SCHOOL OF PUBLIC HEALTH
CENTER FOR VALUE-BASED INSURANCE DESIGN
UNIVERSITY OF MICHIGAN

Reading the Crystal Ball: Clinical and Economic Implications while Awaiting Outcomes for Multi-cancer Early Detection Tests (and other musings on cancer screening)

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www.vbidcenter.org

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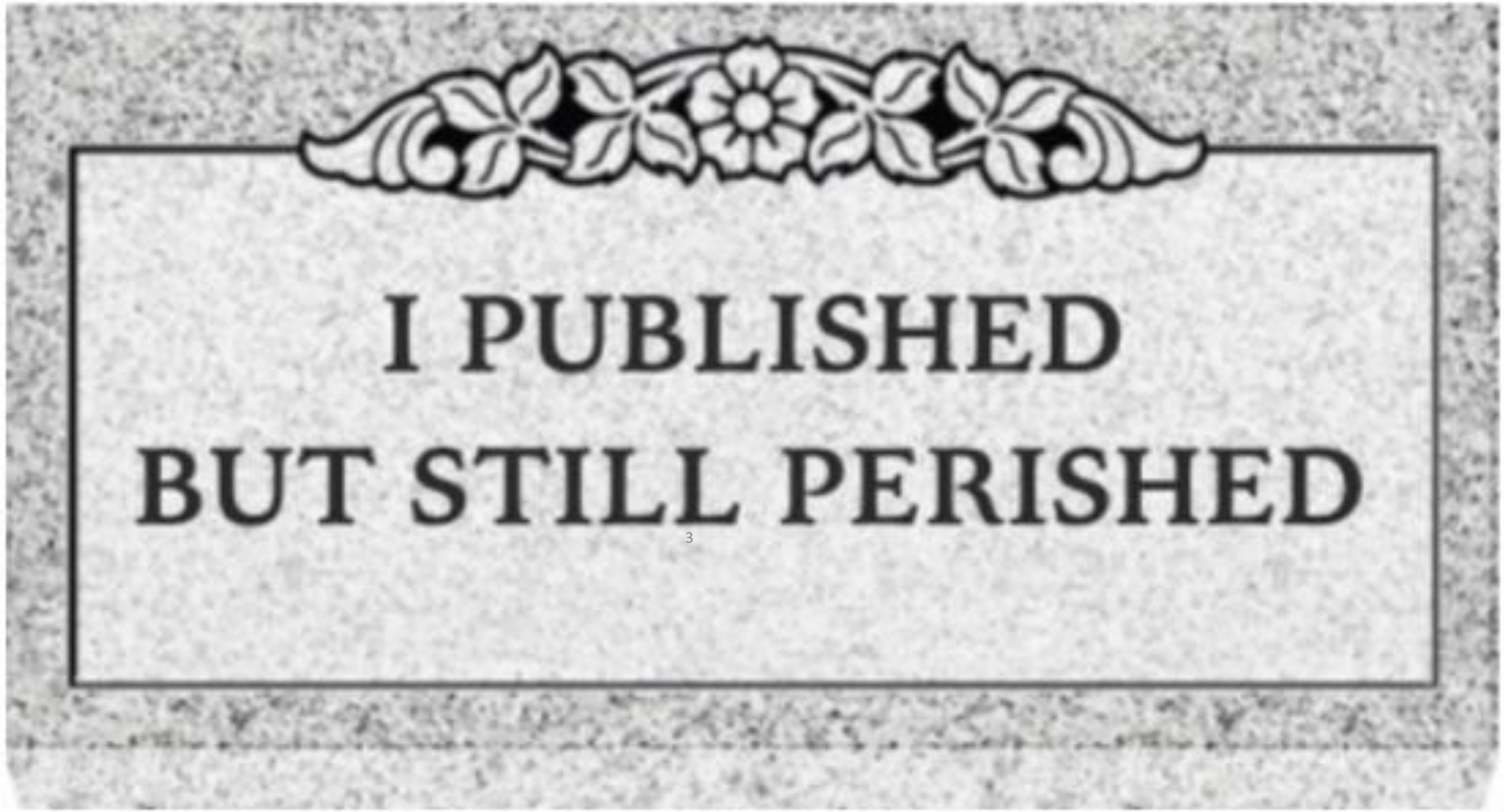
Reading the Crystal Ball: Outline

- A bit about me


I PUBLISHED
BUT STILL PERISHED

Reading the Crystal Ball: Outline

- A bit about me
- An abbreviated Value-Based Insurance Design journey
- Musings about currently recommended cancer screening
- Waiting (impatiently) for the promise MCEDs

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Health care costs now the top policy issue:
Solutions must protect consumers, reward clinicians and preserve innovation

- Innovations to prevent and treat disease have led to impressive reductions in morbidity and mortality
- Irrespective of remarkable clinical advances, cutting health care spending is the primary focus of healthcare reform discussions
- Underutilization of high-value care persists across the entire spectrum of clinical care leading to poor patient-centered outcomes
- Everyone (almost) agrees there is enough money in the US health care system; we just spend it on the wrong services and in the wrong places
- Americans don't care about health care costs; they care about what It costs them

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Inspiration (Still)

"I can't believe you had to spend a million dollars to show that if you make people pay more for something, they will buy less of it."

- Barbara Fendrick (my mother, 1934-2024)

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"Blunt" Cost-Sharing Worsens Health Care Disparities (Surprise)

Effects of Increased Patient Cost Sharing on Socioeconomic Disparities in Health Care

Michael Chernew, PhD[1] Teresa B. Gibson, PhD[2] Kristina Yu-Isenberg, PhD, RPh[3]
Michael C. Sokol, MD, MS[4] Allison B. Rosen, MD, ScD[5], and A. Mark Fendrick, MD[5]

Cost-sharing worsens disparities and adversely affect health, particularly among economically vulnerable individuals and those with chronic conditions

Chernew M. *J Gen Intern Med* 23(8):1131–6.

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A Clinically Based Alternative to "Blunt" Consumer Cost-sharing: Value-Based Insurance Design - More of the Good Stuff and Less of the Bad Stuff

- Sets consumer cost-sharing on clinical benefit – not price
- Little or no out-of-pocket cost for high-value care; higher cost-sharing for low-value care
- Implemented by hundreds of public and private payers
- Bipartisan political support
- Enhances equity

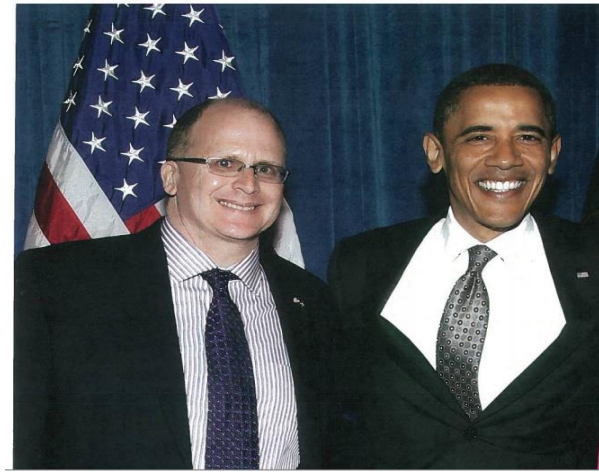
By Niteesh K. Choudhry, Katsiaryna Bykov, William H. Shrank, Michele Toscano, Wayne S. Rawlins, Lonny Reisman, Troyen A. Brennan, and Jessica M. Franklin

Eliminating Medication Copayments Reduces Disparities In Cardiovascular Care

Putting Innovation into Action: Translating Research into Policy

THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

ACA Sec 2713: Preventive Services Provision
Selected Preventive Services Must be Provided without Cost-Sharing



- Receiving an A or B rating from the United States Preventive Services Taskforce (USPSTF)
- Immunizations recommended by the Advisory Committee on Immunization Practices (ACIP)
- Preventive care and screenings supported by the Health Resources and Services Administration (HRSA)

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By amending Sec 2713, the CARES Act of 2020 mandated COVID-19 testing and vaccines to be provided without patient cost-sharing

ASPE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION | OFFICE OF HEALTH POLICY

ISSUE BRIEF

January 11, 2022

HP-2022-01

Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act

- Over 230 million Americans have enhanced access to preventive services
  - 150 million with private insurance – including 58 M women and 37 M children
  - 61 million Medicare beneficiaries
  - Approximately 20 million Medicaid adult expansion enrollees
- A majority of studies showed increases in use of fully covered services
- Studies that included socioeconomic status reported more substantial increases in utilization of preventive services in financially vulnerable patients, suggesting that **the policy reduced disparities in the delivery of preventive care**

The NEW ENGLAND JOURNAL of MEDICINE

CURRENT I

PERSPECTIVE

Preventive Care at the Supreme Court

Author: Nicholas Bagley, J.D. Author Info & Affiliations

Published July 23, 2025 | DOI: 10.1056/NEJMp2506684 |

- **Supreme Court upheld the ACA preventive care mandate (for now)**
- **HHS secretary can exercise control over the task force**

Pay attention to actions directed at the USPSTF

CANCER SCREENING

The Impact of a Celebrity Promotional Campaign on the Use of Colon Cancer Screening

The Katie Couric Effect

Peter Cram, MD, MBA; A. Mark Fendrick, MD; John Inadomi, MD; Mark E. Cowen, MD, SM; Daniel Carpenter, PhD; Sandeep Vijan, MD, MS

2000

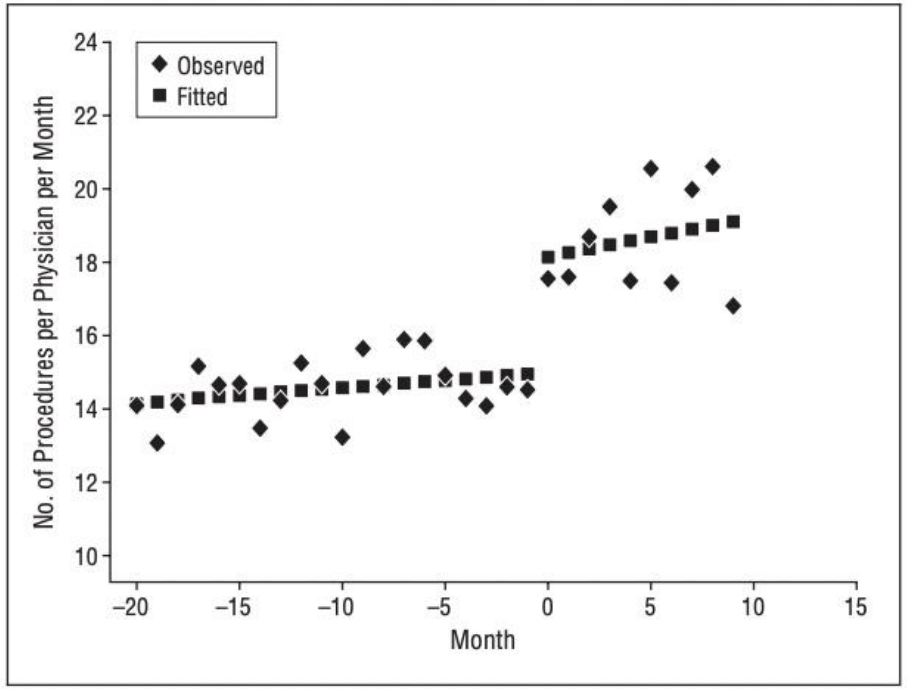


Figure 1. Monthly colonoscopy rates in the Clinical Outcomes Research Initiative database from July 1998 to December 2000. Ms Couric's cancer awareness campaign was televised on the *Today Show* in March 2000 (month 0).

2003

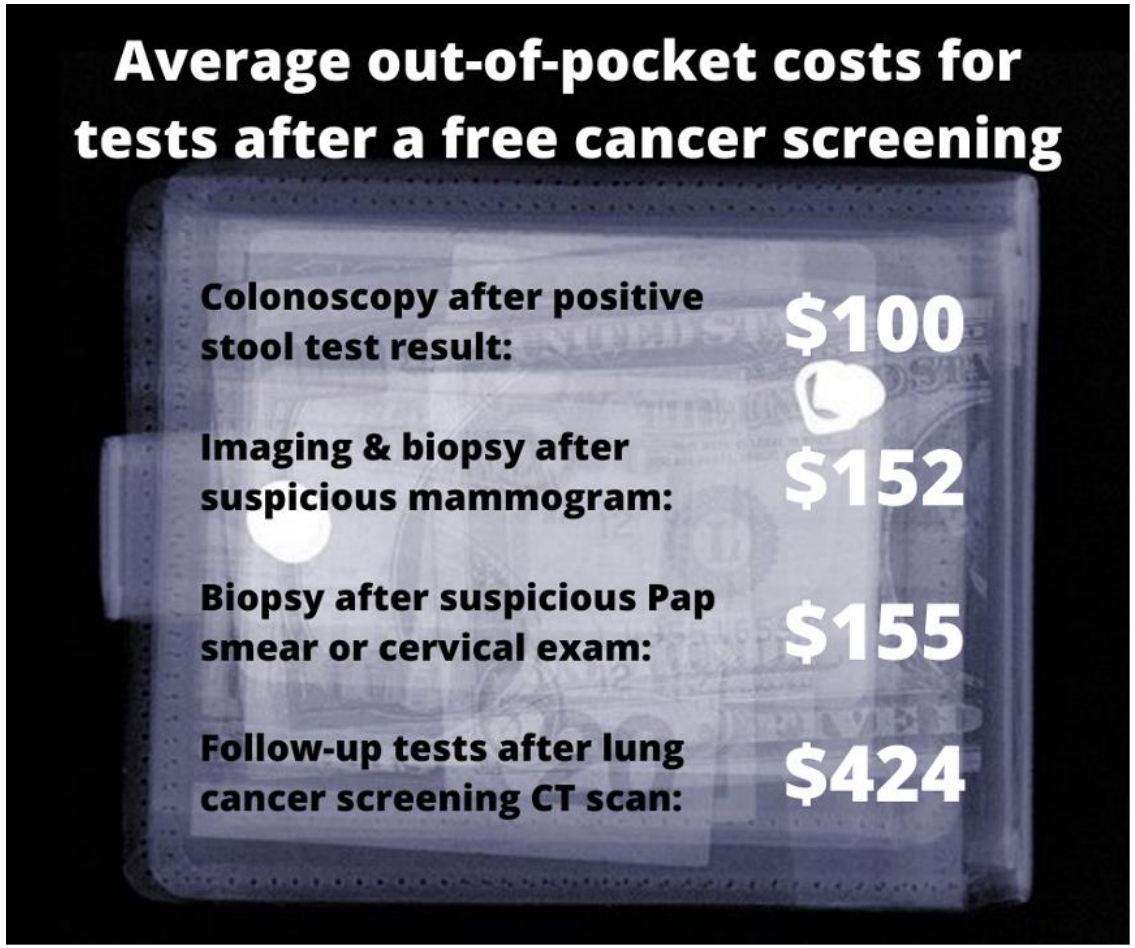
Your Free Cancer Screen Shows Trouble: What If You Can't Afford the Follow-Up?

While the ACA provision that eliminated consumer cost-sharing increased use of initial cancer screening tests for:

- **Breast**
- **Cervical**
- **Colorectal**
- **Lung**

[1] [2] [3] [4]

Out-of-pocket costs were common and non-trivial for necessary follow-up testing after initial, no-cost, abnormal cancer screening tests.



- JAMA Network Open. 2021;4(8):e2121347
- Obstetrics & Gynecology. 2022;139(1): doi:10.1097/AOG.0000000000004582
- JAMA Network Open. 2021;4(12): doi:10.1001/jamanetworkopen.2021.36798
- JACR E-pub ahead of print. 2021.DOI:https://doi.org/10.1016/j.jacr.2021.09.015

Quote about the process

Screening is a process, not a single test; it is only complete when all follow-up procedures are performed to definitively confirm or exclude a cancer diagnosis

Redefining Cancer Screening Coverage—Screening to Diagnosis

Crystal D. Taylor, MD, MPH, MS[1]; A. Mark Fendrick, MD[2]; Lesly A. Dossett, MD, MPH[1]

The Cost to Breathe: Eliminating Cost Sharing Associated with Lung Cancer Screening

J'undra N. Pegues[1,5], Erin E. Isenberg[2,4,6], and A. Mark Fendrick[3]

Eliminating Consumer Cost-Sharing for the Entire Prostate Cancer Screening Pathway

A. Mark Fendrick

Arnav Srivastava and A. Mark Fendrick

Coverage for the Entire Cervical Cancer Screening Process Without Cost-Sharing: Lessons From Colorectal Cancer Screening

Allison Ruff, MD, MPHE[a,*], Diane M. Harper, MD, MPH, MS[b,c,d], Vanessa Dalton, MD[c], A. Mark Fendrick, MD, MPH[a]

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 51, FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION

January 10, 2022

Q7: Are plans and issuers required to cover, without the imposition of any cost sharing, a follow-up colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization test (e.g., sigmoidoscopy, CT colonography)?

Yes. A plan or issuer must cover and may not impose cost sharing with respect to a colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization screening test for colorectal cancer for individuals described in the USPSTF recommendation. As stated in the May 18, 2021 USPSTF recommendation, the follow-up colonoscopy is an integral part of the preventive screening without which the screening would not be complete.[31] The follow-up colonoscopy after a positive non-invasive stool-based screening test or direct visualization screening test is therefore required to be covered without cost sharing in accordance with the requirements of PHS Act section 2713 and its implementing regulations.

CMS proposes follow-up colonoscopy after at-home test be considered preventive service

Riz Hatton - Friday, July 8th, 2022

Colorectal Cancer Screening

For CY 2023, we are proposing two updates to expand our Medicare coverage policies for colorectal cancer screening in order to align with recent United States Preventive Services Task Force and professional society recommendations. First, we are proposing to expand Medicare coverage for certain colorectal cancer screening tests by reducing the minimum age payment limitation to 45 years. Second, we are proposing to expand the regulatory definition of colorectal cancer screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. Both of these proposals reflect our desire to expand access to quality care and to improve health outcomes for patients through prevention and early detection services, as well as through effective treatments.

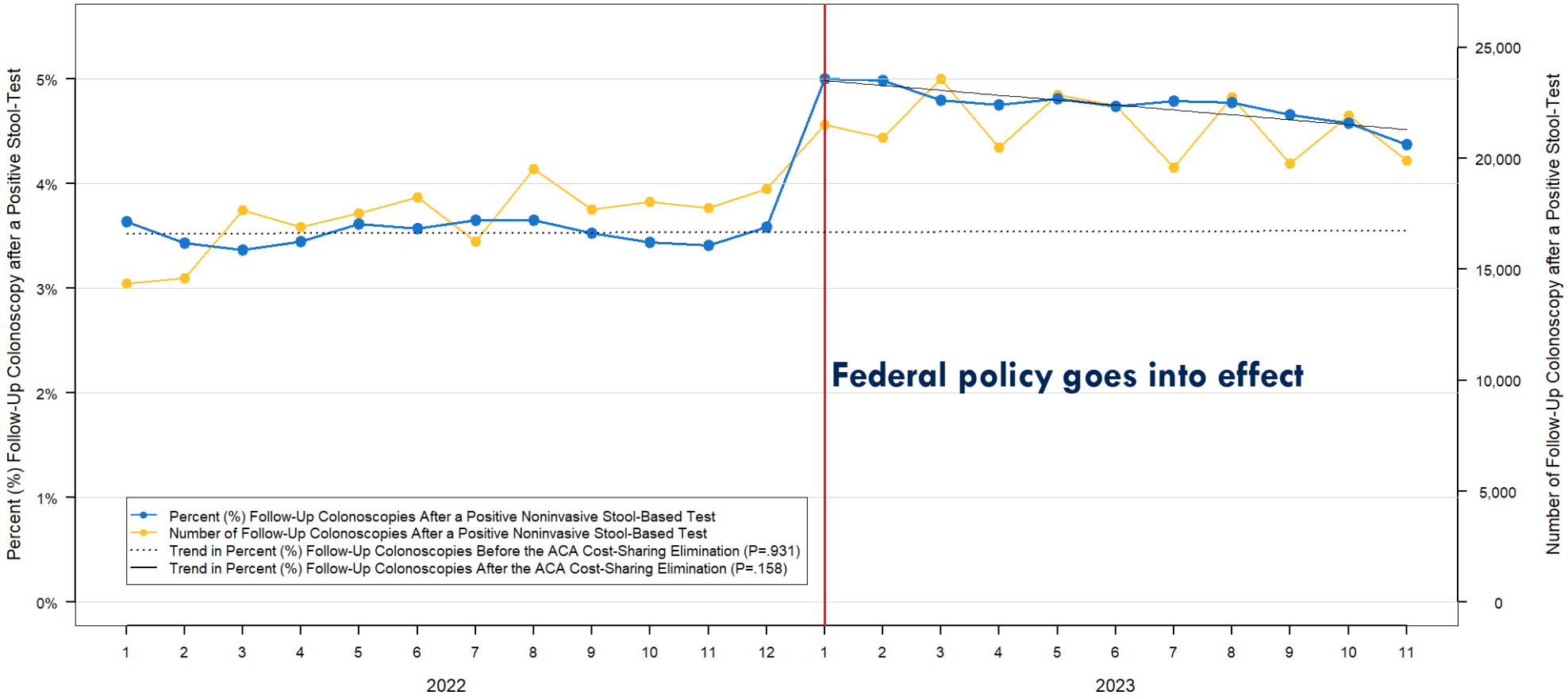
RESEARCH ARTICLE

OPEN ACCESS

Check for updates

Completing the colorectal cancer screening process: impact of eliminating cost-sharing for follow-up colonoscopy

If you make people pay less for something, they will buy more of it



American Cancer Society Position Statement on the Elimination of Patient Cost-Sharing Associated with Cancer Screening and Follow-up Testing

- It is the position of the ACS that cancer screening should be understood as a continuum of testing rather than a single screening test
- Screening is a process that includes a recommended screening test and all follow-up tests described as diagnostic and judged to be integral and necessary to resolve the question of whether an adult undergoing screening has cancer.
- These tests should be covered without any patient cost-sharing consistent with the 2022 FAQ specifying no patient cost-sharing for follow-up colonoscopy after a positive non-colonoscopy colorectal cancer screening examination.
- Insurers must cover and should not impose cost-sharing for these recommended examinations, regardless of the patient's designated risk.

From Breast Cancer Screening to Diagnosis

New Recommendations for Expanded Coverage and Patient Navigation

Table. Recommendations for Breast Cancer Screening and Patient Navigation for Breast and Cervical Cancer Screening[a]

Recommendation	Eligibility	Prevention services included
Breast cancer screening	Women at average risk of breast cancer who are 40 years and older[b]	Annual or biennial mammography screening beginning no earlier than age 40 years and no later than age 50 years, and continuing through at least age 74 years; age alone should not be the basis for discontinuing screening
		Additional imaging (eg, magnetic resonance imaging, ultrasonography, mammography) and pathology evaluation when needed to complete the screening process or address findings on the initial screening mammography
Patient navigation services for breast and cervical cancer screening and follow-up	Patients eligible for breast or cervical cancer screening and needing assistance accessing screening and follow-up services	Individualized navigation services based on assessment of the patient's needs and involving person-to-person contact with the patient can include person-centered assessment and planning, health care access and health system navigation, referrals to appropriate support services (eg, language translation, transportation, social services), and patient education

Upon approval by the Health Resources & Services Administration, breast cancer screening follow-up and navigation services are covered without co-pay or deductible charges for most women under the prevention services no-cost coverage requirements of the Patient Protection and Affordable Care Act beginning in 2026.

Significant progress on federal policies that require first dollar coverage of the entire cancer screening continuum – 3 down, 1 to go

Cancer screening services:

What's covered at no cost to the patient?

Screening covered for eligible individuals	Follow-up diagnostic services	Screening navigation services
Colorectal cancer (e.g. stool test or colonoscopy) 	**Colonoscopy after non-invasive test** (as of 2023)	Not included in no-cost coverage
Breast cancer (Screening mammography) 	**Mammography, MRI, ultrasound, or biopsy** (as of 2026)	**Personal assessment, education, referrals to services** (as of 2026)
Cervical cancer (Pap test +/- HPV test, or self-collected HPV test) 	**Additional testing needed to complete screening** (as of 2027)	**Personal assessment, education, referrals to services** (as of 2026)
Lung cancer (Low-dose CT) 	Not included in no-cost coverage	Not included in no-cost coverage

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Incentivizing Health Plans: NCQA implementing new cancer screening HEDIS measures that include follow up after abnormal initial tests

Follow-Up After Abnormal Mammogram Assessment (FMA-E)*

Breast cancer implemented 2025

The percentage of episodes for persons 40-74 years of age with inconclusive or high-risk BI-RADS assessments that received appropriate follow-up within 90 days of the assessment.

Proposed New Measure for HEDIS®[1] MY 2027:
Follow-Up After Positive Colorectal Cancer Non-Invasive Screening Test (COF-E)

Colorectal cancer proposed 2027

NCQA seeks comments on a proposed new measure for inclusion in HEDIS Measurement Year (MY) 2027.

Follow-Up After Positive Colorectal Cancer Non-Invasive Screening Test (COF-E): Assesses the percentage of persons 45-85 years of age who received a colonoscopy for a positive colorectal cancer non-invasive screening test within 180 days of a positive stool-based test. See measure specification for more information.

Quality metrics for cancer screening tests must include measures of diagnostic resolution

Cancer screening services:

Policies to ensure patients complete the screening process

Screening covered for eligible individuals	Follow-up diagnostic services	Screening navigation services	HEDIS measure includes follow-up services
Colorectal cancer (e.g. stool test or colonoscopy) 	**Colonoscopy after non-invasive test** (as of 2023)	Not included in no-cost coverage	**Receipt of colonoscopy within 180 days after non-invasive test** (proposed 2026)
Breast cancer (Screening mammography) 	**Mammography, MRI, ultrasound, or biopsy** (as of 2026)	**Personal assessment, education, referrals to services** (as of 2026)	**Receipt of appropriate follow-up within 90 days after screening mammography** (as of 2025)
Cervical cancer (Pap test +/- HPV test, or self-collected HPV test) 	**Additional testing needed to complete screening** (as of 2027)	**Personal assessment, education, referrals to services** (as of 2026)	No measure
Lung cancer (Low-dose CT) 	Not included in no-cost coverage	Not included in no-cost coverage	No measure

As of Spring 2026 - Michigan Medicine/University of Michigan VBID Center

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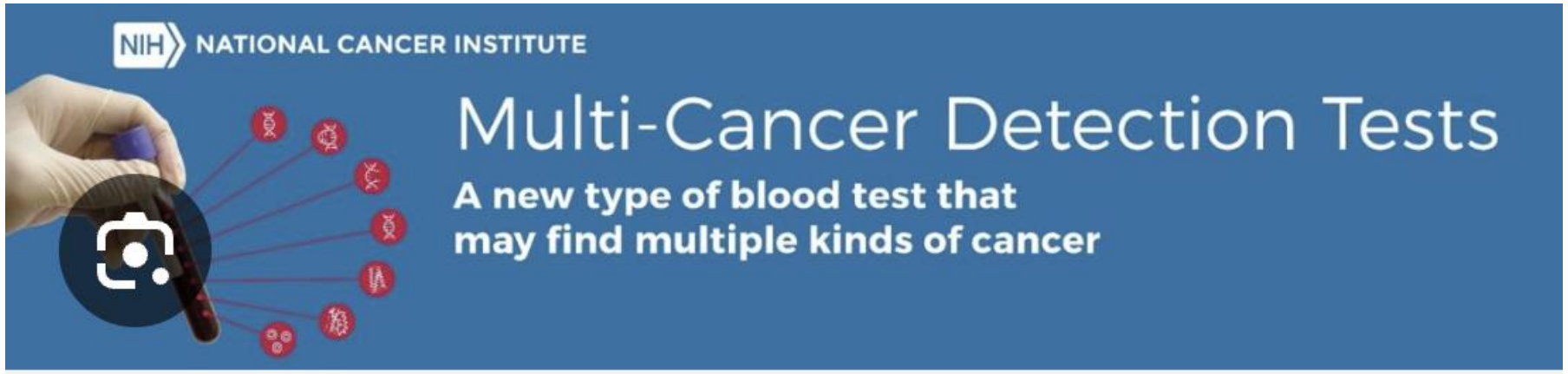
Reading the Crystal Ball: Awaiting Outcomes for Multi-cancer Early Detection Tests



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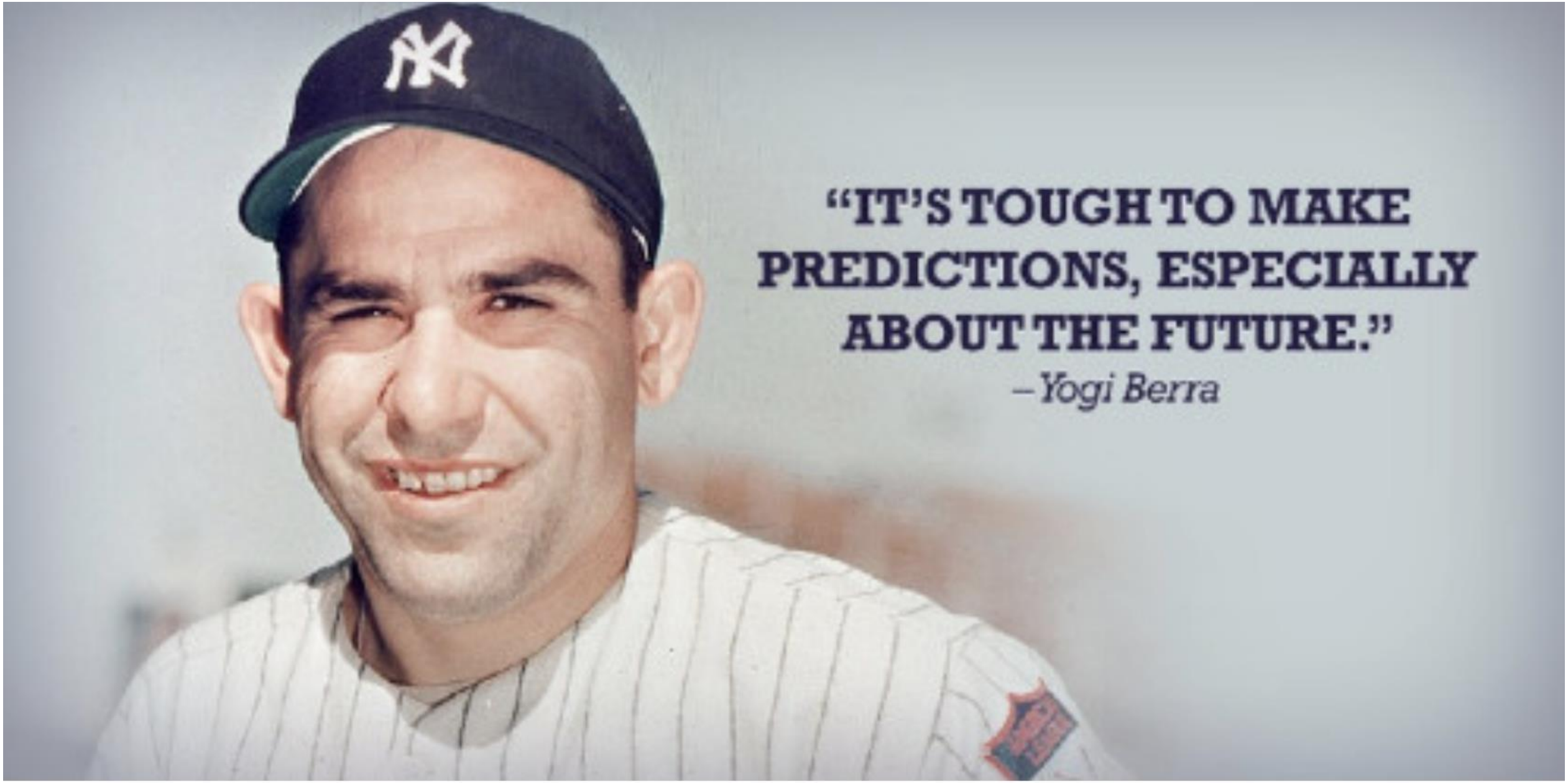
"IT'S TOUGH TO MAKE PREDICTIONS, ESPECIALLY ABOUT THE FUTURE."
–Yogi Berra

Consequences of Multicancer Early Detection (MCED) Testing Key Issues

- Motivation for MCED Tests
- State of the Science
- Clinically Indicated Follow-Up Care After a Positive MCED Test Must Be Easily Accessible and Affordable
- Payer Coverage Must Be Examined Before Complete Evidence Is Available
- MCED Tests Should Not Substitute for Recommended Cancer Screenings

Statistics suggest is that there is enormous room for improvement regarding the early diagnosis of cancer

- In 2025, it was estimated that 2.0 million Americans were diagnosed with cancer (not including skin carcinomas) leading to 618,000 deaths
  - 87% of cancers diagnosed in patients over the age of 50.
- The number of cancers diagnosed will increase to 2.3 million cases, likely through 2050, mostly related to the "baby boom" generation aging out
  - Expected deaths will likely increase, but no precise number can be calculated due to expected advances in cancer diagnosis and treatment
- More than half of cancer-related deaths result from cancers that do not have USPSTF guideline-recommended screenings

Limitations of Current Cancer Screening

- Current screening paradigm is one cancer at a time
  - Designing swabs, samples and scans to detect >200 cancers is not feasible
- While half of cancers diagnosed have screening recommendations, only 14% of all diagnosed cancers are detected by screening
- Only half of diagnosed cases of screenable cancers, are detected by screening
  - Access and adherence to the 4 cancer screening tests currently recommended by the USPSTF has proven to be challenging

Suboptimal Adherence Rates to USPSTF Recommended Cancer Screening

Cancer	Adherence Rate: *Overall*	Adherence Rate: *Uninsured*	US Incident Cancers Discovered at Late Stage Annually[7] (2017-2021)
Breast[2] Women aged ≥40 years	73%	42%	80,548 (31.2%)
Cervix[3] Women aged 25-65 years	73%	51%	6,415 (50.6%)
Colon and rectum[4] Adults aged ≥45 years	60%	23%	83,825 (59.8%)
Lung[5] Eligible adults[b]	17%	4%	141,561 (64.9%)
Prostate[6] Men aged ≥50 years	37%	13%	48,295 (21.5%)

1. ACS *Cancer Prevention & Early Detection Facts & Figures 2025-2026*. Atlanta: American Cancer Society; *2025-2026*. 2. Behavioral Risk Factor Surveillance System, 2022. 3. National Health Interview Survey, 2021. 4. National Health Interview Survey, 2023. 5. Behavioral Risk Factor Surveillance System, 2022 6. National Health Interview Survey, 2023. 7. State Cancer Profiles 2017-2021 https://statecancerprofiles.cancer.gov/

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Unlocking the Promise and Potential of MCEDs
Necessary Steps

- Rigorous evidence of clinical benefit
- Establishment of recommendations for follow up diagnostic testing
- Guideline endorsement
- Regulatory approval
- Healthcare insurance coverage

1. Eisenstein M. Putting early cancer detection to the test. Naure. Feb, 2025.

Eligibility Criteria for MCED tests

Who Is Eligible?

- Age ≥50 years
- Family or personal history of cancer
- Known genetic mutations

Who Is NOT Eligible?

- Pediatric populations (age <21 years)
- Pregnant patients
- Patients with active cancer diagnosis or treated for cancer in last 3 years

Cancer Risk Factors

- Alcohol use
- Exposure (e.g., pollution, radiation, sunlight)
- Immunosuppression
- Infectious agents (e.g., viruses)
- Obesity
- Tobacco use

As cancer risk increases, clinical benefit and cost-effectiveness of MCEDs improve

1. Putcha G, et al. *JCO Precis Oncol*. 2021:574-5762; 2. Multicancer Early Detection Consortium.

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State of the Science
Evidence Needed, Including

- **Can MCEDs reliably detect cancers early?**
- **Does MCED testing lead to reduced mortality?**
- **What are the optimal starting and stopping age, and frequency of MCED testing?**

It would take a trial of at least 10 years in length to acquire the data needed to establish the clinical utility of MCED tests.

- **In the interim, the use of surrogate endpoints and modeling studies can be used to assess MCED tests' *potential* benefits and economic impact to guide decision making.**

Multicancer early detection testing: Guidance for primary care discussions with patients. Cancer. 2025 Apr 1;131(7):e35823.

MCEDs: State of the Science: What did the NHS Galleri Trial tell us about MCED effectiveness?

Early results from the NHS-Galleri trial (announced Feb 2026):

- **Did NOT meet its primary endpoint of significantly reducing late-stage (III-IV) cancers**
- **However, the trial demonstrated a substantial reduction in Stage IV diagnoses and a four-fold higher detection rate of early-stage cancers compared to standard care**

https://www.nhs-galleri.org/trial-updates/summary-of-early-nhs-galleri-trial-results-shared#:~:text=Professor%20Richard%20Neal%2C%20Co%2DChief,website%20as%20they%20become%20available.

MCEDs: State of the Science: What did the NHS Galleri Trial tell us about MCED effectiveness?

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  compared to standard care

GRAIL: NHS-Galleri Trial Results Are A Foul Ball, Not A Strikeout

A question remains: Even though Galleri yields outstanding results in detecting Stage IV cancers, will that be clinically helpful?

- **Detecting cancers at that advanced stage is unlikely to yield a substantial reduction in mortality, the main objective screening**

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State of the Science
Given the insufficient evidence, ACS guidance for clinicians

- Can MCEDs reliably detect cancers early?
-
-
- ting?

"Currently, there are no data from population-based studies on whether MCED screening can reduce cancer-related morbidity, mortality or leads to changes in early cancer indicators that would be accepted as predictive of mortality…."

"Clinicians are not obligated to initiate discussions about MCEDs until more is known about their effectiveness."

Multicancer early detection testing: Guidance for primary care discussions with patients. Cancer. 2025 Apr 1;131(7):e35823.

Considerations When Discussing MCED Testing With Patients: Potential Advantages

- **Screening for multiple cancers at the same time with the ease of a single blood test**
- **MCEDs tests can detect cancers for which screening is not currently recommended (account for >50% of US of the cancer deaths)**
- **MCED tests have an increased positive predictive value (PPV) compared to single cancer screenings and fewer false positives (<1% vs. 5-10%)**
- **Negative test can reduce 'cancerphobia'**

1. Klein EA, et al. *Ann Oncol*. 2021;32(9):1167-1177; 2. MCED Consortium.
3. Welch HG, Kramer B. *STAT*. January 12, 2022. www.statnews.com/2022/01/12/medicare-shouldnt-cover-liquid-biopsies-early-cancer-detection/; 4. Hoffman RM, Wolf AMD, Raoof S, Guerra CE, Church TR, Elkin EB, Etzioni RD, Shih YT, Skates SJ, Manassaram-Baptiste D, Smith RA. Multicancer early detection testing: Guidance for primary care discussions with patients. Cancer. 2025 Apr 1;131(7):e35823.

Considerations When Discussing MCED Testing With Patients: Potential Disadvantages

- MCED tests are not covered by most insurance and the cost of testing (around $800) is out of pocket.
- "No cancer detected" does not rule out future cancer.
- Cancers may be found early, but may not extend life
- Possible harm from unnecessary diagnostic procedures due to false positives (<1%) or missed diagnoses
- Overdiagnosis and overtreatment of cancers that would have otherwise never bothered the patient
- Inequities will increase if tests are not widely available, affordable, and acceptable to minority groups
- No guideline recommendations for who should be tested, testing interval, and the best diagnostic pathway for a positive MCED signal.

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Regarding MCED “Signal Detected” Result

- Like other cancer screening tests, MCED is not a diagnostic test
- A ”signal detected” requires follow-up diagnostic procedures to confirm the presence of that cancer
- Those diagnostic procedures may be invasive (a biopsy) or noninvasive (a CT, MRI, or PET scan)

Expert Opinion Suggested Initial Diagnostic Steps Following a MCED "Signal Detected" Result

CSO Prediction	Proposed First-Line Procedures	
Multiple myeloma	Blood workup including peripheral blood smear, CBC with differential; chemistry tests including creatinine clearance, protein electrophoresis of blood/urine	
Upper GI (esophagus, stomach)	Blood work	Endoscopy
Colorectal		Colonoscopy
Head and neck		Physical exam, fiber optic exam, U/S, CT or MRI with contrast, PET-CT[2]
Pancreas, gallbladder		CT abdomen with IV contrast, MRCP, GI referral
Ovary		CA-125 analysis[3], abdominal/pelvic exam, U/S (preferred)
Lung		CT chest with or without IV contrast
Liver, bile duct		U/S, CT, GI referral
Breast		Diagnostic mammography with U/S (MRI if mammography screening within last 3 months)
Lymphoid neoplasm		CT (neck, chest, abdomen, pelvis) with IV contrast, PET-CT
Indeterminate		CT (neck, chest, abdomen, pelvis) with IV contrast, PET-CT

CBC, complete blood count; IV, intravenous; MRCP, magnetic resonance cholangiopancreatography; PET, positron emission tomography.

1. Adapted from Nadauld LD, et al. *Cancers (Basel)*. 2021;13(14):3501; 2. Fearington FW, et al. *Oral Oncol*. 2024;152:106809; 3. Funston G, et al. *PLoS Med*. 2020;17:e1003295.

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What keeps me up at night: Access and Affordability to Follow-up Diagnostics and Cancer Treatment

- If an MCED test generates a cancer signal (many of those will be false), a variety of diagnostic tests will be required to verify the existence of cancer
- It is unlikely that all those individuals would have access to and/or could afford the cost of the diagnostic follow-up (not unique to MCEDs, applies to some cancer screenings)
  - Based on our prior work in other cancer screening programs, a third of those individuals would not complete indicated diagnostic tests
- In the unlikely scenario where everyone received the necessary diagnostic tests, would recommended cancer treatments be accessible? (also not unique to MCEDs, applies to all cancer screenings)

Payer Coverage of MCED Testing and Indicated Follow-up Must Be Examined As Evidence Is Being Generated

- When considering MCED coverage, payers must balance the health and cost impacts of the many years it will take for trials to demonstrate a net survival benefit against the potential harms of delaying their use
- In the interim, the use of surrogate end clinical points and modeling studies are being used to assess MCED tests' *potential* net survival benefit to guide decision making
- Coverage with evidence development - paying for testing only when associated with data collection could solidify the evidence base

Can we wait for clinical validity before coverage? Potential role coverage with evidence development

- Coverage with evidence development has been used for other services with mixed/uncertain evidence of effectiveness
  - Monoclonal antibodies against amyloid for Alzheimer's Disease
  - Lung Volume Reduction Surgery
  - CAR-T cell therapy
- If MCED tests were to be made available to all eligible individuals, it would cost >$50 billion per year
- The opportunity costs of coverage with evidence development would have to be considered as to whether that $50 billion would achieve better outcomes if it were allocated to other services

Can we wait for clinical validity before coverage? Nope. Congressional Action Mandates Medicare MCED Coverage Upon FDA Approval

On World Cancer Day, Rep. Sewell Celebrates Signing of the Nancy Gardner Sewell Multi-Cancer Early Detection Act

This bill created the authority for CMS to cover blood-based MCED tests and future test methods once approved by the FDA and shown to have clinical benefit.

What is meant by 'shown to have clinical benefit' remains unclear.

Is the Horse is Out of the Barn? MCEDs are available to consumers and testing is on the rise

Despite a lack of:

- **Rigorous evidence of clinical benefit**
- **Regulatory approval**
- **Guideline endorsement**
- **US healthcare insurance coverage**

MCED testing is on the rise. As of late 2025, over 420,000 Galleri multi-cancer early detection tests have been prescribed or sold commercially

1. Eisenstein M. Putting early cancer detection to the test. Naure. Feb, 2025.

Given Growing MCED Use, Ensure that MCEDs do not Substitute for Recommended Cancer Screenings

- Current MCED tests are additive to, not replacements for, current cancer screening tests.
- Although a more convenient blood-based screening test may prompt more patients to undergo cancer screening, it may also result in the misconception that patients have been adequately screened with only a MCED test
- To mitigate this unwanted consequence, implementation programs for MCED testing should be designed as a 'teachable moment' to complement efforts to increase recommended (in many instances, no-cost) cancer screenings

Key Takeaways

- Interventions are needed to increase rates of evidence-based cancer screenings and ensure diagnostic resolution is achieved for those with abnormal initial tests
- There is enormous room for improvement regarding the early diagnosis of cancer
- While evaluations of MCEDs are underway:
  - Clinically indicated follow-up care after a positive MCED test (and treatment) must be accessible and affordable
  - Coverage strategies must be considered while evidence is being generated
  - MCED tests must not substitute for recommended cancer screenings
- Once clinical benefit is established, we must work collaboratively to ensure appropriate access and affordability of both MCED tests and follow-up testing to optimize their clinical, equity and economic impact.

“If we don’t succeed then we will fail.”

Dan Quayle

Questions?

Sorry,
not sorry ;)