2025 Screen Smart Dinner

Wi-Fi: Hilton Honors
Password: Meetings2025

Access the 2025 Screen Smart Lookbook here:

screen smart
data • access • adherence

Gold Sponsors

2025 Screen Smart Dinner

screen smart
data • access • adherence

Gold

EXACT SCIENCES

Exact Sciences gives patients and health care professionals the clarity needed to take life-changing action earlier. Building on the success of the Cologuard® and Oncotype® tests, Exact Sciences is investing in its pipeline to develop innovative solutions for use before, during, and after a cancer diagnosis.

GUARDANT

Guardant Health is a leading precision oncology company revolutionizing patient care by using advanced blood and tissue tests, real-world data, and AI analytics to provide critical insights into cancer. Its innovative approach helps improve outcomes across all stages, from early detection and recurrence monitoring to treatment selection for advanced cancer patients.

Thank you for your generous support.

colorectal cancer alliance

Welcome and Introductions

Welcome and Introductions

Michael Sapienza
Chief Executive Officer
Colorectal Cancer Alliance

Event Agenda

5:45-6:00pm

Welcome and Introduction

Remarks by Michael Sapienza, Chief Executive Officer, Colorectal Cancer Alliance

6:00-6:20pm

Update on Screening Tests

Michael Sapienza, Chief Executive Officer, Colorectal Cancer Alliance

6:20-6:35pm

Modeling Studies Framework

Dr. Uri Ladabaum, Professor of Medicine, Director of the Gastrointestinal Cancer Prevention Program and Head of Clinical Service of the Division of Gastroenterology and Hepatology at Stanford University School of Medicine

6:35-7:25pm

Adherence Panel: What modeling studies tell us and what we still need to learn

7:25-8:15pm

Access Panel: The future of screening access and the United States Preventative Services Task Force (USPSTF)

Moderator, Eric Waskowicz, Senior Policy Manager, US of Care

8:15-8:30pm

Closing and Next Steps

Michael Sapienza, Chief Executive Officer, Colorectal Cancer Alliance

8:30-9:30pm

Cocktail Hour

Sponsors

Thank you for your generous support!

Gold

EXACT SCIENCES

GUARDANT

Silver

eneoscopy
Transforming Gastrointestinal Health

Bronze

Braintree
A PART OF SEBELA PHARMACEUTICALS®

natera™

polymedco

With additional support provided by Freenome

Innovation Update

A Practical Framework Update

2025 Screen Smart Dinner

Updates from Manufacturers

screen smart
data • access • adherence

2024

May

May 6th: ColoSense is FDA-approved to screen for colorectal cancer, advanced adenomas, and sessile serrated lesions, in average-risk individuals over the age of 45.

June

July

July 2024: FDA Approval for Shield, for first line use with immediate Medicare Coverage for Shield

Aug

August 2024: Cologuard 10-year anniversary with 19 M people screened; 525,000 advance precancers lesions and 42,000 early-stage cancers detected

Sep

Oct

October 2024: FDA approval of Cologuard Plus as a test for detection of both cancer and precancer

October 2024: Platform presentation at ACG 2024 describing 1-year clinical follow-up in ECLIPSE study participants

Nov

Dec

January 2025: CY2025 Physician Fee Schedule Final Rule released with CMS removing cost-sharing for a follow-on colonoscopy after a blood-based screening test for Medicare beneficiaries.

Polymedco is collecting data on the potential clinical utility of a quantitative version of FIT and we are evaluating the possibility of pursuing a regulatory action to bring quantitative FIT to market.

2025

Jan

Feb

February 2025: Abstract Title: Performance of a blood-based test for colorectal cancer screening adjusted to the US census age and sex distribution

February 2025: Abstract Title: Clinical evaluation of a blood-based screening test for the early detection of colorectal cancer

Mar

March 2025: Cologuard Plus launches with Medicare coverage and inclusion in HEDIS CRC screening measure.

Apr

April 2025: Publication of additional clinical utility data demonstrating integration of Shield alongside stool/colonoscopy increases CRC screening completion rates from 45% to 90%.

May

Current modeling study is in peer review at CGH. We anticipate publication in May 2025.

May 2025: Three DDW poster presentations further demonstrating the clinical utility of Shield for CRC screening.

EXACT SCIENCES | FREENOME | GENEOSCOPY | GUARDANT HEALTH | POLYMEDCO

colorectal cancer alliance

Evaluating Colorectal Cancer Screening Options

A Practical Framework Update

Sensitivity	Colonoscopy	CTC	FIT	Cologuard		Cologuard Plus	ColoSense	Shield	PREEMPT CRC
	Recommended by the U.S. Preventive Services Task Force					Emerging Tests			
Test Type	Visual (endoscopy)	Computed tomography	Hemoglobin in stool	Mt-sDNA		Mt-sDNA	Mt-sRNA	Cell-free DNA blood test	Blood
CRC overall	95%	86-100% Size of adenomas >6mm: 89% >7mm: 91% >8mm: 94% >9mm: 93% >10mm: 94%	79%	92%		94%	94.4%	83%	81.1%
Stage I	75-80%		75%	90%		87%	100%	65%(55% clinical)	63.5%
Stage II	85-90%		88%	100%		94%	83%	100%	100%
Stage III	85-90%		82%	90%		97%	100%	100%	80.5%
Stage IV	>95%		89%	75%		100%	100%	100%	100%
APL/AA	90-95%	89% for adenomas ≥10 mm	24% (APL)	42% (APL)		43% (APL)	46% (AA)	13.2%	13.7% (AA)
High grade dysplasia	75-93%	<10%	-	69%		75%	65% (HGD or ≥10 adenomas)	22,6%	29%
Sessile serrated	70-80%	-	5%	42%		46%	17% (hyperplastic and SS ≥10 mm combined)	11% in SSL's greater than 1cm	_

APL = advanced precancerous lesion = Includes advanced adenomas (high-grade dysplasia or with ≥25% villous histologic features or measuring ≥1 cm in the greatest dimension) and sessile serrated polyps measuring 1 cm or more in diameterAA = Advanced Adenoma

	Specificity	All	Negative Colonoscopy
Recommended by the U.S. Preventive Services Task Force	**Colonoscopy**	90%	–
	CTC	94% Size of adenomas >6mm: 80% >7mm: 87% >8mm: 92% >9mm: 95% >10mm: 96%	-
	FIT	93%	–
	Cologuard	87%	93%
FDA approved awaiting USPSTF recommendation	**Cologuard Plus**	94%	93%
	ColoSense	86%	88%
	Shield	89.6% (negative advanced neoplasia)	89.9% (non-neoplastic findings and negative colonoscopy)
Not yet approved	**PREEMPT CTC**	91.5% (non-advanced colorectal neoplasia)	–

		Access	Cost
Recommended by the U.S. Preventive Services Task Force (USPSTF)	**Colonoscopy**	Medicare	$2,750 (avg. cash price)
	CTC	Medicare	$265 per screening year
	FIT	Widely available/covered	$18 – $21 estimation of $153 per screening cycle when including the patient support costs
	Cologuard	Widely available/covered	$508 (Medicare)
FDA approved awaiting USPSTF recommendation	**Cologuard Plus**	Medicare covered and included in HEDIS	$592 (Medicare)
	ColoSense	Not currently guideline-recommended but is FDA-approved to screen for colorectal cancer, advanced adenomas, and sessile serrated lesions, in average-risk individuals over the age of 45	$508 (Medicare)
	Shield	Available under the CRC screening National Coverage Determinations (NCDs) Current Coverage through Medicare and VA CCN	$1495 (Medicare)
Not yet approved	**PREEMT CRC**	Not currently available	_

		Adherence (%)		Follow-up colonoscopy	Interval
Recommended by the U.S. Preventive Services Task Force	**Colonoscopy**	About 30%	Real World Peer-reviewed Data Accumulative	n/a	10
	CTC	30–34%	Real World Peer-reviewed Data Accumulative	-	5
	FIT	35% (w/o navigation) 41.5% (w navigation) (real-world and study)	Real World Peer-reviewed Data Accumulative	47% - 83%	1
	Cologuard	71%	Real World Peer-reviewed Data N= 1,557,915	71.5% – 84.9% (real-world)	3 (1-3)
FDA approved awaiting USPSTF recommendation	**Cologuard Plus**	96.8%	Study N=24,032	–	3 (anticipated)
	ColoSense	78%	Study N=14,263	88% 74% combined test and follow up (study)	3 (anticipated)
	Shield	96%	Real World Data Not Peer-reviewed N= 10,000	49% (within 6 months of positive results (real-world))	1-3 years
Not yet approved	**PREEMT CRC**	96%	Study N=49,170	_	3

To ask questions

Adherence Panel: What Modeling Studies Tell Us and What We Still Need to Learn

Using Real-World Data and Modeling to Improve Adherence and Increase Screening Rates

Screen Smart Adherence Panel

Moderator

Uri Ladabaum, MD, MS
Professor of Medicine, Director of the Gastrointestinal Cancer Prevention Program and Head of Clinical Service of the Division of Gastroenterology and Hepatology at Stanford University School of Medicine

Erica Barnell, MD, PhD
Chief Medical Officer and Co-Founder
Geneoscopy

Durado Brooks MD, MPH
Associate Chief Medical Officer
Exact Sciences

Craig Eagle, MD
Chief Medical Officer
Guardant Health

Todd W. Kelley, MD
Chief Medical Officer
Polymedco

T.R. Levin, MD, MS
Associate Director for Cancer Research, KPNC Division of Research, The Permanente Medical Group, Inc.

Jimmy Lin, M.D., Ph.D., MHS
Chief Scientific Officer Freenome

Courtney Moreno, MD
Professor in the Department of Radiology and Imaging Sciences at Emory University School of Medicine

Uri Ladabaum, MD
Professor of Medicine, Director of the Gastrointestinal Cancer Prevention Program and Head of Clinical Service of the Division of Gastroenterology and Hepatology at Stanford University School of Medicine

Modeling Studies Framework

Exploring the use of real-world data and modeling to increase the adherence rates and get more people screened?

Why do modeling? How to use results?

1. To explore questions with clinical and policy relevance when primary data are insufficient
2. Models can help inform decisions – but cannot provide “the answer”
3. Models are thought experiments – there is greater risk of unconscious or conscious bias than in real-world experiments

An efficient strategy for evaluating new non-invasive screening tests for colorectal cancer: the guiding principles

Robert S Bresalier ,[1] Carlo Senore ,[2] Graeme P Young ,[3] James Allison,[4] Robert Benamouzig,[5] Sally Benton,[6] Patrick M M Bossuyt,[7] Luis Caro,[8] Beatriz Carvalho ,[9] Han-Mo Chiu ,[10] Veerle M H Coupé,[11] Willemijn de Klaver,[12] Clasine Maria de Klerk,[13] Evelien Dekker ,[14] Sunil Dolwani,[15] Callum G Fraser ,[16] William Grady ,[17] Lydia Guittet,[18] Samir Gupta,[19] Stephen P Halloran,[20] Ulrike Haug,[21] Geir Hoff,[22,23] Steven Itzkowitz,[24] Tim Kortlever ,[25] Anastasios Koulaouzidis ,[26] Uri Ladabaum,[27] Beatrice Lauby-Secretan,[28] Mārcis Leja ,[29] Bernard Levin,[30] Theodore Robert Levin ,[31] Finlay Macrae,[32] Gerrit A Meijer ,[9] Joshua Melson,[33] Colm O'Morain,[34] Susan Parry,[35,36] Linda Rabeneck,[37] David F Ransohoff,[38] Roque Sáenz,[39] Hiroshi Saito,[40] Silvia Sanduleanu-Dascalescu,[41] Robert E Schoen ,[42] Kevin Selby,[43] Harminder Singh ,[44] Robert J C Steele ,[45] Joseph J Y Sung ,[46] Erin Leigh Symonds ,[47] Sidney J Winawer,[48] Members of the World Endoscopy Colorectal Cancer Screening New Test Evaluation Expert Working Group

Bresalier RS, *et al*. *Gut* 2023;**72**:1904–1918. doi:10.1136/gutjnl-2023-329701

DNA Test

Effectiveness of a new test can be evaluated by comparison with a proven comparator non-invasive test. The faecal immunochemical test is now considered the appropriate comparator, while colonoscopy remains the diagnostic standard. For a new test to be able to meet.

Bresailer RS, et al. *Gut* 2023;**72**:1904-1918.doi:10.1136/gutjnl-2023-329701

screen smart
data • access • adherence

What would you choose for you or for your family?

	Sensitivity: CRC	Sensitivity: advanced adenoma	Sensitivity: advanced SSL	Specificity	How often?
FIT (20 mcg/g)	74%	23%	Not reported	96%	1-2 y
FIT-DNA v1	92%	42% APL*	42%	93%	3 y
FIT-DNA v2	94%	43% APL*	{49% APL*}	93%	3 y
FIT-RNA	95%	46%	Not reported	88%	[3 y]
cf-DNA	83%	13% APL*	Not reported	90%	3 y
Colonoscopy	>95%	90%	>80%?	99+%	10 y

*Advanced precancerous lesion

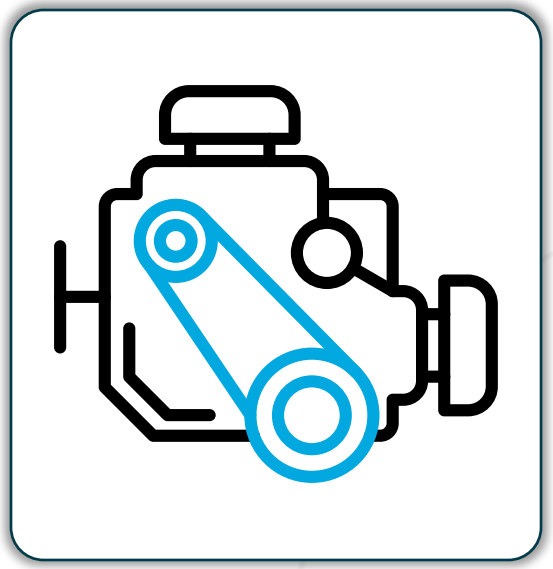
colorectal cancer alliance

Why do modeling? How to use results?

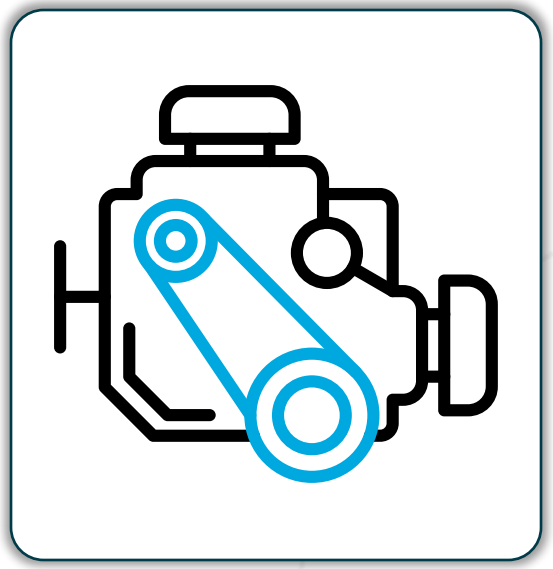
Modeling can synthesize data and provide estimates for long-term outcomes (predictions based on extrapolation).

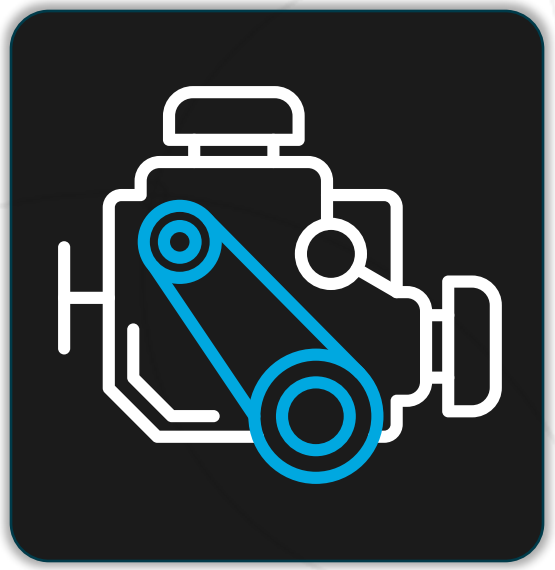
Risk of Bias

Models: Transparency vs. the Black Box

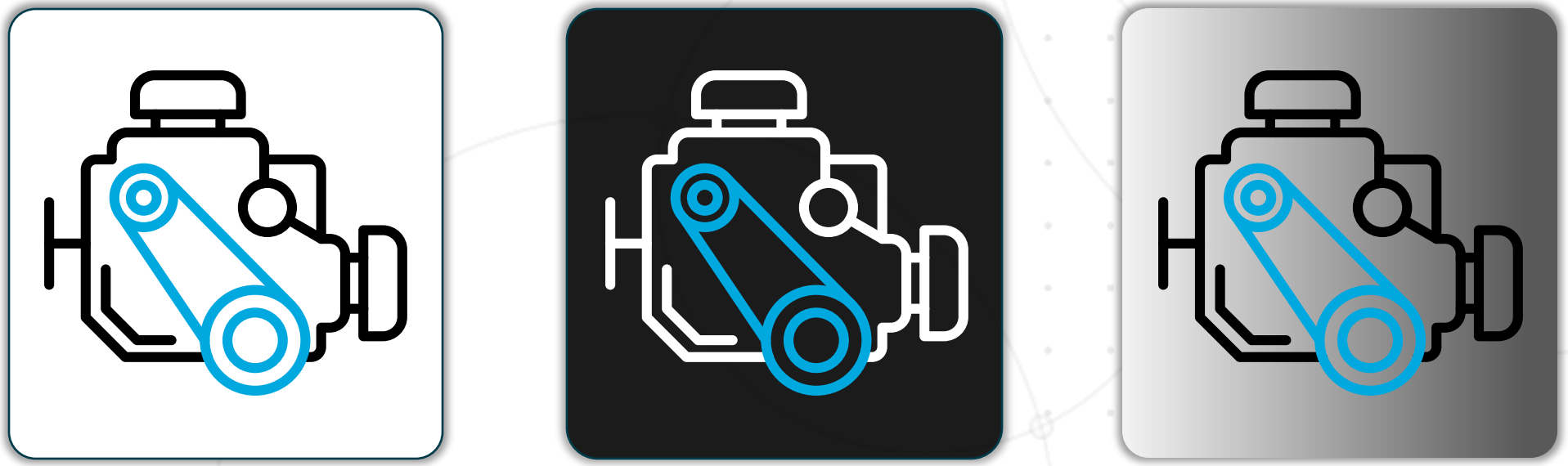


Models: Transparency vs. the Black Box

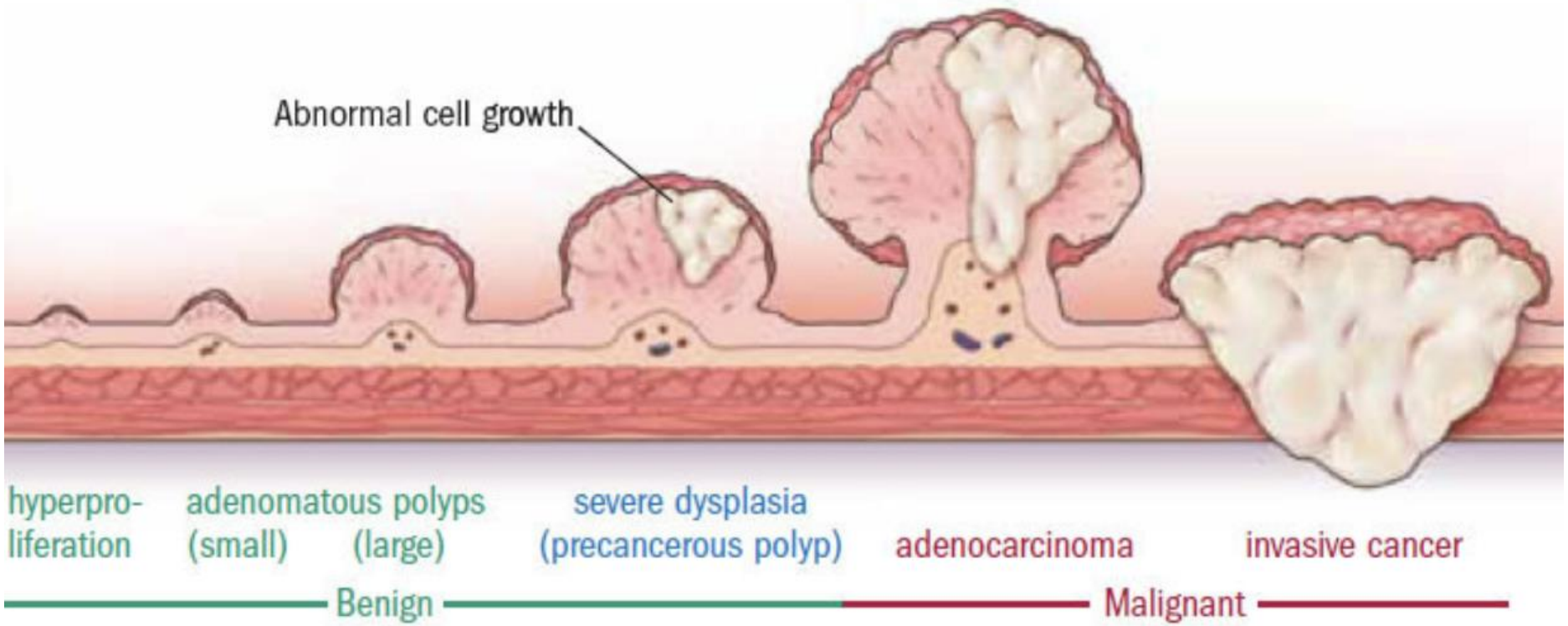




Models: Transparency vs. the Black Box

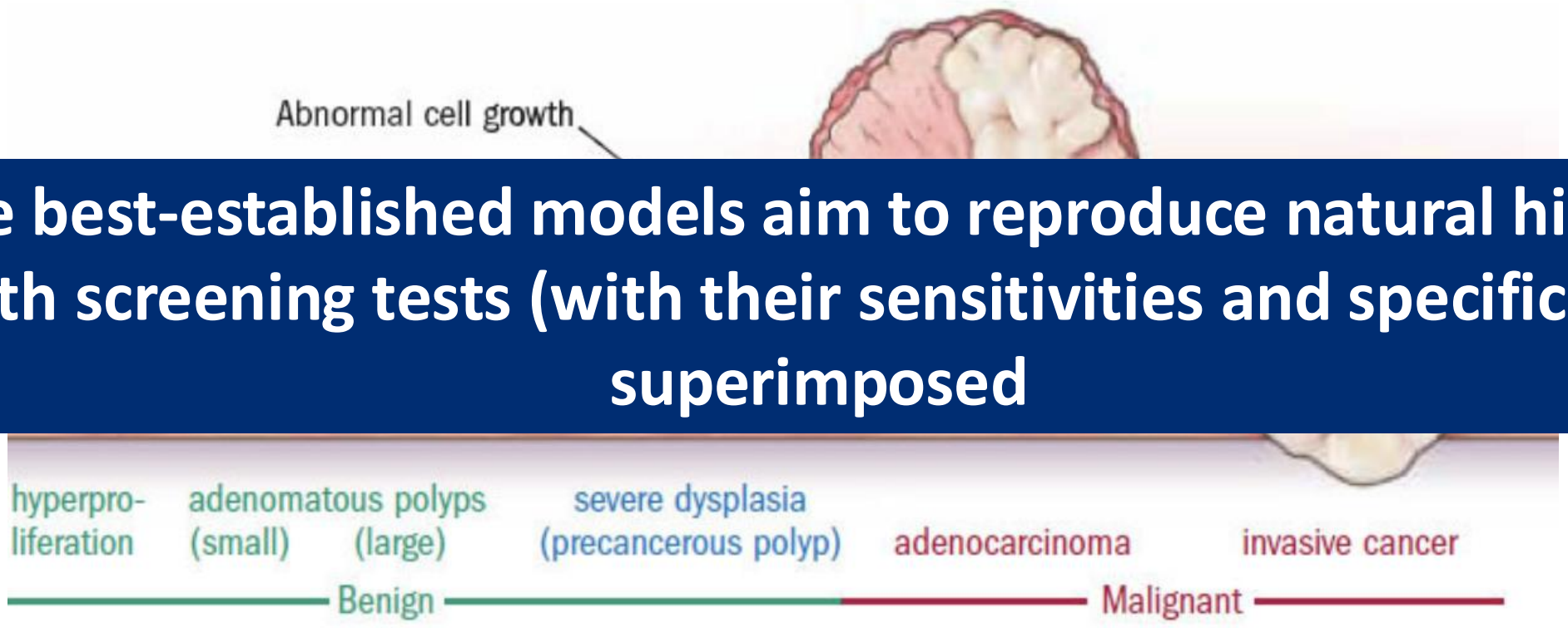


How a colon polyp progresses to cancer



https://www.health.harvard.edu/diseases-and-conditions/they-found-colon-polyps-now-what

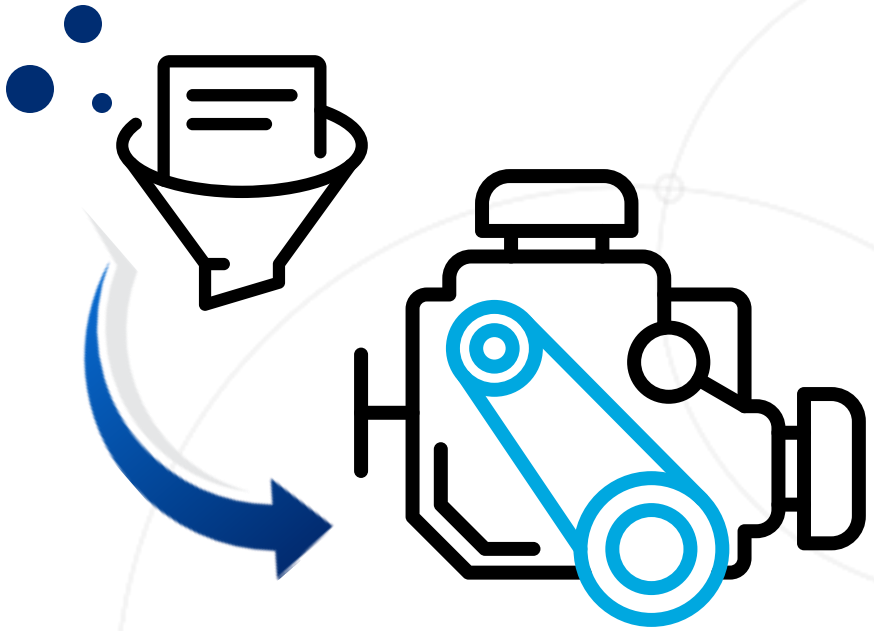
How a colon polyp progresses to cancer



The best-established models aim to reproduce natural history, with screening tests (with their sensitivities and specificities) superimposed

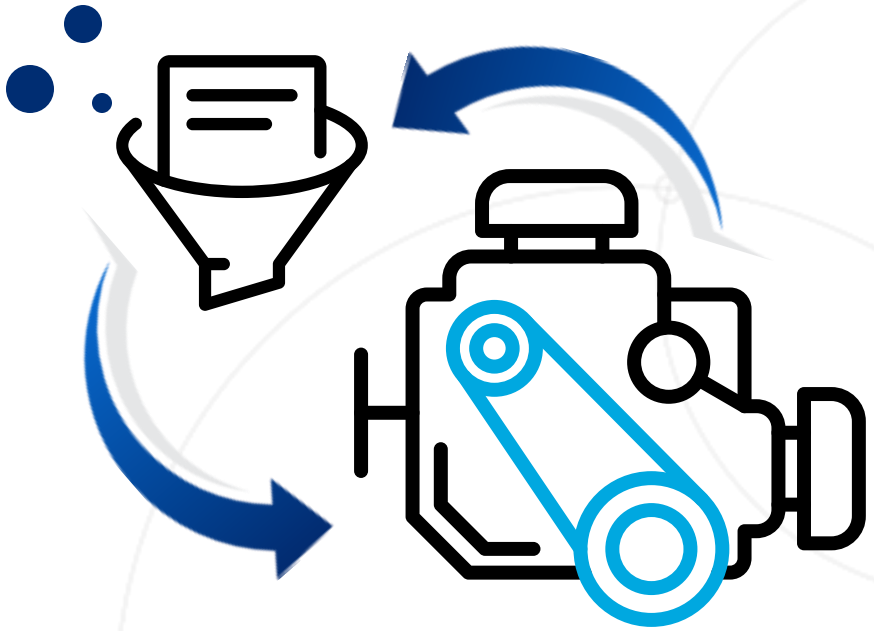
https://www.health.harvard.edu/diseases-and-conditions/they-found-colon-polyps-now-what

Is this a good model even if it's a black or gray box to me?



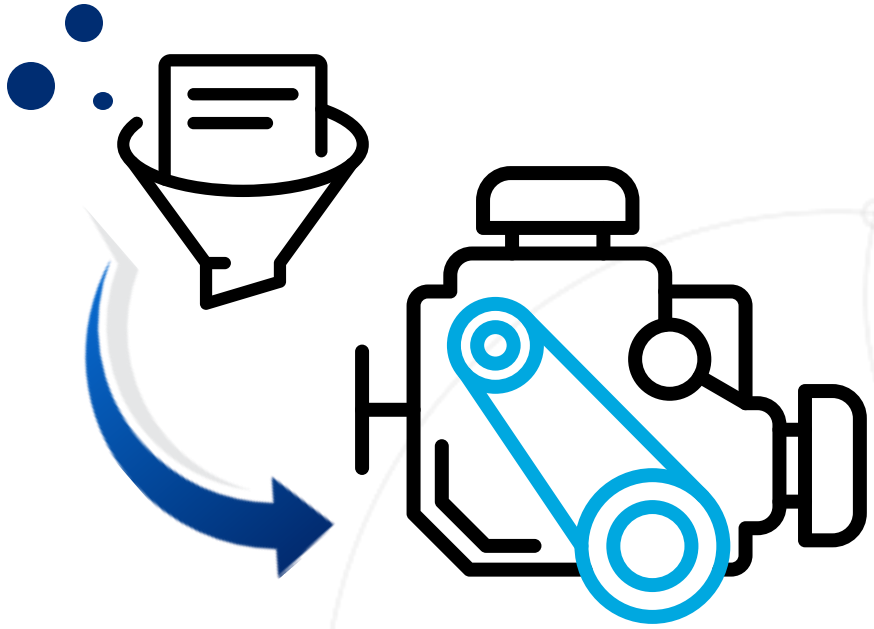
Calibration

Is this a good model even if it's a black or gray box to me?



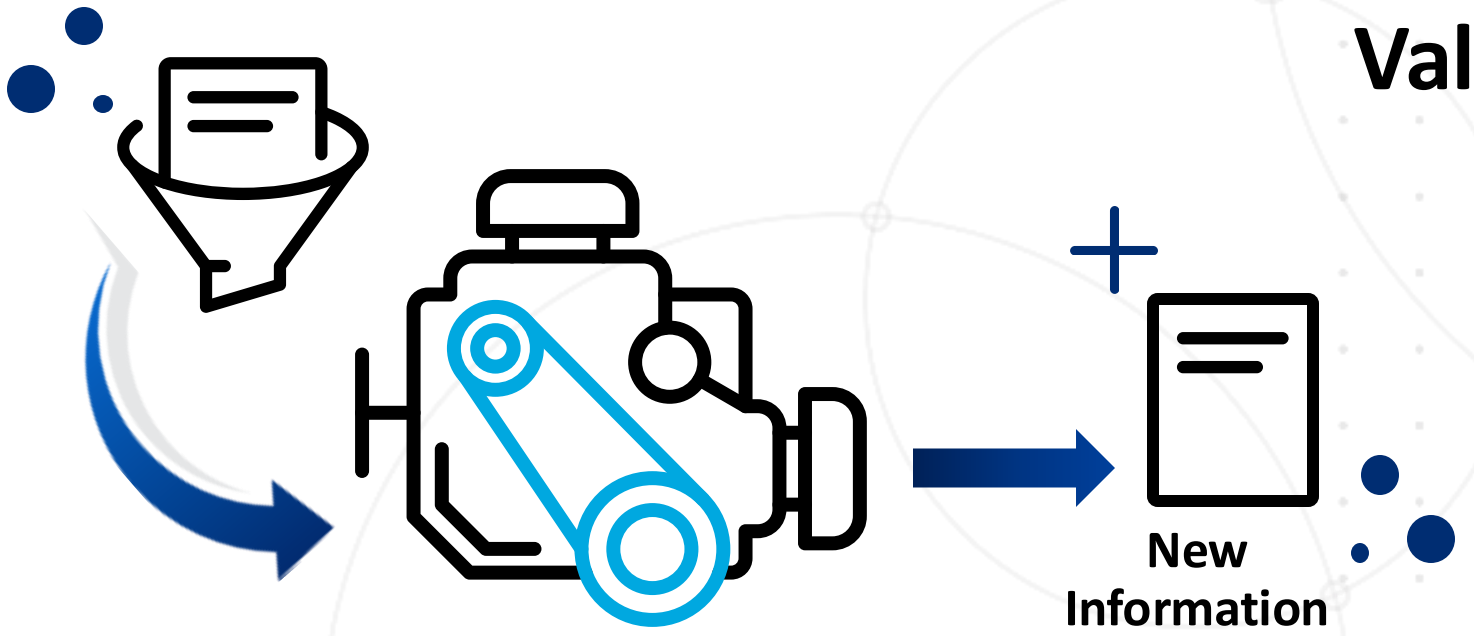
Calibration

Is this a good model even if it's a black or gray box to me?

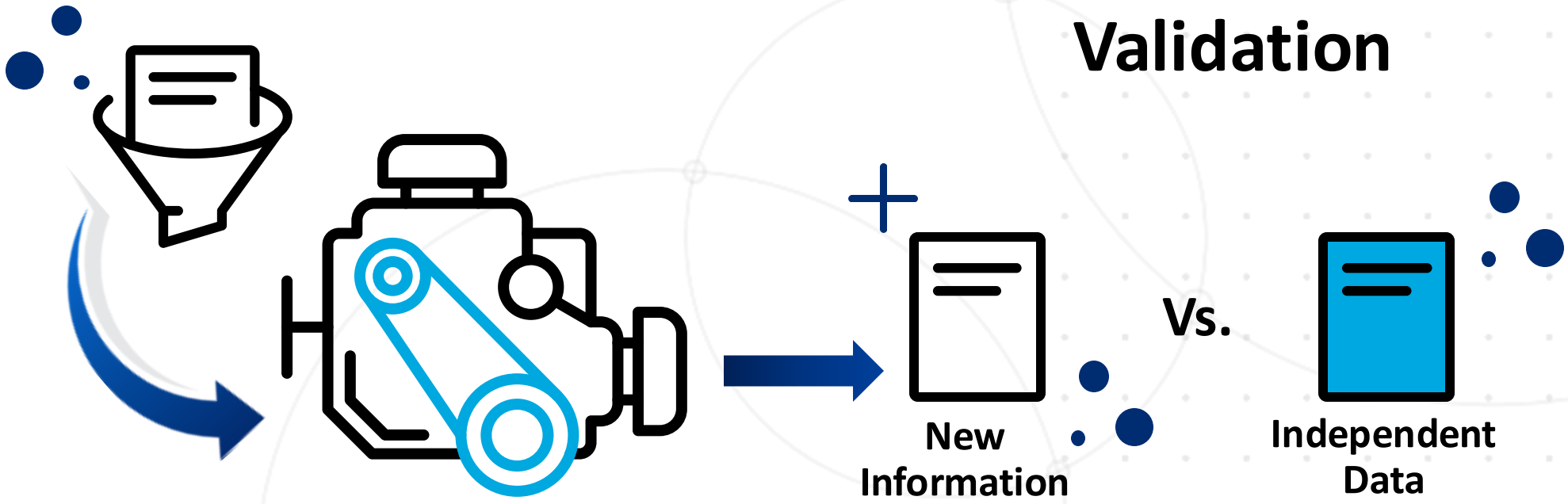


Validation

Is this a good model even if it's a black or gray box to me?

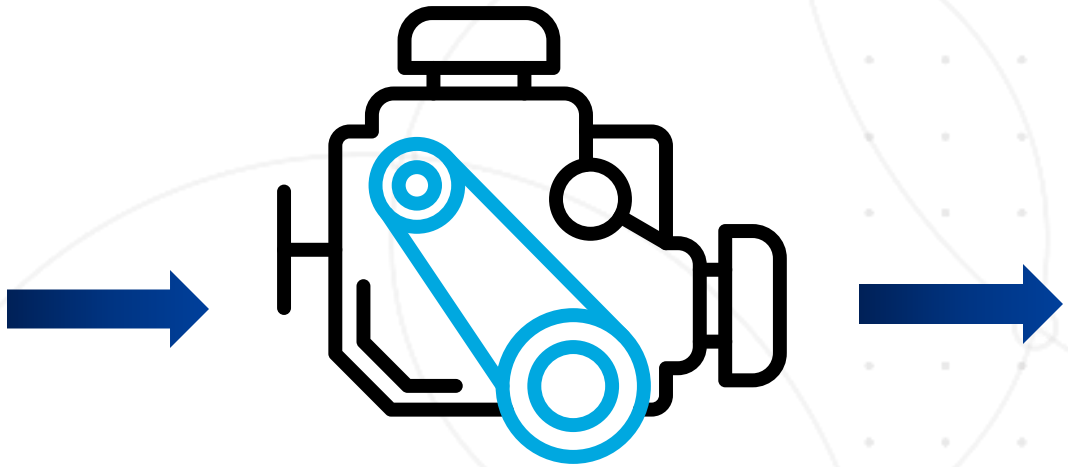


Is this a good model even if it's a black or gray box to me?



screen smart
data • access • adherence

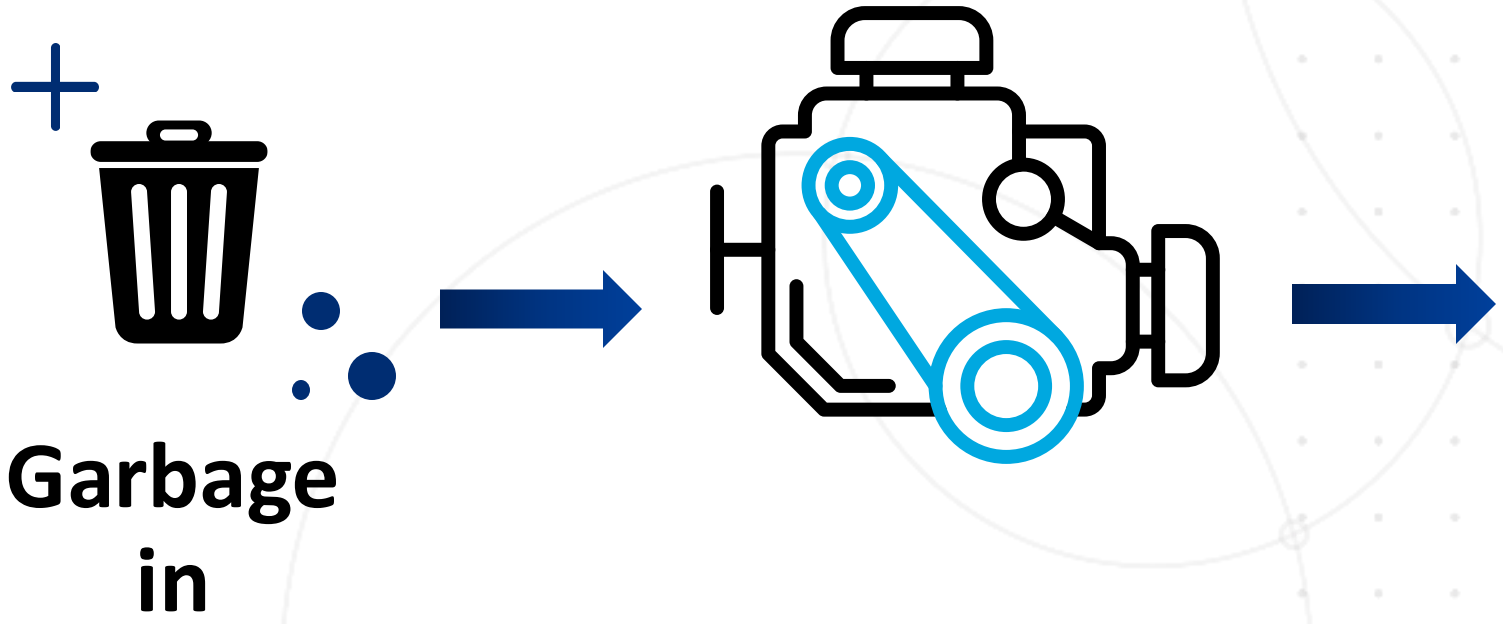
So the engine is good – what are you putting into it?



colorectal cancer alliance

screen smart
data • access • adherence

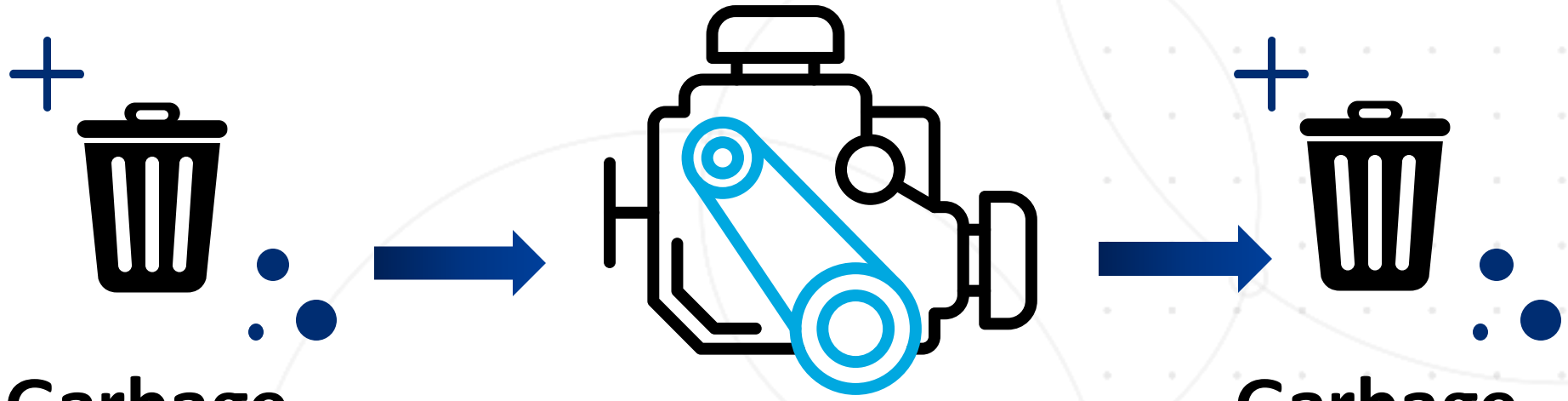
So the engine is good – what are you putting into it?



colorectal cancer alliance

screen smart
data • access • adherence

So the engine is good – what are you putting into it?



colorectal cancer alliance

Effectiveness = Efficacy x Participation

Modeling Studies

Sidney J. Winawer

"The best test is the one that gets done and done well"

Winawer S, Dig Dis Sci 2015; 60:596-608

Extreme examples crystalize concepts

	How good is it?	Will people take it?	Outcome
Medication 1	Cures everyone		
Medication 2	Cures 60%		

Extreme examples crystalize concepts

	How good is it?	Will people take it?	Outcome
Medication 1	Cures everyone	Never! (cost, side effects, etc.)	
Medication 2	Cures 60%	Half of people will	

Extreme examples crystalize concepts

	How good is it?	Will people take it?	Outcome
Medication 1	Cures everyone	Never! (cost, side effects, etc.)	**0 cures**
Medication 2	Cures 60%	Half of people will	**30% cured**

Effectiveness = Efficacy x Participation*

*If you model longitudinal adherence, the assumptions are critical

“But you assumed 100% adherence! That is NOT realistic!”

- This is a misplaced criticism
- NOBODY thinks 100% adherence is realistic
- This “maximum predicted effectiveness” estimate is necessary, and highly informative, as an anchor point
- Without it, the impact of differential adherence cannot be appreciated adequately

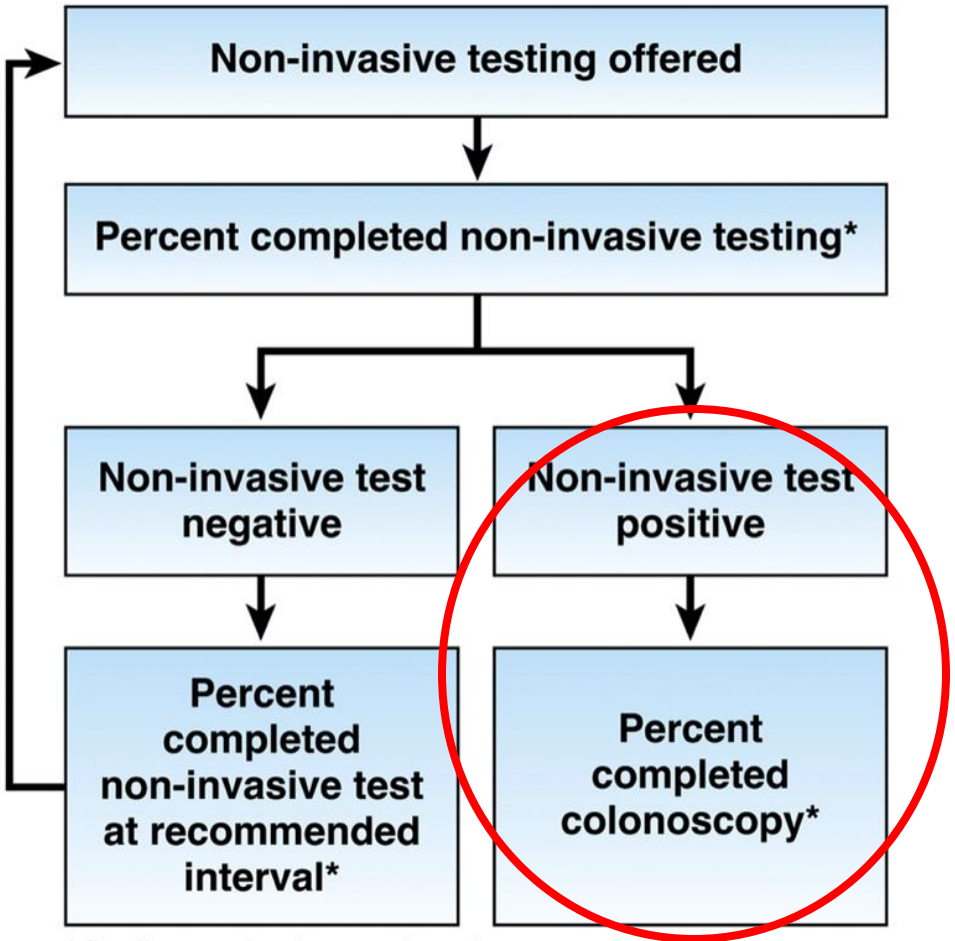
Expanding quality metrics?

AGA SECTION

Gastroenterology 2022;163:520–526

Reducing the Burden of Colorectal Cancer: AGA Position Statements

David Lieberman,[1,*] Uri Ladabaum,[2,*] Joel V. Brill,[3,4] Folasade P. May,[5,6,7] Caitlin Murphy,[9] Richard Wender,[10] and Kathleen Teixeira[11] Lawrence S. Kim,[8]



*Quality metrics for non-invasive screening program

Original Research

ORIGINAL RESEARCH

Annals of Internal Medicine

Projected Impact and Cost-Effectiveness of Novel Molecular Blood-Based or Stool-Based Screening Tests for Colorectal Cancer

Uri Ladabaum, MD, MS; Ajitha Mannalithara, PhD; Robert E. Schoen, MD, MPH; Jason A. Dominitz, MD, MHS; and David Lieberman, MD

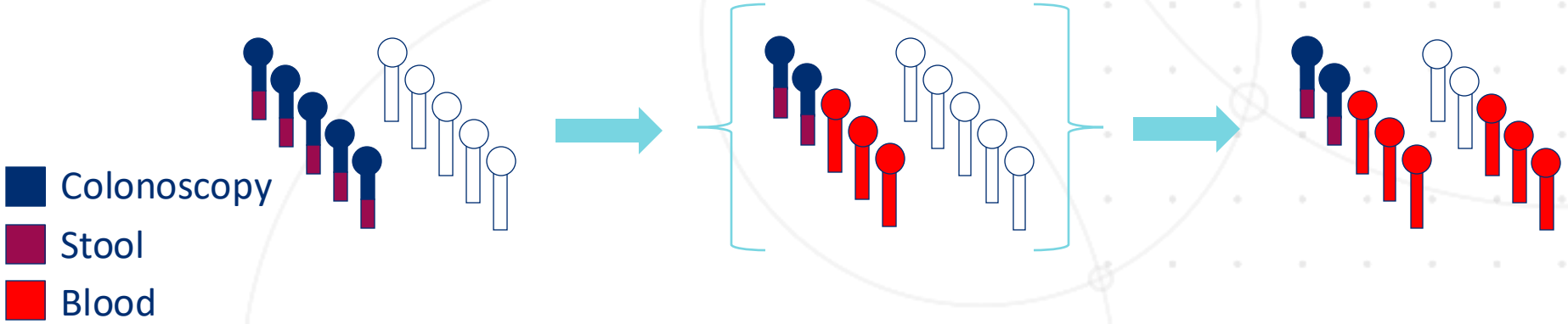
Primary Funding Source:

The Gorrindo Family Fund.

Ladabaum et al, Ann Int Med 2024; 177:1610

Key points: Population impact

For every 3 people who substitute cf-DNA for stool tests or colonoscopy…:
… >2 people who would otherwise NOT SCREEN must be added to screening with cf-DNA in order to improve outcomes at the population level



Ladabaum et al, Ann Int Med 2024; 177:1610

Clinical – Alimentary Tract

Gastroenterology 2016;151:427–439

CLINICAL—ALIMENTARY TRACT

Comparative Effectiveness and Cost Effectiveness of a Multitarget Stool DNA Test to Screen for Colorectal Neoplasia

Uri Ladabaum and Ajitha Mannalithara

Division of Gastroenterology and Hepatology, Department of Medicine, Stanford University School of Medicine, Stanford, California

Clinical – Alimentary Tract

Gastroenterology 2016;151:427–439

CLINICAL—ALIMENTARY TRACT

Comparative Effectiveness and Cost Effectiveness of a Multitarget Stool DNA Test to Screen for Colorectal Neoplasia

Uri Ladabaum and Ajitha Mannalithara

Division of Gastroenterology and Hepatology, Department of Medicine, Stanford University School of Medicine, Stanford, California

Funding
This study was funded by an unrestricted research grant from Exact Sciences Corporation. Exact Sciences Corporation had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the manuscript.

Clinical – Alimentary Tract

Gastroenterology 2016;151:427–439

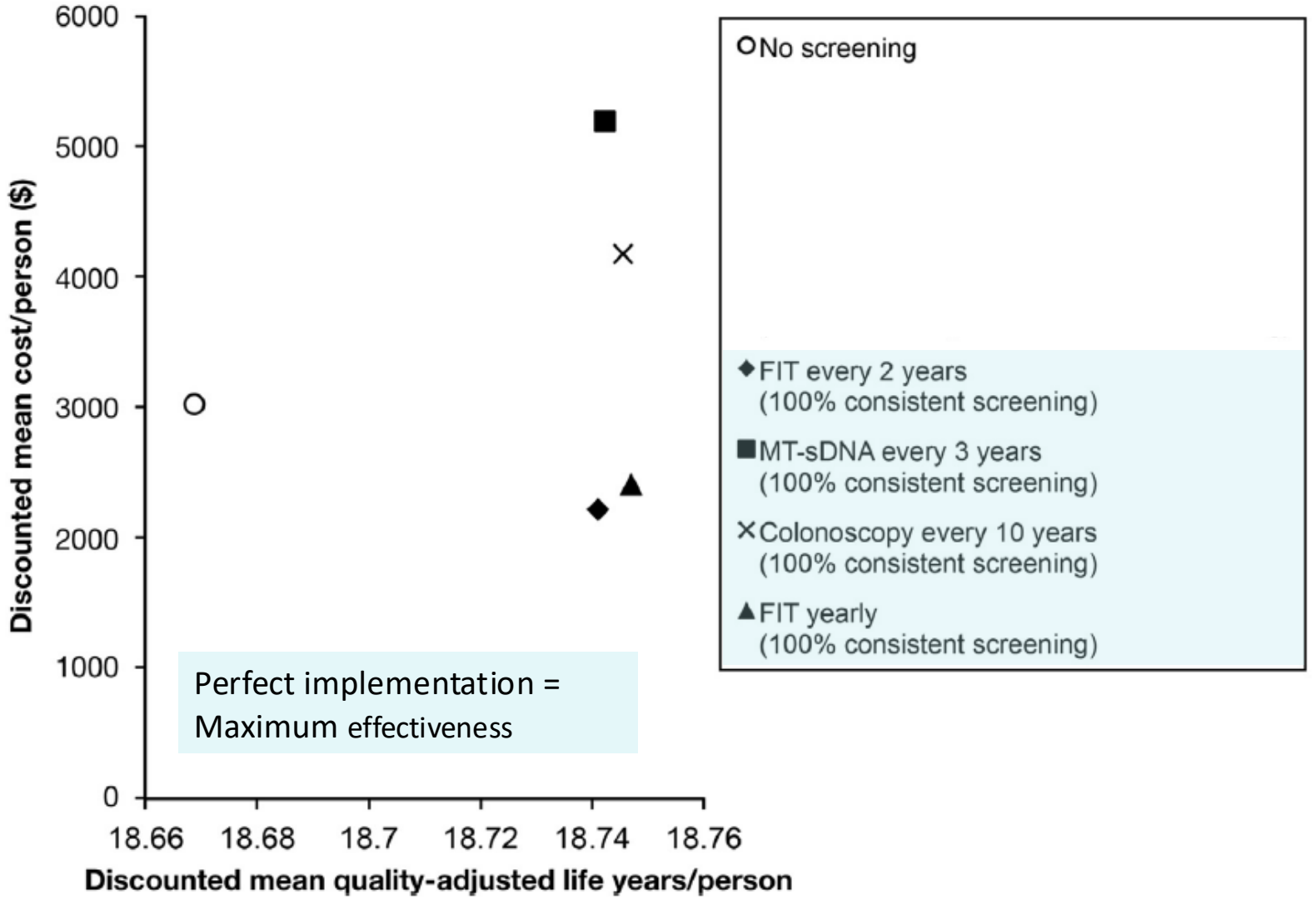
CLINICAL—ALIMENTARY TRACT

Comparative Effectiveness and Cost Effectiveness of a Multitarget Stool DNA Test to Screen for Colorectal Neoplasia

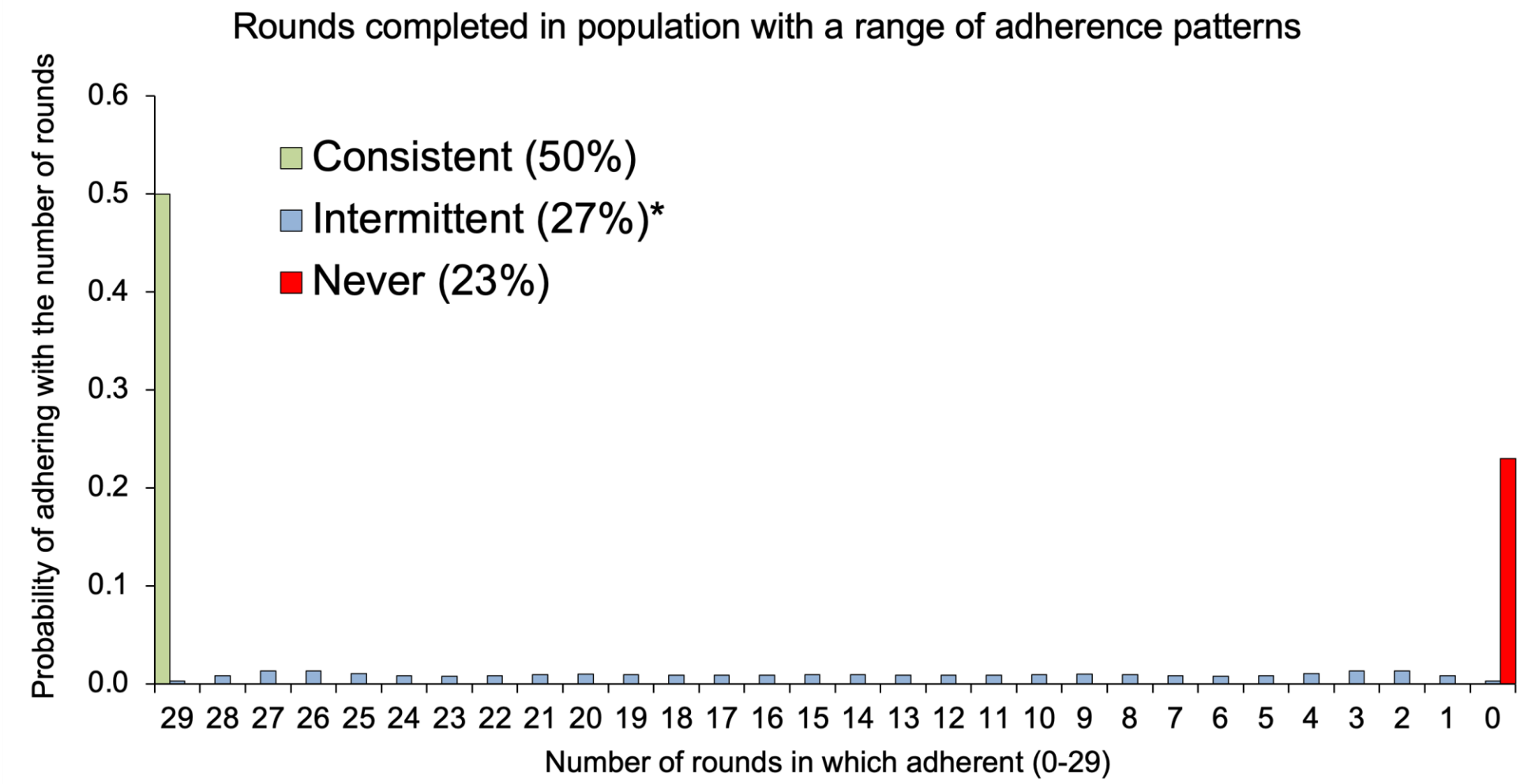
Uri Ladabaum and Ajitha Mannalithara

Division of Gastroenterology and Hepatology, Department of Medicine, Stanford University School of Medicine, Stanford, California

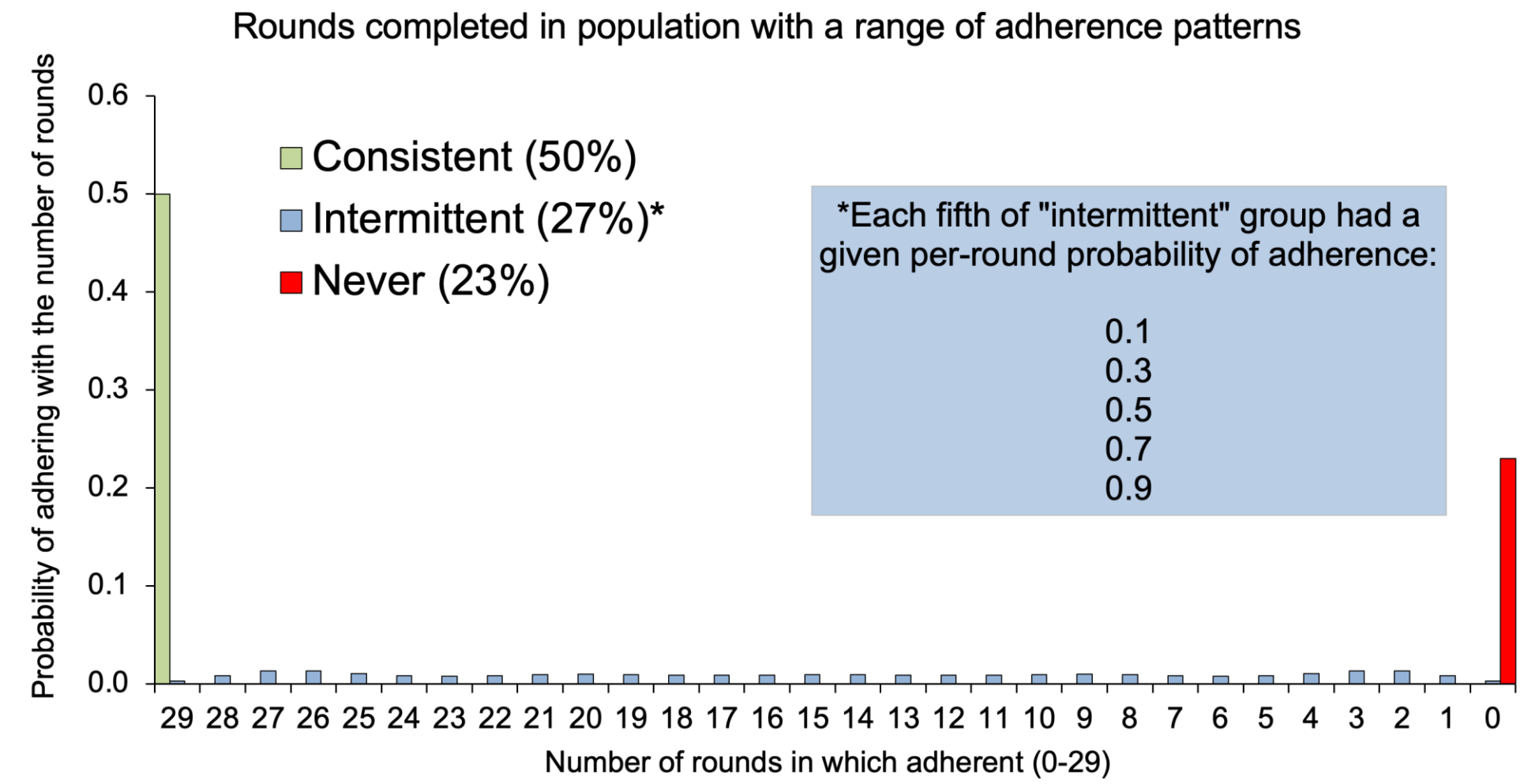
Conflicts of interest
This author discloses the following: Uri Ladabaum was a consultant to Exact Sciences Corporation in 2014, and currently serves as a consultant to Given Imaging and as a scientific advisor to Mauna Kea Technologies. The remaining author discloses no conflicts.



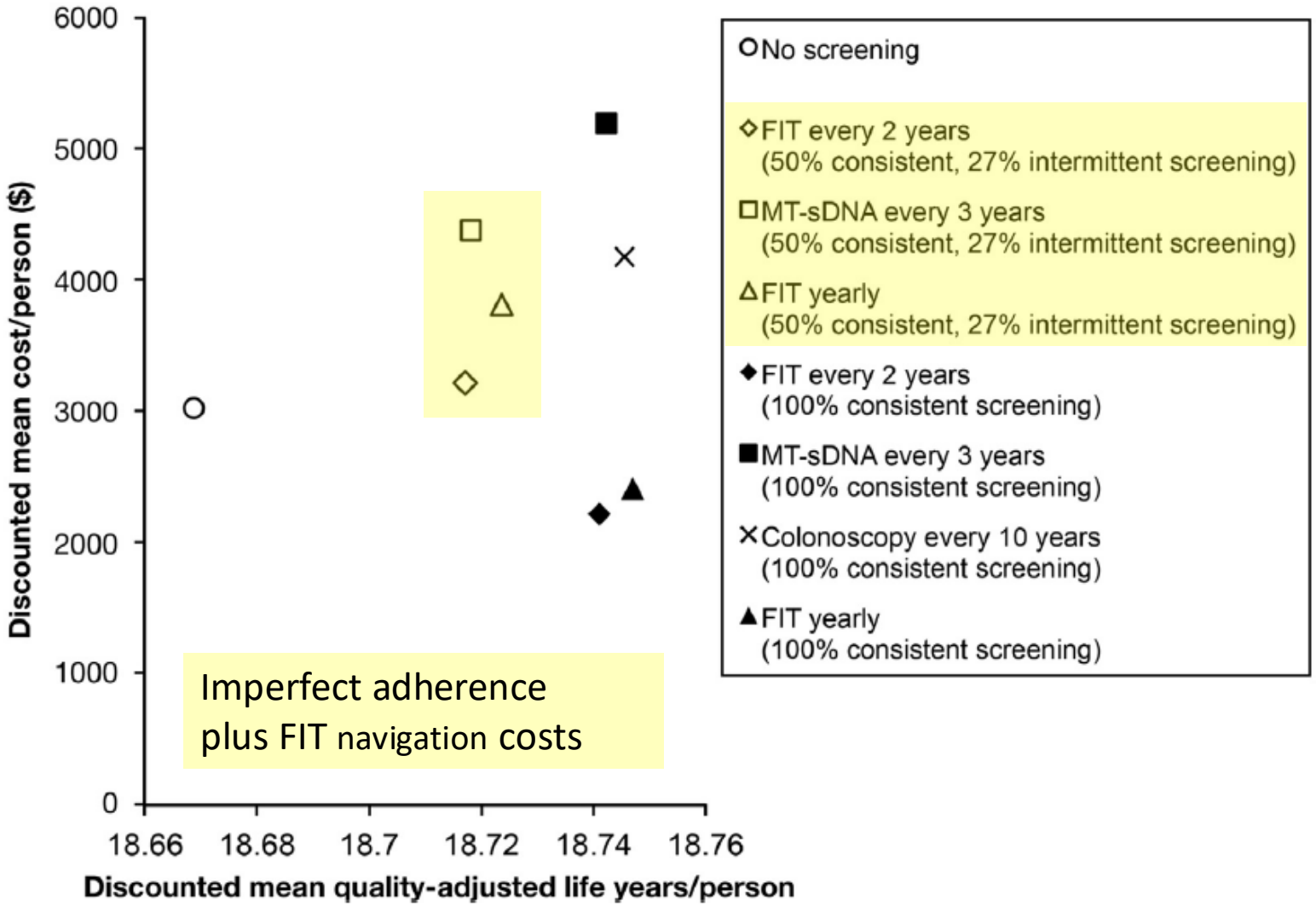
Ladabaum et al, Gastroenterology 2016; 151:427



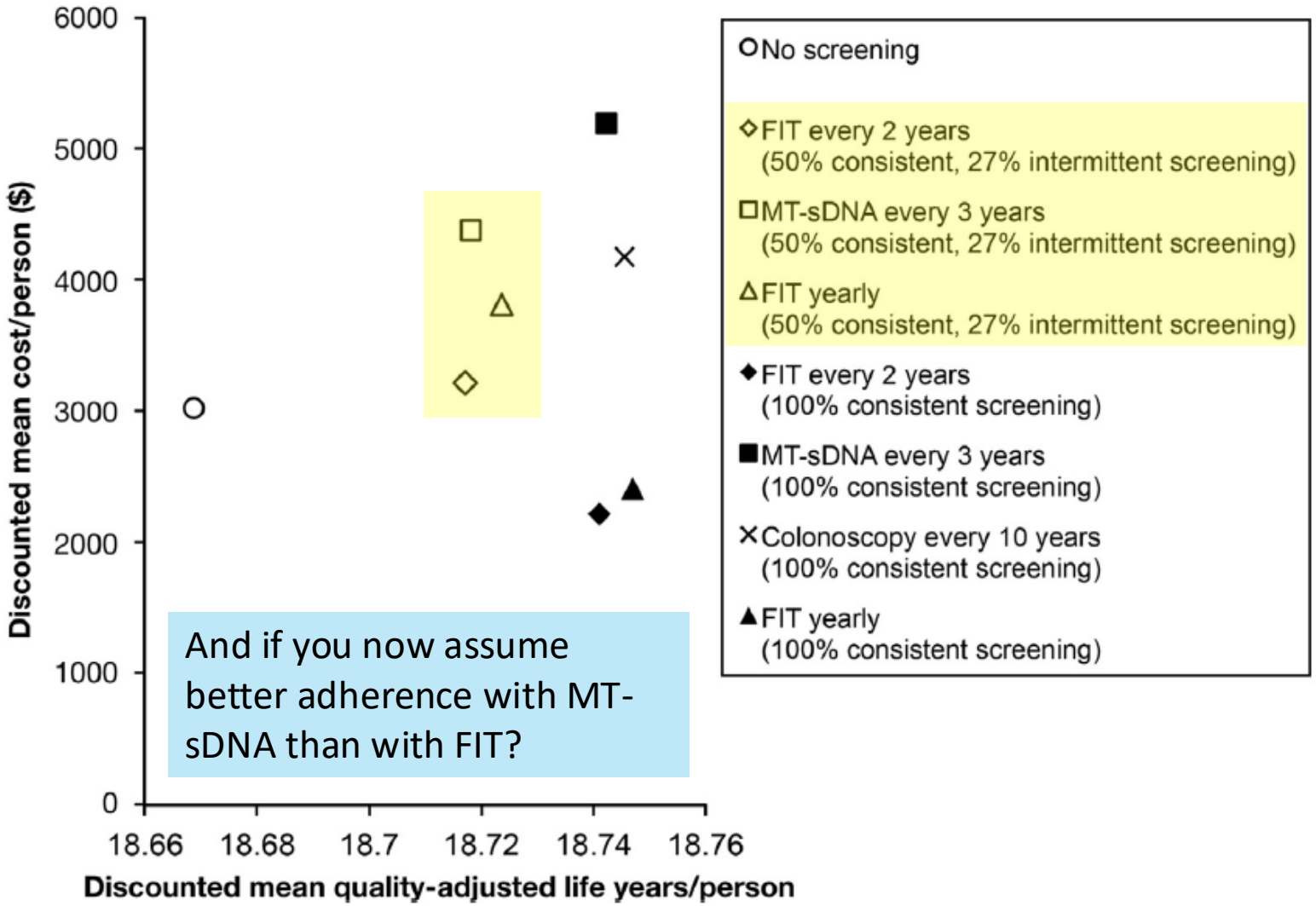
Ladabaum et al, Gastroenterology 2016; 151:427



Ladabaum et al, Gastroenterology 2016; 151:427

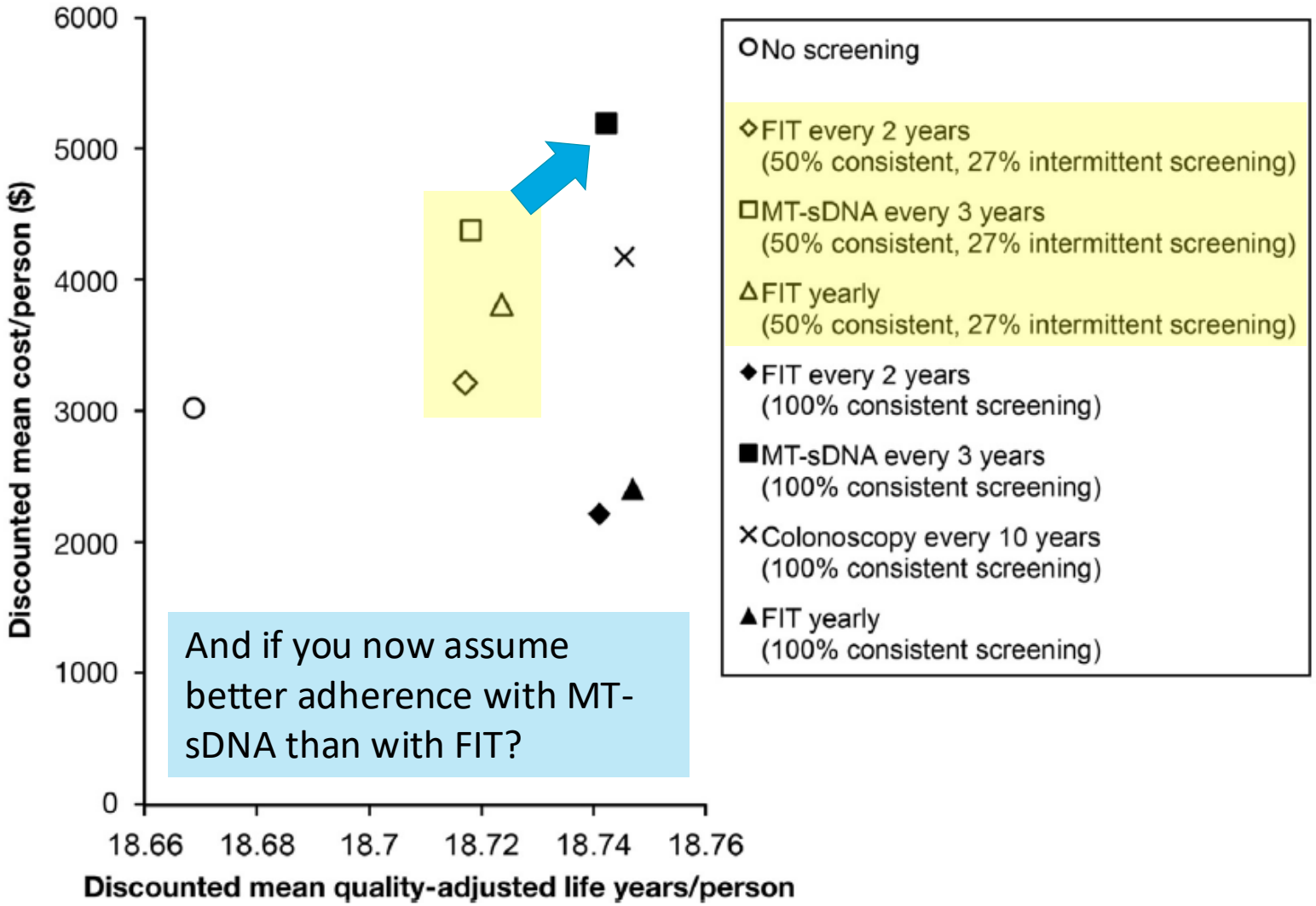


Ladabaum et al, Gastroenterology 2016; 151:427



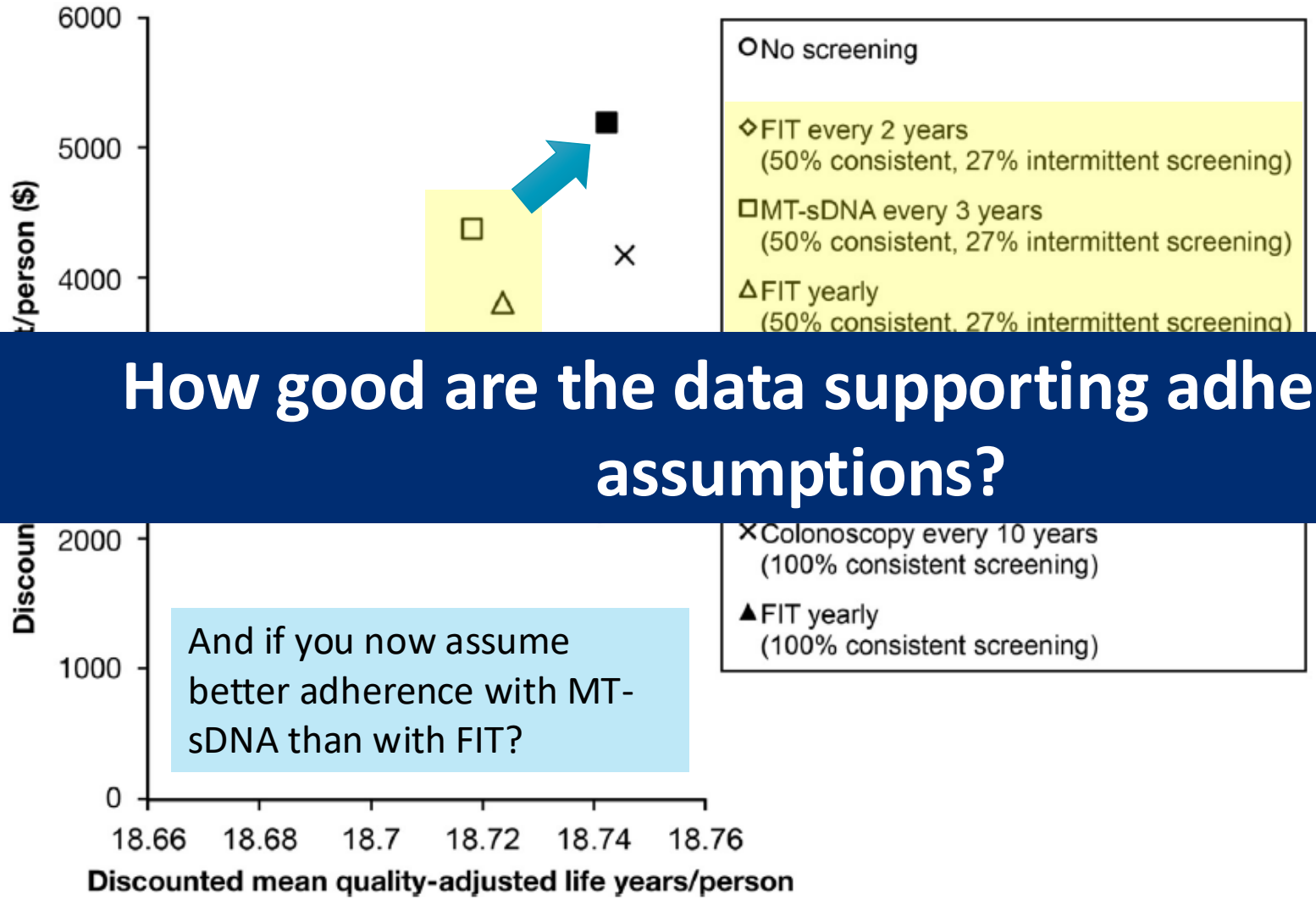
And if you now assume better adherence with MT-sDNA than with FIT?

Ladabaum et al, Gastroenterology 2016; 151:427



Ladabaum et al, Gastroenterology 2016; 151:427

How good are the data supporting adherence assumptions?



And if you now assume better adherence with MT-sDNA than with FIT?

Ladabaum et al, Gastroenterology 2016; 151:427

Screen Smart Adherence Panel

Moderator

Uri Ladabaum, MD, MS
Professor of Medicine, Director of the Gastrointestinal Cancer Prevention Program and Head of Clinical Service of the Division of Gastroenterology and Hepatology at Stanford University School of Medicine

Erica Barnell, MD, PhD
Chief Medical Officer and Co-Founder
Geneoscopy

Durado Brooks MD, MPH
Associate Chief Medical Officer
Exact Sciences

Craig Eagle, MD
Chief Medical Officer
Guardant Health

Todd W. Kelley, MD
Chief Medical Officer
Polymedco

T.R. Levin, MD, MS
Associate Director for Cancer Research, KPNC Division of Research, The Permanente Medical Group, Inc.

Jimmy Lin, M.D., Ph.D., MHS
Chief Scientific Officer Freenome

Courtney Moreno, MD
Professor in the Department of Radiology and Imaging Sciences at Emory University School of Medicine

Questions for panelists

Key discussion points for our panelists:

- What real-world adherence data do you currently have? Please be ready to share that information clearly.
- What opportunities exist for generating new adherence data—individually or through collaboration?
- What strategies are you pursuing—or could you pursue—to improve adherence in practice?

CT Colonography

Courtney Moreno, MD

colorectal cancer alliance

Adherence data for CT Colonography (aka “Virtual Colonoscopy”)

screen smart
data • access • adherence

Background:

- CT Colonography (CTC) remains an underutilized test.
- As of January 2025, CTC is covered by Medicare for colon cancer screening.
- In many centers, utilized for “edge” cases such as:
  - Not enough GI doctors for optical colonoscopy
  - Incomplete colonoscopy (example, stricture or hernia)
  - Positive stool-based test but negative colonoscopy (CTC performed as a “double check”)
  - Patient thought to be too high risk for sedation for optical colonoscopy (no sedation for CTC)

colorectal cancer alliance

Adherence data for CT Colonography (aka “Virtual Colonoscopy”)

Adherence Data

- Stoop et al (Lancet Oncology 2012) (the Netherlands)
  - 34 % (982/2920) accepted invitation for CTC
  - 22% (1276/5924) accepted invitation for optical colonoscopy
- Moreno et al (Clin Colorectal Cancer 2018) (Atlanta VA Medical Center)
  - 14% (349/2490) of patients recommended for OC based on CTC results
  - 11% (279/2490) of patients underwent OC

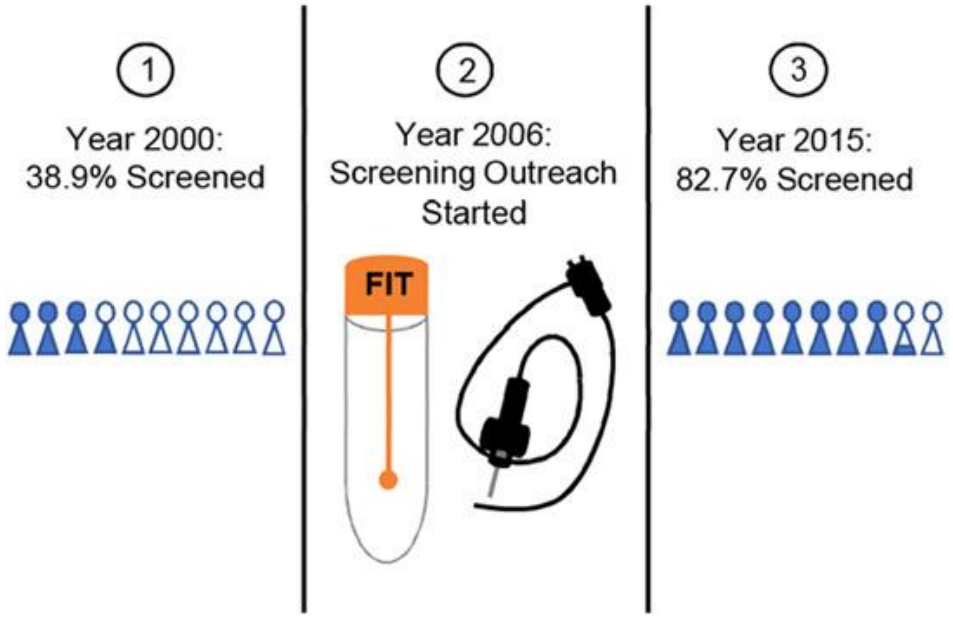
Kaiser Permanente Organized Screening

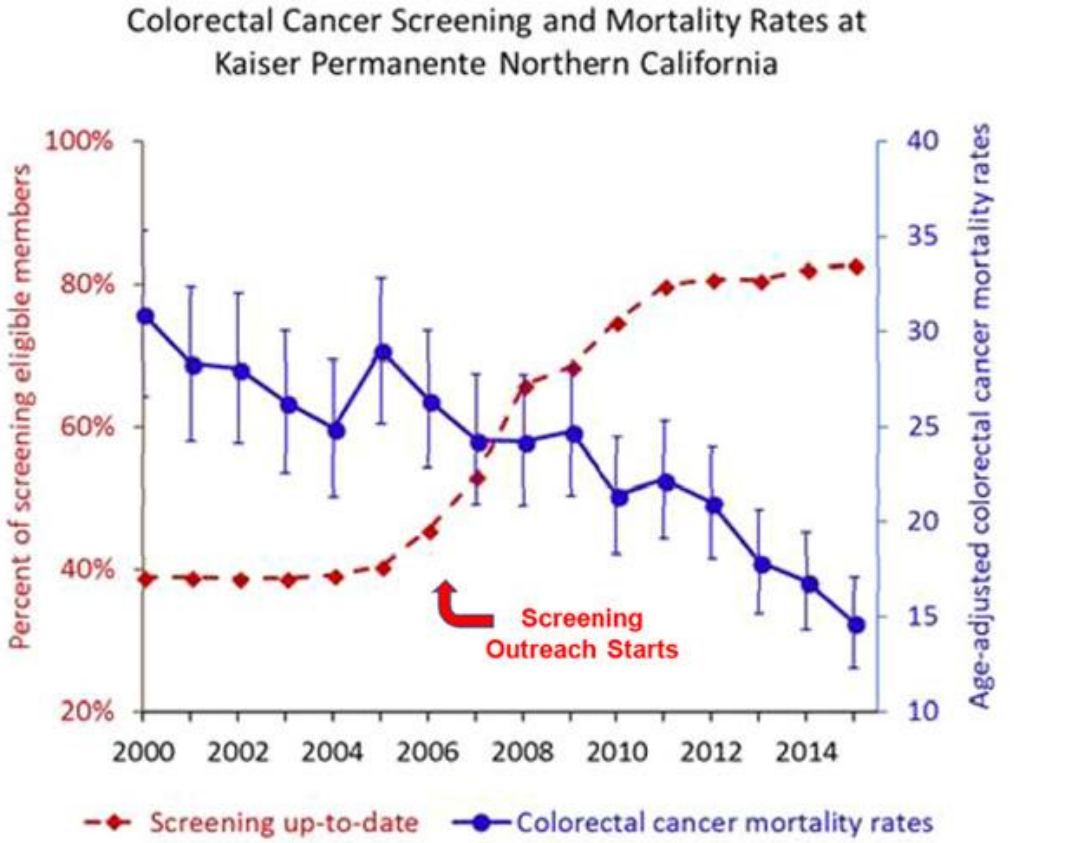
T. R. Levin, MD, MS

colorectal cancer alliance

KPNC launched an organized CRC screening based on mailed FIT outreach in 2006/2007 and sustained it to the present date

CRC deaths declined with the increased penetration of screening

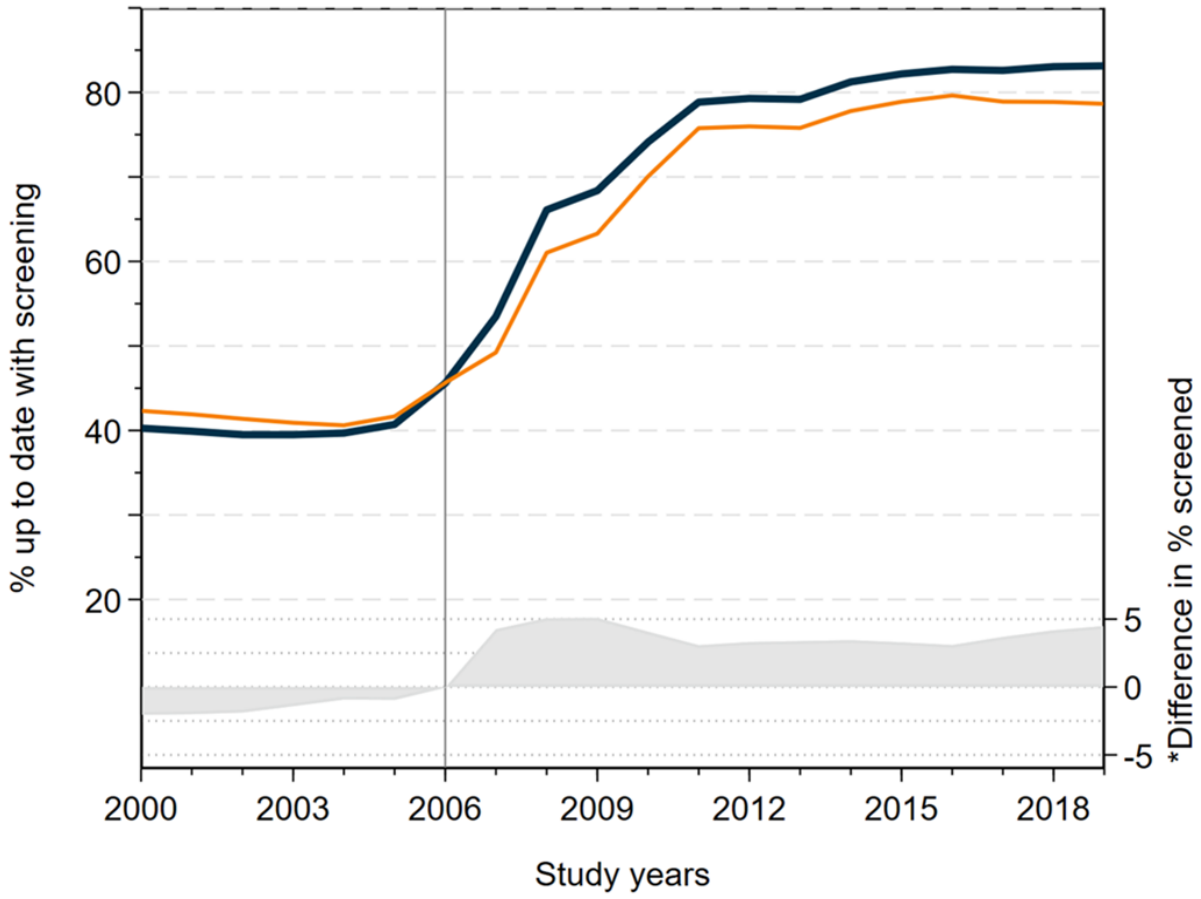




Levin et al. 2018. PMID: 30031768

Gastroenterology

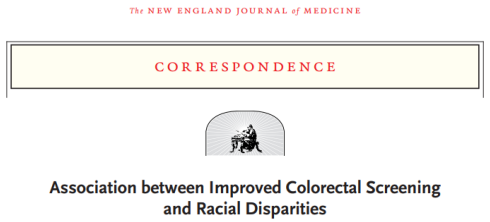
The gains in screening participation rates were high (~80%)



Population by 2019:
NH Black – 88,734
NH White – 703,347

In this study, we evaluated how new cases and deaths **compared across racial and ethnic groups**:

- We focused on non-Hispanic (NH) White vs. NH Black rates

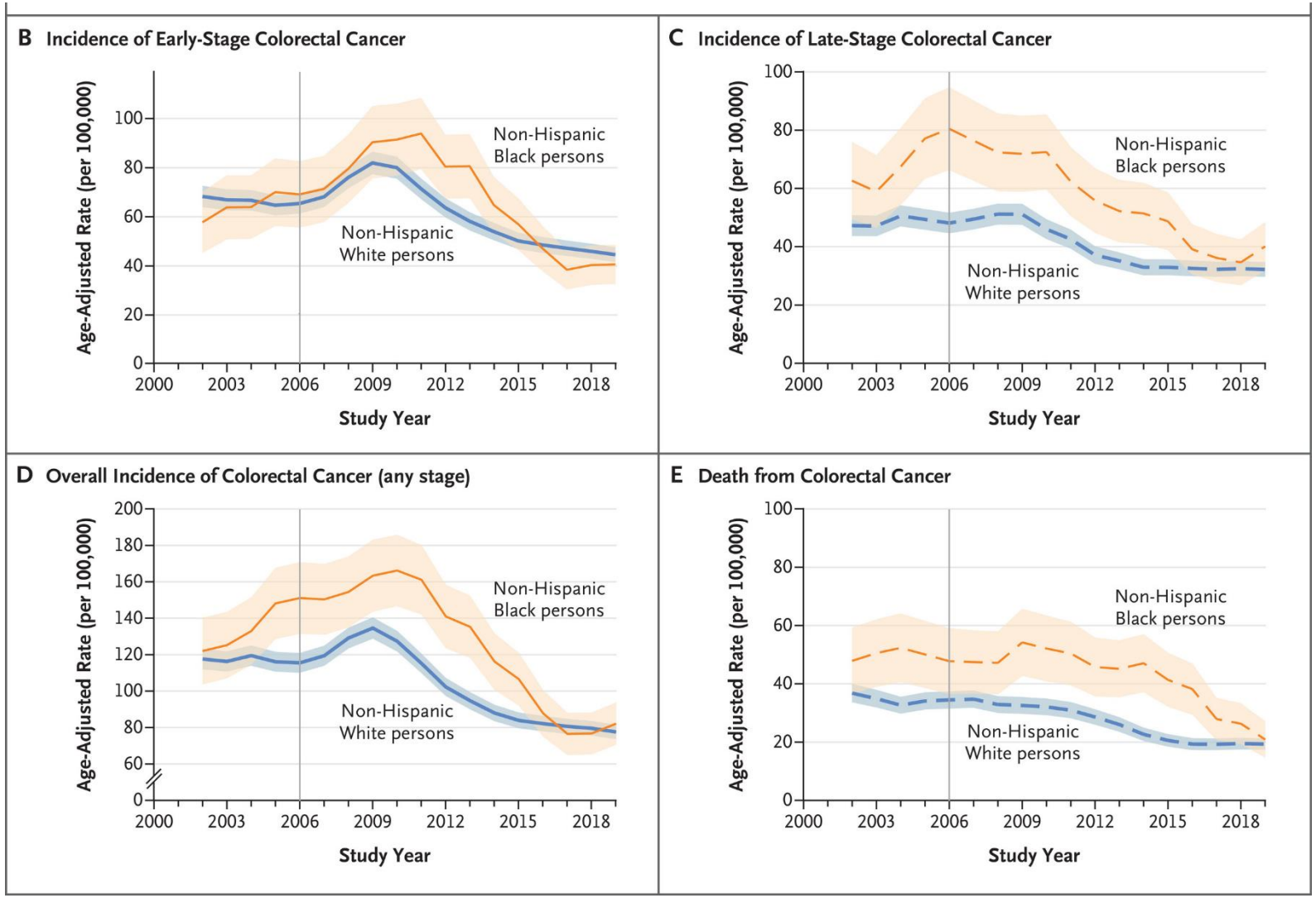


Doubeni, et al. NEJM 2022; 386:796-798

Screening Outcomes among Black and White Persons, KPNC 2000–2019

With improved screening and follow-up, starting in 2006/2007, the rates of early stage CRC went up, at first, and late stage decreased progressively and the gaps essentially closed around 2019

Doubeni et al. NEJM 2022



Polymedco Increasing Adherence to FIT

Todd Kelley, MD

colorectal cancer alliance

Increasing patient adherence to FIT testing

Polymedco Approach

1. **Polymedco: Supplier of a comprehensive line of instruments, reagents and collection kits to laboratory customers in USA/Canada**
   - Enhancing convenience: Direct FIT mailing service
     - Direct mailing of health-system branded at-home patient collection kits to patients due for screening
     - Includes instructions, pre-addressed, pre-paid return mailer for sample
   - Partnership with a third-party navigation service

2. **What factors yield higher patient adherence?**
   - There are numerous studies in a variety of different patient populations (ie. rural, urban, Spanish-speaking, FQHC, etc)
   - Take home messages: education, personalization, navigation

3. ***Influencing IDN/health system approaches**
   - Target management (CEO, CMO, etc) and thought leaders in GI, primary care and quality
   - Refer to *cost-effectiveness modeling studies* that demonstrate potential impacts of increasing adherence
     - Clinical care, quality measures, HEDIS scores, costs

Recent FIT Cost Effectiveness Modeling

Third party modeling study supports FIT as most clinically and cost-effective non-invasive CRC screening strategy

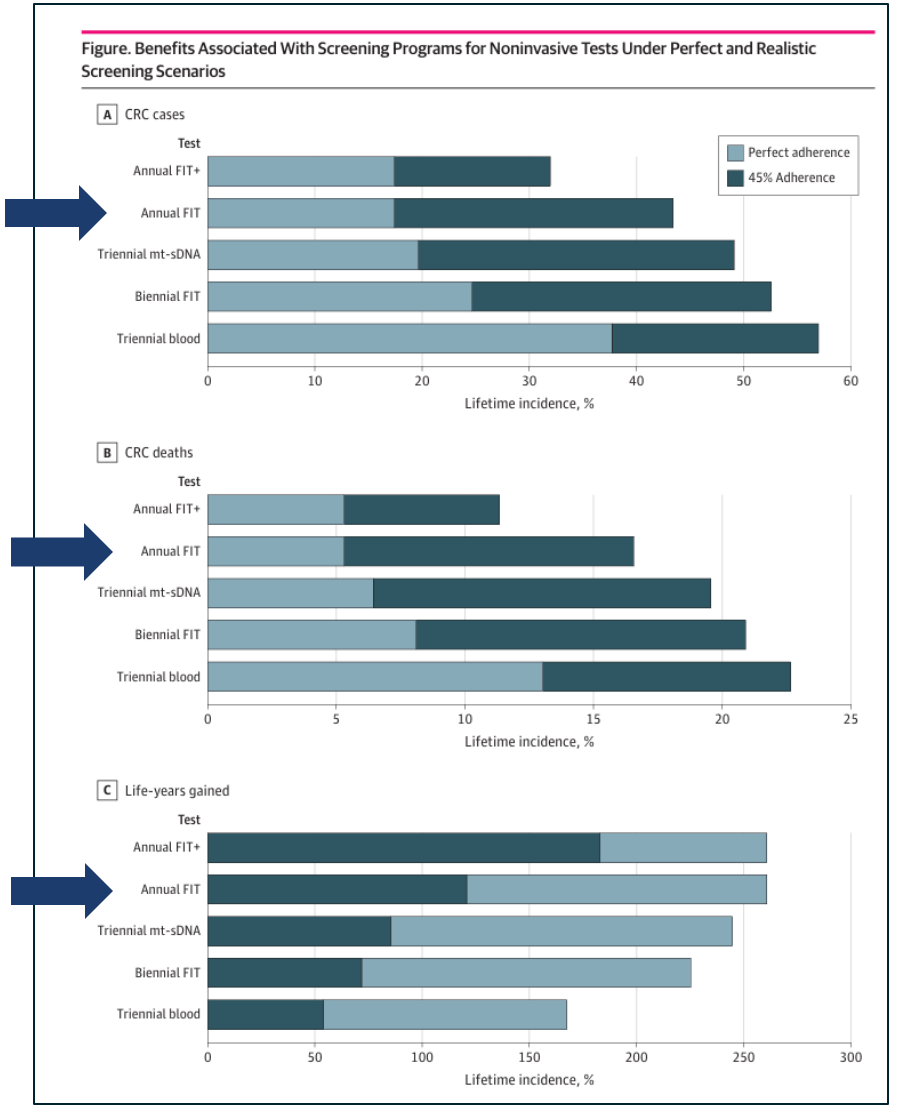
Major findings:

1

- Use of FIT for CRC screening at real-world adherence rates* is associated with fewer CRC cases, fewer CRC deaths, and more life-years gained versus all other non-invasive methods.

2

- Every screening strategy that was modeled reduced treatment costs and yielded quality adjusted life year (QALY) gains, but only FIT-based screening yielded net cost savings versus no screening due to its more substantial reduction in treatment costs.



*Real-world adherence assumes 45% adherence for FIT and 40% adherence to follow up colonoscopy except FIT+ which assumes 80% adherence to follow up colonoscopy

Ref: Nascimento de Lima P. JAMA Network Open.2025;8(1):e2454938

Exact Sciences

Durado Brooks, MD, MPH

colorectal cancer alliance

The adherence data that we have generated:

Adherence to Cologuard testing in the US

Category	Adherence
Overall	(N= 1,111,030) 71.3%[1]
Commercial Insurance	(N= 766,701) 72.3%[1]
Medicare Advantage	(N= 233,935) 70.2%[1]
Traditional Medicare	(N= 96,519) 69.9%[1]
Medicaid	(N= 13,875) 52%[1]
FQHC	(N=266,301) 54.3%[2]
Age 45-49	(N= 775,714) 68.9%[3]
Black	(N=266,981) 62%[4]
Hispanic	(N=519,191) 64.3%[2]
Asian	(N=238,305) 71%[5]

EXACT SCIENCES

Key message:

This study aimed to evaluate adherence rates of multi-target stool DNA (mt-sDNA) testing.

This **retrospective cohort** study used aggregated data, examining new users (first-time testers) aged 45–85 with commercial, Medicare, or Medicaid insurance who received mt-sDNA test kits (point-of-care) between January 1, 2023, and June 1, 2023.

Among **1,557,915** patients, the overall adherence rate to mt-sDNA testing was **71.3% (commercial insurance 72.3%, Medicare Advantage 70.2%, Medicare 69.9%, Medicaid 52.0%).**

Reference:

[1] Le, Q.A., Greene, M., Gohil, S. et al. Adherence to multi-target stool DNA testing for colorectal cancer screening in the United States. Int J Colorectal Dis 40, 16 (2025). https://doi.org/10.1007/s00384-025-04805-0

[2] Data on file

[3] Greene M, Camardo M, Johnson WK, Ozbay AB, Fendrick AM, Dore M, Limburg PJ. Multi-target stool DNA test adherence among average-risk 45-to 49-year-old patients from 2017-2023. https://doi.org/10.1200/JCO.2025.43.4_suppl.102

[4] Greene, M., Gohil, S., Camardo, M., Ozbay, A. B., Limburg, P., & Lovelace, J. (2025). Adherence to mt-sDNA testing for colorectal cancer screening among new users in a U.S. black population. Current Medical Research and Opinion, 1–13. https://doi.org/10.1080/03007995.2025.2475074

[5] Greene M, Camardo M, Le QA, Johnson WK, Ozbay AB, Fendrick AM, Dore M, Limburg PJ. Adherence to multi-target stool DNA test in the US Asian population from 2017-2024. https://doi.org/10.1177/10732748251330695

Additional adherence data for continuum of care

Adherence to follow-up colonoscopy after positive stool-based testing in the US

Category	mt-sDNA	FIT
Overall	(N=220,894) 77.2%	(N=15,862) 44.7%
Age 45-49	(N=6,369) 85%	(N=2,261) 35.2%
Black	(N=14,221) 71.5%	(N=3,127) 44.6%
Hispanic	(N=11,990) 74.4%	(N= 4,703) 45.1%
Asian	(N=3,966) 74.4%	(N=2,080) 41.1%
White	(N=142,049) 77.3%	(N=19,912) 45.4%
Commercial Insurance	(N=131,196) 80.8%	14,678) 42.3%
Medicare FFS	(N=10,500) 76.4%	(N=1,486) 47.8%
Mediare Advantage	(N=66,390) 72.8%	(N=10,288) 47.9%
Medicaid	(N=17,132) 70%	(N=5,264) 47.4%

Key message:

While adherence to initial screening is important, follow-up colonoscopy after a positive stool-based test is crucial to complete the screening.

Data shows that the **adherence to follow-up colonoscopy after positive mt-sDNA is significantly higher compared to FIT among young adults, difference races and payers**.

Reference:

[1] Greene M, Steiber B, Ozbay, et al. Adherence to FU COL in patients ages 45-49 years - mt-sDNA vs FIT/FOBT. Digestive Disease Week, 2025. May 3-6, San Diego, CA.

[2] Greene M, Steiber B, Ozbay, et al. Adherence to FU COL by race - mt-sDNA vs FIT/FOBT. Digestive Disease Week, 2025. May 3-6, San Diego, CA.

[3] Greene M, Steiber B, Ozbay, et al. Adherence to FU COL by payor - mt-sDNA vs FIT/FOBT. Digestive Disease Week, 2025. May 3-6, San Diego, CA.

Novel data that we are generating

Longitudinal adherence to stool-based testing in the US

Re-Screening rate	Mt-sDNA	FIT
2nd	(N=732,978) 83.2%	23.40%
3rd	(N=60,589) 92.6%	10.60%

Key message:

Data from 01/01/2023-12/31/2023 for Insured patients (45-85 years) who were shipped an mt-sDNA test during the data coverage period and had previously completed mt-sDNA screening with a negative result ≥ 2.5 years prior were included.

Of 793,567 patients (50-75 years: 89.0%; female: 62.0%), the re-screening adherence rate was 84.0% (from 66.5% for Medicaid to 90.2% for Medicare).

Reference:

[1] Greene M, Pew T, Dore M, Ebner DW, Ozbay AB, Johnson WK, Kisiel JB, Fendrick AM, Limburg P. Re-screening adherence to multi-target stool DNA test for colorectal cancer: real-world study in a large national population. International Journal of Colorectal Disease. 2025 Feb 24;40(1):48.

[2] Fisher DA, Princic N, Miller-Wilson LA, Wilson K, DeYoung K, Ozbay AB, Limburg P. Adherence to fecal immunochemical test screening among adults at average risk for colorectal cancer. Int J Colorectal Dis. 2022 Mar;37(3):719-721. doi: 10.1007/s00384-021-04055-w.

Guardant Health

Craig Eagle, MD, MPH

colorectal cancer alliance

Shield can be completed at any patient visit with a blood draw to help increase CRC screening adherence.

Real World Data from Shield Clinical Ordering[1]

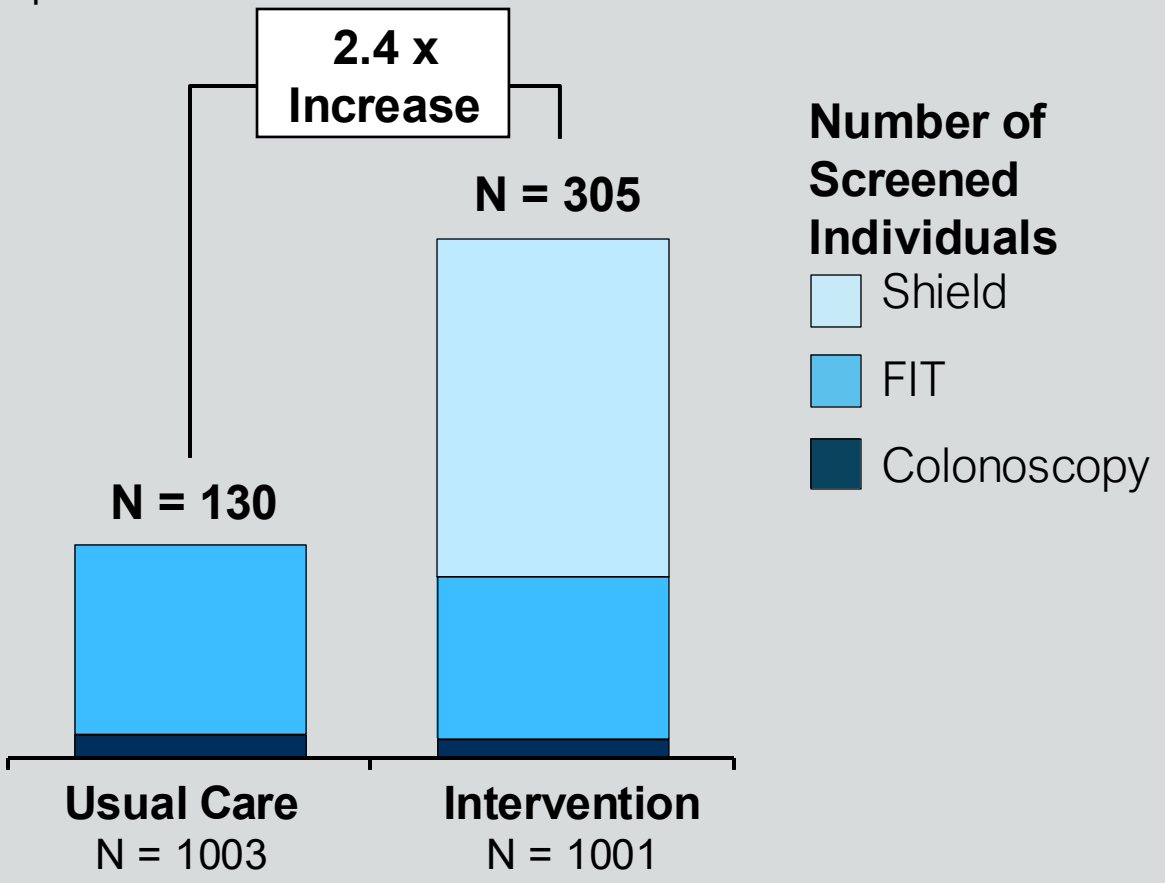
In real-world use, adherence rate for **20,000** patients tested with Shield Laboratory Development Test (LDT) was **~90%** [1]*

People who opt for Shield are no less likely to complete colonoscopy than those who opt for stool[2]

In a real-world analysis using Claims data, **49%** of Shield positive undergo follow-up colonoscopy within 6 months (48% observed for stool-based testing in a separate, similarly conducted claims analysis)

Prospective Study with Kaiser Permanente[3]

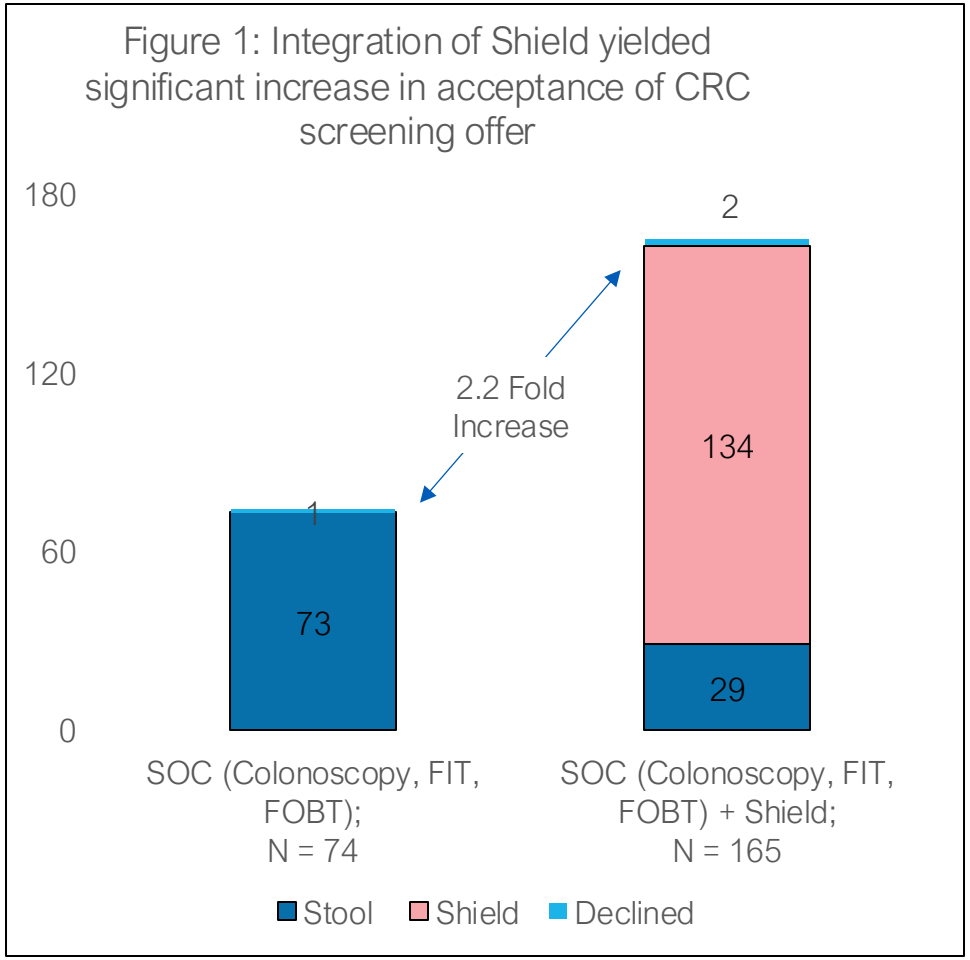
In a separate randomized study, Shield was offered to patients who hadn't completed FIT

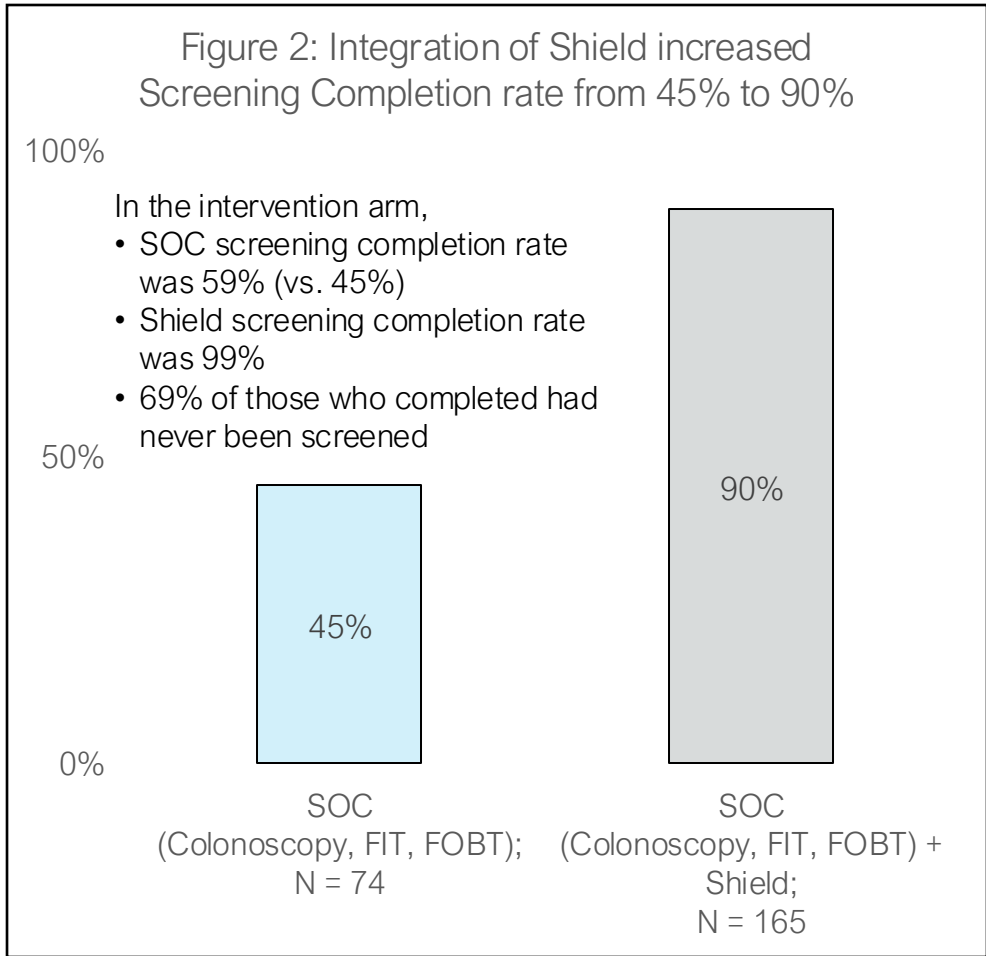


*Based on the first 20,000 patients offered Shield LDT which has not been cleared or approved by the FDA

1. Internal Guardant data on file, May 2024 2. Coronado, 2024, 2. Zaki, et al. DDW 2025. 3. Coronado GD, Jenkins CL, Shuster E, et al. Blood-based colorectal cancer screening in an integrated health system: a randomized trial of patient adherence. Gut.2024;73(4):622-628. doi:10.1136/gut jnl-2023-330980.

Integration of Shield leads to an increase in both CRC screening acceptance and completion





Acceptance: Defined as patient agreed to complete a screening test; **Completion rate:** Patient accepted the offer, completed the test, and results were returned. In the cohort of patients who selected Shield, 100% (134) completed the test, but 2 samples failed QC and results were not returned.

GUARDANT

Haynes, et al. 2024. Blood-based Colorectal Cancer Screening: Implementation into Two Appalachian Primary Care Clinics. Am J of Preventive Medicine. *In Press. Available online.*

Shield Adds an Effective Blood-Based Screening Option Alongside Guideline-Recommended Stool-Based Tests

Shared Decision Making

Direct Visualization

Colonoscopy

Prioritized option

Non-Invasive

mt-sDNA

FIT

HSgFOBT

Mailed Home / Provided at Office → **Stool Collection**

Patients do not decline stool tests, they do not complete them

Tracking and monitoring completion often challenging in primary care setting

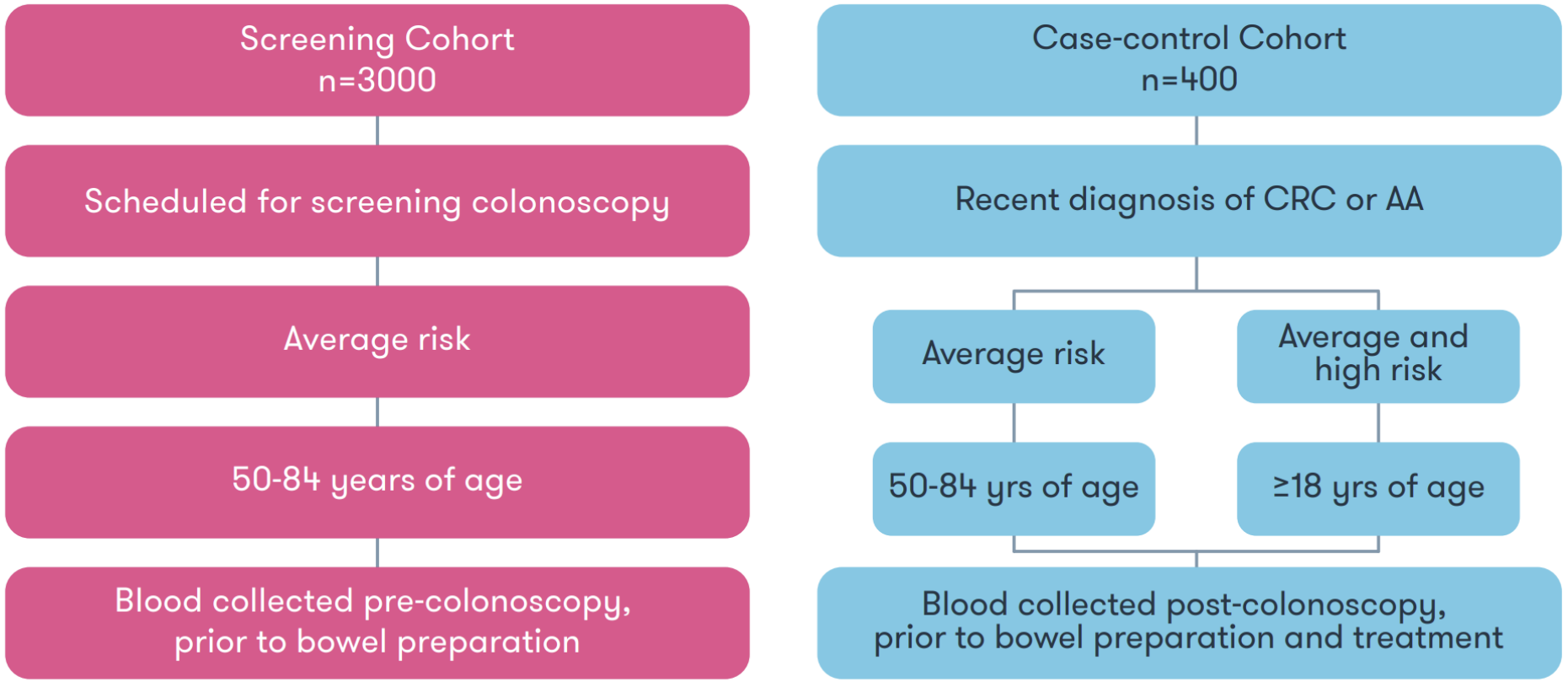
Freenome

C. Jimmy Lin , MD, PhD, MHS

colorectal cancer alliance

Freenome AI-EMERGE Study

Figure 2. AI-EMERGE® Study Design (NCT03688906)



Evidence Synthesis
Number 202

Screening for Colorectal Cancer: An Evidence Update for the U.S. Preventive Services Task Force

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No. HHSA-290-2015-00007-I-EPC5, Task Order No. 6

Prepared by:
Kaiser Permanente Evidence-based Practice Center
Kaiser Permanente Center for Health Research
Portland, OR

Investigators:
Jennifer S. Lin, MD, MCR
Leslie A. Perdue, MPH
Nora B. Henrikson, PhD, MPH
Sarah I. Bean, MPH
Paula R. Blasi, MPH

Adherence to initial screening in other studies

A comprehensive review of adherence (Khalid-de Bakker and colleagues) included 100 prospective studies of CRC screening, only 10 of which were conducted in the United States.[99] The review included a meta-analysis to determine a pooled estimate of adherence to a first-time invitation to screening that spanned a wide range of studies over nearly three decades. They found that overall adherence was 47 percent for gFOBT, 42 percent for FIT, 35 percent for FS, 28 percent for colonoscopy, and 22 percent for CTC. A comprehensive systematic review conducted by Holden and colleagues found a wide variation in adherence in studies whose purpose was to improve adherence to CRC screening.[100] Adherence in usual care groups (no intervention to improve adherence to screening) ranged from 17 to 51 percent for stool tests,

Geneoscopy

Erica Barnell , MD, PhD

colorectal cancer alliance

ColoSense showed high overall adherence to non-invasive screening and follow-up colonoscopy

Subjects were enrolled across 49 states
Colonoscopies were completed in >5,400 ZIP codes
Colonoscopies were completed at >3,800 endoscopy centers

64% of enrolled subjects had never before been screened with any modality (colonoscopy, FIT, or molecular test).

70% of subjects did not have a colonoscopy scheduled at time of enrollment and required navigation to colonoscopy.

~80% of subjects completed a ColoSense test and ~80% of those were successfully navigated to colonoscopy as part of the study.

Overall compliance with the ColoSense test system was 74%

Q&A

To ask questions

Screen Smart Potential Access Panelist

Moderator

Eric Waskowicz
Senior Policy Manager
US of Care

Anu Dairkee, JD, MD
Access Clinical Instructor, Health Law and Policy Clinic, Center for Health Law and Policy Innovation,
Harvard Law School

Lee Dranikoff, JD
Chief Executive Officer
Practical Strategy

Steven Itzkowitz, MD, FACP, FACG, AGAF
Professor of Medicine, Oncological Sciences and Medical Education, Ichan School of Medicine at Mount Sinai

Ellen Riccobene
Vice President, Clinical Care Transformation
Independence Blue Cross

Eric Waskowicz
Senior Policy Manager,
US of Care

Protecting People's Access to Preventative Care

An overview of the ACA's no-cost preventive services mandate

UNITED STATES of CARE

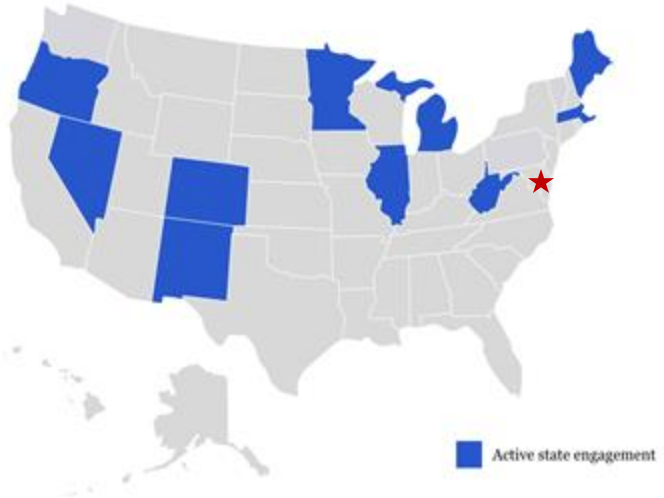
About United States of Care (USofCare)

screen smart
data • access • adherence

Our Mission

To build a future where all people have dependable access to high-quality health care that meets their unique needs at prices they can afford.

Where We Engage



Our Approach

- We are pioneering a new, equitable, people-centered approach to health care.
- We believe that in order to have a health care system where everyone can access quality affordable health care, we must start by **listening to people** and include them at every step of change.
- With our grassroots mentality and grasstops approach to advocacy, we are promoting change in one state, one policy, & one action at a time.

UNITED STATES of CARE

colorectal cancer alliance

The Big Picture

The Affordable Care Act contains a **mandate requiring insurers** to cover recommended **preventive services** with **no out-of-pocket costs.**

Free access to these services is **popular** and **effective** to improve health outcomes and lower costs more generally.

Kennedy v. Braidwood **calls into question** the ability of certain advisory bodies to recommend which services will be covered at no cost.

Source: American Journal of Preventive Medicine and AJMC

screen smart
data • access • adherence

Who calls the shots?

ACIP

Advisory Committee on Immunization Practices
(vaccines & immunizations)

USPSTF

U.S. Preventive Services Task Force
(general adult preventive services)

HRSA

Health Resources & Services Administration
(preventive services & screenings for women & children)

100+

services covered

UNITED STATES of CARE

colorectal cancer alliance

screen smart
data • access • adherence

A Closer Look: Colorectal Cancer (CRC) Screenings

The preventive services mandate **requires cost-free coverage of CRC screenings for adults ages 45-75** (ages 50-75 before 2021).

The preventive services mandate has **likely led to increased CRC screening rates, better health outcomes,** and **decreased health disparities.**

Regular CRC screenings have **yielded approximately 700,000 to 1.9 million additional life-years** for US adults.

Source: BMC Health Services Research

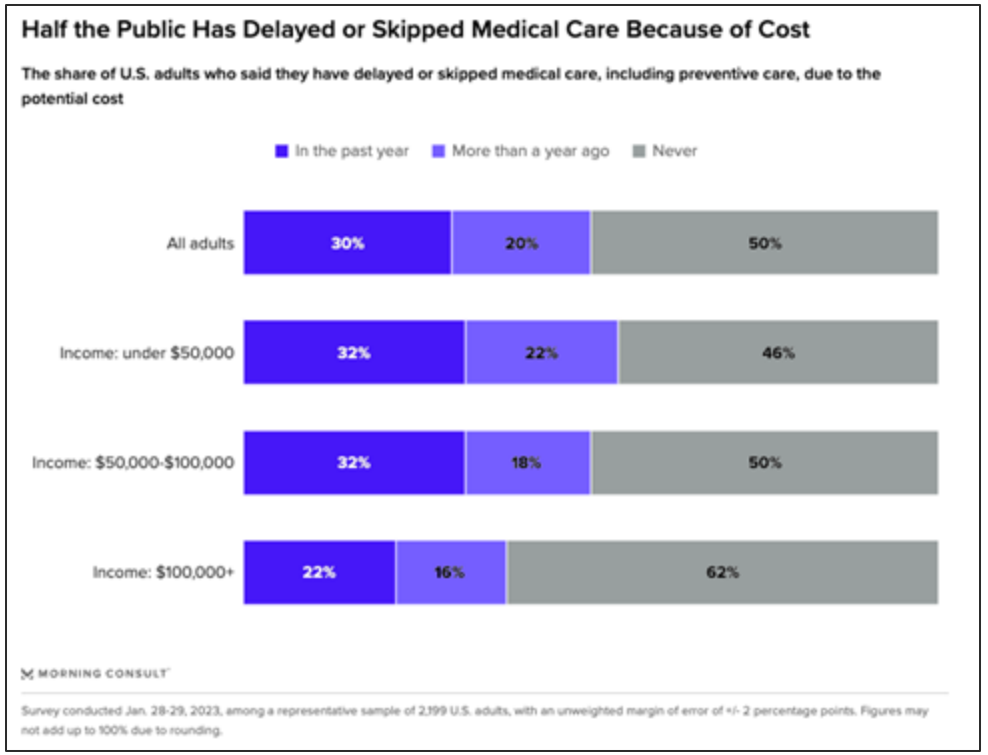
UNITED STATES of CARE

colorectal cancer alliance

Before the Affordable Care Act

- Many plans simply didn't cover critical preventive care services , including CRC screenings.
  - Prior to the ACA, there was no national standard for coverage of preventive services.
  - Only 28 states required full coverage of full range of CRC screenings, six covered some screenings.

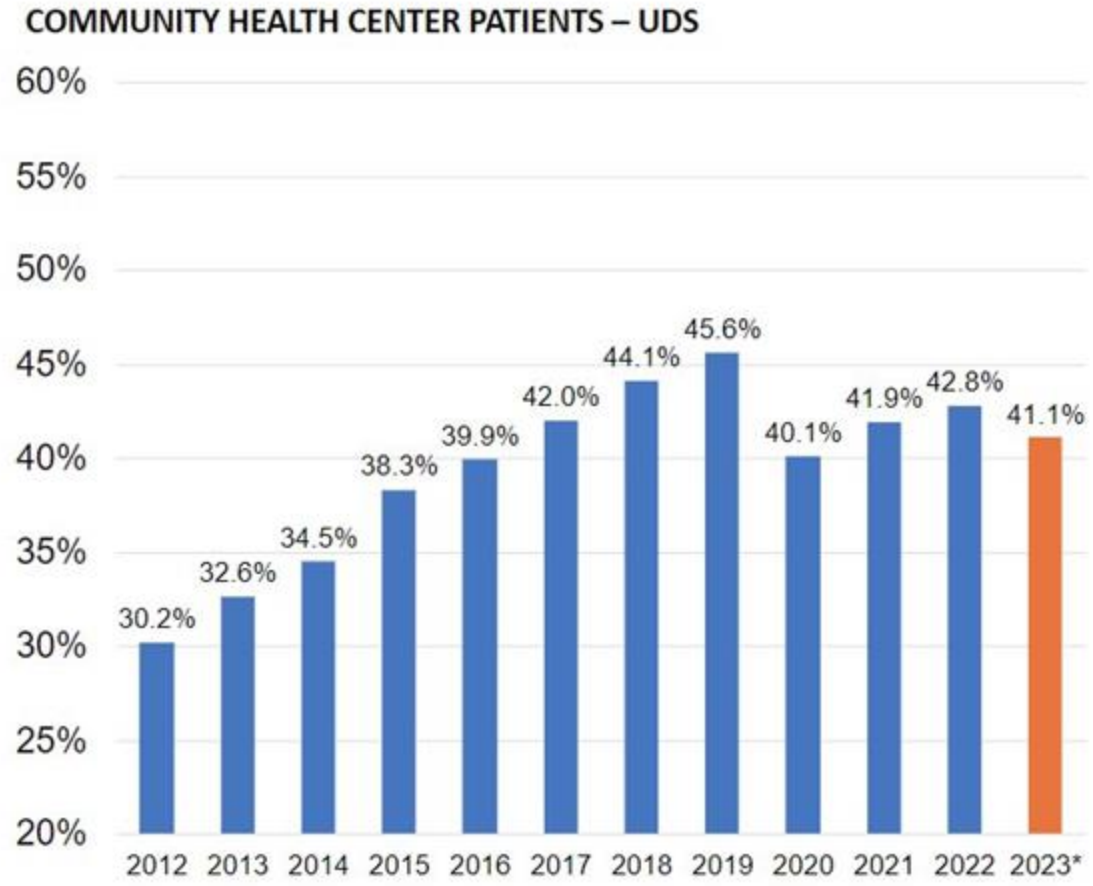
- Cost-sharing, even as low as a dollar or two, can be a huge barrier to people seeking care that ultimately protects them and saves them and the system costs long-term.



Source: Morning Consult

CRC Screening Rates Since the ACA's Passage

- People's access to all forms of cost-free preventive care, including CRC screenings, has **vastly increased** since the passage of the ACA.
- Nearly two-thirds (66.5%) of US adults aged 50-75 are up-to-date with their CRC screenings.
- These gains are even more pronounced amongst those already experiencing disparities, including Black and Hispanic adults.



Source: Health Center Data, HRSA

Adapted from the ACS NCCRT Chair Presentation, Dr. Steven Itzkowitz, November 21, 2024.

screen smart
data • access • adherence

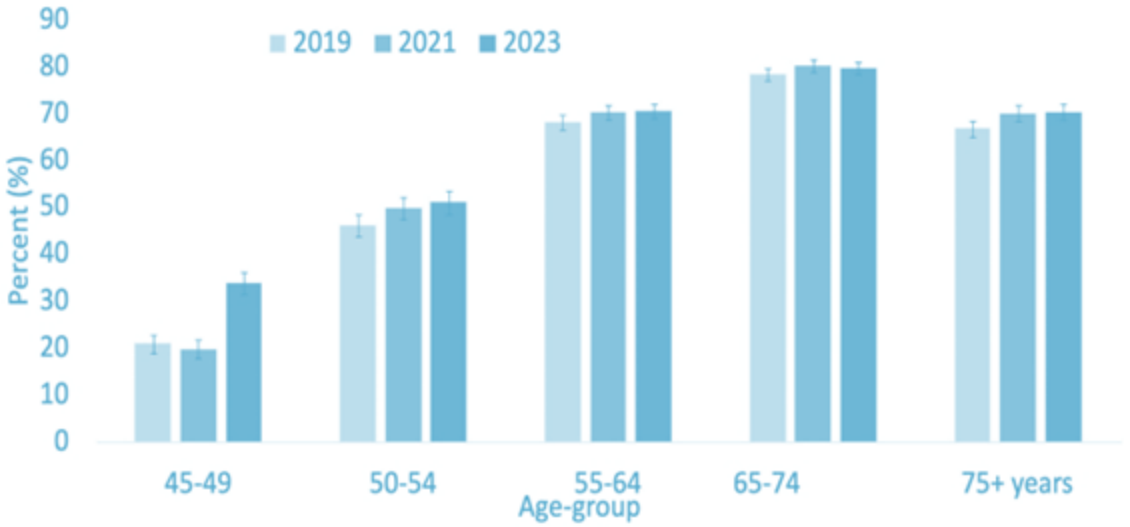
Changes to CRC Screening Recommendations Since 2010

Recommended screening age

- ACS guidelines released in 2018 recommended that the age to begin CRC screening be lowered from 50 to 45.
- USPSTF recommendations followed in 2021, requiring cost-free coverage for this new population.

Modalities covered

- Stool DNA testing, including Cologuard, was first recognized by the USPSTF in 2016 and listed as a recommended CRC screening strategy subject to no-cost sharing in 2021.



Source: National Health interview Survey (2019, 2021, 2023); American Cancer Society, *Cancer Prevention & Early Detection Facts & Figures, 2023-2024*
Adapted from the ACS NCCRT Chair Presentation, Dr. Steven Itzkowitz, November 21, 2024.

UNITED STATES of CARE

colorectal cancer alliance

Additional Coverage Updates

- After the ACA passed, insurers would sometimes require cost-sharing if a polyp was discovered and removed during a CRC screening.
  - In 2013, HHS clarified that "**polyp removal is an integral part of a colonoscopy**" also subject to no-cost sharing requirements under the ACA's preventive services mandate.

- Further updates
  - In 2022, HHS also clarified that follow-up colonoscopies conducted after a positive non-colonoscopy test (i.e. stool-based or direct visualization) **must also be covered cost-free**.
  - Its rationale cited the follow-up colonoscopy as an "integral part" of the CRC screening.

Access to no-cost CRC screenings is at risk

***Kennedy v. Braidwood* could undo 15 years of progress by:**

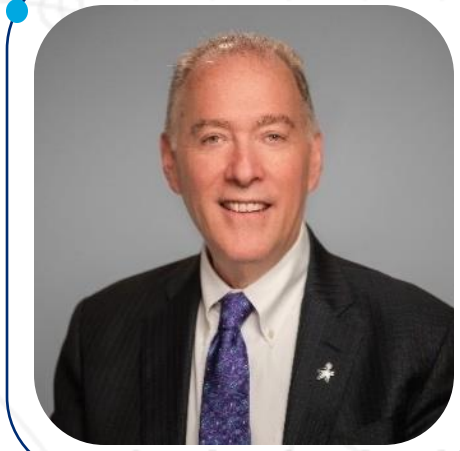
- Reimposing CRC screening cost-sharing for certain populations.
- Reverting to a patchwork of state CRC screening requirements.
- Limiting people's access to certain CRC screening modalities.
- Impacting new CRC screening research and development initiatives.
- Introducing uncertainty amongst physicians, nurses, and other providers.

Thank you!

@USofCare

Screen Smart Potential Access Panelist

Lee Dranikoff, JD
Patient Representative
Chief Executive Officer
Practical Strategy



Steven Itzkowitz, MD, FACP, FACG, AGAF
Professor of Medicine, Oncological Sciences and Medical Education, Ichan School of Medicine at Mount Sinai

screen smart
data • access • adherence

No more no-cost mandate: what's the impact?

5%

rise in annual colorectal cancer cases amongst US adults.

7%

drop in the number of individuals **with at least one CRC screening** by age 75.

8.7%

rise in **CRC mortality** (deaths per 100,000 individuals)

Source: Journal of the National Cancer Institute

UNITED STATES of CARE

colorectal cancer alliance

Anu Dairkee, JD, MD
Access Clinical Instructor, Health Law and Policy Clinic, Center for Health Law and Policy Innovation, Harvard Law School

The Kennedy v. Braidwood Threat to Preventive Care

CHLPI
CENTER *for* HEALTH LAW *and* POLICY INNOVATION
HARVARD LAW SCHOOL

USPSTF

- 16 volunteer members who are experts in preventive medicine and primary care with varied specialty backgrounds.
- Members are appointed and can be removed by Secretary of HHS, but by statute they make their recommendations independently.
- They develop their recommendations based on rigorous scientific studies.
- Only services with an A or B recommendation are covered under the preventive care mandate.
  - Currently: 54 recommendations
  - Examples: Colorectal screening (2021), PrEP coverage (2019), hepatitis C screening regardless of risk (2020), gestational diabetes screening (2021), statins for CVD (2021)
  - Since 2021, USPSTF has pushed to bring a health equity lens to its recommendations Example: More gender inclusive language in recent recommendations

The Kennedy v. Braidwood Threat to Preventive Care

- Filed in 2020 in federal district court for N.D. Texas
- Assigned to Judge Reed O'Connor

Plaintiffs	Defendants
Conservative Christian company and individuals Plaintiffs' Attorney: Johnathon Mitchell	Secretaries of HHS, Treasury, Labor

Plaintiffs' Arguments

ACA Preventive Services Mandate violates:

1

Appointments Clause of the U.S. Constitution

USPSTF improperly appointed as "principal officers"

2

Nondelegation Doctrine

The preventive care provisions of the ACA do not provide an "intelligible principle"

3

Religious Freedom Restoration Act (RFRA)

PrEP preventive care requirement burdens religious belief

District Court's Ruling (March 2023)

1	Requirement to cover services recommended by USPSTF on or after March 23, 2010, without cost-sharing, violates the Appointments Clause because the structure of the USPSTF was unconstitutional
2	Does not violate nondelegation
3	Requirement to cover PrEP violates religious plaintiffs' rights under the Religious Freedom Restoration Act (RFRA), limited relief to the Plaintiffs

Judge O'Connor issues a nationwide ruling preventing enforcement of the federal ACA preventive care mandate (but it never went into effect).

Appeal

Both sides appeal to the Fifth Circuit (intermediate appellate court for TX, LA, and MS)

Federal government did not appeal the RFRA ruling

Decision issued on June 21, 2024

Fifth Circuit's Ruling: USPSTF

Mandate to cover all USPSTF-recommended services violates Appointments Clause, but for procedural reasons, the district court's nationwide injunction is thrown out.

The preventive care provision does not violate nondelegation

Lower court RFRA decision was not appealed

Fifth Circuit's Ruling: ACIP & HRSA

USPSTF

HHS Secretary has no authority to "ratify" (meaning approve/reject) what they do.

ACIP & HRSA

HS Secretary has authority to ratify what they do—but did he legally do that?

Legal questions remain -> remand to district court

Arguments before the Supreme Court (gov't)

- Appointments Clause Defense:
  - USPSTF are "inferior officers" with adequate HHS oversight.
  - HHS Secretary has implicit removal and oversight powers.

- Proposed Remedy:
  - Severability: sever statutory independence; grant Secretary direct oversight.
  - Would resolve the constitutional concern without dismantling ACA preventive care rule entirely.

Arguments before the Supreme Court (Braidwood)

- Appointments Clause Violation:
  - USPSTF are “principal officers” hence they require Presidential nomination and Senate confirmation.
  - Statute mandates independence, removing necessary supervision.

- Opposition to the Proposed Remedy:
  - Oppose severing statutory provision
  - Argue the remedy wouldn’t resolve the Constitutional injury and severing it would improperly rewrite Congressional intent.

SCOTUS Oral Argument on April 21, 2025

Is the USPSTF independent or not?

Does the Secretary really have hiring and firing power over the Task Force members?

Potential Outcomes	
Government Keep the USPSTF in place but the HHS Secretary now has immense power to influence the recommendations	**Braidwood** The USPSTF A & B recommendations are no longer required to be covered without cost-sharing by most private insurers.

Overall outcome for our health care

Access to free preventive care will change no matter which side wins.

What is additionally at stake?

Could set a precedent for improper overreach of government into the realm of scientific expertise.
Broad impacts on healthcare policy, health outcomes and health disparities.

Connect with Us

Anu Dairkee
udairkee@law.harvard.edu
chlpi@law.harvard.edu · www.chlpi.org · @HarvardCHLPI

Sign up for Health Care in Motion:

USPSTF A & B recommendations chart:

Screen Smart Potential Access Panelist

Ellen Riccobene
Vice President, Clinical Care Transformation
Independence Blue Cross

Call To Action

OUR MESSAGE

We must continue to protect people's access to no-cost preventive care services.

ADVOCATES, PROVIDERS, OTHER STAKEHOLDERS:

- Spread the word about Braidwood.
- Use the resources on USofCare's Preventive Services Hub.
- Ask your employers, insurers, HR departments, and third-party administrators what their plans are to continue cost-free coverage of preventive services.
- Address the confusion: As of right now, people continue to have cost-free access to these preventive services.

Q&A

To ask questions

Closing Remarks and Next Steps

Gold Sponsors

2025 Screen Smart Dinner

screen smart
data • access • adherence

Gold

EXACT SCIENCES

Exact Sciences gives patients and health care professionals the clarity needed to take life-changing action earlier. Building on the success of the Cologuard® and Oncotype® tests, Exact Sciences is investing in its pipeline to develop innovative solutions for use before, during, and after a cancer diagnosis.

GUARDANT

Guardant Health is a leading precision oncology company revolutionizing patient care by using advanced blood and tissue tests, real-world data, and AI analytics to provide critical insights into cancer. Its innovative approach helps improve outcomes across all stages, from early detection and recurrence monitoring to treatment selection for advanced cancer patients.

Thank you for your generous support

colorectal cancer alliance

Cocktail Reception

Please join us across the hall