders this test for free! Crazy that my medical insurance doesn't cover this!... [See more](#)

**Galleri**
Josephine A. Martindale
GRAIL ID: GAL4CCB009

Multi-cancer early detection test report

Patient	Sample	Ordering Provider
Name: Josephine A. Martindale	GRAIL ID: GAL4CCB009	Name: Chi Truong
Patient ID: -	Sample Type: Whole Blood	Location: Recurs Health
DOB: 01-MAR-1980	Report Date: 20-OCT-2024 / 14:10 ET	Address: 309 N Washington Ave Suite 13
Bio Sex: Female	Collection Date: 07-OCT-2024	Bryan, TX 77803
		Phone: 18336911714
		Fax: -

Your Result
**No Cancer Signal Detected**
The Galleri® test did not detect DNA methylation patterns that are associated with cancer in your blood sample. In a clinical study*, on average, fewer than 2 out of 100 people with a "No Cancer Signal Detected" result received a cancer diagnosis (Negative Predictive Value or NPV).

We've Been Here Before



genomeweb

A CRAIN FAMILY BRAND

Business & Policy Technology Research Diagnostics Disease Areas Applied

[Home](#) » [Diagnostics](#)

Patient Group Urges HHS Panel to Push for Oversight of Dx Firms' Marketing Practices

Oct 14, 2009

We've Been Here Before

- **How the laboratories market these tests to doctors and consumers**

People are making medical decisions today based on test results, sometimes in the absence of evidence. Therefore, the information that labs provide about these tests, and how they market them to doctors and consumers are significant matters. In 2009, we provided [testimony to the Secretary of Health's Advisory Committee on this topic](#), and based on that testimony, the FDA implemented a mechanism for health care providers to report adverse events stemming from laboratory tests.

Recommendations

- Require rigorous validation of MCED tests for diverse populations and in high-risk settings prior to commercialization.
- Require transparency about test benefits, risks, limitations and clinical utility in marketing materials to providers and in plain language for patients.
- Promote equitable access to guideline-recommended, risk-based cancer screening and preventive services for people of every risk level.
- Once validated, assure access for marginalized, over-burdened and under-resourced populations.