

Session 4: Strategies for Implementing MCDs into Clinical Practice

Health Care Delivery System Perspective

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NAM Workshop on Multicancer Detection Tests

October 28, 2024

Disclosures

- None

Sent: Thursday, February 1, 2024 5:10 PM

Subject: Upcoming Program through MGH Cancer Center's Early Detection and Diagnostics Clinic

On behalf of the Cancer Early Detection and Diagnostics Clinic, Douglas Micalizzi MD Ph.D., Clinical Director, and Lecia V. Sequist MD, MPH Program Director



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Dear Colleague,

We are reaching out to you today because over the next 1-2 months, some patients from your practice who are age 50 or older and insured via

“... some patients from your practice who are age 50 or older... will be receiving an invitation from their insurer to participate in a program offering a blood test to screen for multiple types of cancer. Point32Health is partnering with GRAIL (a diagnostics company) to cover the cost of this new blood test...”

you answer anticipated questions can be found below. Importantly, please know that we will encourage all patients we see to stay up to date with applicable standard cancer screening recommendations regardless of their blood test results. We will relay the blood test results to both the patients and to you. Should a test return with a cancer signal detected, we will work collaboratively with you to arrange further work-up as appropriate at an MGB location that is convenient for the patient. For additional information about the GRAIL Galleri® test and to see a copy of the invitation that your patients will be receiving, please visit <https://view-su2.highspot.com/viewer/641de13feec195a8185803a5>.



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Point32Health and Grail Expand Pilot Access to Galleri® Multi-Cancer Early Detection Blood Test

September 2023 | [News](#) [Press Releases](#)

Test is now available to certain Point32Health members who receive primary care with Mass General Brigham affiliated providers

Canton, Mass. and Menlo Park, Calif., September 28, 2023 — Point32Health, the parent company of Harvard Pilgrim Health Care and Tufts Health Plan, and GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, today announced the expansion of their pilot to offer GRAIL's groundbreaking Galleri® multi-cancer early detection screening test. The pilot includes members meeting eligibility requirements whose primary care provider (PCP) is a Mass General Brigham affiliated provider and who are covered under a Harvard Pilgrim Health Care or Tufts Health Plan employer-sponsored plan or a Harvard Pilgrim Health Care Massachusetts Connector plan.

"At Point32Health, we are proud to offer cutting-edge, innovative solutions that focus on improving the health and wellness of our members and the communities we serve," said Cain A. Hayes, president and CEO at Point32Health.

"We are excited to expand our pilot to include Mass General Brigham by offering members this early detection screening test that could potentially save countless lives."

7104-4-18



Go further with cancer screening

“We are partnering with GRAIL to offer our policy owners the Galleri® test, a multi-cancer early detection test...
...your test comes at no additional cost. GRAIL will share your results with you and not MassMutual – and your results will not impact your current policy.”

access vital information.

We're partnering with GRAIL to offer our policyowners the Galleri® test, a multi-cancer early detection test. Today, only 5 cancers have recommended screening tests. Through a single blood draw, the Galleri® test is able to detect more than 50 types of cancer, increasing the chance of finding cancer

Ready to get started?
Start your online visit now.

ion Test

Get started

Galleri Multi-Cancer Early Detection Test

\$949 / test
one-time charge

- 1 complete Galleri blood draw kit
- Includes lab visit & blood draw
- Receive results within about 2 weeks following blood draw
- Understand positive or negative cancer signals in blood
- Includes consultation & follow-up

Start online visit

er Early Detection Test

detection with the Galleri®
for over 50 types of
blood draw.

Where/How is MCD Testing Being Incorporated?

- Payers/health insurers
- Other insurers (e.g., outreach to life insurance policy holders)
- Direct to consumer marketing
- Health care provider organizations
 - Oncology clinics
 - Clinics for patients at high risk for cancer
 - Primary care clinics

→ Focus on use in average-risk screening populations



A Good Cancer Screening Test

- Finds cancer before symptoms occur
- Screens for cancer that is easy to treat and cure when found early
 - And facilities for diagnosis & treatment are available
- Has minimal risks and few false negative & false positive results
- Decreases cancer mortality
 - Has minimal/no overdiagnosis



Cancer Screening & Early Detection is Changing

The New York Times

*An Alternative to the Pap Smear
Is Here, No Speculum Required*

August 15, 2024



The New York Times

*A Colonoscopy Alternative Comes
Home*

January 11, 2021



The New York Times

*F.D.A. Approves Blood Test for Colon
Cancer Detection*

July 29, 2024



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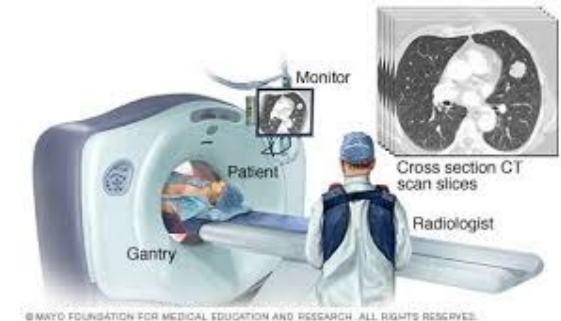
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The Level of Evidence Required Before Adopting a Screening Test is Also Changing

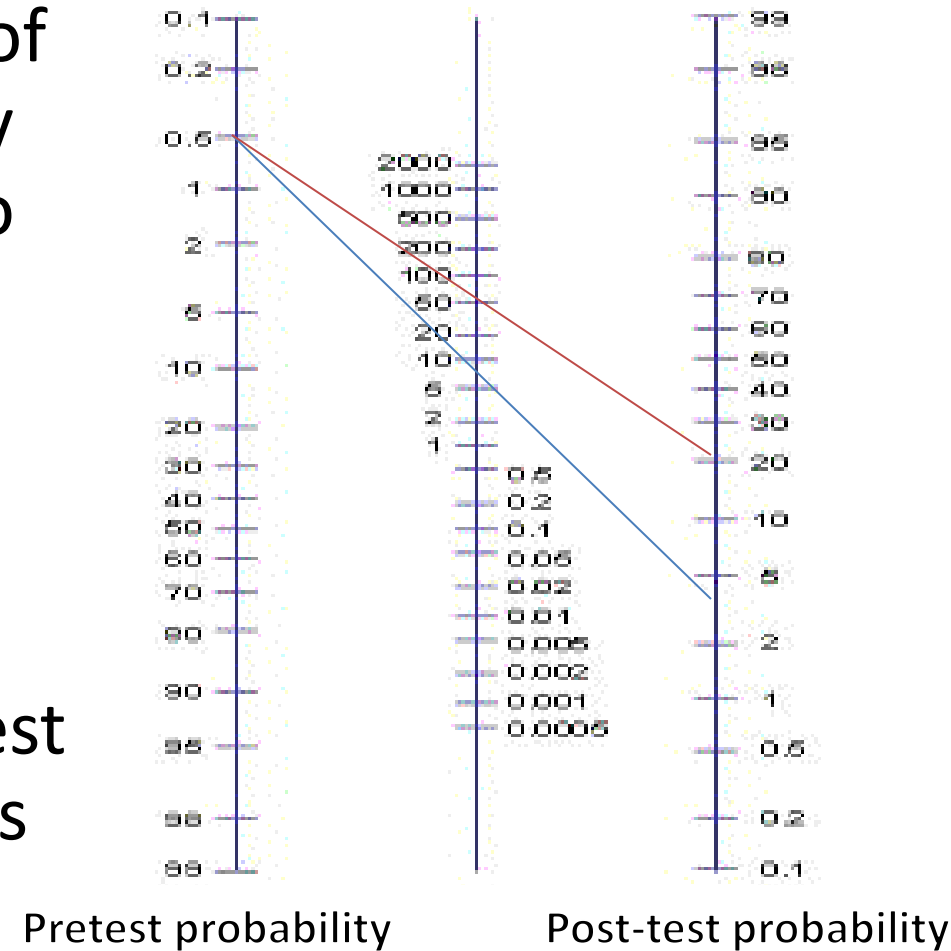
- RCT showing cancer specific mortality benefit
- Compelling comparison studies showing high sensitivity and specificity of a test to detect early-stage cancer for which benefits of screening established



Will MCD Testing Be Useful for Screening?

- Screening populations have low prevalence of disease and thus very low pretest probability
→ even good tests, when positive, do little to increase post-test probability
 - Assume sensitivity 87.5% & specificity = 89.9%
 - Likelihood ratio = $\frac{\text{sensitivity}}{1-\text{specificity}} = \frac{0.875}{0.101} = 8.67$
- older populations higher cancer risk (pre-test probability), but higher risk of overdiagnosis

Likelihood Ratio Nomogram



What Are the Risks of MCDs for Low-Risk Populations?

- Expand the number of people to be assessed for cancer
 - Numerous tests and some invasive searching for cancer that may or may not be found or need to be treated
 - Capacity issues with testing
 - What is a negative test result? When to stop looking for cancer?
- Overdiagnosis and overtreatment
 - Cancer cell in the body may not cause disease in lifetime
- False positives
 - Could tests be finding cells of benign diseases that look like the tumor cells
- Cascade testing of incidental findings
 - Anxiety, risks of complication, financial costs, access

What is Ahead?

- Will (or when will) FDA first approve MCD testing?
 - What type of evidence will be required? How will FDA approval in absence of outcome data influence test use?
- Will Congress pass legislation to “create a pathway for Medicare to cover MCD screenings once they are FDA approved”?

PRESS RELEASES

Home / Media / Press Releases

The Nancy Gardner Sewell Medicare MCD Screening Coverage Act Passes Unanimously in the House Ways and Means Committee

June 27, 2024

- Education needed to help public understand the limitations of test

What Additional Evidence is Coming Relatively Soon?

- NHS-Galleri trial of 140,000 individuals aged 50-77
 - RCT of Galleri + existing cancer screening vs. existing screening alone
 - Primary endpoint: incidence rate of stage III/IV cancer
- REACH study of 50,000 individuals aged 50+ with Medicare coverage (goal of 20% from under-represented populations)
 - Not an RCT-comparison group is passively enrolled contemporaneous group who receive usual care
 - Primary end point: incidence rate stage IV cancers

NHS

Galleri Trial

GRAIL



KING'S COLLEGE LONDON
CANCER PREVENTION
TRIALS UNIT

Galleri in the Medicare Population

Real-world Evidence to Advance Multi-Cancer Early Detection Health Equity

Neal et al, Cancers 2022; 14:4818; clinicaltrials.gov/study/NCT05673018



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Key Questions for Stakeholders

- Do benefits of MCD tests outweigh the harms?
 - How does this differ for (1) general populations, (2) high-risk populations, and (3) cancer survivors
 - How will various Guideline Committees consider the relative balance of benefits to harms? How to ensure trust when recommendations differ?
- How to address testing before clear evidence about benefits and harms?
 - How can we educate patients and clinicians about what is known and not known?
 - Who will be tested? What systems are needed for tracking MCD tests performed in absence of strong evidence and directing follow up evaluation?

Additional Questions for Implementation

- How is a high quality diagnostic evaluation defined? What is “negative” follow up testing? How to ensure that patients have access to and complete diagnostic testing?
- Can we utilize registries to ensure evidence generation, high-quality shared decision making, and tracking of testing and follow up?
- What is the cost of the test? Of follow up testing? Of implementing screening programs? Who pays?
- How does access to testing & care vary by patient characteristics? How can delivery systems ensure that all patients with a positive test have access to testing and resulting treatment?

Questions/Comments
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