THE 2024 COLORECTAL CANCER CARE REPORT

Improving Colorectal Cancer Prevention & Care in the United States

FIGHT COLORECTAL CANCER

Contents

ON THE COVER

"Never ever give up hope. Commit to living with cancer, rather than dying from it. Find gratefulness, love, and joy in each day you are given. Let people know how you're feeling, and what you need from them. They want to help!"

CHRISTI ANDRINGA

CAREGIVER TO HUSBAND, STAGE IV COLON CANCER SURVIVOR

FIGHT COLORECTAL CANCER

We fight to cure colorectal cancer and serve as relentless champions of hope for all affected by this disease through informed patient support, impactful policy change, and breakthrough research endeavors.

MORE *Quality* TIME!

Acknowledgments & Disclaimers

Fight Colorectal Cancer (Fight CRC) has convened a diverse group of partners to create the Colorectal Cancer Care Initiative (CRCCI), a coalition dedicated to leveraging our combined expertise and resources to confront colorectal cancer's pressing challenges. We crafted this report with input from and on behalf of patients with colorectal cancer, their caregivers, and their care providers, alongside researchers and industry partners who are collectively devoted to reducing the impact of this disease. This consensus document is a data-driven plan to set actionable goals to improve colorectal cancer screening and treatment. The effort is spearheaded by Anjee Davis, President, and Molly McDonnell, Vice President of Advocacy, of Fight CRC.

Fight CRC thanks the many individuals who have provided input into the framing and refinement of this document. We particularly thank the following people and organizations for their support.

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DATA CONTRIBUTORS

Organizations who submitted analyses of raw data, insights, or analytical input to inform the content and conclusions made in this report. All data analyses were provided in-kind.

Freenome, komodo HEALTH, Epic, flatiron.

DISCLOSURE *Freenome is developing a blood-based colorectal cancer screening test. Fight CRC worked directly with the real-world data team to assist with data analysis.*

CASE STUDY CONTRIBUTORS

Individuals or organizations submitted case studies with detailed information, experiences, and insights for report.

EXACT SCIENCES, inspira HEALTH NETWORK, ASGE American Society for Gastrointestinal Endoscopy, KAISER PERMANENTE

In March 2023, Fight CRC convened a working group meeting to launch the CRCCI as a collaborative endeavor. We would like to express our sincere gratitude to the working group members for their valuable contributions. Over 40 organizations were represented.

Full List Available Here

FINANCIAL DISCLAIMER

All content in this report was developed independently and reviewed by Fight CRC's staff and writing committee. While Fight CRC receives sponsorships from companies involved in CRC screening and treatment, these sponsorships did not influence the content or recommendations in this report.

This report was supported by unrestricted grants from Merck, Agenus, Takeda, and Guardant Health. Fight CRC's Catalyst program, which supports state advocacy efforts, is funded by an unrestricted grant from Exact Sciences. Additionally, in-kind contributions of data and writing were provided by various partners, with no content restrictions. To ensure the report's recommendations are evidence-based and patient-centered, a diverse group of stakeholders reviewed all data for accuracy and impartiality.

FIGHT COLORECTAL CANCER

Letter from the CEO

DEAR LEADERS AND SUPPORTERS,

We are proud to present the Colorectal Cancer Care Initiative (CRCCI) and this report, highlighting key areas where improvement is essential to make meaningful progress in the fight against colorectal cancer. Fight CRC's mission is to ensure everyone affected by colorectal cancer has more time—time to celebrate milestones and live fully. This report reflects our commitment to identifying and addressing the challenges that remain.

The stories and data here underscore advances in early detection and personalized treatment, driven by researchers, healthcare professionals, patients, and advocates. Yet, disparities in care persist, and we're dedicated to ensuring high-quality care for every patient, regardless of background.

Setting clear, actionable goals is essential, as what gets measured, gets done. These goals serve as tools for health systems and the CRC community to assess progress, identify gaps, and allocate resources.

Our continued efforts in early detection and screening are vital to reducing CRC's burden. Awareness, resources, and advocacy remain crucial to catch cancer early, while ensuring those diagnosed receive timely, optimal care. Going forward, we'll use insights from this report to shape strategies and drive real change.

In the years ahead, we'll focus on partnerships, advancing research, and championing patient-centered care. We aim to amplify patient voices, which guide our mission, envisioning a future where colorectal cancer is preventable, treatable, and curable.

This vision requires scientists, healthcare providers, and policymakers to work together. To our donors, your contributions fund groundbreaking research and patient education. To our advocates, patients, and caregivers, your dedication fuels the progress in this report.

Let's continue pushing boundaries and ensuring those facing colorectal cancer have more moments with loved ones. United in purpose, we can transform the future of colorectal cancer care.

With gratitude,

ANJEE DAVIS, MPPA
CEO, Fight CRC

MORE *Fight* TIME!

"Our mission is to ensure that everyone affected by colorectal cancer has more time – time to celebrate milestones, cherish moments with loved ones, and live life fully."

Glossary of Terms

Biomarker testing
A type of somatic testing that examines specific characteristics of colorectal cancer (CRC) tumors to guide treatment decisions. Biomarkers may include DNA mutations, methylation patterns, RNA expression profiles, and elevated protein levels that can predict treatment response or prognosis.

Blood-based ctDNA test
An FDA-approved blood test that detects signals for colorectal cancer from circulating tumor DNA (ctDNA) shed into the blood. It is approved as a primary non-invasive CRC screening test for average-risk individuals, age 45 or older. Patients with a positive result should have a follow-up colonoscopy evaluation. [Test name: Shield™]

Colonoscopy
A diagnostic and screening procedure that uses a flexible endoscope to visualize the entire colon. It is used for routine CRC screening and for further examination following abnormal results from non-invasive CRC screening tests.

Colorectal cancer (CRC)
A type of cancer that originates in the colon or rectum. It is a common form of cancer that can often be detected early through screening.

Colorectal Cancer Care Initiative (CRCCI)
A collaborative effort designed to develop and implement strategies addressing challenges in CRC prevention and care, aiming to reduce the impact of colorectal cancer through coordinated actions among stakeholders. This report is the foundational document guiding the efforts of this working group.

Computed tomography (CT) colonography
A CRC screening test that utilizes a CT scan to create detailed images of the colon and rectum. It is a less invasive alternative to traditional colonoscopy and can detect abnormalities.

Early-onset colorectal cancer (EO CRC)
Colorectal cancer diagnosed in individuals under the age of 50. EO CRC typically presents with different biological characteristics compared to CRC diagnosed in older individuals and is increasingly being diagnosed in younger populations.

Fecal immunochemical test (FIT)
A non-invasive, at-home CRC screening test that detects hidden blood in stool samples, which may indicate the presence of cancer or large polyps.

Flexible sigmoidoscopy
A screening procedure that uses a flexible endoscope to visualize the rectum and the lower part of the colon. It is less comprehensive than a full colonoscopy, as it does not examine the entire colon.

Follow-up colonoscopy
A colonoscopy performed after an abnormal non-invasive screening test result to determine whether precancerous or malignant lesions are present. Although "follow-up" and "follow-on" can be used interchangeably, this report uses "follow-up."

Genetic testing
Laboratory testing of DNA obtained from healthy tissue (usually blood or saliva) to identify genetic changes that may predispose an individual to develop certain diseases. In CRC, genetic testing can determine if an individual has inherited a predisposition to colorectal cancer, such as Lynch syndrome.

Guaiac fecal occult blood test (gFOBT)
An at-home CRC screening test that detects hidden blood in stool samples using a chemical reaction. It is one of the older forms of stool tests for cancer screening.

Multitarget stool DNA (mt-sDNA) test (or stool DNA test)
A use-at-home CRC screening test that analyzes a stool sample for DNA and hemoglobin biomarkers associated with colorectal cancer and precancerous lesions. The test is typically recommended every three years if results are negative. Positive results necessitate a follow-up colonoscopy. [Test names: Cologuard® and Cologuard Plus™]

Multitarget stool RNA (MT-sRNA) test
A newly FDA approved (as of May 2024), at-home colorectal cancer screening test that analyzes stool-derived RNA and hemoglobin biomarkers associated with colorectal cancer and precancerous lesions. The test is recommended to be performed every three years. As with other stool-based tests, a positive result requires a follow-up colonoscopy. [Test name: ColoSense®]

Patient navigation
A healthcare service that assists patients in navigating the medical system. Patient navigators help schedule appointments, explain test results, and coordinate follow-up care, particularly in complex processes such as cancer screening and treatment.

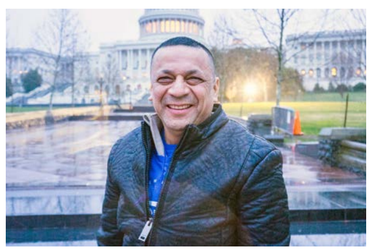
Personalized medicine
A medical approach that tailors prevention and treatment strategies to individual patients based on their genetic, environmental, and lifestyle factors. In CRC, personalized medicine may involve selecting therapies based on the genetic profile of a patient's tumor.

Real-world data
Data collected from real-life settings outside of controlled clinical trials, including information from electronic health records (EHRs), insurance claims, patient registries, and other non-research sources. It is used to understand treatment patterns, outcomes, and patient populations.

Total neoadjuvant therapy (TNT)
A treatment approach for locally advanced rectal cancer (stages 2 and 3) that involves administering chemotherapy and radiation therapy before surgery. This strategy aims to improve outcomes such as disease-free survival, overall survival, and the rate of complete pathological response.

Michael Holtz, stage III rectal cancer survivor

LEFT TO RIGHT *Paula Chambers-Raney, stage I colon cancer survivor, Natalie Keiser, Fight CRC Staff, Cheryl Alston, stage II colon cancer survivor, Kentisha Mazeke, caregiver*



In Loving Memory of Victor Menoscal, Stage IV colon cancer fighter

SCREENING SAVES LIVES

"A simple stool test—no symptoms, no reason to fear, or so I thought. Then came the shock: a positive result. In 2020, I had my first colonoscopy, and a week later, surgery confirmed stage III colon cancer. You never think it's going to be you."

Yla Flores
STAGE III COLON CANCER SURVIVOR

Abbreviations

ACS American Cancer Society

ASGE American Society for Gastrointestinal Endoscopy

CDC Centers for Disease Control and Prevention

COVID-19 Coronavirus Disease 2019

CRC Colorectal Cancer

CRCCI Colorectal Cancer Care Initiative

EO CRC Early-Onset Colorectal Cancer

EHR Electronic Health Record

EMR Electronic Medical Record

FDA Food and Drug Administration

FIT Fecal Immunochemical Test

gFOBT Guaiac Fecal Occult Blood Test

mt-sDNA Multitarget Stool DNA

NCCN® National Comprehensive Cancer Network®

NCCRT American Cancer Society National Colorectal Cancer Roundtable

TNT Total Neoadjuvant Therapy

USPSTF United States Preventive Services Task Force

These abbreviations are used throughout the report to refer to various organizations, tests, and terms related to colorectal cancer screening and care.

Citation Guidance

All content has been developed utilizing data and input from subject matter experts to provide evidence-based insights that will inform clinical practice, policy making, and public health initiatives. We are dedicated to the pursuit of objectivity and have endeavored to present all findings and recommendations in a balanced manner to better advance health equity and improve patient care across all populations in the U.S.

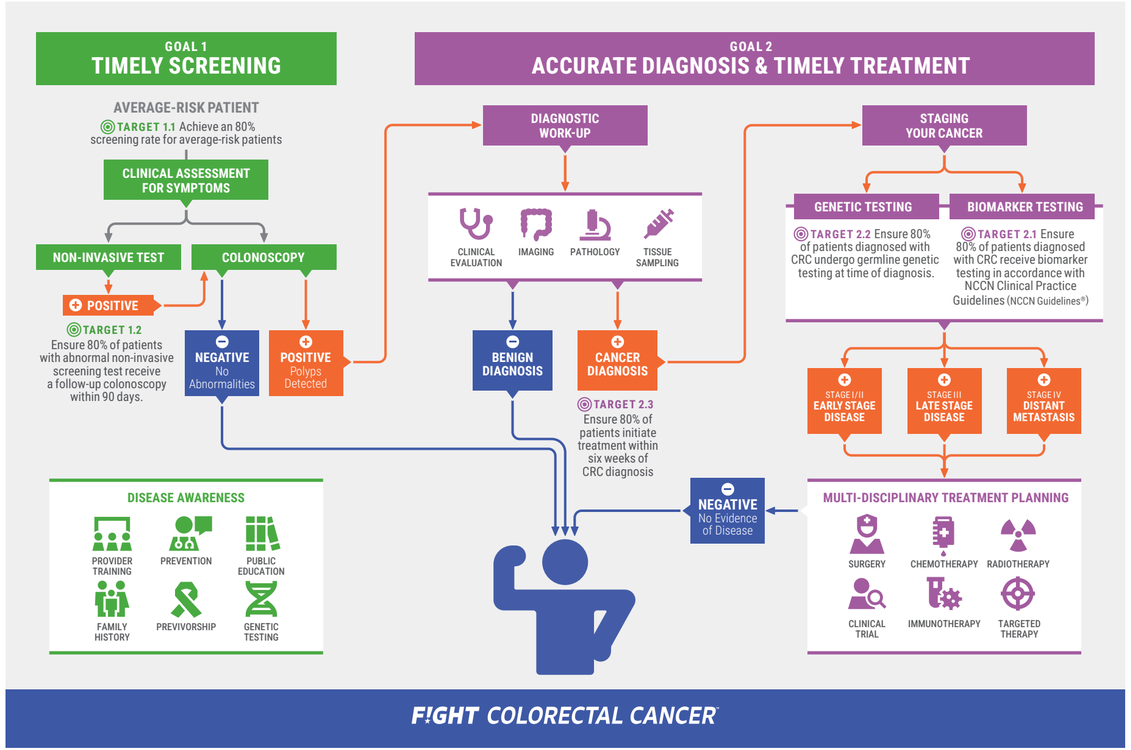
When referencing material from this report, please adhere to the following citation format to ensure proper acknowledgment and uphold the integrity of the information shared:

For general referencing: Fight Colorectal Cancer. *The Colorectal Cancer Care Report: Improving Colorectal Cancer Prevention and Care in the United States* [publication month day, year]. Accessed [month day, year]. URL

Fight Colorectal Cancer. *The Colorectal Cancer Care Report: Improving Colorectal Cancer Prevention and Care in the United States.* [November 20, 2024). Accessed January 15, 2025. https://fightcolorectalcancer.org/crc-research/crcci/

When citing specific statistics, findings, or excerpts, please include details such as section title, page number, and figure or table number to allow readers to find the relevant material within this report.

Colorectal Care Pathway



Introducing the Colorectal Cancer Care Initiative

The CRCCI, as outlined in this report, is a collaborative effort led by Fight CRC, a leading advocacy group for CRC patients in the U.S., in partnership with survivors, caregivers, healthcare professionals, and industry leaders. The CRCCI brings together diverse expertise and resources to tackle the urgent challenges posed by CRC. Despite progress in the field, CRC remains a major health threat, underscoring the need for continued action to increase screening rates, reduce deaths, and improve patient outcomes (Siegel et al., 2024).

To foster a unified approach among all stakeholders, this report presents a practical yet ambitious framework to enhance colorectal cancer screening and care across the country to reach ambitious benchmarks by 2030. The patient care journey is divided into two key phases: screening and diagnosis/treatment. By using insights from real-world data, current scientific research, and patient insights, this report establishes practical targets for health systems to enhance CRC screening, diagnosis, and treatment. The two main goals and their corresponding targets focus on key points where strategic interventions can greatly improve health outcomes, from large academic centers to community-based providers. These goals and targets are designed to help healthcare practices and systems evaluate the effectiveness of efforts aimed at reducing CRC incidence, burden, and mortality.

MORE *Grandma* TIME!

"I fight for a future free of colon cancer so that my grandchildren and others can enjoy and live life to the fullest."

PAM ALLEN
STAGE III COLON CANCER SURVIVOR

Background: From Screening to Treatment

COLORECTAL CANCER OVERVIEW

Colorectal cancer (CRC) is the third most commonly diagnosed cancer and the second leading cause of cancer-related deaths in the United States (Siegel et al., 2024). Although there has been a nearly 50% decline in CRC incidence since 1985 due to lifestyle changes, enhanced screening, and other factors, CRC continues to contribute substantially to the national cancer burden (Siegel et al., 2023).

SCREENING UPTAKE AND CHALLENGES

Despite advancements in CRC screening, uptake remains suboptimal. Currently, only about 70% of eligible individuals are up to date with screening, with rates varying significantly across age groups (Richardson et al., 2022; Siegel et al., 2023). Alarmingly, younger individuals eligible for screening show particularly low rates, which is concerning given the rising incidence of early-onset CRC (Siegel et al., 2023).

More conservative estimates indicate that only 59.3% to 61.8% of the 117.1 million average-risk, screening-eligible Americans are up to date with their CRC screening. This leaves approximately 44.7 million to 47.7 million individuals unscreened. Including those due for rescreening within the next year, the total eligible population ranges from 57.1 million to 59.6 million (Ebner et al., 2024b).

HEALTH DISPARITIES IN CRC

CRC incidence and mortality rates vary significantly by race, ethnicity, and geography, including differences between rural and urban areas (Siegel et al., 2023; Zahnd et al., 2018). These disparities often result from a combination of biological and socioeconomic risk factors, as well as unequal access to and quality of screening and treatment services (Siegel et al., 2023). Systemic inequities, including wealth distribution and systemic racism, exacerbate these issues, leading to inadequate healthcare provision for minority populations and widening health disparities (Gorin, 2019; Siegel et al., 2023).

Evidence-based strategies, such as targeted outreach and patient navigation programs, are crucial for reducing these disparities and ensuring equitable access to healthcare (Doubeni et al., 2022). Expanding these programs is essential to improve outcomes across all populations.

PATIENT NAVIGATION

Patient navigation is an effective strategy to reduce barriers to care and increase access to CRC screening (Dwyer et al., 2022). It plays a critical role in helping patients complete the full screening process, especially ensuring that patients undergo a follow-up colonoscopy after an abnormal non-invasive screening test (Idos et al., 2021). The Community Preventive Services Task Force recommends patient navigation services to enhance CRC screening rates among historically disadvantaged racial and ethnic populations, as well as those with lower incomes (Community Preventive Services Task Force, 2022).

OPPORTUNITY FOR ACTION

With a substantial portion of the population remaining unscreened, rising rates of early-onset cases, and 60% of diagnoses occurring at advanced stages—resulting in higher mortality rates—there is an urgent opportunity for policymakers and healthcare stakeholders to enhance CRC screening efforts. Potential risk stratification strategies include education for patients and providers on symptoms, and the importance of screening, using guideline-recommended screening options, and implementing innovative patient navigation programs to boost screening rates and reduce disparities in CRC management (Berkowitz et al., 2015; Doubeni etal., 2022; Ebner et al., 2024a; Schliemann et al., 2021; Selby etal., 2022).

EARLY-ONSET COLORECTAL CANCER (EO CRC)

Early-onset CRC, also known as early-age onset CRC, affects individuals younger than 50 years and is becoming an increasing concern. Since the mid-1980s and mid-1990s, incidence rates have been rising in adults aged 20 to 39 years and 40 to 54 years, respectively (Siegel et al., 2023). Currently, 12% of all colon cancer cases and 16% of rectal cancer cases occur in individuals under the age of 50 (American Cancer Society, 2023).

Mortality rates among these younger age groups have increased by 1% annually since 2004, with even higher increases of 3% annually for Hispanic and American Indian/Alaska Native individuals since 2011 (Siegel et al., 2023).

These alarming trends highlight the urgent need for targeted research and interventions. Immediate action is required to expand research efforts, improve early screening, and increase disease awareness among younger populations (Siegel et al., 2020).

ADVANCES IN TREATMENT

In addition to improving screening rates, advancements in CRC treatment have led to better patient outcomes. A comprehensive 15-year analysis of approximately 1 million patients with colonic adenocarcinoma shows significant increases in the use of multi-agent chemotherapy, immunotherapy, and minimally invasive surgeries, particularly robot-assisted surgeries. These treatments have notably improved outcomes, especially for patients with locally advanced and metastatic colon cancer, increasing 5-year overall survival rates (Horesh et al., 2024).

Advances in rectal cancer treatment, such as total neoadjuvant therapy (TNT), have improved disease-free survival rates and offer the potential for organ preservation, which is especially important given the rising incidence of early-onset rectal cancer (Bailey et al., 2015; Saraiva et al., 2023; Iv et al., 2022).

GOAL 1

Timely Screening for the Prevention & Early Detection of CRC

Timely screening and prevention are critical components in reducing colorectal cancer (CRC) incidence and mortality. Advances in CRC screening methods and increased awareness have contributed significantly to the decline in CRC cases and deaths (Siegel et al., 2023). These successes highlight the collaborative efforts of healthcare professionals, researchers, patient advocates, and policymakers. However, to build on this progress, it is essential to further refine our screening strategies to ensure that all eligible populations are reached. Setting clear, measurable goals will be key to gauging progress, optimizing strategies, and directing resources effectively.

MORE *Action* TIME!

"There is more fear in the unknown than in the power of knowing. My best advice about getting screened is this: when you know, YOU can truly take action."

KECIA JOHNSON
STAGE IV RECTAL CANCER SURVIVOR

GOAL 1

Timely Screening for CRC Prevention & Early Detection

TARGET 1.1

Achieve an 80% screening rate for average-risk patients.

TARGET 1.2

Ensure 80% of patients with an abnormal non-invasive screening test receive a follow-up colonoscopy within 90 days (3 months).

The Importance of Timely Screening for CRC Prevention

A NATIONAL SCREENING GOAL

The American Cancer Society (ACS) National Colorectal Cancer Roundtable (NCCRT) has set a national goal of achieving an 80% CRC screening rate across the country, first initiated in 2014. Despite significant progress, disparities in screening rates continue, particularly among racial and ethnic minorities, uninsured individuals, and adults aged 45–54 (Siegel et al., 2023). To further address these gaps, the NCCRT launched the "80% in Every Community" campaign, aiming to increase overall screening rates and focus on underserved populations (National Colorectal Cancer Roundtable, 2024).

GUIDELINES FOR SCREENING

Timely screening is crucial for preventing CRC by detecting and removing precancerous polyps and diagnosing CRC at its earlier stages, when it is often asymptomatic and most treatable. Current guidelines from the United States Preventive Services Task Force (USPSTF) and ACS recommend that all adults at average risk of CRC (see definition on next page) complete routine screening from ages 45 to 75, with selective screening for those aged 76 to 85 based on health status, prior screening history, and personal preference (US Preventive Services Task Force, 2021; Wolf et al., 2018).

Colorectal Cancer: Screening Guidelines | United States Preventive Services Taskforce

Several professional organizations publish CRC screening guidelines, but the recommendations from the USPSTF and ACS are the most influential in shaping payer coverage and federal and state policies.

Colonoscopy is a key method for preventing and detecting colorectal cancer early, and non-invasive screening technologies are an important, and growing, part of the screening landscape. The availability of non-invasive screening options has helped overcome traditional barriers, such as the need for bowel preparation before a colonoscopy. However, when a non-invasive test yields an abnormal result, the screening process becomes multistep, requiring a follow-up colonoscopy to complete the assessment (National Comprehensive Cancer Network, 2024b; US Preventive Services Task Force, 2021; Wolf et al., 2018).

Emerging technologies, such as blood tests and a MT-sRNA test, are receiving FDA approval for colorectal cancer (CRC) screening, but are not yet included in the USPSTF or ACS's guidelines. As new tests come to market, the importance of follow-up colonoscopies is further underscored, highlighting the need to monitor this key metric closely to ensure a complete screening service for patients. Healthcare professionals and organizations will need to stay informed about these advancements and their potential impact on screening practices.

GOAL 1 Timely Screening for CRC Prevention & Early Detection

Policy Changes Supporting CRC Screening

In recent years, policy changes have gone into effect at the state and federal level to increase access to CRC screening. These changes, if properly implemented, should help limit costs to patients, a key barrier to completing screening.

REGULATORY UPDATES FOR FOLLOW-UP COLONOSCOPIES

A major policy update went into effect in January 2023 that requires both commercial plans subject to the Affordable Care Act and Medicare to fully cover a follow-up colonoscopy after an abnormal stool-based colorectal cancer screening tests free of cost-sharing for patients aged 45 and older (Fight CRC, 2022; The Lancet Gastroenterology, 2022). This success was achieved through the collaborative efforts of Fight CRC and advocacy partners, including the American Cancer Society Cancer Action Network (ACS CAN) and the American Gastroenterological Association (AGA).

In 2024, the Centers for Medicare & Medicaid Services proposed expanding this follow-up coverage to include colonoscopies after a Medicare covered blood-based screening test. These changes are expected to encourage broader participation in CRC screening, which is crucial for early detection and can significantly reduce overall healthcare costs (Ran et al., 2019).

LEGISLATIVE ADVANCES TO REMOVE FINANCIAL BARRIERS

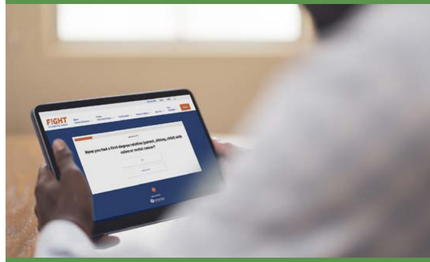
The above regulatory changes built on successful policy change at the state level. Through Fight CRC's Catalyst Program, nine states passed legislation to remove out-of-pocket costs for a colonoscopy following an abnormal non-invasive CRC screening test for state-regulated health plans.

Further policy advancements, such as the passage of the Removing Barriers to Colorectal Cancer Screening Act, protect Medicare beneficiaries from unexpected bills if a polyp is detected and removed during a screening colonoscopy. This law reduces over time the coinsurance for Medicare beneficiaries who have polyps removed during a screening colonoscopy. Coinsurance for these beneficiaries will be completely eliminated in 2030, ensuring that more individuals can undergo screening without the fear of unexpected costs (Fight CRC, 2020). This law was the result of dedicated efforts by a coalition of partners within the CRC community.

AVERAGE-RISK PATIENT

The United States Preventive Services Task Force (USPSTF) defines an average-risk patient for colorectal cancer screening as follows: Average-risk adults are those without a family history of colorectal cancer, certain types of polyps, inflammatory bowel disease, a genetic syndrome like familial adenomatous polyposis or Lynch syndrome, or a history of radiation therapy to the abdomen or pelvic area for a previous cancer.

SCREENING QUIZ



Fight CRC produced an online screening quiz as an educational tool to raise awareness about colorectal cancer (CRC) screening. This interactive quiz can be easily embedded on your website to align with your organization's branding, making it a versatile resource for increasing engagement for those seeking to better understand their screening options.

Call to Action for Reducing Disparities

Despite regulatory and policy improvements, gaps remain, as indicated by the large proportion of the population that remains unscreened. Goal 1 focuses on timely screening for the prevention and early detection of CRC. Using real-world data, health systems can identify key gaps in the screening processes and utilize clear targets to address them. Targets 1.1 and 1.2 can help healthcare systems and medical practices tackle systemic issues that contribute to higher mortality rates in certain communities. This targeted approach is essential for increasing screening rates and ensuring the completion of the screening process. Through advocacy and education, we aim to increase screening rates and reduce disparities, ensuring equitable care for all. Population-based monitoring will be necessary to track the success of these interventions nationwide and identify differences based on geographic region or demographic characteristics.

Candace Henley, stage II colon cancer survivor, Founder of The Blue Hat Foundation

SCREENING EFFECTIVENESS METRICS TO CONSIDER

This list, developed by the CRCCI, offers a range of metrics to help health systems assess and improve the effectiveness of their CRC screening programs. While not exhaustive, these metrics serve as valuable points of consideration for understanding current performance, identifying strengths, and uncovering areas for improvement. Regularly evaluating these metrics can guide more informed decisions and strategic interventions to enhance patient outcomes.

IDENTIFICATION OF SCREENING POPULATIONS

Proportion of patients within designated risk categories, including age. See the average-risk definition on page 17.

Proportion of patients with a recorded family history of CRC and adenomas.

Proportion of high-risk individuals with completed genetic testing.

Proportion of patients with a personal history of polyps.

SCREENING COMPLETION

Proportion of screening-eligible patients up-to-date with their with guideline-recommended screening.

Adherence rates to repeated testing at the guideline-recommended intervals.

Prevalence of various screening modalities used within the health system.

TIME TO COLONOSCOPY

Average time from screening being due to screening colonoscopy completion.

Proportion of patients completing a colonoscopy within 90 days of a positive abnormal non-invasive screening test.

FOLLOW-UP AFTER DETECTION OF ADVANCED ADENOMA

Proportion of individuals with advanced precancerous lesions entering surveillance.

Quality of Colonoscopy Screening

- Proportion of colonoscopy cases with good or excellent bowel preparation.
- Adenoma detection rate by provider.
- Average withdrawal time during screening colonoscopy.

Measures to Assess Screening Effectiveness

Yvette Davis-Atkins, caregiver

To enhance colorectal cancer (CRC) screening efforts, the CRCCI is focused on identifying areas for improvement and developing measures to assess screening effectiveness. This section examines case studies of existing screening methods, such as fecal immunochemical test (FIT) and multi-target stool DNA (mt-sDNA) test, to understand their impact and potential for enhancement. Additionally, we examine emerging blood-based tests as part of a changing CRC detection landscape. By analyzing claims data, we can identify trends and customize action plans to better reach our screening goals. Analyzing these trends will provide a deeper understanding of your community, health system or clinic, enabling you to optimize screening practices, enhance early detection rates, and adopt a more comprehensive approach to your specific program or initiative.

CASE STUDY - ONE

EFFECTIVENESS OF FECAL IMMUNOCHEMICAL TEST (FIT) SCREENING IN REDUCING COLORECTAL CANCER MORTALITY

A recent study by Doubeni et al. (2024) evaluated the effectiveness of a FIT screening program in reducing colorectal cancer mortality within two large, integrated health systems. The study, conducted among a diverse population of adults aged 52 to 85, revealed that individuals who participated in FIT screening had a 33% lower risk of dying from CRC compared to those who did not undergo screening (aOR, 0.67; 95% CI, 0.59-0.76). The most significant reductions in mortality were observed for left-sided colorectal cancers, with a 42% decrease in risk (aOR, 0.58; 95% CI, 0.48-0.71), underscoring the effectiveness of FIT screening for certain tumor locations.

The findings of this study are particularly relevant for health systems aiming to implement a non-invasive CRC screening strategy, followed by colonoscopy for abnormal results. The study demonstrated that the benefits of FIT screening extend across diverse racial and ethnic groups, including significant reductions in CRC mortality among non-Hispanic Asian, Black, and White participants. Although the reduction among Hispanic or Latino individuals was not statistically significant, the overall results support the effectiveness of FIT as a first-line screening tool to reduce CRC mortality across various populations.

SIGNIFICANCE

The success of this program in reducing CRC mortality and promoting follow-up colonoscopies highlights the importance of a structured, population-based approach to screening. Health systems considering a non-invasive test followed by colonoscopy can apply these findings to improve patient outcomes and reduce disparities in CRC care. These further underscore the need to track Goal 1 Target 1.2.

Read the full report

REFERENCE Doubeni CA, et al. (2024). *Fecal Immunochemical Test Screening and Risk of Colorectal Cancer Death.* JAMA Network Open, 7(7): e2423671.

Example of Real World Application of Data: CRC Screening Modalities

DNA STOOLS FOR COLORECTAL CANCER SCREENING GROWING IN POPULARITY, ESPECIALLY FOR PATIENTS UNDER AGE 50

Epic analyzed their Cosmos dataset to examine the method of screening used in over 1.4 million first-time colorectal cancer screenings over a five-year period. They found that in early 2018, colonoscopies accounted for 96% of first-time screenings; however by 2023, colonoscopies accounted for less than 70% of first time CRC screenings while mt-sDNA test utilization increased to 31% of first time CRC screenings. The USPSTF first recommended mt-sDNA (Cologuard) as a screening option in its 2016 update to colorectal cancer screening guidelines.

TRENDS THEY FOUND

- The use of mt-sDNA tests for colorectal cancer screening has increased more than nine-fold since 2018, rising from 3% of screenings in the first quarter of 2018 to 31% of screenings in the fourth quarter of 2023.
- Patients aged 45 to 49 used mt-sDNA testing for their colorectal cancer screening at a higher rate than those aged 50 to 55.
- Patients with the highest social vulnerability index had lower rates of mt-sDNA testing compared to those with less social vulnerability, though the use among each group has increased.

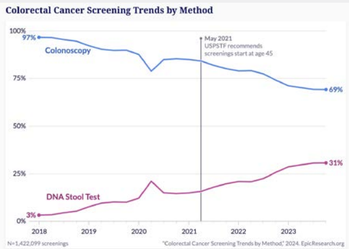
Learn more

REFERENCE *DNA Stool Tests for Colorectal Cancer Screening Growing in Popularity, Especially for Patients Under Age 50 (epicresearch.org)*

EPIC DASHBOARDS AND DATA ANALYSIS

Epic's data dashboards provide visual representations of trends in CRC screenings and diagnoses over time, including the impact of the COVID-19 pandemic on these rates. These dashboards allow health systems to track quarterly rates of overall and advanced cancer diagnoses, helping to identify trends in CRC screening uptake and outcomes. Screenshots of the Epic dashboards illustrate how health systems can use these tools to monitor screening rates, adherence to new guidelines, shifts in CRC detection and progress toward Goal 1 targets.

By leveraging the data and insights from Epic's comprehensive EHR network, healthcare providers can better understand the effects of policy changes on CRC screening rates and identify areas for targeted interventions to improve early detection and patient outcomes.



View Epic's interactive data charts for Colorectal Cancer Screenings and Colorectal Polyp Cases at Adult Cancer Incidents

Epic Research Interactive Data

Balancing Act: Screening Technologies

As new technologies, such as liquid biopsies and blood-based biomarkers, emerge in colorectal cancer screening, it is essential to balance their effectiveness, cost, and the need for follow-up colonoscopies to ensure comprehensive preventive care.

- *Liquid Biopsy for Average-Risk Colorectal Cancer Screening*
- *Effectiveness and Cost-Effectiveness of Colorectal Cancer Screening With a Blood Test That Meets the Centers for Medicare & Medicaid Services Coverage Decision*
- *Comparative Effectiveness and Cost-Effectiveness of Colorectal Cancer Screening With Blood-Based Biomarkers (Liquid Biopsy) vs Fecal Tests or Colonoscopy*
- *Blood-Based Colorectal Cancer Screening in an Integrated Health System: A Randomized Trial of Patient Adherence*

The articles highlighted above provide insights into the effectiveness and cost-effectiveness of emerging CRC screening technologies. As these technologies develop and potentially gain coverage, monitoring the need for follow-up colonoscopies remains crucial for delivering complete preventive services.

Example of Real World Application of Data: CRC Screening in the U.S. in 2014-2019

Freenome's real world data team performed an analysis of electronic health and claims records from 2014 to 2019 to shed light on CRC screening practices. Using a database of 8.1 billion commercial insurance, Medicare, and Medicaid claims from 46 million patients, Freenome analyzed a set of approximately 2 million screening procedures for average-risk individuals.

While this period predates the change in USPSTF recommendations that lowered the screening age to 45 (US Preventive Services Task Force 2021), and mt-sDNA (Cologuard) was recommended as a screening option mid-way through in 2016, this analysis provides key insight into screening behaviors within the U.S. prior to screening disruptions during the COVID-19 pandemic.

THE IMPACT OF THE COVID-19 PANDEMIC ON SCREENING

During the COVID-19 pandemic, screening for CRC fell to unprecedented lows, decreasing by 85%–95% as care delivery shut down. Even after screening operations resumed, the effects of the pandemic continued to be felt, with requirements for COVID testing prior to clinic visits and patient fears of virus exposure impacting colonoscopy scheduling.

The knock-on effects of the reductions in screening are expected to result in delays to diagnosis, leading to increases in CRC incidence and mortality; however, these negative effects may be mitigated by the speed at which screening backlogs have been addressed.

REFERENCE Shaukat, A., & Levin, T. R. (2022). Current and future colorectal cancer screening strategies. Nature Reviews Gastroenterology & Hepatology. DOI:10.1038/s41575-022-00612-y

CRC DATA ANALYSIS COMPLEXITIES HIGHLIGHT THE NEED FOR STREAMLINED RECORDING AND REPORTING

The Freenome analysis of electronic health and claims records highlighted challenges with interpreting how screening is performed across different systems. In many instances, data may be missing or recorded in ways that are difficult to interrogate or extract. These challenges reinforce the critical need for health systems to adopt a uniform set of measures for CRC screening.

Standardization would allow accurate data recording and tracking, which is pivotal for enhancing understanding, improving screening rates and patient care. This necessity aligns with the objectives of Goal 1 targets. By consistently measuring the same metrics, health systems can ensure that patients receive effective and timely screening, which is essential for the early detection and prevention of CRC (See Data Anomalies on page 25).

GOAL 1 Timely Screening for CRC Prevention & Early Detection

USE OF NON-INVASIVE SCREENING OPTIONS BY AGE

- Individuals at average risk for CRC who undergo screening commonly initiate their first screening within a year of reaching the recommended age of screening initiation (age 50 in the period studied).

Among average-risk individuals aged 50-59 years undergoing their initial CRC screening (n=365,386), the median age at the time of first screening was 51.0 years, with colonoscopies emerging as the method of choice.

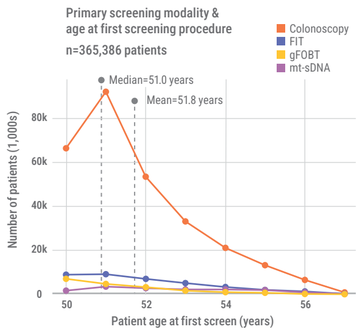


FIGURE 1 *Age at first CRC screening procedure for individuals completing first screening aged 50–59. FIT, fecal immunochemical test; gFOBT, guaiac fecal occult blood test; mt-sDNA, multitarget stool DNA.*

Notably, the majority of individuals who completed an initial screening did so relatively promptly, with few delaying past the age of 55 (Figure 1).

In contrast, Behavioral Risk Factor Surveillance System (BRFSS data indicates that individuals aged 50-54 years are among the hardest to reach for CRC screening, highlighting a gap in early engagement within this age group

- The timing of screening post-eligibility also varied by test type. Colonoscopies and gFOBT were typically used within a median of 12 months after eligibility, while FIT and the mt-sDNA test were utilized after a median of 24 months (Figure 2).

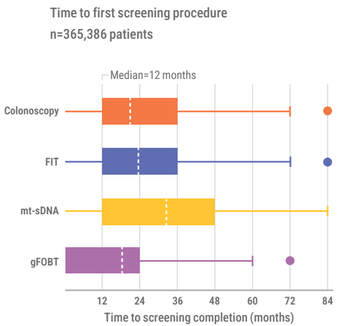


FIGURE 2 *Time (months) to first CRC screening procedure for individuals aged 50–59. FIT, fecal immunochemical test; gFOBT, guaiac fecal occult blood test; mt-sDNA, multitarget stool DNA.*

- Between 2014 and 2019, colonoscopy was the primary method for CRC screening among average-risk adults aged 50–75 (n=2,122,501 procedures). However, the data reveal an increase in the use of FIT or gFOBT screening with advancing age (Figure 3a on page 24). As CRC risk rises with age, improving access to non-invasive screening tests for the older population may boost screening adherence.
- Among non-invasive options, FIT utilization has remained consistent, while gFOBT utilization has declined. The uptake of the mt-sDNA test has climbed annually since the addition of this modality in the 2016 USPSTF CRC recommendations (US Preventive Services Task Force 2016) (Figure 3b on page 24). See Epic's Real-world Data Application on page 21 for more information about the rise in mt-sDNA usage.

These insights are vital for health systems aiming to align with the CRCCI targets as they highlight the need for a flexible approach that accommodates patient utilization of different screening options across different age groups. The data also underscore the critical role that monitoring utilization trends plays in optimizing screening strategies for all patient groups.

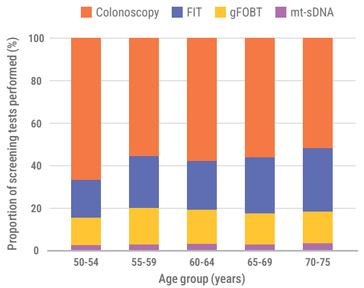


FIGURE 3A

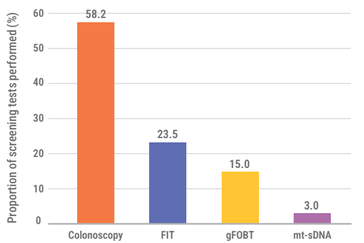


FIGURE 3B *Screening modalities used by age group (fig. 3a) overall and (fig. 3b) across time from 2014–2019. FIT, fecal immunochemical test; gFOBT, guaiac fecal occult blood test; mt-sDNA, multitarget stool DNA (n=1,802,192).*

Key finding: The majority of patients in this study receiving an abnormal FIT or gFOBT result did not undergo follow-up colonoscopy within 1 year

- Alarmingly, fewer than 50% of patients with an abnormal FIT or gFOBT screening result received a follow-up colonoscopy within the critical one-year window.
- Only 36% underwent this vital follow-up within the first 90 days—the period in which follow-up is most likely to occur (Figure 4).
- An additional 7.6% had the procedure between 90 and 180 days post-screening, with negligible numbers after six months.
- Completion of follow-up colonoscopy varied by the type of stool test used, with follow-up rates being highest for mt-sDNA and lowest for gFOBT (Figure 5).
- Studies have shown follow-up adherence differences between gFOBT, FIT, and mt-sDNA screening options, noting that mt-sDNA tests like Cologuard can show higher follow-up compliance.

MAIN POINT: Adhering to recommended follow-up procedures ensures early detection and treatment, significantly improving outcomes for colorectal cancer patients.

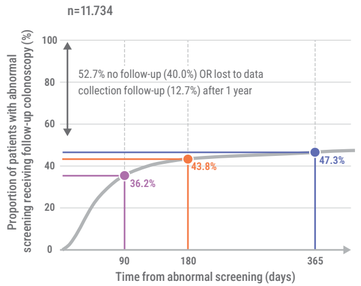


FIGURE 4 *Time to follow-up colonoscopy following abnormal screening*

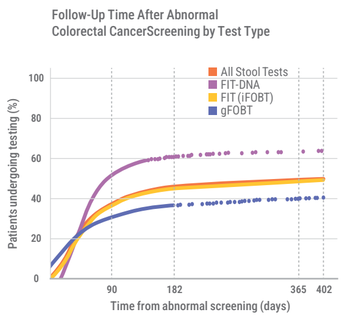


FIGURE 5 *Follow-up colonoscopy uptake by initial stool-based screening test used. FIT, fecal immunochemical test; gFOBT, guaiac fecal occult blood test; mt-sDNA, multitarget stool DNA.*

Melvin Fernandes, stage III colon cancer survivor

These findings highlight a significant gap in care, which has been corroborated in other studies (Ciemins, et al. 2024; Mohl, et al. 2023). Ensuring prompt follow-up colonoscopies after abnormal non-invasive screening tests is essential to improve CRC detection and treatment outcomes (Doubeni, et al. 2019; Zorzi, et al. 2022). Previous data suggest that waiting longer than nine months to complete the follow-up increased risk of CRC diagnosis and risk of advanced CRC at diagnosis, compared with follow-up within 30 days (Corley, et al. 2017).

The value of non-invasive CRC screenings is therefore critically undermined if patients do not complete the necessary follow-up colonoscopies or fail to complete them within a reasonable timeframe. Because non-invasive tests were a common choice for CRC screening in the United States, particularly among older patients, who are more likely to develop CRC, the low rates of follow-up colonoscopy should be an urgent call for action. We must develop and implement targeted strategies to ensure that patients proceed with follow-up colonoscopy.

CHALLENGE: DATA IRREGULARITIES

Anomalies: Sometimes there are anomalies, such as where a patient is recorded as repeatedly undergoing the same procedure within a short period of time. For the Freenome data, a time limit was applied to the types of screening so that repeated records of a procedure within this time limit were classed as one procedure only. For example, all stool tests recorded for a patient within an eight-week timeframe were considered as one stool test.

Multiple outcomes: Some patients underwent more than one type of screening method in a screening episode, and the results provided by the different methods may not have been the same. For the Freenome data, if a patient had one or more screening test produce a positive result, the entire screening was determined to be positive.

Inconsistent strategies: Screening routines are not consistent. There are many different ways by which people are screened and their results are followed up. This makes it very difficult to interpret how well current screening strategies are working, and to make sure that patients are up to date with screening.

Inconsistent recording: In addition, there are many ways to record screening procedures and their outcomes in these record systems, and individual users of these systems may do it differently. When working with large amounts of data, these inconsistencies can make it difficult to identify trends.

SOLUTION: THE CRC DATA COMMONS

- To advance Goal 1, we call for the creation of a CRC Data Commons to streamline the complexity of CRC data analytics. A standardized and accessible data repository would greatly benefit future research and help health systems identify where improvements can be made.
- Curating a data commons that allows consistent recording and reporting of CRC outcomes across datasets will make monitoring CRC screening and disease management across the U.S. easier, especially for outcomes that are difficult to monitor currently, such as adherence to screening over time, repeated non-invasive screening tests, and risk-stratification for screening.
- A colonoscopy registry, such as GiQuIC, could be an important component of the data commons. Creating a registry would require the development of methods to combine colonoscopy and pathology reports as well as accurate classification of colonoscopies as screening or diagnostic/therapeutic.

CASE STUDY - TWO

THE EFFECT OF PROGRAMS DESIGNED TO BOOST FOLLOW-UP COLONOSCOPY ADHERENCE ON HEALTH INEQUITIES

Background: Screening rates are significantly lower among low-income, underinsured, and uninsured adults in the U.S. According to some estimates, 47% of individuals living below the poverty line and 21% of uninsured adults aged 45 or older are being screened for colorectal cancer (CRC), compared to the national target of 80% (Siegel et al., 2023). Disadvantaged communities are also more likely to not complete follow-up testing or receive lower-quality follow-up care (Siegel et al., 2023).

Program Overview: The Centers for Disease Control and Prevention's Colorectal Cancer Control Program provides CRC screening, diagnostic, and surveillance services to low-income individuals at specific sites across the U.S. Data from this program show promising results in improving follow-up colonoscopy adherence and quality (Nadel et al., 2019).

- Between 2009 and 2015, 83% of positive non-invasive stool tests (FIT or gFOBT screening) were followed up by colonoscopy, with 80% of these procedures performed within 90 days of the positive test result.
- The overall quality of colonoscopies conducted was high.

SIGNIFICANCE

Funded, well-organized programs can help reduce health inequities by providing high-quality screening services to underserved populations.

HEALTH EQUITY SPOTLIGHT: SCREENING IN RURAL VERSUS URBAN POPULATIONS

CRC incidence and mortality rates are higher among individuals living in rural areas compared to people living in urban areas (Sutton, et al. 2021). This has been attributed in part to disparities in screening rates, which are lower in rural areas than in urban areas. Individuals in rural communities frequently face common barriers to CRC screening, including cost, lack of insurance coverage, lack of screening education, and lack of physician recommendation. Rural-specific factors such as lack of proximity to endoscopy clinics and a shortage of specialists also impact adherence to screening recommendations in these communities.

Goal 1: Conclusions & Screening Targets

Despite improvements in CRC screening over the last decade, challenges remain in ensuring adherence to screening protocols, particularly in completing necessary follow-up colonoscopies after an abnormal test result. Establishing the targets of an 80% screening rate for average-risk patients and 80% of patients with an abnormal non-invasive screening test result receiving a follow-up colonoscopy within 90 days are one way health systems can assess performance and help determine where gaps exist.

IMPROVING FOLLOW-UP RATES FOR CRC SCREENING

The data presented here reveal a concerning trend, whereby patients with abnormal FIT or gFOBT screening tests results are not proceeding to follow-up colonoscopies. This potentially allows CRC to go undetected, defeating the purpose of screening entirely. Typically, patients who do undergo a follow-up colonoscopy tend to do so within the first 90 days following an abnormal result from FIT or gFOBT screening tests, with a notable decline in follow-up rates thereafter. This gap highlights a crucial area for intervention, as delays beyond this window can increase the risk of disease progression (Flugelman, et al. 2019; San Miguel, et al. 2021).

2023 Fight CRC United in Blue Rally

SETTING BENCHMARKS FOR FOLLOW-UP SUCCESS

The target of 80% of follow-up colonoscopies completed within 90 days of an abnormal non-invasive test will serve as a critical benchmark for health systems to measure and improve non-invasive test follow-up rates. See "An Example For Non-invasive Testing Program" on page 28 to learn how health systems can benchmark performance. This approach could also be used to assess the performance of specific test types or the effectiveness of interventions aimed at increasing follow-up colonoscopy completion.

CASE STUDY - THREE

THE AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY (ASGE) INITIATIVES TO IMPROVE FOLLOW-UP COLONOSCOPY RATES

Background: The American Society for Gastrointestinal Endoscopy (ASGE) is collaborating with a federally qualified health center in Georgia (Community Health Care Systems, Inc.) and the Maryland State Medical Society to develop programs aimed at increasing follow-up colonoscopy rates among underserved patients with abnormal non-invasive stool test results. The initiative targets hundreds of uninsured and underinsured patients, providing colorectal cancer (CRC) screening through stool-based DNA tests and offering navigation support to guide patients through subsequent care, all at no cost to them.

Program Overview: These programs are designed to tackle the low adherence rates to follow-up colonoscopies among uninsured and underinsured populations. Key components include patient education, navigation support, and outreach efforts to assist patients throughout the entire screening and follow-up process.

SIGNIFICANCE

The initiative highlights the importance of comprehensive support services in improving follow-up care for CRC screening, ensuring that vulnerable populations receive timely and adequate care.

DISCLAIMER This project is funded by unrestricted grants from Exact Sciences, Sebela Pharmaceuticals, and Ironwood. Additionally, Sebela Pharmaceuticals' Braintree Laboratories has donated bowel preparation products for patients who require a follow-up colonoscopy.

REFERENCE The American Society for Gastrointestinal Endoscopy, 2024

Strategies to Enhance Follow-Up Rates

To enhance follow-up rates, providers and health systems should adopt proven, evidence-based strategies (refer to the Implementation Strategy for Improved Screening Follow-up on page 30). These strategies include patient navigation programs, automated patient and provider reminder systems, and streamlined referral processes designed to minimize administrative barriers. Educating patients on the importance of timely follow-up care, particularly by highlighting that early diagnosis significantly increases the chances of a cure, can further improve compliance (Ciemins et al., 2024; Kew and Koh, 2020).

When analyzing claims data, it is essential to differentiate between specific non-invasive screening tests, such as FIT, gFOBT, and mt-sDNA. Recognizing these distinctions allows for a more accurate assessment of outcomes and resource allocation, as each test varies in sensitivity, specificity, and follow-up requirements (Gupta et al., 2020; Knudsen et al., 2021). Failure to consider the unique attributes of each test when analyzing data can result in skewed interpretations and hinder effective healthcare planning (Imperiale et al., 2019).

EXAMPLE OUTLINE FOR A NON-INVASIVE TESTING PROGRAM

Develop a way to measure the **proportion of patients who receive follow-up colonoscopy within 90 days of an abnormal non-invasive test** to monitor screening effectiveness.

MEASUREMENT

Identify patients who have undergone non-invasive tests using:

- Records of provider interactions, e.g., stool test request, mail-out, or return
- Assessment of claims database for codes related to stool-test results

Identify patients who have non-invasive stool test results and date of result

- Review records of stool-test results sent to providers
- Assess claims database for codes related to stool-test results
- Calculate number of patients with abnormal non-invasive stool test results

Identify patients with abnormal non-invasive stool test results who have undergone colonoscopy

- Records of provider interactions, e.g., colonoscopy bookings, notifications of colonoscopy results
- Assessment of claims database for codes related to colonoscopy
- Calculate number of patients with colonoscopy follow-ups of abnormal non-invasive stool tests
- Calculate number of patients with colonoscopy follow-up of abnormal non-invasive stool tests within 90 days

Program Evaluation Tip: *Keep in mind that follow-up adherence rates can differ significantly between non-invasive screening modalities such as FIT and multi-target stool DNA (mt-sDNA) tests. For accurate evaluation and planning, ensure that adherence metrics for these tests are measured and considered separately.*

Target progress measurement: Percentage of patients receiving a follow-up colonoscopy within 90 days

- Numerator: n patients with positive non-invasive test result with colonoscopy follow-up within 90 days
- Denominator: N patients with abnormal non-invasive stool test results
- Multiply by 100
- **The target is 80% receiving a follow-up colonoscopy**

CASE STUDY - FOUR

CRC SCREENING IN RURAL POPULATIONS

Background: Life expectancy among rural populations is notably lower than among urban populations, and this gap is widening. Disparities in cancer care across the entire continuum—prevention, diagnosis, and treatment—are key drivers of this divide. The smaller number of residents in rural areas often impacts access to funding for public health initiatives, including cancer screenings. Moreover, different communities face distinct barriers to care provision, so a "one-size-fits-all" approach is ineffective. Guidelines must provide stepwise guidance to organizations, encouraging innovation and collaboration to meet the unique needs of different situations.

Inspira Health is a charitable nonprofit healthcare organization in rural southern New Jersey and the only provider of care in two counties consistently ranked as the poorest and most unhealthy in the state. Several factors contribute to barriers to colorectal cancer (CRC) screening and timely treatment in these areas, including:

- Lack of public transportation
- Lack of high-speed internet access, which precludes some telehealth services
- Limited access to timely commercial shipping pick-up services, inhibiting stool-based CRC screening programs

Innovative Solutions by Inspira Health:
To overcome these challenges, Inspira Health's Cancer Services programs and the Clinical Research Office partner with small local funding agencies and community organizations to maximize outreach and improve CRC screening rates. Key initiatives include:

Promoting Stool-Based Testing: Funding is utilized to encourage the return of stool-based cards for in-house testing. Partnerships between the Clinical Research Office team and local Parish Nurse groups have facilitated the return of mail-back stool-based kits.

Cancer Navigation and Case Management:
Inspira Health has developed a collaborative, case management-focused approach to cancer navigation. This includes one-stop work-up programs, which reduce delays in treatment initiation by consolidating services under one roof and clustering multiple diagnostic and physician appointments into a single visit. Transportation is often provided through a creative rural rideshare partnership.

SIGNIFICANCE

Rural populations face unique barriers to adhering to recommended screening and treatment guidelines, regardless of socioeconomic status. Stepwise approaches and creativity by health systems and organizations are essential to overcome these obstacles, ensuring equitable access to cancer care and improving overall outcomes

Implementation Strategy for Improved Screening Follow-up

Looking ahead, emerging technologies approved by the FDA, such as blood tests, mt-sRNA tests, and others hold promise for reducing barriers to screening. While these new options will bring potential benefits, they will also introduce specific challenges. The experiences and lessons learned from implementing FIT and mt-sDNA screening programs provide valuable insights for effectively integrating these tests into screening strategies.

THE ROLE OF mt-sDNA IN IMPROVING ADHERENCE

To illustrate the impact of screening modality choice and supportive interventions on adherence and follow-up rates, we can look at the case of the mt-sDNA test. Introduced in 2014, the mt-sDNA test not only offered a non-invasive option for colorectal cancer screening but also enhanced the process by incorporating patient navigation support. This assistance begins when the test is ordered and continues through its completion and return to the manufacturer. Such navigation support keeps patients engaged throughout their screening journey, significantly increasing the likelihood of timely follow-up after abnormal results. This underscores the essential role of patient support systems in improving adherence to follow-up procedures and highlights a vital strategy for enhancing colorectal cancer screening outcomes.

Research supports this, showing that follow-up colonoscopy rates after positive results are generally higher for mt-sDNA tests compared to FIT. A study in the Journal of the American Board of Family Medicine found that 71.5% of patients with a positive mt-sDNA result completed a follow-up colonoscopy within six months, compared to 46.7% of those with a positive FIT result (Smith et al., 2023). Similarly, findings from Cancer Prevention Research indicated that patients with positive mt-sDNA tests were more likely to complete follow-up colonoscopies and have subsequent detection of neoplasia than those with positive FIT results (Jones et al., 2023).

APPROACHES TO STREAMLINING CRC SCREENING

1) Protocol Establishment:

- Utilize EHR systems like EPIC or OPTUM for patient identification (Ciemins, et al. 2024).
- Develop patient navigation programs that guide patients through the CRC screening pathway and coordinate their care with providers. These programs may include the initiation of a referral for colonoscopy from the primary care physician, identification of a colonoscopy provider, and scheduling of the colonoscopy, as well as implementing reminder systems such as phone calls prior to appointments (Idos, et al. 2021).

2) Healthcare Provider Interventions:

- Emphasize the importance of timely interventions for CRC and educate on outcomes associated with lack of follow-up (Mohl, et al. 2023).
- Ensure positive stool test results are reported to providers (Idos, et al. 2021; Mohl, et al. 2023). Partnerships with test vendors to ensure results are provided to healthcare insurance plans, physicians, and patients may be beneficial, as health plans may have available resources to coordinate or aid follow-up with both healthcare providers and patients (Barnes, et al. 2023).

3) Patient Engagement and Education:

- Offer channels for patients to communicate concerns and ensure they understand the importance of timely colonoscopies (Kerrison, et al. 2022).

4) Continuous Monitoring and Feedback:

- Extract regular reports from EHR systems to monitor adherence rates and ensure timely follow-ups, as assessed by the follow-up colonoscopy measure (Ciemins, et al. 2024).

Fight CRC's Follow Up Coding Toolkit

CASE STUDY - FIVE

THE EFFECT OF SCREENING TEST MODALITY ON ADHERENCE AND FOLLOW-UP

The mt-sDNA test was approved in 2014 by the Food and Drug Administration (FDA) as a noninvasive CRC screening test for adults 45 years and older at average risk of developing CRC. The American Cancer Society recommends screening with mt-sDNA every 3 years, and in 2016 it was also added as a CRC screening option by the USPSTF. Each mt-sDNA test order is accompanied by a patient navigation program, which may support increased screening adherence, defined as test completion within 365 days.

Screening adherence to the mt-sDNA test. Among commercially-insured individuals and Medicare beneficiaries, overall adherence to the mt-sDNA test ranged from 66.8%–71% (Miller-Wilson, et al. 2021; Weiser, et al. 2021).The adherence rate to the mt-sDNA test for Medicaid beneficiaries at 51.3% was higher than previously reported CRC screening adherence rates in this population (12.3-23.2%) (Miller-Wilson, et al. 2022).

Contribution of the mt-sDNA test to overall screening rates. The recent increase in CRC screening was primarily driven by increased stool-based testing, including the mt-sDNA test (Ebner, et al. 2024a; Shapiro, et al. 2021). For instance, increased screening uptake between 2018 and 2021 was attributed in large part to mt-sDNA test utilization (Ebner, et al. 2024a). At the health system level, another study of adults aged 50–75 years found that screening increased from 26% to 49% across 5 years (2015–2019), with screening colonoscopy remaining steady while mt-sDNA testing increased 40x (Miller-Wilson, et al. 2023).

mt-sDNA test adherence and time to follow up. Among commercially insured individuals aged ≥50 years and Medicare Advantage enrollees, adherence to follow-up colonoscopy within 6 months after a positive mt-sDNA test was 72%, and median time to colonoscopy was 58 days; among those with a positive FIT, adherence to follow-up colonoscopy was 46%, and mean time to follow-up was 127 days (Austin, et al. 2023).

Colonoscopy yield after mt-sDNA testing. In one health system, 77.1% of patients aged ≥40 years with a positive mt-sDNA test presented with a precancerous or malignant lesion at follow-up colonoscopy, and 48.6% of patients with a positive FIT had such findings on colonoscopy (Cooper, et al. 2021). In a statewide registry study, patients with a positive mt-sDNA test had 1.8x greater odds of having clinically relevant serrated polyps at follow-up colonoscopy, compared with undergoing colonoscopy after a positive FIT (Anderson, et al. 2023).

SIGNIFICANCE

Individuals undergoing CRC screening with an mt-sDNA test had higher adherence rates and were more likely to receive a follow-up colonoscopy compared with those screened using other modalities, perhaps in part due to the accompanying patient navigation program. In addition, a positive mt-sDNA test was associated with higher likelihood of clinically relevant findings on follow-up colonoscopy.

GOAL 2

Accurate, Informative Diagnosis & Timely Treatment Initiation

Goal 2 emphasizes the crucial role of accurate diagnosis and swift initiation of treatment in the CRC care pathway. These steps are essential for leveraging advancements in medical technology to improve patient outcomes. Recent studies have confirmed that timely cancer care remains a priority, even amid global health challenges like the COVID-19 pandemic (Shaukat and Levin, 2022). Delays in diagnosis and treatment can lead to disease progression to a more advanced stage, limiting effective treatment options and resulting in poorer outcomes (Lee et al., 2019; Siegel et al., 2024).

MORE *Advocacy* TIME!

"I fight for myself and to prevent other people from going through what I did. My dream is to end cancer as we know it."

MICHAEL HOLTZ

STAGE III RECTAL CANCER SURVIVOR

GOAL 2

Accurate, Informative Diagnosis & Timely Treatment Initiation

TARGET 2.1

Ensure 80% of patients diagnosed with CRC receive biomarker testing in accordance with NCCN Clinical Practice Guidelines (NCCN Guidelines®).

TARGET 2.2

Ensure 80% of patients diagnosed with CRC undergo germline genetic testing at the time of diagnosis.

TARGET 2.3

Ensure 80% of patients initiate treatment within six weeks of a CRC diagnosis.

Advancements in Diagnostic Tools

Accurate and timely diagnosis is necessary to guide subsequent treatment effectively. Advanced diagnostic tools, such as positron emission tomography (PET), computed tomography (CT), and magnetic resonance imaging (MRI), provide precise staging critical for disease management (Furtado et al., 2021; Shi et al., 2022). Since 2009, biomarker testing has been recommended for patients with newly diagnosed metastatic CRC. Current recommendations include testing for KRAS, NRAS, BRAF alterations, HER2 amplifications, and MSI/MMR status to inform treatment choices (National Comprehensive Cancer Network, 2024a). Next-generation sequencing is preferred to identify rare but actionable genetic alterations. However, only 28%–67% of eligible patients undergo recommended biomarker testing (Becker et al., 2021; Freml et al., 2020; Gutierrez et al., 2019). This underutilization means many patients do not receive the most appropriate targeted therapies, which negatively affects overall survival rates (Becker et al., 2021; Kehl et al., 2019).

HEALTH DISPARITIES IN CRC DIAGNOSIS AND TREATMENT

The variability in testing rates highlights broader health inequalities, particularly in rural populations (Illei et al., 2018; Lewis et al., 2023; Lynch et al., 2018; Sabbagh et al., 2024). Additionally, ethnic and racial minorities may be less likely to receive care in line with clinical guidelines than White patients and may experience longer wait times for treatment (Nogueira et al., 2023; Shively et al., 2022). These groups are also more likely to experience treatment complications and higher mortality associated with these complications.

SOMATIC BIOMARKER TESTING

In 2022, the College of American Pathologists published a guideline on mismatch repair (MMR) and microsatellite instability (MSI) testing for immune checkpoint inhibitor therapy, in collaboration with the Association for Molecular Pathology and Fight CRC (Bartley et al., 2022). The ASCO Endorsement Panel officially endorsed the guidelines in 2023 (Vikas et al., 2023).

ENHANCING CRC CARE PATHWAYS

Goal 2 focuses on specific steps within CRC diagnostic and patient management pathways. To develop this goal, we utilized real-world data to identify gaps in care and formulated key targets to assess these gaps and the impact of efforts to address them. Significant delays in treatment initiation and underutilization of germline and biomarker testing can compromise treatment effectiveness.

For many patients, these delays and lack of thorough diagnostic testing mean that the potential benefits of personalized treatment strategies are not fully realized. There is an urgent need to improve the speed and accuracy of CRC treatment protocols, as reflected in Targets 2.1, 2.2, and 2.3, to ensure all patients receive timely and effective care. By focusing on these targets, healthcare providers can evaluate and enhance their diagnostic practices and disease management strategies, ensuring every patient receives the most accurate diagnosis and timely, appropriate treatment, thereby significantly improving CRC outcomes.

GERMLINE TESTING FOR EARLY-ONSET CRC (EO CRC)

Patients diagnosed with early-onset colorectal cancer (EO CRC) often face significant delays from the onset of symptoms to diagnosis and treatment. For instance, one study found that patients under the age of 50 waited an average of 217 days from symptom onset to treatment, compared to just 29.5 days for those over 50 (Scott et al., 2016; Siegel et al., 2020). These delays affect the immediate management of the cancer and impact the timing of critical genetic counseling and germline testing. Germline multigene panel testing (MGPT), recommended by NCCN for individuals diagnosed with CRC under the age of 50, is vital for identifying hereditary cancer syndromes and guiding patient surveillance (National Comprehensive Cancer Network, 2024b). However, when diagnosis is delayed, there is often a corresponding delay in receiving germline testing, which can prevent timely identification of hereditary risks and proper management of both the patient and at-risk family members (Broyles et al., 2024).

EARLY-ONSET COLORECTAL CANCER

"On August 31, 2016, at 18, I was diagnosed with Stage IV colorectal cancer. I had just graduated high school, started college, and was living the life of a typical 18-year-old. I never even knew colorectal cancer was a real thing."

Erin Verscheure
STAGE IV COLON CANCER SURVIVOR

Measures of Effective Diagnosis and Treatment

Effective diagnosis and treatment are critical components in improving outcomes for colorectal cancer (CRC) patients. Accurate and timely diagnosis ensures that patients receive the appropriate care at the right time, while effective treatment strategies enhance the chances of successful outcomes and reduce the risk of recurrence. This section explores various metrics and performance measures that healthcare institutions can use to evaluate and improve their CRC care pathways. By tracking these measures, such as disease staging accuracy, adherence to treatment guidelines, and patient outcomes, healthcare providers can identify areas for improvement and implement evidence-based strategies to enhance patient care.

ANALYZING THE CRC PATIENT CARE JOURNEY

To effectively analyze and enhance the colorectal cancer patient care journey, a hospital or clinic should incorporate these performance measures into their EMR system. These measures provide a structured approach to evaluating and improving CRC patient care.

1. ASSESS DISEASE STAGING AT DIAGNOSIS

Calculate Disease Stage Proportions: Determine the proportion of CRC cases identified at each stage upon diagnosis (American Cancer Society, 2024).

Identify Late-Stage Diagnoses: Calculate the proportion of cases diagnosed at a late stage to identify opportunities for earlier detection (National Comprehensive Cancer Network, 2024a).

2. EVALUATE THE TREATMENT JOURNEY

Measure Time to Treatment Initiation: Track the time from diagnosis to the start of CRC treatment, which is critical for improving survival outcomes (Gorin, 2019; Levit et al., 2020).

Assess Adherence to Treatment Guidelines: Analyze adherence to NCCN-recommended treatment options for the corresponding disease stage (National Comprehensive Cancer Network, 2024b).

Monitor Treatment Start and Completion Rates: Evaluate the proportion of patients who begin recommended radiation and chemotherapy treatments and assess their completion rates (American Society of Clinical Oncology, 2023).

Review Surgical Interventions: Examine the proportion of patients undergoing surgical interventions and monitor the incidence of post-surgery complications (National Cancer Institute, 2022).

3. SCRUTINIZE DIAGNOSTIC TESTING

Track Biomarker Testing: Measure the proportion of CRC cases that receive appropriate biomarker testing as recommended by NCCN guidelines (National Comprehensive Cancer Network, 2024c).

Frequency of Biomarker Testing: Investigate how often biomarker testing is performed in line with NCCN recommendations to support personalized treatment strategies (American Society of Clinical Oncology, 2023).

Ben White, stage III colon cancer survivor

4. MONITOR SURVIVAL AND SURVEILLANCE

Observe Survival Rates: Correlate survival rates with the stage of the disease at the time of diagnosis (Siegel et al., 2023).

Verify Surveillance Adherence: Ensure adherence to the recommended NCCN colonoscopy schedule post-treatment for vigilant patient surveillance (National Comprehensive Cancer Network, 2024d).

By actively employing these measures, your institution can gain a clearer understanding of the CRC patient care trajectory and identify key areas for improvement to enhance patient outcomes.

Example of Real World Application of Data: Time to Diagnosis

Komodo Health analyzed data for 1.28 million adults diagnosed with CRC from 2016 to 2021 from a database of 330 million U.S. patients, determining the time from an initial abnormal stool-based screening to a confirmed CRC diagnosis. The results reveal significant delays that could adversely affect patient outcomes and the effectiveness of treatment.

- It is important to note that the limitations of data. It does not consider the inherent variability in wait times for scheduling an initial screening colonoscopy, which can span weeks to months based on access to endoscopy services. Furthermore, positive results from non-invasive tests such as FIT, gFOBT, or mt-sDNA can lead to expedited scheduling to follow up colonoscopy, which can influence the overall time to diagnosis reflected in these averages.

- Patients who were initially screened by direct visualization had the shortest average time to final diagnosis at 30 days (95% CI: 29.32, 30.10). In comparison, those who underwent only stool-based testing had an average diagnosis time of 130 days (95% CI: 128.15, 132.10), while individuals who proceeded from stool-based testing to direct visualization had an had an average diagnosis time of 104 days (95% CI: 103.35, 105.50).

Main point: Non-invasive tests (ie. gFOBT, FIT, mt-sDNA) are intended to help communities optimize the use of colonoscopy services.

Cohort:	Direct visualization	Stool-based only	Stool-based, then direct visualization
Total (N):	134,035	13,535	30,586
Time from first screening to final diagnosis, days			
Average [SD]	30 [73]	130 [117]	104 [96]
95% CI	(29.32, 30.10)	(128.15, 132.10)	(103.35, 105.50)

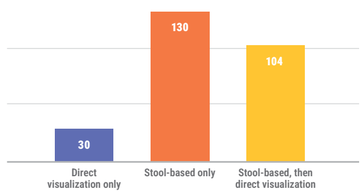


TABLE 1: *Time to diagnosis following initial screening by modality of first screening and subsequent diagnosis method. Table 1 shows the median time from screening to final diagnosis, with Figure 1 depicting this graphically.*

CI: *confidence interval* **SD:** *standard deviation*

Important note on diagnostic methods Stool-based testing alone accounted for 8.2% of the cases (13,535 out of 164,128) in this analysis. These are patients for whom a claim for a colonoscopy was not visible. A patient cannot be diagnosed with stool-based testing alone.

Disparities in diagnosis timelines: Racial and ethnic minorities, particularly Black and Hispanic or Latino patients, experienced longer delays in diagnosis (Table 2). Black patients, whether screened initially by direct visualization or stool-based testing followed by direct visualization, faced longer wait times compared with White patients. Similarly, Hispanic or Latino patients also encountered extended periods between their first screening and diagnosis, especially when screened by stool-based testing followed by direct visualization. These disparities highlight the need for targeted improvements in screening and diagnostic processes to ensure timely care for all patient groups.

***Greg Vaughn,** stage IV colon cancer survivor*

Mean days, n [SD] (95% CI)	WHITE	BLACK	HISPANIC OR LATINO	ASIAN	OTHER	UNKNOWN
Colonoscopy	31 [74] (30.04, 30.97)	38 [80] (36.79, 39.79)	32 [76] (30.45, 34.15)	23 [65] (20.95, 25.50)	28 [71] (25.46, 31.40)	18 [55] (17.31, 19.10)
Stool, then Colonoscopy	103 [95] (102.17, 104.61)	114 [99] (109.72, 118.43)	120 [102] (115.22, 125.08)	107 [98] (100.05, 113.79)	108 [98] (98.12, 117.32)	94 [92] (90.69, 98.10)
Stool only	130 [117] (127.88, 132.44)	138 [118] (131.06, 144.45)	133 [118] (125.47, 140.35)	134 [116] (123.02, 144.18)	132 [118] (113.96, 149.34)	106 [111] (97.38, 115.36)

TABLE 2: *Time in days from first screening to diagnosis by race, categorized by type of first and subsequent screening. Using time to diagnosis value for the White population as the reference, red shading denotes longer times to diagnosis and green shading denotes shorter times to diagnosis.*

CI: *confidence interval* **SD:** *standard deviation*

Example of Real World Application of Data: Time-to-Treatment and Biomarker Testing from 2016 to 2021

ON AVERAGE, PATIENTS WAITED OVER SIX WEEKS AFTER DIAGNOSIS FOR TREATMENT

To understand treatment delays after CRC diagnosis, Komodo Health analyzed the same extensive dataset of 1.28 million CRC patients for their time-to-diagnosis analysis. The time-to-treatment analysis stratified patients by age and examined various factors, including risk status, family or personal history of disease, biomarker testing, and medical/surgical treatment status.

The results indicate a significant delay in initiating treatment post-diagnosis:

- Among newly diagnosed adults represented in the database (n=259,456), treatment records were found for only 68%.
- Of the patients who received treatment, 96% underwent surgery and 59% received chemotherapy.
- On average, treatment began 48 days after diagnosis, with a median time of 16 days.
  - The average time to surgery was 45 days, while the median was 16 days.
  - The average time to chemotherapy initiation was notably longer, with an average of 156 days and a median of 54 days.
- Younger patients typically received treatment more quickly than older patients, although those aged 50 and over experienced the shortest delays to surgery initiation.
- Despite similar average times-to-treatment across different risk groups, high-risk patients tended to receive treatment slightly sooner than those not at high risk—45 days on average compared with 48 days, with a median of 16 days for both groups.

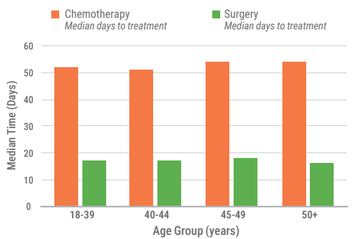


FIGURE 2: *Treatment timelines across age groups*

ANALYSIS OF THE TIME TO BIOMARKER AND/OR GENETIC TESTING DATA INDICATE THAT GENETIC & BIOMARKER TESTING IS NOT ROUTINELY PERFORMED

A significant discrepancy exists in genetic and biomarker testing, with only 37% of the overall patient population having a test recorded.

The median time to perform testing was 27 days after diagnosis. Younger patients were more likely to undergo this testing, with nearly 60% of those aged ≤49 receiving tests compared with just under 40% of those aged 50+.

Patients with a higher risk of CRC, including those with personal or family histories of the disease, were more likely to receive genetic and biomarker testing than the general patient population.

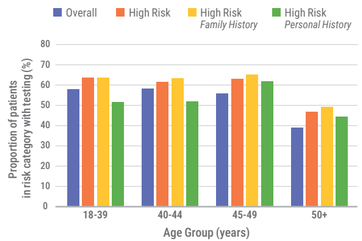


FIGURE 3: *Rates of genetic and biomarker testing by age group and risk category*

Goal 2 Conclusions: Diagnosis & Treatment Targets

This section highlights the potential of leveraging real-world claims data to uncover significant trends in the treatment journey of colorectal cancer (CRC) patients. The Komodo Health data analysis reveals that delays from screening to diagnosis and treatment initiation can profoundly impact patient outcomes, with longer wait times associated with more advanced disease stages and reduced survival rates.

HEALTH EQUITY SPOTLIGHT: ADDRESSING RACIAL & ETHNIC DISPARITIES IN COLON CANCER MANAGEMENT

A study by Greenberg et al., published in the International Journal for Equity in Health, reveals significant racial and ethnic disparities in colorectal cancer (CRC) care (Greenberg et al., 2023). Using data from the National Cancer Database (2010–2017), this research highlights key areas where disparities exist in diagnosis, treatment, and outcomes among racial and ethnic groups, pointing to critical opportunities for improving equity in healthcare.

KEY FINDINGS ALIGNED WITH GOALS 1 AND 2

1. Advanced Stage at Diagnosis:
Non-White patients, particularly Southeast Asian, Hispanic/Spanish, and Black individuals, are more likely to be diagnosed at advanced stages of CRC compared to White patients. This finding supports Goal 1 to reduce late-stage cancer diagnoses through better screening and early detection.

2) Delays in Surgery and Access to Minimally Invasive Surgery (MIS):
Black and American Indian, Aleutian, and Eskimo patients often face delays in receiving surgery and have less access to robotic surgery than White patients, which affects recovery and overall treatment timelines. This disparity highlights the need to improve timely access to advanced surgical options under Goal 2.

3) Chemotherapy Utilization:
Black patients are more likely to experience delays in starting chemotherapy and to forgo chemotherapy due to severe illness or mortality. This underscores the importance of initiating treatment within 6 weeks of diagnosis.

4) Mortality Rates and Modifiable Factors:
Racial and ethnic disparities in mortality rates diminish when adjusting for factors like education, insurance, and income. This demonstrates the significant role socioeconomic disparities play in CRC care outcomes.

IMPLICATIONS FOR PRACTICE AND POLICY

Tailored Interventions: Implement specific strategies that address the unique barriers faced by different racial and ethnic groups, such as providing culturally and language-appropriate educational materials and community outreach programs.

Systemic Changes: Addressing disparities, especially among Black patients, requires comprehensive changes in healthcare policies and practices. This includes improving access to primary care, ensuring equitable treatment options, and delivering culturally competent care.

Data-Driven Approaches: Continued monitoring and research are essential for evaluating the effectiveness of interventions and refining strategies to reduce disparities.

This study reinforces the need to address racial and ethnic disparities in CRC care and aligns with our goals of improving diagnosis accuracy and treatment timeliness to enhance patient outcomes and achieve health equity.

The data also indicate that only a minority of patients receive essential biomarker and genetic testing—a critical step in tailoring treatment to the unique characteristics of an individual's tumor. Timely biomarker testing is vital for identifying appropriate targeted therapies, which can significantly enhance treatment efficacy and improve patient survival rates (Iyer et al., 2022; Lewis et al., 2023).

However, these findings reveal substantial gaps in current practice, highlighting areas where improvement is needed.

Actionable Targets for Improvement

To close these gaps and improve outcomes, health systems must implement robust protocols that ensure timely CRC screening, diagnosis, and treatment initiation. By focusing on these key targets, we aim to achieve accurate and informative diagnoses, as well as timely treatment, by 2030:

Target 2.1: Ensure that 80% of CRC patients receive biomarker testing in accordance with NCCN guidelines.

Target 2.2: Ensure that 80% of CRC patients undergo germline genetic testing at the time of diagnosis.

Target 2.3: Ensure that 80% of CRC patients initiate treatment within 6 weeks of diagnosis.

Reaching these targets is crucial for enhancing the effectiveness of therapies and improving the overall survival rates of CRC patients. This commitment underscores the significant impact that integrating real-world data into clinical practice can have on patient care.

Challenges to Biomarker & Genetic Testing

Despite the benefits, several barriers to biomarker and genetic testing persist, including low reimbursement rates, complex reimbursement processes, high costs for underinsured or uninsured patients, and long turnaround times (Iyer et al., 2022; Lewis et al., 2023; Sundin). These challenges disproportionately affect individuals in rural areas, those with lower educational attainment, and members of racial and ethnic minority groups (Sabbagh et al., 2024; Siegel et al., 2023).

EFFORTS TO ADVANCE POLICY TO INCREASE ACCESS TO BIOMARKER TESTING

While there are many challenges to equitable access to biomarker testing, one significant issue is that insurance plans do not always cover this testing for patients who need it. Fight CRC and other patient advocacy groups have been working with the American Cancer Society Cancer Action Network (ACS CAN) to advance state legislation to ensure better insurance coverage of biomarker testing so that more patients can access this essential tool for precision medicine.

To date, legislation aligning insurance coverage of biomarker testing with the latest medical and scientific evidence has been enacted in 20 states: Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Minnesota, New Mexico, New York, Oklahoma, Pennsylvania, Rhode Island, and Texas.

Learn more

A lab procedure is described to Research Advocates.

Strategies to Enhance Outcomes

Potential strategies to address these challenges include:

Education and Advocacy: Educating clinicians, patients, and payors about the importance of biomarker and genetic testing and its alignment with treatment guidelines (Broyles et al., 2024; Lewis et al., 2023).

Improving Reimbursement Processes: Advocating for better reimbursement processes and educating payors about the value of timely and comprehensive testing (IQVIA, 2020; Lewis et al., 2023).

Enhancing Testing Processes: Streamlining testing processes to reduce turnaround times and adopting best practices for tissue handling, test selection, and result reporting (IQVIA, 2020).

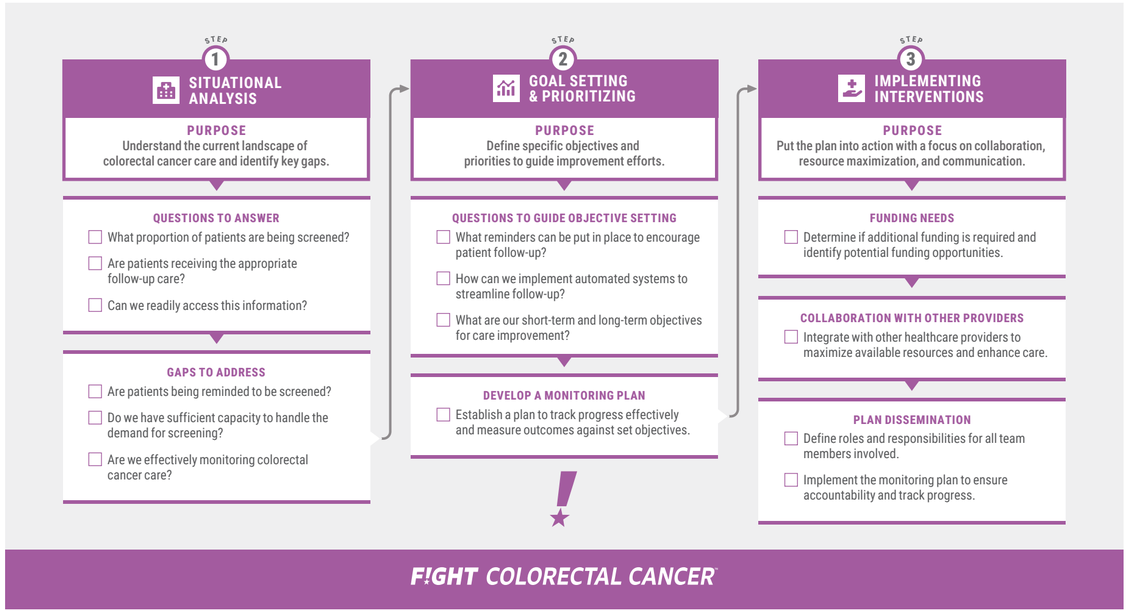
Adopting Innovative Techniques: Utilizing non-invasive liquid biopsy techniques to reduce costs, morbidity, and turnaround times (Batool et al., 2023).

Next Steps: Blueprint for Successful Implementation

To effectively enhance CRC care, it's crucial to assess the existing landscape, identify gaps, set clear goals, and implement targeted interventions. The following infographic provides a structured approach to improving CRC screening and follow-up care, helping healthcare providers and stakeholders evaluate their current practices, prioritize their efforts, and implement effective strategies.

IMPLEMENTING STRATEGIES FOR IMPROVEMENT

Health systems should prioritize the strategies outlined above to meet the targets for 2030 and enhance CRC patient care.



BIOMARKER TESTING FOR CRC PATIENTS

Biomarker testing involves analyzing multiple genetic and molecular markers to guide targeted therapy in CRC. According to ASCO and NCCN guidelines, this testing includes:

- *KRAS and NRAS Mutations*
- *BRAF Mutations*
- *Microsatellite Instability (MSI) or Mismatch Repair Deficiency (dMMR)*
- *HER2 Amplification*
- *NTRK Fusions*
- *Next-Generation Sequencing (NGS)*

Billing Guidance

Prior authorization may be required, and documentation must support medical necessity per ASCO and NCCN guidelines (ASCO, 2023; NCCN, 2024).

Keeping Up to Date

As biomarker testing recommendations evolve with advancing science, staying informed is crucial for ensuring the most effective care for CRC patients.

Strategies for Improving Timely Biomarker and Genetic Testing

1) Training for Clinicians

Provide training on guidelines for biomarker testing (Lewis et al., 2023) and germline genetic testing (Broyles et al., 2024).

2) Enhance Reimbursement Processes

Improve reimbursement for biomarker (Lewis et al., 2023) and germline genetic testing (Broyles et al., 2024).

Ensure reimbursement coverage aligns with the latest recommendations, such as NCCN guidelines, and is linked to adherence to these guidelines (IQVIA, 2020; Lewis et al., 2023).

Improve coding systems for better reimbursement (Sundin).

3) Develop Best Practices for Health Systems

Secure high-quality tissue for biomarker testing as part of routine care or utilize liquid biopsy methods recommended by NCCN guidelines (Batool et al., 2023; IQVIA, 2020; National Comprehensive Cancer Network, 2024a).

Simplify the selection of biomarker tests and the reporting of results (IQVIA, 2020).

Reduce turnaround times for biomarker testing, such as using liquid biopsy tests, which offer faster results than traditional tissue testing (Batool et al., 2023; IQVIA, 2020).

4) Engage and Educate Patients

Educate patients on the importance of biomarker testing (Lewis et al., 2023) and germline genetic testing (Broyles et al., 2024).

5) Increase Access for Under- and Uninsured Patients

Pursue funding strategies to increase testing rates for under- and uninsured patients, such as seeking state-level funding (Broyles et al., 2024; Lewis et al., 2023).

6) Monitor Progress

Regularly monitor progress to ensure improvement in testing rates and effectiveness. (See "How to Measure Performance Against Goal 2 Targets 2.1 and 2.2: Examples" below.)

In order to determine how well any improvement strategies are working, it is important to create a measure that assesses performance against the target. Examples of how to measure progress towards Target 2.1 and Target 2.2 are given in the box below.

GOAL 2 Accurate, Informative Diagnosis & Timely Treatment Initiation

HOW TO MEASURE PERFORMANCE AGAINST GOAL 2 TARGETS 2.1 AND 2.2: EXAMPLES

To measure the success of Target 2.1 (biomarker testing) and Target 2.2 (germline testing), follow these steps:

STEP 1: IDENTIFY PATIENTS DIAGNOSED WITH CRC

Determine Diagnosis and Date

- Review records of provider interactions, such as colonoscopy outcomes and department referrals following a diagnosis.
- Assess claims databases for diagnosis-related codes (details provided in Appendix 2.1).

STEP 2: IDENTIFY PATIENTS WHO HAVE RECEIVED TESTING

For Biomarker Testing (Target 2.1) and Germline Testing (Target 2.2)

- Check records of pathology requests and transfers, and review pathology reports.
- Examine claims databases for codes related to biomarker and genetic analysis (details provided in Appendix 2.2).
- Calculate the number of patients who have undergone biomarker testing (for Target 2.1) and germline testing (for Target 2.2).

STEP 3: CALCULATE TARGET PROGRESS

Percentage of Patients Receiving Testing

Numerator: Number of patients who received either biomarker or germline testing.
Denominator: Total number of patients diagnosed with CRC.
Calculation: Multiply the result by 100 to obtain the percentage.
Target Value: 80% of patients should receive testing.

Additional Measure

Calculate the proportion of patients who received treatment based on the results of biomarker testing to assess the impact of testing on treatment decisions.

Jack Birren, stage III colon cancer and Lynch syndrome survivor

Denelle Suranski, stage II rectal cancer & Lynch Syndrome survivor

Strategies to Reduce Delays in Diagnosis & Treatment

To reduce delays in diagnosing CRC, implementing a fast-track referral system for patients with pre-defined alarm symptoms can be effective (Gorin, 2019). Additionally, evaluating current processes to eliminate, streamline, or improve steps can help shorten the time between diagnosis and treatment (National Health Service Advancing Change Team, 2014).

Patient-centered approaches are also critical. Educating patients about the importance of timely interventions, involving them in decision-making, and fostering trust between patients and healthcare providers can enhance care and promote health equity (Greenberg et al., 2023).

Reducing the time from diagnosis to treatment initiation is essential for improving CRC outcomes. Delays can lead to disease progression and worse prognoses, highlighting the importance of strategies that address both systemic and patient-related barriers. By effectively managing these delays, healthcare providers can ensure timely care, optimize resources, and improve the overall quality of patient outcomes.

HOW TO MEASURE PERFORMANCE AGAINST GOAL 2, TARGET 2.3: AN EXAMPLE

This guide provides a clear framework for tracking and assessing this critical performance metric, helping healthcare providers continuously enhance their CRC care delivery.
To evaluate progress towards initiating treatment within six weeks of a colorectal cancer (CRC) diagnosis, use the following steps:

STEP 1: IDENTIFY ELIGIBLE PATIENTS

Determine CRC Diagnosis and Date

- Review records of provider interactions, such as colonoscopy outcomes and department referrals following a diagnosis.
- Analyze claims databases for diagnosis-related codes (details in Appendix 2.1).

STEP 2: IDENTIFY PATIENTS WHO HAVE STARTED TREATMENT

Determine Treatment Commencement and Date

- Review records of treatment appointments, notifications, and bookings.
- Assess claims databases for codes related to CRC treatment (details in Appendix 2.3).

STEP 3: CALCULATE NUMBER OF PATIENTS STARTING TREATMENT WITHIN 6 WEEKS

Identify Patients Meeting the Target

Calculate the number of patients whose treatment began within 6 weeks of their diagnosis date.

STEP 4: MEASURE TARGET PROGRESS

Calculate the Percentage of Patients Initiating Treatment Within 6 Weeks

Numerator: Number of patients who started treatment within 6 weeks of diagnosis.
Denominator: Total number of patients diagnosed with CRC.
Calculation: Divide the numerator by the denominator, then multiply by 100 to get the percentage.

Target Value: The goal is for 80% of patients to begin treatment within 6 weeks.

This method provides a clear framework for tracking treatment initiation timelines and ensures that performance against Target 2.3 can be effectively measured and improved.

GOAL 2 Accurate, Informative Diagnosis & Timely Treatment Initiation

IMPLEMENTATION STRATEGY FOR REDUCING TIME TO TREATMENT INITIATION

1. Identify and Address Care Bottlenecks

Assess Diagnosis and Treatment Journeys: Determine where patients experience the longest waits.

Example: Are delays occurring because radiology departments are over capacity?

Investigate if this is due to a lack of equipment or insufficient staffing.

Explore ways to streamline processes to increase capacity.

Consider retraining staff to redistribute workload and improve efficiency.

2. Identify and Address Care Inefficiencies

Reduce Unnecessary Appointments: Consolidate testing into a single visit, reduce follow-up visits, and eliminate unnecessary procedures and tests.

Eliminate Hidden Delays: Identify process inefficiencies, such as test results only being reviewed once or twice a week, or patient referrals being scheduled infrequently.

Plan Ahead: Coordinate care by scheduling staff and equipment in advance to reduce waiting times.

3. Minimize Patient-Related Delays

Educate Patients: Provide clear information about the necessity, expectations, and outcomes of procedures and treatments.

Reduce Missed Appointments: Use timely reminders to ensure patients attend their appointments.

Identify Patient Barriers: Recognize specific obstacles that patients face, such as transportation issues in rural areas, and seek funding to develop solutions like a patient transportation program.

4. Monitor and Track Progress

Continuously monitor improvements and adjust strategies as needed. (See "How to Measure Performance Against Goal 2 Target 2.3: An Example" on page 46.)

To effectively reduce delays in colorectal cancer care, it's crucial to measure our progress against specific targets. One of the most important factors in improving patient outcomes is ensuring that treatment begins promptly after diagnosis. Starting treatment within a short timeframe can greatly impact survival rates and the overall quality of care. (Gorin, 2019; Levit et al., 2020; National Health Service Advancing Change Team, 2014; Zarcos-Pedrinaci et al., 2017).

Mike Mancini, stage IV fighter

LEFT TO RIGHT *Diego Davis-Olegario, stage III colorectal cancer survivor, Traci Bryan, caregiver, Johanna Poremba, stage II colorectal cancer survivor, Patrick Moote, stage III colorectal cancer survivor*

Conclusion: Turning Data into Action

While meaningful progress has been made, CRC remains a major public health concern in the U.S. and globally (Siegel et al., 2024). Screening, early diagnosis, and more effective treatments have all played a crucial role in reducing CRC incidence and mortality (Shaukat and Levin, 2022; Siegel et al., 2023). This has been the result of a collective effort from across the CRC community. This report builds on those efforts and provides a unified framework that connects policymakers, advocacy groups, healthcare providers, health systems, industry partners, and data scientists around common goals and metrics. It identifies key gaps in CRC care and offers strategies to address these gaps and measure improvements.

By uniting around these measures, we can help enhance CRC management and promote equitable and improved outcomes across the entire care continuum.

We encourage all partners committed to improving patient outcomes and strengthening our health systems to join us in this effort. By tracking and assessing progress against the targets set in this report, we aim to drive continuous improvement in CRC care across the U.S. healthcare system.

Through collaborative efforts in systematic monitoring and data collection, we can turn these insights into practical strategies that improve care delivery and patient health.

Together, we can enhance the quality of care and ultimately reduce the burden of CRC nationwide.

Join Us in the Fight!

MORE_____TIME!

"Every day I wake up, I say, what am I gonna do today to make a difference? What am I going to do to reach the goals I've always wanted to reach but maybe have not tried because there was no motivation behind me?"

IN LOVING MEMORY
MICHAEL STERN
STAGE IV COLON CANCER FIGHTER

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