American Cancer Society | NATIONAL COLORECTAL CANCER ROUNDTABLE | 80% IN EVERY COMMUNITY

# STEPS For Increasing Colorectal Cancer Screening Rates

## A Manual for Primary Care Practices

# ACKNOWLEDGMENTS

The National Colorectal Cancer Roundtable (NCCRT) would like to thank the following people who generously offered their time and expertise to the development of this updated second edition to the first edition of the NCCRT's Steps for Increasing Colorectal Cancer Screening Rates: A Manual for Community Health Centers that was originally published in 2014. This edition has been expanded to include all primary care settings and updated to reflect current guidelines, new screening modalities, and updated literature references. The first edition was one of the most popular resources downloaded from the NCCRT website (**www.nccrt.org**) and has been instrumental in helping primary care practices throughout the United States achieve improvements in their colorectal cancer screening rates.

NCCRT is grateful to **HealthEfficient** for serving as the lead author on this second edition.

## First Edition Authors:

- Maria Syl D. de la Cruz, MD
- Mona Sarfaty, MD, MPH

## First Edition Contributing Editors:

- Durado Brooks, MD, MPH
- Mary Doroshenk, MA
- Richard Wender, MD

## Second Edition Contributing Editors:

- Michelle Tropper, MPH
- Stephanie Rose, CCE
- Emily Butler Bell, MPH
- Caleb Levell, MA
- Laura Makaroff, DO
- Aubree Thelen, MPH
- Kaitlin Sylvester, MPA

## Second Edition Reviewers/Contributors:

- Robby Amin, MD
- Debra Barnhart
- Rachel Benatar
- Durado Brooks, MD, MPH
- Frank Colangelo, MD, MS-HQS
- Amanda DeCrew
- Chastity Dolbec, RN
- Heidi Emerson
- Katleen Felezzola, RN
- Magdalene Godena
- Marquita Iddirisu, MPH
- Ugo Iroku, MD, MHS
- Jessica Jamison, MPH
- Rita Knause, MD
- Suzanne LaGarde, MD
- Karin Leschly, MD
- Benjamin Oldfield, MD
- Kathy Orchen, PA, MPH, MS
- Nishie Perez, MA, BSN, RN
- Rina Ramirez, MD
- Joseph Ravenell, MD
- James Rogers, MD
- Michael Serlin, MD
- Swathi Sudha Suresha
- Christopher Utman, PhD
- Pascale White, MD
- Stacey Will, MSB, BSN, RN
- Keith Winfrey, MD, MPH, FACP
- Trudy Wright, BSN, RN, CLSSGB

## Second Edition Advisory Committee

- Lynn Basilio, MS
- Lynn Butterly, MD
- Gloria Coronado, PhD
- Neeraj Deshpande, MBBS, MPH, MHA
- Andrea Garcia, JD, MPH
- Beth Graham, MPH
- James Hotz, MD
- Djenaba Joseph, MD, MPH
- Cheryl Modica, PhD, MPH, BSN
- Michael Potter, MD
- Catherine Rohweder, DrPH
- Laura Scott, MBA
- Kaitlin Sylvester, MPA

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# INTRODUCTION

## How Can This Manual Help Primary Care Practices Improve Screening Rates?

The goal of this manual is to offer evidence-based, expert-endorsed recommendations for planning and implementing strategies in primary care practices to improve colorectal cancer (CRC) screening rates. This manual provides a succinct step-by-step guide for primary care teams to improve CRC screening and outcomes in practice. These simple steps will assist teams to effectively:

- Agree on and implement an office screening strategy
- Provide education on appropriate and high-quality screening
- Help patients to complete timely, recommended screening
- Track follow-up of screening and results
- Build networks among primary care, specialty care, and health systems
- Provide examples of workflows from successful programs

**Since screening recommendations originate in primary care, these settings offer the greatest opportunity to achieve the NCCRT's goal to increase CRC screening rates to 80% in every community.**

## Instructions for Using This Manual

This manual offers practical advice for implementing expert-endorsed processes for improving CRC screening and follow-up care – one step at a time. It is organized into four primary sections:

1. **A Background section that provides information on the importance of CRC screening**
2. **A Steps for Increasing Colorectal Cancer Screening Rates section that maps out a plan for improving your CRC screening rates and gives step-by-step instructions for doing so**
3. **Ten case studies from exemplary and diverse practices from across the country**
4. **An Appendices section that provides field-tested tools, templates, and resources to get you started**

We suggest that you use the manual by focusing only on the topic pages that you need at any particular time. Be sure to also make use of the appendices, which have several templates, tools, and resources to save you time.

**Document Navigation Tip** » If you use the jump (live) links throughout the manual, you can return to your original position by pressing "**Alt+Left Arrow**" on a PC or "**Command+Left Arrow**" on a Mac.

# BACKGROUND

**The NCCRT acts as a catalyst to stimulate work on key issues around colorectal cancer.**

**About the National Colorectal Cancer Roundtable**

The National Colorectal Cancer Roundtable (NCCRT), established by the American Cancer Society, in partnership with the Centers for Disease Control and Prevention, in 1997, is a national coalition of more than 200 membership organizations. NCCRT members include public organizations, private organizations, voluntary organizations, and invited individuals, each dedicated to reducing the incidence of and mortality from colorectal cancer (CRC) in the U.S., through coordinated leadership, strategic planning, and advocacy. Visit the NCCRT website, **www.nccrt.org**, to learn more.

## 80% in Every Community

80% in Every Community is an NCCRT initiative in which more than 1,800 organizations are working toward the shared goal of reaching colorectal cancer (CRC) screening rates of 80% and higher in communities across the nation. Through dedication, determination, and collective action, we are seeing community health centers, other primary care practices, health systems, health plans, employers, counties, and many others achieving CRC screening rates of 80% and higher.

**But not everyone is benefiting equally.** There are still too many communities with low CRC screening rates – certain racial and ethnic communities and low-income communities, among others. We will continue working to bring down barriers to screening because everyone deserves to live a life free from colorectal cancer. Our mission isn't achieved until we achieve 80% screening rates in every community. Visit **nccrt.org/80-in-every-community** to learn more.

## Evidence-Based Recommendations for Colorectal Cancer Screening

**Major Guidelines Now Recommend Colorectal Cancer Screening Starting at Age 45**

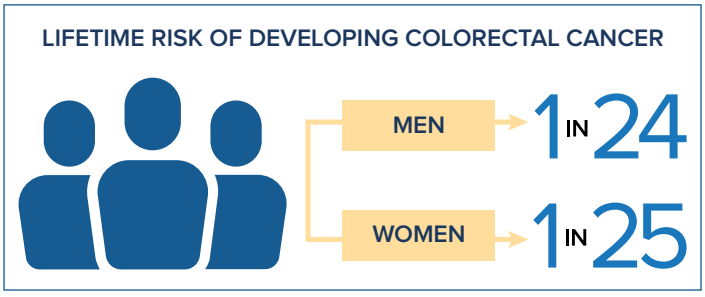
The American Cancer Society and the United States Preventive Services Task Force (USPSTF) recommend that CRC screening begins at age 45 for both men and women at average risk, a change from the previous recommendation to begin screening at age 50. Universal coverage of CRC screening at age 45 will not be fully required of all health plans until 2023. However, many plans are already covering screening at age 45 in 2022. Learn more about the change to recommend screening at age 45 and the implementation timeline for different types of health plans in **NCCRT's June 7, 2021 webinar**. Information about changes to national performance measures to begin capturing screening rate data for ages 45-49 can be found on **page 17**.

# Why Focus on Colorectal Cancer Screening?

> **"Colorectal cancer is often considered the most preventable, yet least prevented, cancer."**
>
> **– Steven H. Itzkowitz, MD, NCCRT Chair[1]**

Excluding skin cancers, colorectal cancer (CRC) is the third most commonly diagnosed cancer in the United States. CRC is the third leading cause of cancer-related deaths in men and in women, and the second most common cause of cancer deaths when numbers for men and women are combined.

Overall, the lifetime risk of developing colorectal cancer is about 1 in 24 (4.2%) for men and 1 in 25 (4.0%) for women. In 2022, an estimated 151,030 people will be diagnosed with CRC in the United States, and 52,580 people are expected to die from the disease.[2]




## Screening for colorectal cancer can save lives.

Because CRC usually begins as a small growth known as a polyp, some of which can develop slowly into cancer over a period of 10 to 20 years, regular screening is an important opportunity for both prevention (removing the polyps) and early detection (finding the cancer early if there is one).[3]

Based on a Veterans Affairs (VA) national study published in 2018, there was an estimated 61% lower risk of death from CRC in patients who underwent colonoscopy screening.[4] In the Kaiser healthcare system, initiation of organized CRC screening (annual fecal immunochemical testing and colonoscopy) increased the up-to-date status of screening, from 38.9% in 2000 to 82.7% in 2015, and was associated with a 25.5% reduction in annual CRC incidence and a 52.4% reduction in cancer mortality.[5]

## Screening for colorectal cancer costs less than cancer treatment.

Cancer treatment, especially the treatment of advanced cancer, is associated with significant increases in health care costs. In a 2018 Medicare study, the average annual treatment cost per patient with a primary diagnosis of CRC increased according to disease stage at diagnosis – from early diagnosis in stage I ($32,000), increasing with stage II ($45,000), and peaking with stage IV at diagnosis ($64,000). Mean spending for the terminal year across all stages peaked at $74,000.[6] In contrast, based on findings from the CDC's Colorectal Cancer Control Program published in 2019, the average screening test costs are $2,060 per person, ranging from $1,057 for both a stool-based test and colonoscopy (if follow up is needed) to $3,153 for colonoscopy alone. All components were, on average, the most expensive for colonoscopy programs.[7] A systematic review of CRC screening in 2020 showed that all CRC screening techniques are more cost-effective than not screening.[8]

# Early Age Onset Colorectal Cancer

## Half of new diagnoses are now in people 66 and younger

Research now indicates the burden of colorectal cancer is swiftly shifting to younger individuals as incidence increases in young adults and declines in older age groups. An estimated 18,000 cases of CRC (12%) were diagnosed in people under 50 in 2020, with 1 in 4 patients younger than 50 diagnosed with metastatic disease.

Ensure your patients take advantage of potentially life-saving screening as soon as they become eligible – at 45 for people at average risk or earlier for people at increased or high risk of the disease. People of any age with symptoms should undergo an appropriate diagnostic workup.[9]

## Colorectal cancer screening disparities persist

In 2020, 72.1% of adults in the United States were up to date with CRC screening, but disparities persist. For example, screening prevalence was 16.1 percentage points lower among those aged 50-64 years (66.4%) than among those aged 65-75 years (82.5%). In 2020, screening was lowest among American Indian/Alaska Native people (63.1%), Asian American people (64.3%), Hispanic people (64.9%), individuals with less than a high school education (64.4%), individuals with an income below $15,000 per year (66.7%), individuals without insurance (44.1%), and individuals without a regular health provider.[10] In spite of widespread knowledge that Black adults have higher CRC incidence than white adults, Black adults are less likely than white adults to receive a recommendation for CRC screening.[11,12]

> **"The USPSTF recognizes the higher colorectal cancer incidence and mortality in Black adults and strongly encourages clinicians to ensure their Black patients receive recommended colorectal cancer screening, follow-up, and treatment."**
>
> **– United States Preventive Services Task Force Final Recommendation Statement, Colorectal Cancer Screening, May 2021**

In community health centers (health centers), which largely serve underrepresented populations, the national CRC screening rate in 2019 was 45.6%, ranging from 29.3% (Oklahoma) to 64.8% (Delaware).[13] In 2020, the national CRC screening rate was 40.1% amongst health centers.[14] The decline in screening was expected given the myriad of challenges health centers faced and continue to face due to the ongoing COVID-19 pandemic. Notably, despite these challenges, health centers screened 2,448,976 patients in 2020, close to the total number screened in 2018 (2,491,769). In 2021, health centers' national CRC screening rate began to recover to the pre-pandemic rate and increased to 41.9% across all health centers, ranging from 27.1% (Nevada) to 62.0% (Maine), with a total of 2,680,583 patients screened nationally.[15]

The existence of these disparities suggests that health centers have tremendous potential to reduce CRC morbidity and mortality in racially and ethnically diverse, socioeconomically challenged communities across the country.

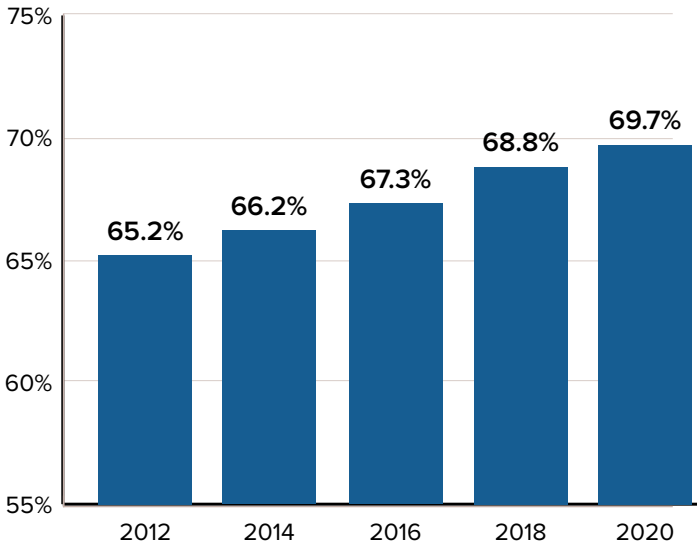
# Colorectal Cancer Screening Rates

NCCRT monitors all available national data to assess our progress in reaching the goal of 80% of adults ages 45 or older screened for colorectal cancer. There are strengths and limitations of each data set.

Note: In the last few years, many major guidelines have changed their colorectal cancer screening recommendations to recommend CRC screening for average-risk adults starting at age 45. However, most screening data sources do not yet include data for adults ages 45-49.

## National Screening Rate – BRFSS

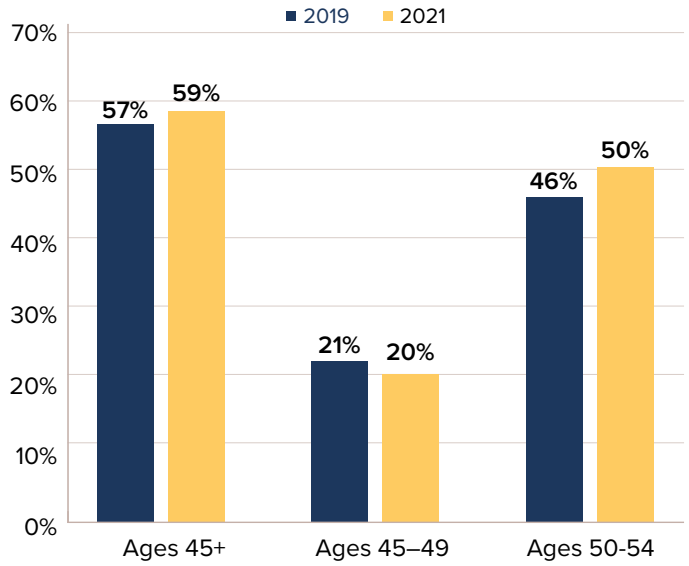
Percentage of U.S. Adults Age 50-75 years Up-to-Date with CRC Screening, Behavioral Risk Factor Surveillance System[16]




The increase in the screening rate between 2012 and 2018 represents an additional 9.3 million adults screened for colorectal cancer.

## National Screening Rate – NHIS

CRC Screening Among Adults Aged 45+ Years, US, 2019-21, National Health Interview Survey[17]

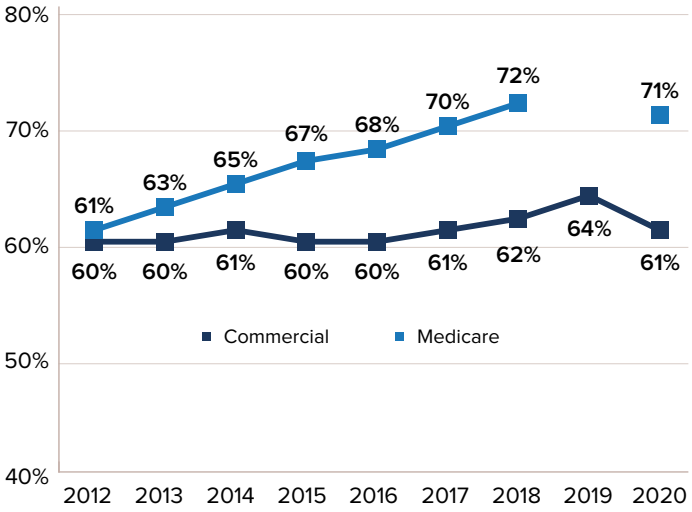



The prevalence of up-to-date screening with any recommended test among individuals aged 45 years and older increased from 57% in 2019 to 59% in 2021. Screening prevalence remains lower in younger screening-eligible age groups, especially among ages 45-49.

Visit the **NCCRT Data & Progress webpage** to find up-to-date statistics on CRC screening, incidence, and mortality.

## Insured Adults – HEDIS

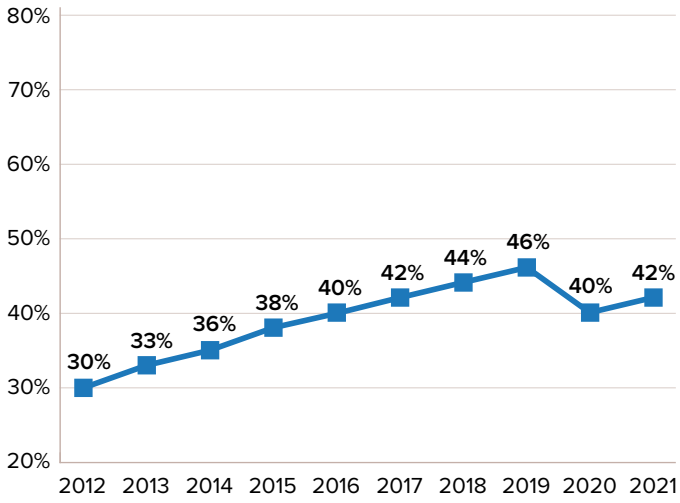
Percentage of U.S. Adults Age 50-75 years Up-to-Date with CRC Screening, Healthcare Effectiveness Data and Information Set.[18]




Screening rate data for Medicare plans is not available for 2019 because in March 2020 the Centers for Medicare & Medicaid Services (CMS) **suspended Medicare quality reporting requirements** in response to COVID-19. Visit the **80% Hall of Fame** to see the list of health plans that have achieved 80%.

## HRSA Uniform Data System (UDS)

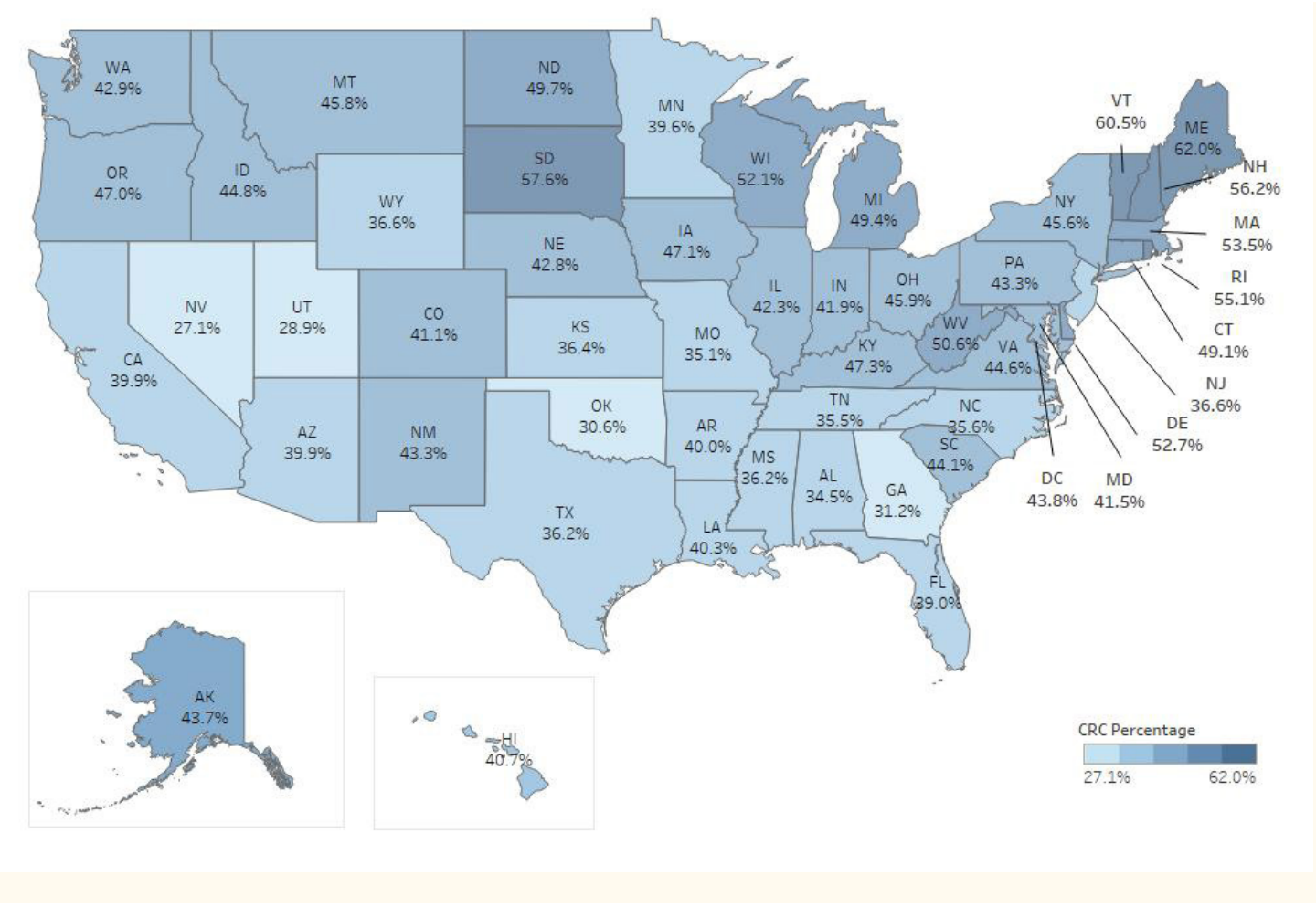
Percentage of HRSA-funded Health Center Patients Ages 50-75 years Up-to-Date with CRC Screening, Uniform Data System.[15]




The UDS CRC screening rate was 41.9% in 2021, which amounts to 2,680,583 patients screened in 2021 alone. In 2021, 21 out of 1,373 health centers reached or exceeded an 80% screening rate, up from 11 in 2020.

A map of 2021 UDS colorectal cancer screening rates in health centers by state follows.

**Figure 1. Colorectal Cancer Screening Rates in Community Health Centers by State, 2021 Data**



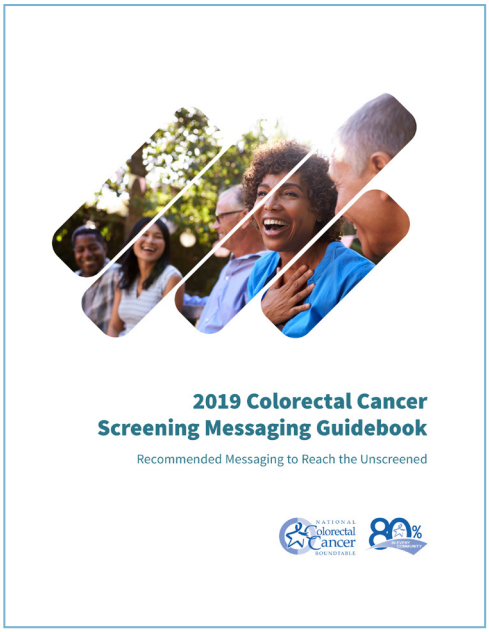

Data Source: UDS data 2021.[15]

Adults 50-75 years of age who received any of the following: FOBT or FIT during the reporting year, mt-sDNA during the reporting period or previous two years, colonoscopy during reporting year or previous nine years, CT colonography during the reporting year or previous four years, or flexible sigmoidoscopy conducted during reporting year or previous four years.

# Additional Sources of CRC Data and Screening Rates

The following sources provide CRC screening, incidence, and mortality rates and data visualizations:

- **Colorectal Cancer Facts & Figures, 2020-2022 (ACS)** – state level screening, incidence, and mortality rates
- **Colorectal Cancer Screening State Profiles (CDC)** – state level screening rates by race/ethnicity, sex, insurance status, and age group
- **United States Cancer Statistics: Data Visualizations** (CDC)
  - **CRC Screening** – state- and county-level estimates
  - **CRC Incidence and Mortality** – state- and county-level estimates
  - **CRC Incidence and Mortality Trends** – state-level trends
- **Cancer Statistics Center (ACS)** – state level screening, incidence, and mortality rates
- **State Cancer Profiles (NCI)** – county level screening, incidence, and mortality rates
- **500 Cities Project (CDC)** – screening rate estimates for 500 major U.S. cities




## Reaching the Unscreened

In 2018, NCCRT and the American Cancer Society conducted market research with screened and unscreened populations to better understand and address screening disparities. The market research was used to produce the **2019 Colorectal Cancer Screening Messaging Guidebook: Recommended Messages to Reach the Unscreened**.

Self-reported barriers to CRC screening include:

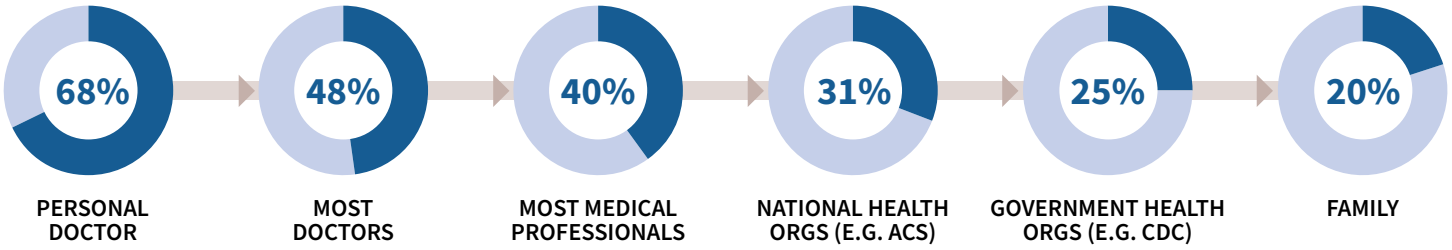
- **Procrastination** – This is the leading barrier to screening across many unscreened groups. Unscreened people may be knowledgeable about CRC screening but tend to prioritize other life demands over the need for screening.
- **Unpleasantness** – Unscreened people often have a basic understanding of CRC screening. But they typically have strong beliefs about the unpleasantness of the test procedure. They describe the test as embarrassing and invasive.
- **Cost** – Unscreened people have a common perception that colorectal cancer screening is not affordable.
- **No Family History** – Many unscreened people believe that colorectal cancer is primarily hereditary. Since they have no symptoms or family history, they feel that the need for screening doesn't apply to them.[19]

The market research found the following message to be the most preferred across a diverse range of demographic profiles:

**A colonoscopy isn't the only option for colorectal cancer screening. There are simple, affordable options, including tests that can be done at home. Talk to your doctor about which option is right for you. Ask which tests are covered by your health insurance.**

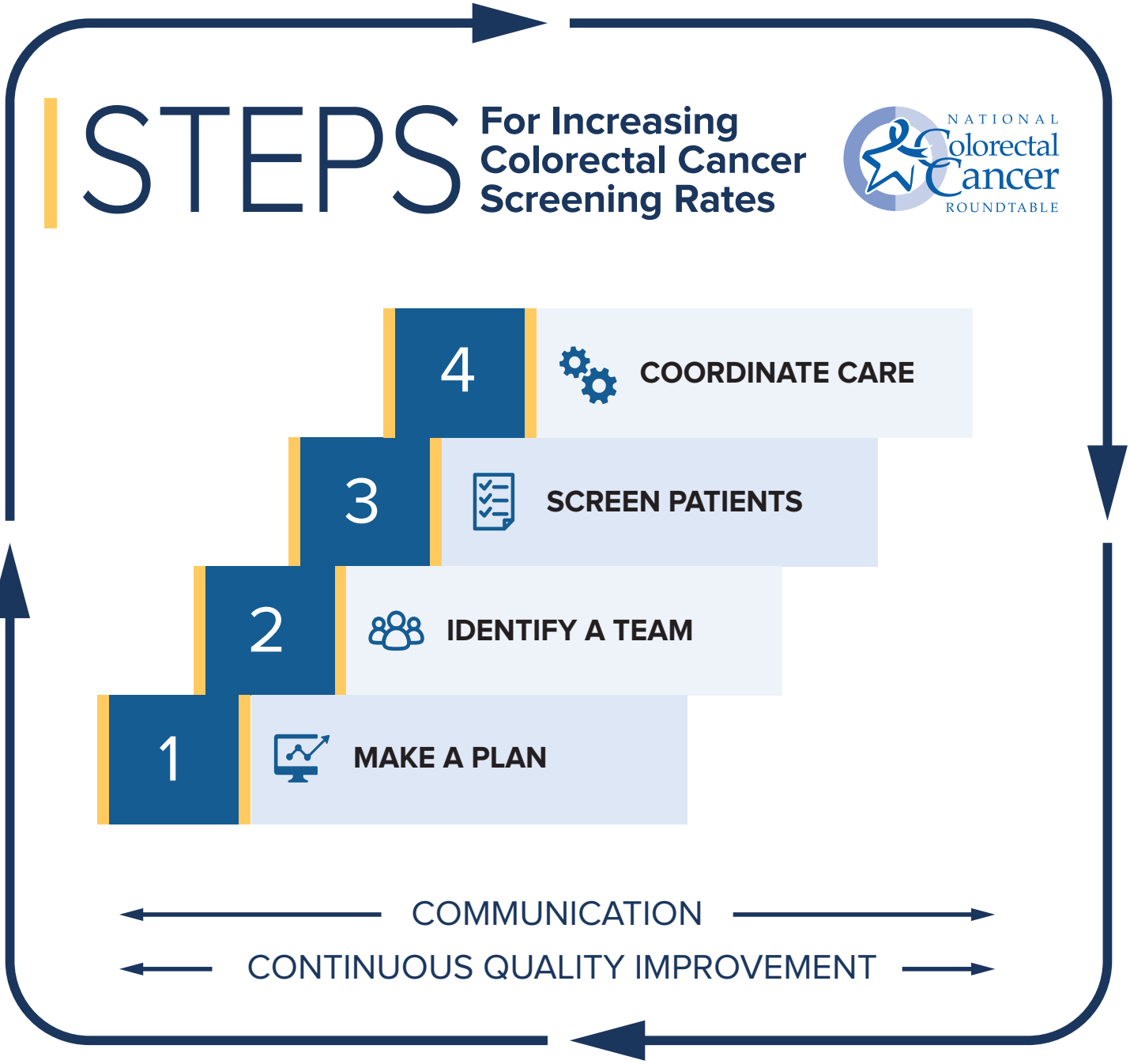
When it comes to delivering CRC screening messages, clinicians are a top source of trusted information. The following graphic shows the percentage of respondents that trusted these six sources for CRC screening information.

## Trusted Messengers




Visit the NCCRT Resource Center to find additional market research-based messaging guidance, including the **2022 NCCRT Messaging Guidebook for Black & African American People: Messages to Motivate for Colorectal Cancer Screening**, **Hispanics/Latinos and Colorectal Cancer Companion Guide**, and **Asian Americans and Colorectal Cancer Companion Guide**, which include tested messages in Spanish and several Asian languages. Partners can use the NCCRT's market research and the recommended messaging provided to strengthen communications campaigns and create resources that resonate with target audiences by using personal creativity, innovation, and spokespersons.

To find evidence-based interventions (EBIs) to improve communications about CRC screening, in addition to the numerous resources found in this guide, details of additional EBIs to mitigate communications barriers can be found in the CDC's Community Guide[20] and National Cancer Institute's (NCI) **Evidence-Based Cancer Control Programs** (EBCCP). This Steps Guide provides practical approaches and guidance for primary care practices to apply these EBIs in practice as part of a comprehensive approach to increase CRC screening.


STEPS
For Increasing Colorectal Cancer Screening Rates
NATIONAL Colorectal Cancer ROUNDTABLE
4
COORDINATE CARE
3
SCREEN PATIENTS
2
IDENTIFY A TEAM
1
MAKE A PLAN
COMMUNICATION
CONTINUOUS QUALITY IMPROVEMENT

# OVERVIEW OF THE SCREENING PROCESS

## STEP 1 MAKE A PLAN

### Determine Baseline Screening Rates

- Identify your patients due for screening.
- Identify patients who received screening.
- Improve the accuracy of the baseline screening rate.

### Design Your Practice's Screening Strategy

- Assess the readiness of your practice to implement changes.
- Choose a screening method.
- Understand the importance of offering screening test options.
- Understand insurance complexities.
- Calculate need for colonoscopy.
- Consider a direct endoscopy referral system.

## STEP 2 IDENTIFY A TEAM

### Form an Internal Leadership Team Within the Practice

- Select an internal champion.
- Define roles of internal champions.
- Utilize patient navigators.
- Define roles of patient navigators.
- Agree on team tasks.

### Partner with Colonoscopists

- Identify a clinical champion.

## STEP 3 SCREEN PATIENTS

### Prepare the Clinic

- Conduct a risk assessment.

### Prepare the Patient

- Provide patient education materials.
- Order the screening test.
- Consider mailed stool-based testing.

### Make a Recommendation

- Empower reluctant patients to get screened.

### Ensure Quality Screening for a Stool-based Screening Program

### Track Return Rates and Follow-up

### Measure and Improve Performance

- Celebrate success.

## STEP 4 COORDINATE CARE

### Coordinate Follow-up After a Colonoscopy

- Establish a medical neighborhood.

4 COORDINATE CARE

3 SCREEN PATIENTS

2 IDENTIFY A TEAM

1 **MAKE A PLAN**

# STEP #1: MAKE A PLAN

"The best screening test is the one that gets done well."

– Sidney J. Winawer, MD, DrSc, principal investigator of the National Polyp Study, the sentinel study that demonstrated adenoma removal reduces CRC risk

## Determine Baseline Screening Rates

The first step involves calculating the baseline screening rate for the organization. This is critical to measuring practice improvement at the end of the implementation process. This requires the following steps:

**Identify patients who are due for screening** → **Identify patients who have received screening** → **Validate and improve the accuracy of the data** → **Calculate the screening rate**

### Identify Your Patients Due for Screening

An important step involves identifying the active, current patients who are eligible for screening based on the performance measures' criteria. For example, a practice may consider a patient active if they have been seen in the past one or two years.

Providing individual clinician or practice-wide reports on clinical quality measures to clinicians and practice staff is a core competency in the Patient Centered Medical Home (PCMH) model and is crucial for holding the practice and providers accountable for performance. Electronic Health Records (EHRs) provide the ability to document the primary care provider (PCP) selected by the patient during patient registration or between visits.[22] This makes the process of generating reports by PCP panel easier.

## Performance Measure Alignment

The Centers for Medicare & Medicaid Services (CMS) maintains an Electronic Clinical Quality Improvement (eCQI) Resource Center website that includes performance measure specifications across care settings. The measure steward for the colorectal cancer (CRC) screening measure is the **National Committee for Quality Assurance (NCQA)**. The **Health Resources Services Administration (HRSA) Uniform Data Set (UDS)** is used to assess federally-qualified health center (FQHC) performance aligned to the **same electronic clinical quality measure (eCQM)** that's used to assess the performance of non-FQHC practices. Regardless of what measure is being used, one of the keys to identifying patients due for screening is understanding the criteria used for defining the denominator.

The **2022 UDS measure** and the **eCQI Measure 130 v. 10** for CRC screening require identifying **patients 50-75 years** of age with a visit during the measurement period. According to HRSA, patients who have had at least one documented in-person or virtual visit with a clinician during the calendar year should be counted as active patients.[21] According to CMS, the 2023 eCQI Measure 130 v. 11 will require identifying patients starting at age 45.[22]

HEDIS (Healthcare Effectiveness Data and Information Set), which is a performance improvement tool published by the NCQA, serves as performance indicators for many commercial and Medicare plans. The **2022 HEDIS CRC screening measure** will begin to measure CRC screening among **patients 45-75 years of age** in measurement year (MY) 2022 to reflect the 2021 USPSTF guideline. The Medicaid product line has also been added for reporting in MY 2022.[23]

Providing individual clinician or practice-wide reports on clinical quality measures to clinicians and practice staff is a core competency in the Patient Centered Medical Home (PCMH) model and is crucial for holding the practice and clinicians accountable for performance. Electronic Health Records (EHRs) provide the ability to document the primary care clinician selected by the patient during patient registration or between visits.[22] This makes the process of generating reports by primary care clinician panel easier.

### Identify Patients Who Have Received Screening

Several performance measures exist to monitor colorectal cancer (CRC) screening rates within health systems and practices. **Appendix A-1** includes a table providing a comprehensive overview of these measures.[25] **Appendix A-2** includes information for health centers on how to calculate CRC screening rates using HRSA's UDS specifications.

The USPSTF CRC screening guidelines were updated in May 2021, lowering the starting age for CRC screening in average-risk individuals from age 50 to age 45. NCQA expanded the HEDIS measure to include the 45- to 49-year-old age group beginning in the measurement year 2022. The eCQM for 2023 indicates that it will change the eligible population age to match the updated USPSTF recommendations.

The following diagnosis and billing codes (ICD and CPT codes) can be useful in identifying the patients who meet the criteria for having received CRC screening:

- ICD-9-CM: 45.22, 45.25, 45.42-45.43, V76.51
- ICD-10: Z12.10, Z12.11, Z12.12 R19.5
- CPT- 45330-45345, 44388-44397, 45355-45392, 81528, 82270, 82274, G0104, G0105, G0106, G0107, G0120, G0121, G0328, G0464

Although ICD-9 codes were transitioned to ICD-10 codes in 2015, there are still likely patients in the practices who had colonoscopies within the last ten years that would have had ICD-9 codes associated with the test.

## Improve the Accuracy of the Baseline Screening Rate

Even after incorporating all of this data, there will be patients who have received CRC screening who are missing documentation. Some strategies to address this issue include:

- **Appropriate Documentation** – Develop written procedures on how to appropriately document CRC screenings and exclusion criteria in the EHR following best practice guidelines for the analytics/reporting tool used by the organization. The documentation of the screening should include the date performed, the type of test, and the result. Performance measure specifications **do not allow self-reporting. Evidence of the test must be included in the patient's record.**
- **Prior to the Visit** – Review the patient's chart prior to their visit to review gaps in care, including preventive screenings such as CRC screening.
- **Use Health Information Exchange** – Look for CRC screenings performed outside the practice that may be available through a local Health Information Exchange (HIE) or frameworks such as CareQuality or CommonWell.
- **Care Team Huddle** – Use huddles to review the items needed for the patients being seen for the day and ensure the entire care team knows what screenings and tests are needed for the patient. Several EHRs' integrated data overlay and/or care management platforms offer patient care gap summaries that are extremely valuable for use during team huddles.
- **During the Visit** – Order appropriate screenings needed and make a plan for tests needed before their next appointment jointly with the patient.
- **Clinical Protocols** – Establish a protocol for staff and clinicians to ask patients about prior screening during the patient visit. Potentially add standing orders/referrals for screening.
- **Checklists** – Use a written self-administered preventive care checklist for patients with adequate literacy and appropriate language skills.
- **Alerts/Flags** – Use HIT/EHR clinical decision support to alert clinicians or flag patients who are not up to date with screening so that recommendations and orders can be integrated into the upcoming appointment. Make it easy to order the needed tests to satisfy the alert using order sets.

# Design Your Practice's Screening Strategy

## Assess Readiness of Your Practice to Implement Changes

A number of readiness assessment tools are available to assess current screening processes in the practice, as well as gaps and needs. The results of the assessment can be used to help prioritize whichever step(s) need the most adjustment. Examples of these readiness assessment tools are included in **Appendix A-3** and are also described in Section 2 on identifying a team and documenting current state workflows. The assessment is best conducted with the practice team to gain a full picture of how each member of the staff contributes to or can potentially contribute to improving the screening process.

## Choose a Screening Method

There are multiple screening tests available to screen patients for colorectal cancer. The most effective strategies to improve screening are multi-component and multi-level, addressing barriers at the patient, clinician, and health system levels.[26]

In 2018, the ACS updated its recommendations for colorectal cancer screening to begin screening at age 45 for individuals at average risk of colorectal cancer.[27] In 2021, the USPSTF also updated its recommendations for colorectal cancer screening to align with the starting age of 45 for individuals at average risk of colorectal cancer.[28]

### CRC Screening Test Options
American Cancer Society

**Stool-based tests**

- Highly sensitive fecal immunochemical test (FIT) every year
- Highly sensitive guaiac-based fecal occult blood test (gFOBT) every year
- Multi-targeted stool DNA test (mt-sDNA) every 3 years

**Visual (structural) exams of the colon and rectum**

- Colonoscopy every 10 years
- CT colonography (virtual colonoscopy) every 5 years
- Flexible sigmoidoscopy (FSIG) every 5 years

If a person chooses to be screened with a test other than colonoscopy, any abnormal test result should be followed up with a timely colonoscopy.

Source: American Cancer Society 2018 CRC Screening Guideline: **https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html**

### CRC Screening Test Options
USPSTF

**Stool-based tests**

- High-sensitivity gFOBT every year
- FIT every year
- mt-sDNA every 1 to 3 years

**Visual (structural) exams of the colon and rectum**

- CT colonography every 5 years
- Flexible sigmoidoscopy every 5 years
- Flexible sigmoidoscopy every 10 years + FIT every year
- Colonoscopy screening every 10 years

Positive or abnormal findings identified by non-colonoscopy screening require follow-up colonoscopy for screening benefits to be achieved.

Source: USPSTF 2021 CRC Screening Guideline: **https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening**

## Colorectal Cancer Screening Recommendations

The **American Cancer Society** recommends that people who have no symptoms and are at average risk* of colorectal cancer start regular screening at age 45. This can be done either with a stool-based test or visual (structural) exam (e.g., colonoscopy).

People who are in good health and with a life expectancy of more than 10 years should continue regular colorectal cancer screening through the age of 75.

For people ages 76 through 85, the decision to be screened should be based on a person's preferences, life expectancy, overall health, and prior screening history. This should be a shared decision made after a discussion with your physician.

People over 85 should no longer get colorectal cancer screening.

*For screening, people are average risk if they do **not** have:

- A personal history of colorectal cancer or certain types of polyps
- A family history of colorectal cancer
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- A confirmed or suspected hereditary colorectal cancer syndrome, such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC)
- A personal history of getting radiation to the abdomen (belly) or pelvic area to treat a prior cancer

## Table 1. Characteristics of Recommended Colorectal Cancer Screening Tests

| | Benefits | Performance and Complexity* | Limitations | Test Time Interval |
|---|---|---|---|---|
| **Visual Examinations** | | | | |
| Colonoscopy | ■ Examines entire colon<br>■ Can biopsy and remove polyps<br>■ Can diagnose other diseases<br>■ Required for abnormal results from all other tests | **Performance:** Highest<br>**Complexity:** Highest | ■ Full bowel cleansing<br>■ Can be expensive<br>■ Sedation usually needed, necessitating a chaperone to return home<br>■ Patient may miss a day of work<br>■ Highest risk of bowel tears or infections compared with other tests | 10 years† |
| Computed tomographic colonography (CTC) | ■ Examines entire colon<br>■ Fairly quick<br>■ Few complications<br>■ No sedation needed<br>■ Noninvasive | **Performance:** High (for large polyps)<br>**Complexity:** Intermediate | ■ Full bowel cleansing<br>■ Cannot remove polyps or perform biopsies<br>■ Exposure to low-dose radiation<br>■ Colonoscopy necessary if positive<br>■ Not covered by all insurance plans | 5 years |
| Flexible sigmoidoscopy | ■ Fairly quick<br>■ Few complications<br>■ Minimal bowel preparation<br>■ Does not require sedation or a specialist | **Performance:** High for rectum & lower one-third of the colon<br>**Complexity:** Intermediate | ■ Partial bowel cleansing<br>■ Views only one-third of colon<br>■ Cannot remove large polyps<br>■ Small risk of infection or bowel tear<br>■ Slightly more effective when combined with annual fecal occult blood testing<br>■ Colonoscopy necessary if positive<br>■ Limited availability | 5 years |
| **Stool Tests** (Low-sensitivity stool tests, such as single-sample FOBT done in the doctor's office or toilet bowl tests, are not recommended.) | | | | |
| Fecal immunochemical test (FIT) | ■ No bowel cleansing or sedation<br>■ Performed at home<br>■ Low cost<br>■ Noninvasive | **Performance:** Intermediate for cancer<br>**Complexity:** Low | ■ Requires multiple stool samples<br>■ Will miss most polyps<br>■ May produce false-positive test results<br>■ Slightly more effective when combined with a flexible sigmoidoscopy every five years<br>■ Colonoscopy necessary if positive | Annual |
| High-sensitivity guaiac-based fecal occult blood test (gFOBT) | ■ No bowel cleansing or sedation<br>■ Performed at home<br>■ Low cost<br>■ Noninvasive | **Performance:** Intermediate for cancer<br>**Complexity:** Low | ■ Requires multiple stool samples<br>■ Will miss most polyps<br>■ May produce false-positive test results<br>■ Pre-test dietary limitations<br>■ Slightly more effective when combined with a flexible sigmoidoscopy every five years<br>■ Colonoscopy necessary if positive | Annual |
| Multitargeted stool DNA test (Cologuard®) | ■ No bowel cleansing or sedation<br>■ Performed at home<br>■ Requires only a single stool sample<br>■ Noninvasive | **Performance:** Intermediate for cancer<br>**Complexity:** Low | ■ Will miss most polyps<br>■ More false-positive results than other tests<br>■ Higher cost than gFOBT and FIT<br>■ Colonoscopy necessary if positive | 3 years, per manufacturer's recommendation |

*Complexity involves patient preparation, inconvenience, facilities and equipment needed, and patient discomfort.

†For average-risk individuals, e.g., does not apply to those who have a history of adenoma.

Source: ACS Colorectal Cancer Facts & Figures 2020-2022: **https://www.cancer.org/research/cancer-facts-statistics/colorectal-cancer-facts-figures.html**

## Visual (Structural) Exams of the Colon and Rectum

All three direct visualization screening tests for colorectal cancer visualize the inside of the colon and rectum, although flexible sigmoidoscopy can only visualize the rectum, sigmoid colon, and descending colon, while colonoscopy and CT colonography can generally visualize the entire colon. For colonoscopy and flexible sigmoidoscopy, a camera is used to visualize the inside of the colon, while CT colonography uses X-ray images. **When positive or abnormal results are found on flexible sigmoidoscopy or CT colonography, follow-up with colonoscopy is needed for further evaluation.** Unlike colonoscopy and flexible sigmoidoscopy, CT colonography may reveal extracolonic findings that require additional workup.[29,30]

Although clinical trials have established that flexible sigmoidoscopy is an effective screening method for average-risk patients, flexible sigmoidoscopy is not in frequent use for screening in the United States.[28] In locales where high-quality flexible sigmoidoscopy is available, it can continue to be used by clinicians as long as positive or abnormal screening results are followed up with colonoscopies.[27]

## Stool-based Tests

A high-sensitivity guaiac-based FOBT (HSgFOBT) refers to modern highly sensitive forms of the guaiac stool-based test, such as Hemoccult II Sensa, which detect colorectal cancer at much higher rates than older tests (Hemoccult II, Seroccult). Screening guidelines specify that only high-sensitivity forms of guaiac-based tests (like Hemoccult II Sensa) or FIT should be used for colorectal cancer screening.[31]

The fecal immunochemical test (FIT) uses antibodies against hemoglobin to specifically detect human blood in the stool and is about twice as likely as most gFOBT products to detect both advanced adenomas and cancer. Many individuals prefer FIT over gFOBT because of its convenience, lack of dietary restrictions, and collection of fewer stool samples.[28]

A multitarget stool DNA test (also known as mt-sDNA) combines the FIT test with a test that looks for abnormal/altered sections of DNA in the stool. Cologuard is the only mt-sDNA test currently available in the US. Like all other stool tests, mt-sDNA testing is appropriate only to screen individuals at average risk for CRC. Medicare, most commercial insurers, and the majority of state Medicaid programs cover mt-sDNA testing.[32]

Screening for colorectal cancer can reduce mortality rates only if screening is performed with adequate quality. It is important to emphasize that **in-office stool testing by digital rectal exam is not an appropriate method for screening for colorectal cancer.** An in-office single digital stool test missed 90% of cancers found at subsequent colonoscopy in one study.[32] A high-quality stool-based screening program requires that specimens be collected at home or with a spontaneously-passed stool in the medical home, that the stool-based test be repeated regularly (annually for FIT and high-sensitivity gFOBT and every three years for mt-sDNA), and that all positive or abnormal stool tests results are followed up with colonoscopies.

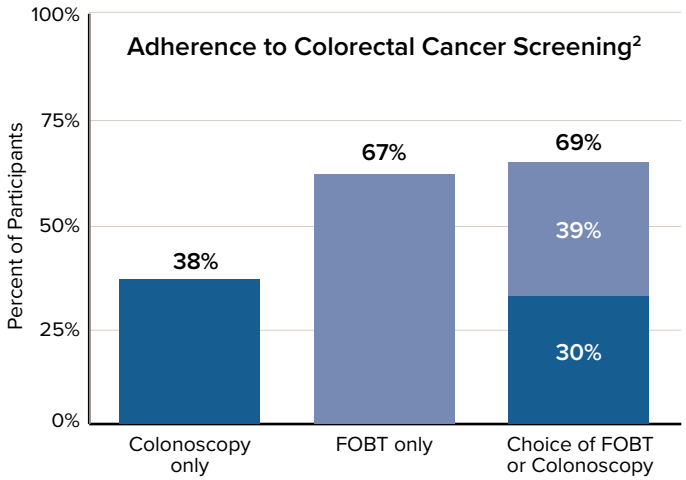
## Understand the Importance of Offering Colorectal Cancer Screening Test Options

Awareness of the benefits of stool-based tests, FIT, high-sensitivity gFOBT, and mt-sDNA testing is needed to set the record straight. In a survey of 180 clinicians, 92% of survey respondents viewed colonoscopy as "highly effective," but most misjudged stool tests, with only 25% assessing FIT as "highly effective" and less than 10% perceiving gFOBT this favorably. In addition, colonoscopy was preferred despite the fact that 51% of clinicians reported colonoscopy was not readily available for their patients, and 82% felt that many of their patients had financial barriers to screening with colonoscopy.[33]

As highlighted in this manual, achieving target screening rates will require the use of both colonoscopy screening and a stool-based strategy. Many patients prefer a less invasive test; using FIT, HSgFOBT, or mt-sDNA offers an evidence-based alternative. On the other hand, reaching high screening rates with a stool-based strategy alone is challenging, demanding a very organized approach to the annual recalling of patients and access to timely colonoscopy after a positive or abnormal stool-based test.

**Achieving target screening rates will require the use of both colonoscopy screening and a stool-based strategy.**

One advantage of using colonoscopy as a primary screening method for a population is that screening is required only once every 10 years. Thus, the individuals who are screened in one year don't need to be recalled the next year; this enables a focus on other patients. However, offering only colonoscopy may be problematic. One study in a community health center population found that screening adherence was lower in patients who were offered screening colonoscopy alone compared to those who were offered a stool-based method alone or a choice between the two options (screening status after one year is illustrated in the chart below).[34] In a three-year follow-up study, those participants offered a choice between a stool-based test and colonoscopy, continued to have high adherence to CRC screening.[35]

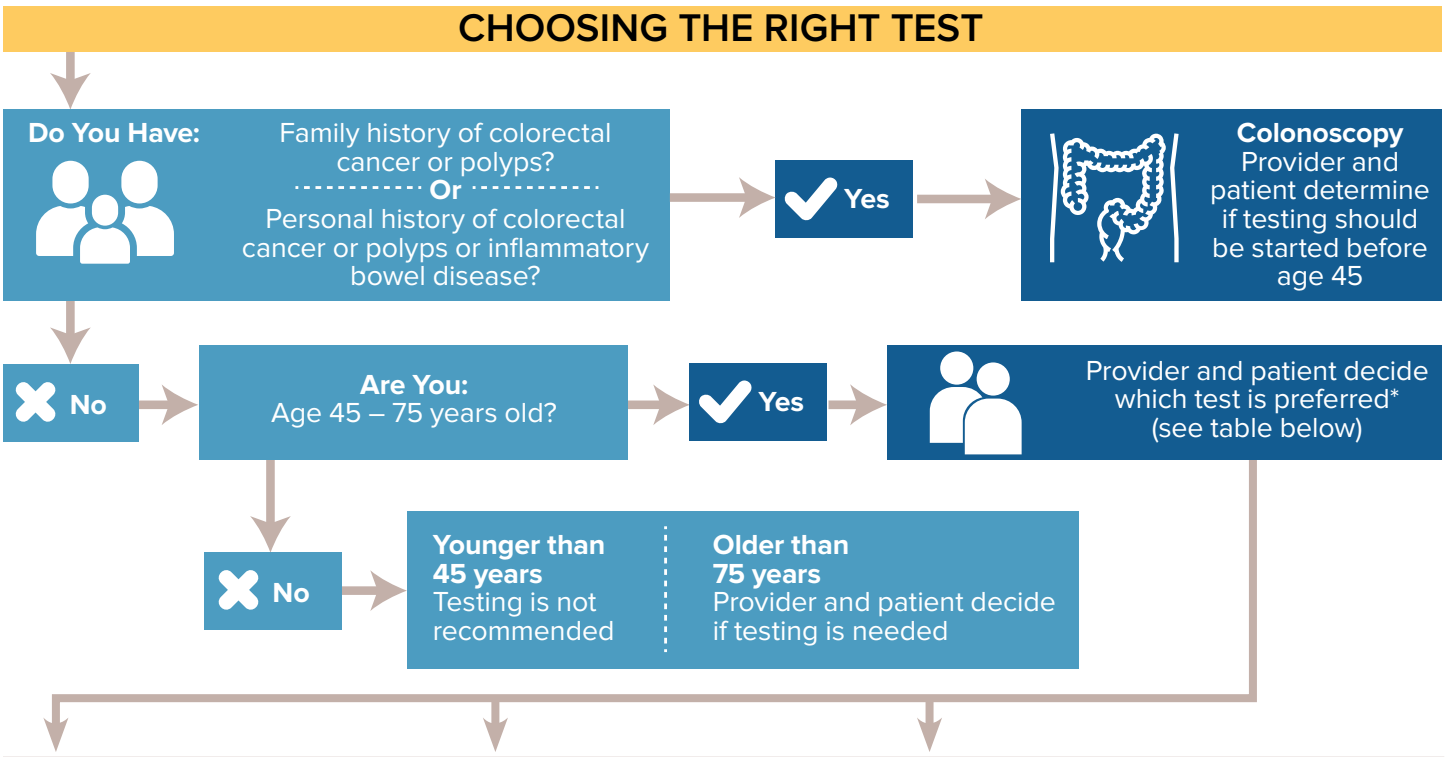



If possible, programs should offer patients options: stool-based testing, screening colonoscopy, or CT colonography. The screening strategy should also consider the characteristics of the patient population, including patient history and risk level, patient preferences (culture, language), insurance status, and local health care resources.

Some organizations may face difficulty in ensuring access to colonoscopy for their patients. These organizations may opt to choose a stool-based test as their primary screening modality. Even if that is the choice, it is critical to remember that colonoscopy will still be needed for patients with positive or abnormal stool-based test results. In fact, patients with positive or abnormal results from CT colonography, high-sensitivity gFOBT, FIT, or mt-sDNA should only be counted as having completed the screening process AFTER a colonoscopy is performed. A summary of the characteristics of each screening method is in Figure 2.

> **"Positive results on stool-based screening tests require follow-up with colonoscopy for the screening benefits to be achieved."**
>
> **– US Preventive Services Task Force. Final Recommendation Statement Colorectal Cancer: Screening. May 18, 2021**

## Figure 2. Choosing the Right Test[36]




| gFOBT/FIT† | mt-sDNA | Colonoscopy |
|---|---|---|
| **Key facts**<br>■ Reduces death from colorectal cancer<br>■ Safe, available, and easy to complete<br>■ Done on your own at home and returned<br>■ Finds most cancers early by finding blood in the stool<br>■ Done annually if negative | **Key facts**<br>■ Reduces death from colorectal cancer<br>■ Safe, available, and easy to complete<br>■ Done on your own at home and returned<br>■ Finds most cancers early by finding blood or altered DNA in the stool<br>■ Done every 3 years if negative | **Key facts**<br>■ Reduces death from colorectal cancer<br>■ Can prevent cancer by removing polyps (or abnormal growths in the colon) during the test<br>■ Examines entire colon<br>■ Finds most cancers or polyps that are present at the time of the test<br>■ Done every 10 years if no polyps are found |
| **Things to consider**<br>■ May produce positive or abnormal test results, even when no polyps or cancer are in the colon<br>■ When the test is positive or abnormal, colonoscopy is required<br>■ The person testing themselves comes into brief close contact with stool samples on a test kit | **Things to consider**<br>■ May produce positive or abnormal test results, even when no polyps or cancer are in the colon or rectum<br>■ When the test is positive or abnormal, colonoscopy is required<br>■ Covered by most insurance companies, including **Medicare**<br>■ Requires an entire bowel movement to be sent to the lab | **Things to consider**<br>■ Stomach pain, gas or bloating is possible before, during or after test<br>■ Must be performed at a hospital or clinic, usually with sedation or anesthesia, and someone must go with the person to take him or her home after the test<br>■ A clear liquid diet is required before test<br>■ Must take medication that will cause loose bowel movements to clean out the colon prior to test<br>■ Likely needs to take a day off work/activities<br>■ Small risk of serious complications (for example, bleeding or perforated colon) |

† High-sensitivity guaiac-based fecal occult blood test (gFOBT) or fecal immunochemical test (FIT)
* Flexible sigmoidoscopy may not be readily available and has largely been replaced by colonoscopy in the US. SOURCE: **American Cancer Society Colorectal Cancer Facts & Figures 2020-2022** and **USPSTF**.
+ FOBT should be high-sensitivity gFOBT, such as Hemoccult Sensa.

Performance characteristics of different types of stool-based tests are summarized in the tables below, which show that high-sensitivity gFOBT, FIT and mt-sDNA are all more sensitive and specific than older guaiac-based FOBT.[31]

### Figure 3. Performance Characteristics of Stool Tests[31]

**Three types of stool tests are available – FIT, guaiac-based FOBT and mt-sDNA**

**Fecal Immunochemical Tests (FITs)** look for hidden blood in the stool and are specific for human blood while older guaiac-based tests (gFOBTs) are not. Unlike gFOBT, FIT results are not impacted by food or medication. There is evidence that patient adherence with FIT may be higher than with gFOBT possibly because no dietary and medication restrictions are required before collecting samples, or because some brands of FIT require collection of only 1 or 2 specimens for a completed test. It is important to note that not all FITs are equally effective. As of July 2016, there are 26 FDA-cleared FITs available for purchase in the US, however, most do not have published data on their performance for detection of cancer. To assist with choosing a FIT for use in your setting, the table below includes FITs that have published data on sensitivity and specificity for cancer.

| FIT Brand Name | Manufacturer | Sensitivity for Cancer †‡ | Specificity for Cancer †‡ | Number of Stool Samples |
|---|---|---|---|---|
| **Automated (non-CLIA waived) FITs** | | | | |
| OC Auto-FIT* | Polymedco | 65% - 92.3%[37,38] | 87.2% - 95.5%[37,38] | 1 |
| **CLIA-waived FITs** | | | | |
| OC-Light iFOB Test (OC Light S FIT) | Polymedco | 78.6%-97.0%[39,40] | 88.0%-92.8%[39,40] | 1 |
| QuickVue iFOB | Quidel | 91.9%[39] | 74.9%[39] | 1 |
| Hemosure One-Step iFOB Test | Hemosure, Inc. | 54.5%[37] | 90.5%[37] | 1 or 2 |
| InSure FIT | Clinical Genomics | 75.0%[40] | 96.6%[40] | 2 |
| Hemoccult-ICT | Beckman Coulter | 23.2%-81.8%[37] | 95.8%-96.9%[37] | 2 or 3 |

*Used with OC-Sensor DIANA and OC-Auto Micro 80 automated analyzers.
†Detection limits for cancer vary across FIT brand and by study such that direct comparison between FIT brands is not possible.
‡Cited studies should be interpreted in the full context of the published literature given variation in study size and quality.

**Guaiac-based FOBTs (gFOBTs)** have been the most common form of stool tests used in the US prior to FIT becoming widely available. Modern high-sensitivity tests have much higher cancer and adenoma detection rates than older tests, resulting in fewer missed cancers. Hemoccult II SENSA is the only test in this category for which published performance data is available. Screening guidelines now specify that only high-sensitivity forms of guaiac-based tests should be used for colorectal cancer screening. **Hemoccult II and similar older guaiac-based tests should not be used for colorectal cancer screening.**

| gFOBT Brand Name | Manufacturer | Sensitivity for Cancer | Specificity for Cancer | Number of Stool Samples |
|---|---|---|---|---|
| Hemoccult II SENSA | Beckman Coulter | 61.5%-79.4%[38] | 86.7%-96.4%[38] | 3 |

**mt-sDNA** is a stool test that looks for altered DNA biomarkers that are released into the stool as cells from colorectal cancer and adenomas degenerate. Mt-sDNA tests for the presence of 10 DNA biomarkers plus hemoglobin in the stool sample. Cologuard is the only stool DNA test currently marketed in the US.

| mt-sDNA Brand Name | Manufacturer | Sensitivity for Cancer | Specificity for Cancer | Number of Stool Samples |
|---|---|---|---|---|
| Cologuard | Exact Sciences | 92.3%[41] | 89.8%[41] | 1 |

Source: NCCRT Clinician's Reference: Stool-Based Tests For Colorectal Cancer Screening: **https://nccrt.org/resource/fobt-clinicians-reference-resource/**

## Understand Insurance Complexities

Although great progress in insurance coverage for colorectal cancer screening has occurred in the past few years, organizations need to help patients understand and navigate through the coverage complexities.

The Patient Protection and Affordable Care Act (ACA) requires private health insurers to cover recommended preventive services without any patient cost-sharing, such as co-pays and deductibles. Colorectal cancer screening is one of these covered benefits.

The ACA requires non-grandfathered plans to cover services with an "A" or "B" recommendation from the United States Preventive Services Task Force to be covered free of cost sharing. This includes the following screening tests for average-risk patients ages 45 to 75 who are not having symptoms of colorectal cancer:

- High-sensitivity gFOBT or FIT every year
- mt-sDNA every 1 to 3 years
- CT colonography every 5 years
- Flexible sigmoidoscopy every 5 years
- Flexible sigmoidoscopy every 10 years + FIT every year
- Colonoscopy screening every 10 years

Note that federal regulations have specified that non-grandfathered private plans offer colonoscopy free of cost-sharing even when a polyp is discovered and that anesthesia services are offered free of cost sharing if the attending clinician deems it to be medically appropriate. In addition, as of May 31, 2022, non-grandfathered private plans and Medicaid expansion plans must cover follow-up colonoscopies with no cost sharing after a positive or abnormal non-invasive stool test. Coverage for patients with symptoms or for diagnostic testing may be subject to co-pays and deductibles.

The American Cancer Society, the American Cancer Society Cancer Action Network (ACS CAN), gastroenterology societies, the NCCRT, and other advocacy organizations worked for nearly a decade to remove the Medicare coinsurance and copayment when a polyp is removed during the colonoscopy.[43,44] In December 2020, the US House of Representatives unanimously passed the *Removing Barriers to Colorectal Cancer Screening Act*, commonly referred to as the "Medicare Loophole" bill. The bipartisan legislation phases out surprise out-of-pocket expenses that can act as a barrier to lifesaving CRC screenings for Medicare beneficiaries starting in 2023.[45]

Colonoscopies that are performed to evaluate specific symptoms, such as intestinal bleeding or anemia, are not typically classified by private insurers and Medicare as screening procedures and, therefore, may not be eligible for waiver of deductible and copay requirements. See Table 2 for an overview of when cost sharing may apply for CRC screening.[42]

## Table 2. Overview of Colorectal Cancer Screening Cost Sharing

| | Colorectal cancer screening – no polyp discovered | Colonoscopy screening when a polyp is discovered | Colonoscopy following a positive or abnormal stool-based test |
|---|---|---|---|
| **ACA-compliant non-grandfathered private plans** | Covered by federal law; free of cost-sharing | Covered by federal law; free of cost-sharing | Covered by federal law; free of cost-sharing** |
| **Grandfathered private plans** | Not required by federal law, but could be required by state law; cost-sharing requirements vary | Not required by federal law – cost-sharing may apply | Not required by federal law – cost-sharing may apply |
| **Medicare** | Covered by federal law; free of cost-sharing | Covered by federal law; no deductible, but co-pay applies* | Covered by federal law; cost-sharing may apply*** |

*Legislation passed in 2020 will phase out these out-of-pocket expenses starting in 2023.[45]

**Federal FAQs published in January 2022 clarify that plans and issuers must provide coverage without cost sharing for plan or policy years beginning on or after May 31, 2022.[42]

***On July 8, 2022, the CMS released proposed changes to the 2023 Medicare program that, if finalized, would eliminate cost sharing for colonoscopies after a positive or abnormal, non-invasive screening test.[46]

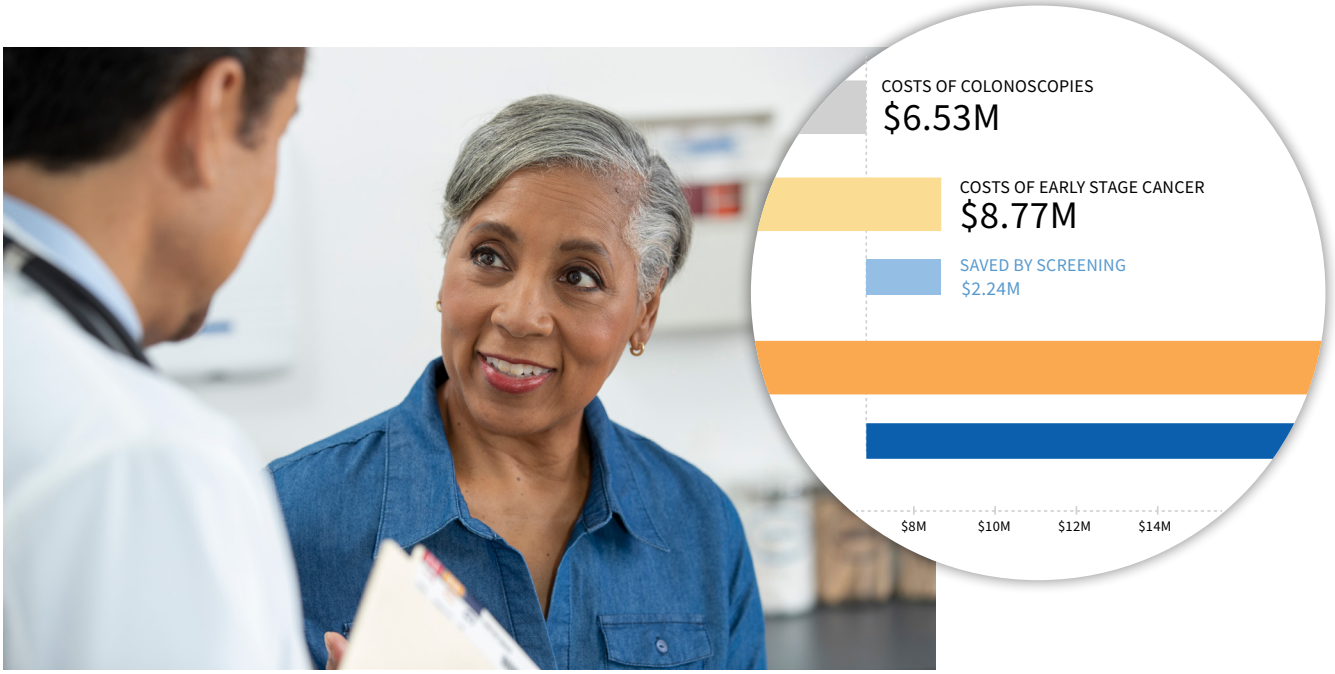
## Calculate the Need for Colonoscopy

Colorectal cancer screening programs in many locations depend on stool testing as the primary screening method.

In some locations, limited capacity for colonoscopy results from an inadequate supply of colonoscopists to meet population needs, low rates of insurance coverage, or restricted acceptance of uninsured and under-insured patients by colonoscopists. Thus, determining the clinic's real need for colonoscopy is an essential strategic planning calculation. Though the need may seem to be difficult to achieve, in fact, it is typically finite and measurable.

**All programs must have colonoscopies available for increased-risk patients and for diagnostic purposes for patients with positive or abnormal screening test results.**

Calculating the extent of the need for colonoscopy will help organizations understand the real size and find a solution for meeting the need. Approaching specialists and local hospitals for help in meeting the need for a specific number of colonoscopies per year is more effective than making an open-ended request.




The NCCRT's **Colonoscopy Needs Calculator**, found in the **NCCRT Learning Center**, allows practices to estimate the number of colonoscopies that can be realistically anticipated with a high-quality stool-based CRC screening program. Estimates are based on various screening rate goals and other data inputs. The tool also estimates the total system costs of colonoscopy and compares the costs of treating cancer with the costs of providing colonoscopies. You have the option to create an account to track your progress.

If you prefer to use an Excel spreadsheet that allows full manipulation of data inputs, the **Colonoscopy Volume Calculator** (calculations illustrated below) produces an estimate of the number of colonoscopies that would be needed, but does not include information on estimated costs.

### A: Colonoscopies for High-Risk Patients

# of 40-75 Year Old Patients x .15* **THEN**

**Divide** by number of years it will take to get those tests done, e.g., 1/3 per year for first 3 years, 1/5 per year for subsequent years

= Colonoscopies per year for high-risk patients

### B: Colonoscopies for Average-Risk Patients

# of 45-75 Year Old Patients x .85** x .05***

= Colonoscopies per year for average-risk patients

**A + B = Colonoscopies needed per year**

* research suggests ~ 15% of the population 40-75 is at High Risk[40,47]
** Since 15% of patients are High-Risk, the remaining 85% are at Average Risk
*** research suggests ~ 5% at average risk are expected to have positive stool tests[48]

Because colonoscopy is performed in a facility and often involves an anesthesiologist and pathologist, enlisting the aid of a colonoscopy champion and/or a hospital-based physician champion will help to line up the array of clinicians and facilities that are needed for your patients. This medical neighborhood will include the entire “assembly line” to coordinate the care of this patient: facility, pathology, anesthesia, backup surgery, radiology, hospital, and possibly oncology. While access to colonoscopy does depend on location, it is important to note that successful colonoscopy-based screening programs have been implemented in such geographically diverse regions of the country as New York City, rural Georgia, New Hampshire, and Colorado. Many established programs rely in part on donated colonoscopies. See the following sections on identifying an internal champion and a physician champion who will help build a local culture that promotes cancer screening in the community.

## Consider a Direct Endoscopy Referral System

The use of a direct endoscopy referral system eliminates the need for a gastroenterology consult prior to colonoscopy.

Many programs have found they can reduce the need for pre-procedure appointments with colonoscopists by sending patients who are fully prepared for colonoscopy and can receive the procedure on the day of their first contact with the colonoscopist. This direct endoscopy referral system (DERS), sometimes called open access, is designed to allow primary care clinicians to prepare patients to go directly for colonoscopy. In order to do this, the patient needs to:

- Be well-oriented and have completed the appropriate prep before the procedure.
- Have someone with them to drive them home from the procedure.
- Have a good understanding of the procedure.

In New York City's colonoscopy screening program, as many as 80% of participants have no contraindications and can be processed through the direct endoscopy referral system. The eligibility criteria for DERS and **sample forms** used for direct endoscopy referral are available in **Appendix C-3** and C-4 and can be tailored to meet the specifications of referral sites.[49,50]

While some health systems have found ways to include the DERS form in their electronic health record (EHR), for many, a paper or faxed copy is still used if no electronic interface is available to transmit the referral between different EHR systems.

4 COORDINATE CARE

3 SCREEN PATIENTS

2 **IDENTIFY A TEAM**

1 MAKE A PLAN

# STEP #2: IDENTIFY A TEAM

**"Coming together is a beginning.
Keeping together is progress.
Working together is success."**

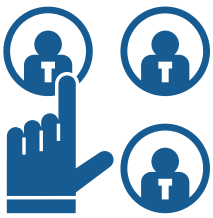
**– Henry Ford**

## Form an Internal Leadership Team Within the Practice

A clear organizational structure is needed early in the process of developing an effective colorectal cancer (CRC) screening system. The internal team can include the medical director, clinic manager, primary care clinician, medical assistants, nurses, quality improvement leaders, and other staff. Once the executive leadership is committed, identifying and training an internal champion who will lead the process is helpful.

A key component of the New Hampshire Colorectal Cancer Screening Program's success is the use of at least one internal champion – someone who is enthusiastic, dedicated, and supported by the organization's leaders. This internal champion can have a medical or administrative background or a combination of the two. Below are helpful examples from the New Hampshire program on what makes a good champion and a description of the responsibilities.[51]

### Select an Internal Champion



- Consider someone who has a personal interest in CRC or cancer screenings.
- Choose someone who is motivated and respected in the organization.
- Consider having two champions – one medical and one administrative.
- Consider population health staff, marketing staff, practice administrator, informatics staff, and clinical staff.

## Define Roles of Internal Champion

- Set up an introductory meeting with practice staff to discuss how to increase CRC screening rates and to review strategies that will be implemented.
- Become familiar with the evidence-based interventions (EBIs) for increasing CRC screening rates available from the Community Guide and National Cancer Institute's (NCI) evidence-based cancer control programs (EBCCPs).[49] Work with practice staff to develop a year-long plan that may include presentations on current CRC screening guidelines, the development of a screening policy, workflow analysis, small media campaigns, community outreach, and setting goals for increasing CRC screening rates.
- Act as a spokesperson for the practice.
- Serve as the point of contact for practice staff and meet via phone at least monthly and face-to-face quarterly.
- Commit to an average of one to two hours per week, with more time needed in the initial phases of the project, and less time as everyone on the staff learns their roles and responsibilities and as patients become more familiar with the program.

## Utilize Patient Navigators

Barriers to CRC screening can be addressed with the assistance of patient navigators, community health workers, and/or health educators. Patient barriers to CRC screening include medical comorbidities, difficulty following the preparation and other screening steps, negative screening experiences of others, high costs, low patient awareness and knowledge about CRC and screening, and cultural or psychosocial issues.[53,54] Other studies have identified a lack of trust in physicians, lack of symptoms, fear of pain and discovering cancer, the shame of being seen as sick or weak, and feelings of violation as reasons for not getting screened.[55]

Navigators have provided a significant boost to screening programs for underserved populations, including CRC screening.[56,57] They can assist with patient education, scheduling appointments, appointment reminders, transportation, cultural barriers, communicating between referring clinicians, and coordinating follow-up care after procedures. Navigators can be recruited and trained from among patients, social workers, community health workers, nurses, or case managers.[58,59] For additional information on how to design a patient navigation intervention for colorectal cancer screening, see references in **Appendix D**.[60]

Successful patient navigation has been implemented in CRC screening programs in states and regions around the country, including colonoscopy-based programs.[58] In the New Hampshire Colorectal Cancer Screening Program, navigators helped to reduce the no-show rate to zero and had fewer than 1% inadequate bowel preps.[60] The Cancer Coalition of South Georgia's patient navigation system has led to a 2% no-show rate and less than 5% of inadequate bowel preps. The effective use of patient navigators by Operation Access in San Francisco has led to a 97% patient compliance rate.[62]

A health center in Boston, Massachusetts, had a higher number of navigated patients who completed colonoscopies compared to those without navigation (54% vs. 13%).[63] In another program in Mount Sinai Hospital in New York, twice the number of navigated patients completed screening colonoscopies compared to non-navigated patients (66% vs. 34%), with a decrease in the no-show rate from 40% to 9.8%, and only 5% inadequate bowel preps.[64]

Additionally, patient navigation has proved to be valuable in stool-based CRC screening programs. Navigators in such programs have assisted with test choice, scheduling appointments, patient support and motivation, appointment reminders, and education about stool-based blood tests and bowel prep for follow-up colonoscopy after a positive or abnormal stool-based test.

An East Harlem, New York, program with a largely Hispanic, low-income, and publicly-insured population saw an increase up to 42% of navigated patients completing stool-based tests compared to 25% of non-navigated patients.[65] Navigated patients at a health center in Somerville, Massachusetts, who received an average of four hours of telephone navigation, were more likely to be screened with gFOBT and colonoscopy within six months compared to those not receiving navigation (31% vs. 9%).[66]

In a study including four health centers and two public hospital-based clinics in Massachusetts, navigated patients were more likely to complete gFOBT and/or colonoscopy screening at 12 months than non-navigated patients (33.6% vs. 20%).[56]

**Colorectal cancer screening patient navigation is a health care strategy and intervention that has proven to be effective when integrated in the health care setting.**

One health center in Fair Haven, Connecticut, has even partnered with a local community college to create a patient navigation certification with online modules.[67] This empowerment of the navigator role has been very successful. It is important to note that patient navigators can be of assistance with other aspects of health, including chronic disease management, preventive care, and other cancer screenings.

## Define Roles of Patient Navigators

Below is a list of possible functions a patient navigator could complete for your practice. Additional resources and manuals for patient navigators are available in **Appendix D**.

**Utilize population health management tools and/or EHR registries to identify and flag individuals who are not up-to-date with colorectal cancer screening.**

### Patient Level

- Provide patients with education on CRC screening targeted to specific patient populations (i.e., culture- and age-appropriate educational materials and methods).
- Explain and distribute FIT/HSgFOBT kits, and track returns and results.
- Explain and request referrals (for those who choose colonoscopy or CT colonography).
- Expedite referrals for follow-up colonoscopy after positive or abnormal stool-based test results.
- Arrange appointments (CT colonography, colonoscopy, and follow-up tests).
  - Use a direct line to the colonoscopy center to schedule the appointment that same day.
  - Empower the patients and educate them about the preparation.
- Assist with financial barriers (transportation, bowel prep supplies).
- Conduct calls for appointment reminders and to reinforce instructions for colonoscopy preparation.
- Track appointment adherence and results.
- Arrange initial surgical treatment when necessary.
- Transition patients diagnosed with cancer to oncology patient navigation.
- Document interventions and number of people reached.

### Staff Level

- Conduct in-service educational training with staff on CRC screening – why it is important and how it is done.
- Collaborate with the staff to share insights into characteristics of the population served, including potential language or cultural barriers.

### Community Level

- Use community health data such as cancer mapping to identify areas of high-need CRC screening services.
  - Work with faith-based organizations, local businesses or employers, pharmacies, schools, libraries, and other community groups to increase colon and rectal health awareness (involve the community in program planning whenever possible).
  - Promote CRC screening at health fairs, at local festivals, announcements at local sporting events, or with local media.
- Formulate and implement strategies and methods to reach the target population.
- Provide the community with educational classes on CRC prevention, early detection, and screening guidelines.

To ensure patients are properly prepped and show up, successful practices have implemented protocols for following up with patients. As an example, the health center in Fair Haven, Connecticut, has navigators contact patients one to three weeks before their colonoscopy to review the procedure and then calls patients the week and the day before to anticipate any problems. The **colonoscopy preparation navigator checklists** are included in **Appendix C-6**. Practices can also consider partnering with local businesses to donate the prep materials to the center.

An important question for programs includes how to obtain funding for patient navigators. Several programs with patient navigation systems currently have used grants through the American Cancer Society (ACS), the Centers for Disease Control and Prevention (CDC), or the National Cancer Institute (NCI). Other programs have used funding sources from local foundations, state cancer coalitions, county hospitals, or state and city health departments. The following resources address possible funding sources for patient navigation:

- **Paying for Colorectal Cancer Screening Patient Navigation Toolkit and Interactive Website** (NCCRT)
- **Patient Navigation** (CDC)

## Agree on Team Tasks

The team should agree on a screening strategy (see Step #1), provide CRC screening education to all staff, and assess barriers for patients beforehand (i.e., language, cultural, travel, missed work time). A list of helpful tasks includes:

- Define program goals, objectives, and time frame.
- Formulate a patient navigator role description.
- Identify the supervisor (for feedback and support) of the patient navigator role.
- Identify potential costs (patient navigator hiring, training, salary, and benefits, supplies, materials, and equipment, computers, patient education/support/outreach materials, colonoscopy prep, transportation for patients who need it, outreach incentives, advertising, evaluation).
- Define activities and processes.
  - Develop a screening protocol.
    - A screening policy template adapted from the New Hampshire Colorectal Cancer Screening Program is available in **Appendix C-1**.
- Various tools to help organize your steps and assess your practice workflows for CRC screening can be found in **Appendix A-3**. The following tools can be used to assess which evidence-based interventions may work best for the practice, as well as help to determine what changes need to occur to implement the interventions:
  - **Clinical Decision Support/Quality Improvement Worksheet** and CRC screening example (**Appendix A-3.1**)
  - West Virginia Program to Increase Colorectal Cancer Screening Partner Clinic Readiness Assessment Toolkit (**Appendix A-3.2**)
  - New York State Department of Health Clinic Assessment Tool – This tool is intended to be part of a larger assessment process and to stimulate conversation and communication about the various included topic areas. The intended use is to set the stage for continued communication with clinics about their activities. (**Appendix A-3.3**)
  - CDC's publication, Increasing Colorectal Cancer Screening: An Action Guide for Working with Health Systems[90]
- Choose the specific type of stool-based kit, and decide whether to process lab work in-house or externally. Find a list of evidence-based stool-based tests in the NCCRT publication, **Clinician's Reference: Stool-Based Tests For Colorectal Cancer Screening**.
- Navigator/staff training – examples of training manuals from several programs (**Appendix D**)
- Develop or adopt clinical practice tools (standardized intake form, tracking system/ follow-up log, brochures describing the program):
  - Standard history and physical form with labs (Operation Access) (**Appendix C-3**)
  - Workflow and follow-up for HSgFOBT/FIT (**Appendix A-4**)

- Direct endoscopy referral – sample referral form from the New York Citywide Colon Cancer Control Coalition (C5) (**Appendix C-4**)
- Sample colonoscopy appointment letters in English and Spanish (Operation Access) (**Appendix C-5**)
- Navigator checklists – sample colonoscopy preparation checklists that can be reviewed with patients before the procedure (**Appendix C-6**)
- FluFIT and FluFOBT – evidence-based programs that allow clinic staff to identify eligible patients and offer home-based stool tests at the time of their annual flu shots. Coupling CRC screening with established annual flu shot activities can be an excellent way to introduce the importance of CRC screening to clinic teams and patients and has been shown to improve screening outreach.[69,70] For a description of five steps for implementing a FluFIT or FluFOBT in your primary care practice, see **Appendix C-7.2**. For additional websites describing evidence-based programs that could be useful in your community, see **Appendix D**.
  - Visit **http://flufit.org/** to find guidance, program materials, and publications to support implementing a successful FluFIT or FluFOBT program.
  - The FluFIT program incorporates the evidence-based concept of giving nurses **standing orders** to offer flu shots and CRC screening to eligible patients during routine primary care.[53]
  - Several of the practices interviewed for the case studies identified the use of **standing orders** to rely on clinical staff other than primary care physicians to assist with offering CRC screening to eligible patients.

- Reminder follow-up tools are available in **Appendix C**[68], including:
  - Sample reminder cards (**Appendix C-8**)
  - Sample patient reminder letter for screening (**Appendix C-9**)
  - Sample patient reminder letter to return test (**Appendix C-10**)
  - Sample patient letter regarding a negative test (**Appendix C-11**)
  - Sample memorandum of understanding with gastroenterology and other specialty physicians (Operation Access) (**Appendix C-13**)
- Determine the resources you are going to devote to follow-up and adherence.
  - EHR support (chart prompts, clinician and staff prompts and alerts, guidelines in EHR, EHR-generated patient reminders/letters), staff involvement (calls/letters/postcards) (**Appendix C-12**)
- Identify program evaluation methods (assess collected data, assess whether the program is meeting goals and objectives, assess the effect on the target population, assess efficiency and effectiveness of program methods). The **NCCRT Evaluation Toolkit** can help inform evaluation efforts in your setting.
  - Assess your progress worksheet[90] (**Appendix A-3.4**)

The organization should engage the team in creating, supporting, and following the policy. The screening process and office flow should be evaluated on an ongoing basis. Strategies can include fostering a team approach to care, standardizing and reducing variation at each step, analyzing each step systematically to troubleshoot areas of concern, training and supporting the staff in the process change, and continually reviewing the quality improvement infrastructure.

## Partner with Colonoscopists

A 2004 study by the CDC found there was sufficient capacity to screen the entire risk-eligible population in the United States within one year using a stool-based test, reserving colonoscopy for patients with positive or abnormal screening tests.[74] However, from a geographic point of view, capacity varies in different parts of the country. It is important to understand the level of need and capacity for colonoscopy in your community (see Step #1). Once this information is available, one of the most helpful strategies for finding colonoscopists is to identify a physician champion.

In 2014, ACS and NCCRT launched the **Links of Care pilot project** to build specialty care linkages for Federally Qualified Health Center (FQHC) patients in need of CRC screening and follow up. The Links of Care pilot program was successfully implemented in three sites that varied in geographic location, patient population, and available external resources. Pilot participants from both FQHCs and specialty care practices emphasized the critical importance of patient navigation in establishing and maintaining mutually beneficial medical neighborhood relationships.[71]

## Identify a Clinical Champion

Whether your program is based on offering all patients a colonoscopy or emphasizing home stool testing for average-risk patients, access to colonoscopy services is essential for the success of any colorectal cancer screening program.

These efforts to improve screening often start at the physician level and grow by recruiting other physicians and clinical leaders to the cause. Oncologists and cancer surgeons are often the best hospital-based champions because they see many patients with late-stage disease that could have been prevented through screening. This experience becomes a strong motivator. This clinical champion can be instrumental in organizing the entire “assembly line” to care for patients, including the facility, pathology services, anesthesia, surgery, radiology, hospitalization, and oncology.

**Several pilot programs have implemented colorectal cancer screening programs in primary care practices with a clinical champion as a key component of their success.**

Following is a table outlining programs that have been championed by physicians with a description of their effective strategies.

**Table 3. Example Programs with Physician Champion(s) and Strategies of Success**

| Program | Description | Physician Champion and Strategies of Success |
|---|---|---|
| **Colon Cancer Prevention Network**[72] | Partnership between the University of South Carolina Center for Colon Cancer Research and several South Carolina Gastroenterology Association (SCGA) member physicians to perform free colonoscopy screenings for underinsured patients throughout South Carolina. | ■ Started as a grassroots effort by a small group of physicians and researchers.<br>■ Obtained grant from South Carolina State Legislature and Blue Cross Blue Shield of South Carolina for patient navigators.<br>■ Utilized network of colleagues to enlist gastroenterologists throughout the state to participate. |
| **Surgery on Sunday Louisville, Inc.**[73] | Community-wide colorectal cancer screening program offering free colonoscopies and surgery to uninsured and underinsured community members. | ■ Initiated by a small group of surgeons and gastroenterologists wanting to make a difference and do the right thing for the city.<br>■ Built on a collaborative model – every hospital in the area shares responsibility for providing in-kind services.<br>■ Formed a not-for-profit 501c3 and developed a business strategy. |
| Cancer Coalition of South Georgia | Community cancer screening program to increase cancer screening among uninsured and underinsured patients of health centers | ■ Initiated by local gastroenterologists.<br>■ Strong collaboration between PCPs, specialists, hospitals, and community health centers.<br>■ Coalition estimates county needs and apportions patients to colonoscopists.<br>■ The use of patient navigators led to a 2% no-show rate and fewer than 5% inadequate bowel preps. |
| New Hampshire Colorectal Cancer Screening Program | Statewide CDC-funded program that provides free, high-quality colonoscopy to uninsured and underinsured patients | ■ Gastroenterology champion led efforts to recruit other gastroenterologists.<br>■ Utilization of internal champions.<br>■ Highly effective patient navigation.<br>■ Clear protocols.<br>■ Secured the commitment of leadership at community health centers, hospitals, and endoscopy sites. |

4 COORDINATE CARE

3 SCREEN PATIENTS

2 IDENTIFY A TEAM

1 MAKE A PLAN

# STEP #3: GET PATIENTS SCREENED

**A primary care clinician recommendation is the most powerful influence on a patient's decision to get screened for cancer**

## Prepare the Clinic

Train and educate all staff on the following:

- Colorectal cancer (CRC) screening guidelines and protocols
- CRC screening strategy used by the practice, addressing approaches to stool-based and colonoscopy screening
- Appropriate screening intervals based on average- and elevated-risk categories
- How to assess and document CRC risk and exclusions to CRC screening
- HIT/EHR features – Templates, order sets, alerts, and dashboards
- Documentation required as evidence of prior screening (date, test, result, evidence of the test (such as the electronic or paper test result or report) added to the chart and recommended follow-up.
- **In-office stool testing by digital rectal exams (DRE) is not an appropriate method of screening for colorectal cancer.** One study demonstrated that the in-office stool test missed 90% of cancers found at subsequent colonoscopy.[31]
- One health center's innovative approach to collecting spontaneously-passed stool samples in the patient's medical home ("poop on demand") is featured in this **short video segment** and in this **blog post**.

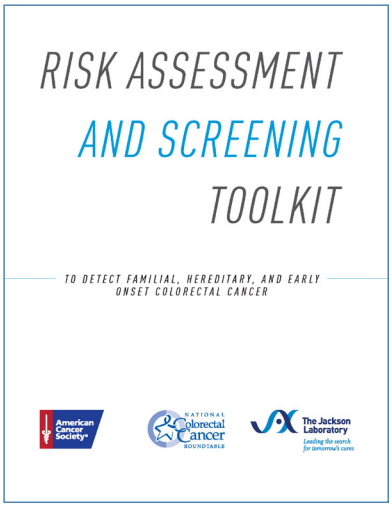
It is important to keep in mind that most patients are at average risk. If your practice has very low baseline screening rates, it is perfectly acceptable to start a robust stool-based screening program, even if only a very basic risk assessment can be performed.

Over time, look for ways to assess and document risk more comprehensively, such as utilizing the EHR, especially in a community where patients are unlikely to have complete information about their medical and family histories.

## Conduct a Risk Assessment

| | | |
|---|---|---|
| An **average-risk** individual is someone without any of the risk factors described in the other two categories. | **Increased-risk** patients have a personal or family history of adenomatous polyps or colorectal cancer with no known hereditary colorectal cancer syndrome. | **High-risk** patients include those with a history of colorectal cancer or adenoma in close relatives; those with hereditary colorectal cancer syndromes, such as hereditary non-polyposis colorectal cancer (HNPCC) also called Lynch Syndrome, familial adenomatous polyposis (FAP), and another form of FAP, called Attenuated FAP (AFAP), which is a milder version of the disease.<br><br>Other high-risk patients include those with Crohn's disease or ulcerative colitis (their risk increases with the extent and duration of the disease, usually after at least eight years)[74], as well as those with a history of abdominopelvic radiation for previous cancer. |

For a more detailed description of the criteria and screening recommendations for increased-risk and high-risk patients, see the **US Multi-Society Task Force on Colorectal Cancer Guidelines for Colonoscopy Surveillance After Screening and Polypectomy**, which is also available in **Appendix D-2.1**.[75]




Additionally, refer to **Appendix D-2.2** for the **NCCRT Risk Assessment and Screening Toolkit to Detect Familial, Hereditary and Early Onset Cancer** and the corresponding **Risk Assessment and Screening Quick Start Guide**. The American Cancer Society's Sample Screening Algorithm for Assessing Personal and Family Risk, per the 2018 ACS Guidelines is included in **Appendix D-2.3** for Ages 45+.

Genetic testing should be offered to those who have a personal or family history suggestive of one of the hereditary colorectal cancer syndromes. Most cancer genetics clinics now offer telehealth services, which helps increase access for patients in rural areas without a major cancer center nearby. Primary care clinicians can find a cancer genetic counselor for their patients at **www.findageneticcounselor.com**. See the list below for websites with additional information.

## Resources for Genetic Testing and Genetic Counseling

- **American Cancer Society** – Provides information on genes and cancer, family cancer syndromes, and genetic testing for cancer risk
- **National Society of Genetic Counselors** – Includes information on genetic counseling, questions to ask before genetic testing, a guide to collecting family history, information on genetic testing and genetic counselors, and a directory of genetic counselors
- **American Board of Genetic Counseling** – Offers additional information on how to find a genetic counselor
- **National Cancer Institute** – Provides a list of services related to cancer genetics (cancer risk assessment, genetic counseling, genetic susceptibility testing)

# Prepare the Patient

## Provide Patient Education Materials

Many patient education materials are available to you. Options include:

- **In the waiting room and exam room**, consider offering educational video(s) on CRC screening.
  - The American Cancer Society offers numerous videos that describe test options in **English** and **Spanish**, as well as **an animated video illustrating a colonoscope and colonoscopy**.
  - The CDC offers **several videos on the importance of CRC screening**.
  - Kaiser Permanente's Center For Health Research's mailed FIT website offers **numerous videos on CRC screening and FIT testing**.
  - The FluFIT and FluFOBT website offers **multilingual videos with instructions on conducting a stool-based test** (available in 10 languages).
  - East Boston Neighborhood Health Center offers instructional videos for patients on how to conduct sample collection for the Insure ONE FIT kit: **Patient Instruction Video – English** and **Patient Instruction Video – Spanish**.
  - T.R. Levin, Chief Gastroenterologist, Kaiser Permanente Northern California, speaks to the **importance of CRC screening**.
  - Instructional video for patients on **collecting and returning multi-target stool DNA** (mt-sDNA or Cologuard) test samples and other **patient videos and information**.

- **In the office and community**, post and distribute multicultural and multilingual health information materials, including infographics, flyers, inserts, posters, brochures, fact sheets, letters, postcards, phone scripts, greeting cards, or birthday cards.
  - The ACS offers numerous patient resources, including:
    - **Get Screened for Colorectal Cancer**
    - **You Can Help Prevent Colorectal Cancer**
    - **2018 Colorectal Cancer Screening Guideline for Men and Women at Average Risk infographic**
    - **Colorectal Cancer: Catching It Early infographic**
    - **Colorectal Cancer Fact Sheet**
    - **Cancer information about cancer including prevention, early detection, treatment, and more in 13 languages**
    - **Colonoscopy Frequently Asked Questions**
  - The CDC offers several **print materials, shareable graphics, social media post content, and radio scripts on the importance of CRC screening** (English and Spanish).
  - **MIYO (Make it Your Own)** offers a library with hundreds of templates for creating customized and culturally-tailored patient education materials in multiple languages.
  - Kaiser Permanente's Center For Health Research's mailed FIT website offers **numerous educational materials on CRC screening and FIT testing**.
  - The New York City Department of Health provides a **novella on colonoscopy preparation**.
- **In the lab or triage area**, staff should ask about family history and prior screening with a checklist. If not screened, provide patients information on options for CRC screening or explain the health center's protocol for screening.

## Order the Screening Test

Train staff to communicate with patients and to provide appropriate test instructions. See below for sample counseling scripts for average- and increased-risk patients. During the rooming process, a FIT kit can be left on the counter as a reminder prompt to the clinician to complete the process of recommending and ordering the screening test during the visit.

When placing the order for CRC screening, associate the order with the appropriate ICD-10 Diagnosis Code (Z12.11 for CRC screening, either FIT, mt-sDNA or colonoscopy – average risk; R19.5 for colonoscopy as follow-up of positive or abnormal stool tests).

- For patients going straight to colonoscopy, provide direct access to endoscopy when available. See **Appendix C-4** for eligibility criteria for direct endoscopy referral.
- For those patients who are unsure about screening, flag the chart so a clinician will discuss it during their clinic visit.
- Another option for average-risk patients who are not up to date with CRC screening is mailed stool test kits (FIT or mt-sDNA).

The ACS provides this two-page **CRC screening fact sheet for healthcare professionals**, which could be used as a primer for educating all staff on CRC screening.

## Consider Mailed Stool-based Testing

Kaiser Permanente in Northern California has been mailing FIT kits to patients for several years, resulting in an increased screening rate between 2005 and 2010 among the commercially insured from 37% to 69% and in the Medicare population from 41% to 78%.[37,76] In 2017, Kaiser Permanente in Northern California was able to achieve 82% screening participation from a combination of prior endoscopy, a large initial response to mailed FIT kits, and smaller responses to automated reminders and personal contacts.[77]

mt-sDNA (Cologuard) is a mailed CRC screening test that is shipped directly to the patient's home. When a clinician submits an order for mt-sDNA testing to Exact Sciences, the company's Customer Care team contacts the patient, confirms their address, and arranges for UPS® delivery of the mt-sDNA test collection kit. A single bowel movement is needed to process the test. Once collected, the patient can either schedule a UPS pick-up from their home or can drop their used kit at a nearby UPS shipping center. When the sample is received by the Exact Sciences Laboratories, it is processed, and the lab provides the results to the ordering clinician within two weeks. Each mt-sDNA order comes with a built-in patient navigation program, which includes a patient support line available 24/7 in more than 200 languages, reminder phone calls and letters, as well as an option for email and/or text reminders (at the patient's discretion).

The COVID-19 pandemic disrupted CRC screenings in 2020 and 2021 in profound ways. Screening colonoscopies came to a standstill while health systems pivoted to address the urgent needs of patients with COVID-19 and reduce the risk of the spread of the virus in healthcare settings, especially in the early phase of the pandemic. Health systems that were already offering patients the option of stool testing (especially mailed FIT and mt-sDNA) were able to continue their screening programs with fewer disruptions.[78] Increased use of stool-based CRC screening participation, particularly through organized mailed outreach may help to limit the undoing of public health progress in CRC and, perhaps, even contribute to achieving the NCCRT goal of 80% adherence to screening nationwide.[79]

In 2022, the National Association of Chronic Disease Directors and Kaiser Permanente Center for Health Research developed a **Mailed FIT Implementation Guide** that provides step-by-step instructions for planning and implementing a mailed FIT outreach program.[80]

## Sample Average-risk Counseling Script for Stool-based Screening Program

"I would like you to be tested because colorectal cancer is the second most common cause of cancer-related deaths. Testing may help prevent cancer or find it early while it can often be treated successfully. This is especially important because there are usually no symptoms for colorectal cancer when it's first starting. I recommend testing for all of my patients 45/50 years of age and older. **[NOTE: as of May 2021, USPSTF, ACS, NCCN, and ACG all recommend 45 and older – check patients' insurance coverage prior to recommending.]**

We offer screening for patients who are at average risk with a take-home test (FIT/HSgFOBT) that looks for blood in the stool, or the mt-sDNA test that looks for blood or DNA changes in the stool that might indicate the presence of cancer or polyps. If you are found to have abnormal results on a stool test, you will need a follow-up colonoscopy. A colonoscopy is an exam in which the doctor inserts a thin, flexible tube to look at the inside of the intestine. This procedure allows us to find and painlessly remove growths (polyps) in the colon. The main risks are perforation (making a small hole in the intestine), complications from anesthesia, or bleeding from the removal of a polyp.

These risks are very uncommon.

Finding and removing polyps can help prevent cancer. These tests can also find cancers at an early stage while they can often be treated successfully. If we find a cancer, then you can start to receive treatment right away."

## Sample Average-risk Counseling Script for Program Offering Stool-based Test or Colonoscopy

"I would like you to be tested because colorectal cancer is the second most common cause of cancer-related deaths. Testing may help prevent cancer or find it early while it can often be treated successfully. This is especially important because there are often no symptoms for colorectal cancer. I recommend testing for all of my patients 45 years of age and older.

Our practice offers two main ways that you can get tested:

1. A colonoscopy is an exam in which the doctor inserts a thin, flexible tube to look at the inside of the intestine. This procedure allows us to find and painlessly remove growths (polyps) in the colon. If you have a polyp, it can be removed right there during the time of the colonoscopy and taking it out can help prevent cancer. The main risks are perforation (making a small hole in the intestine), complications from anesthesia, or bleeding after polyp removal. These risks are very uncommon.
2. You can also choose a take-home test, FIT/HSgFOBT that looks for blood in the stool, or the mt-sDNA test that looks for blood or DNA changes in the stool that might indicate the presence of cancer or polyps. If you are found to have abnormal results on a stool test. If you are found to have abnormal results on a stool test, you will need a follow-up colonoscopy.

Finding and removing polyps may help prevent cancer. These tests can also find cancers at an early stage while they can often be treated successfully. If we find a cancer, then you can start to receive treatment right away."

## Sample Increased-risk Counseling Script

"Because you are at increased risk for colorectal cancer (state the reasons), I recommend that you have a colonoscopy. A colonoscopy is an exam in which the doctor inserts a thin, flexible tube to look at the inside of the intestine. This procedure allows us to find and painlessly remove growths (polyps) in the colon. If you have a polyp, it can be removed right there during the time of the colonoscopy and taking it out may help prevent cancer. The main risks are perforation (making a small hole), complications from anesthesia, or bleeding following removal of a polyp. These risks are very uncommon. If there is any chance that we find a cancer, then treating it early may help save your life."[81]

# Make a Recommendation

**Multiple studies have shown that a recommendation from the primary care clinician (or a member of the clinician's team) is the most influential factor inpatient screening behavior.**[82-84] If the practice is able to offer screening options to patients because they have access to colonoscopy (which is usually the case for Medicare patients, those with commercial insurance and some Medicaid patients), clinicians should explore individual patient preferences.

For example, patients who place a high value on having only one test less frequently may prefer to have a colonoscopy so that potential pre-cancerous or cancerous polyps can be removed and analyzed at the same time. Patients who place a high value on convenience, reassurance from more frequent testing, or are uncomfortable with the more invasive test, may prefer a stool-based test every year (HSgFOBT/FIT) or every three years (mt-sDNA).

Studies have shown that average-risk patients are more likely to complete screening when given a choice, and a significant number of patients prefer a stool test over colonoscopy.[85-87] Based on the patient's risk factors (personal and family history) and individual preferences, the clinician can help provide the best screening recommendation using shared decision making – a practice encouraged by CRC screening guidelines from the American Cancer Society, US Preventive Services Task Force and other organizations.

Helpful recommendations include one-on-one patient-clinician discussions that avoid the use of medical jargon, focus on the benefits and positive aspects of screening, and limit the key information to three to five points. Patient education materials, such as prep instructions in various languages at appropriate literacy levels, translation services, and multilingual staff can also be helpful in promoting patient understanding.

Visual aids may be helpful for people who do not read well, as well as bilingual instructions in English and the patient's native language. The patient may have family members at home who can help the patient understand and adhere to your recommendations. For information on resources to assist with patient decision-making, see the section on Preparing the Patient on **page 44** of this manual.

## Empower Reluctant Patients to Get Screened

There will still be patients who are reluctant to get screened despite receiving a clinician recommendation. At every visit, the primary care clinician and members of the clinician team should continue to recommend screening. In a health center focus group study, all of the clinicians believed it was important to take time to explain the purpose of screening and to communicate its significance on a personal level. They suggested using examples from real life, such as other patients who had a delayed cancer diagnosis.

Communication plays a strong role between clinician and patient. Several clinicians reported they would sometimes speak bluntly to patients (especially those in a high-risk group) and provide statistics to motivate them to get screened. Others stated they also gave their patients time to process the information or discuss it with their families before committing to a decision.

It was also considered necessary to follow-up with the patient and revisit the screening decision with the patient at the next visit. One clinician noted that in his experience patients are more likely to accept a stool-based test after first discussing a colonoscopy; they were more amenable to a stool-based test because they did not want to go through the steps necessary for a colonoscopy.[88]

Another project designed to increase CRC screenings in federally qualified health centers in northern Louisiana focused on a health literacy intervention. Helpful lessons learned from this project include:

- Patients and clinicians should provide input on educational materials.
- Staff can provide a mock stool test demonstration and have patients demonstrate what they learn.
- Offering the screening test before the primary care visit is well received.
- Regularly scheduled clinic-wide orientations and in-service trainings are beneficial.[89]

**An excellent resource for recommended messages for those who are reluctant to be screened for CRC is the 2019 Colorectal Cancer Screening Messaging Guidebook: Recommended Messages to Reach the Unscreened.**

## Ensure Quality Screening for a Stool-based Screening Program

If the practice chooses a primarily stool-based screening program, it will be important to obtain high test completion rates. The steps below are helpful to ensure high-quality test collection and processing:

| CRC screening using HSgFOBT/FIT requires: | CRC screening using mt-sDNA requires: |
|---|---|
| ■ That stool samples are collected at home or by spontaneously-passed stool in the medical home.<br>■ Verify the date of collection with the patient if the date is not written on the sample container.<br>■ Use trained, experienced personnel to develop and report the test kits.<br>■ When possible, send test kits to a central laboratory for processing to assure good quality control.<br>■ Monitor test positivity rates (usually will be between 5-10%, depending on patient population and test characteristics).[49] | ■ Verification of patient phone number and address to assure that the Exact Sciences Customer Care team can contact the patient to answer any questions about the test and arrange shipment of the collection kit to the patient's home.<br>■ That stool samples are collected at home or by spontaneously passed stool in the medical home.<br>■ Specimens should be shipped (via UPS) within 24 hours of collection.<br>■ All specimens must be shipped to the Exact Sciences laboratory for processing, assuring good quality control. |

When giving normal (negative) results, it is always helpful to set expectations by informing patients that a repeat test will be needed in one year after a negative HSgFOBT/FIT or in three years after a negative mt-sDNA test. It's also a good idea to set up a system to ensure that patients will be reminded to get screened or to get a new kit sent to them a month before their next test is due.

Once CRC screening has been completed, it is critical to follow up on positive or abnormal results. Practices should track test results and refer all patients with positive or abnormal test results for colonoscopy. Positive or abnormal results should be documented in the patient's medical problem list as well as in the electronic health record. This helps ensure that clinicians caring for the patient will be alerted to the result and will need to follow up if the patient fails to get a colonoscopy immediately.

For patients with a positive or abnormal stool test who have not yet had a follow-up colonoscopy, patient navigators or other clinic staff can help reach out to these patients. All available resources should be used – text, phone, email, or mail. Collaborate with the colonoscopist to assure prompt and proper follow up.

Similarly, for patients who have undergone colonoscopy that resulted in the detection of adenomatous polyps or cancerous lesions, systems should be in place to ensure that these patients receive timely follow-up and/or cancer care as needed.

The final important step is to sustain regular test completion with a HSgFOBT or FIT (annual) or mt-sDNA test (every three years). On an ongoing basis, the practice should assess numbers and rates of the following: eligible patients, test kits provided, test kits returned and processed, test kits rejected by the laboratory, positive or abnormal test results, and colonoscopy for positive or abnormal test results.[89] These programmatic quality features are summarized in the NCCRT brief: **Clinician's Reference: Stool-Based Tests For Colorectal Cancer Screening**.

## Track Return Rates and Follow-up

An organized system to track screening tests and follow-up is very important in a screening program. Different options are available, depending on practice resources.

Organizations should use a closed loop system to track stool-based lab test orders and diagnostic imaging/referrals ordered using the EHR (Computerized Provider Order Entry). EHR and health information technology eliminate the need to keep paper tracking systems. Results that are electronically received through an interface typically are associated with the order, where results received by paper will need to be attached to the order. Orders should be routed to the ordering clinician for review, the result entered, and the positive or negative result communicated to the patient. Organizations should use their EHR to identify orders that are outstanding and follow up within 30 days by a staff member.[66]

The EHR can also provide prompts to the clinician when patients who are due for screening seek care at the clinic. Seeing the alert, the clinician can refer the patient for colonoscopy or prescribe an mt-sDNA test or the office-based support staff can distribute screening stool-based kits at the time of a clinician visit or flu clinic.

Electronic prompts in the EHR can track patients and even provide reminders to them at specified intervals to return their stool cards. A primary care practice can create a registry in the EHR for CRC screening status that will show the last screening date, overdue status, and the patient's next scheduled visit. The EHR can also flag the chart with positive or abnormal results so that staff can notify patients and refer them for a follow-up colonoscopy.

Orders with no accompanying results within a specified timeframe (i.e., within two weeks of the visit) can be followed up with a phone call by a staff member.[66]

To help ensure patients follow through on referrals, patient navigators can help schedule the colonoscopy, assist the patient with logistical barriers, follow through until the test result is completed, and track the necessary follow-up interval for screening. See **Appendix C** for some helpful tools for following up with patients.

## Measure and Improve Performance

A program measures its success by demonstrating an improvement from baseline screening rates. Some programs have found it helpful to provide monthly screening rate reports, allowing for ongoing reevaluation of the process.

Important components include:

- Collect, monitor, and report data (you can use **Assess Your Progress Work Sheet**[90] in **Appendix A-3.4**)
- Ensure thorough documentation of screening tests, results, and tracking follow-up.
- Gather feedback from staff, patients, navigators, clinicians, and specialty physicians on processes.
- Share responsibility and attain good communication between colonoscopists and primary care clinicians.

In places with a more rigorous quality reporting environment, insurers provide gap reports on quality measures. These gap reports indicate patients who are missing preventative health screenings. The use of this list can be another opportunity to reach out and engage those patients who have still not yet been screened.

The **Clinical Decision Support for Quality Improvement Worksheet**, developed by the Office of the National Coordinator, Clinical Decision Support for Meaningful Use, can be used to assess current practice workflows, identify gaps, and recommend enhancements for improving CRC screening processes within the practice. This process provides a holistic approach to clinical quality improvement and higher likelihood of success in implementing initiatives to improve screenings. An example of a mapped-out workflow for CRC screening is included in **Appendix A-3.1**.

Ongoing evaluation by the staff and team is the only way to improve. Internal champions and patient navigators can provide feedback on continued barriers and fine-tune interventions during the process. Successful programs can contribute to performance improvement in other practices by disseminating their strategies.

## Celebrate Success

As you measure and improve performance, take time to celebrate your success, both for the practice as a whole and for individual members of the team. By celebrating milestones reached in working toward your goals, you can help to disseminate best practices and spread friendly competition.

When you reach significant goals, consider sharing your success more broadly. Each fall, the NCCRT accepts nominations for the *80% in Every Community National Achievement Awards*. Visit **nccrt.org/awards** to learn more and consider nominating your practice or individual clinical champions for their success.

4 COORDINATE CARE

3 SCREEN PATIENTS

2 IDENTIFY A TEAM

1 MAKE A PLAN

# STEP #4: COORDINATE CARE ACROSS THE CONTINUUM

**"Delaying colonoscopy after an abnormal stool test can have major consequences, including increased risk for cancer diagnosis, late-stage cancer at diagnosis, and death from colorectal cancer."**

**– Dr. Samir Gupta, VA San Diego Healthcare System**[91]

## Coordinate Follow-up After a Colonoscopy

Electronic health record systems are expanding their capacity to share patients' clinical information across primary and specialty care sites, making it easier for primary care practice and specialty gastroenterology practices to deliver coordinated care. Nevertheless, good communication between colonoscopists and primary care clinicians is essential. Such communication can ensure that the colonoscopist receives adequate information about the patient's clinical history in order to 'clear' the patient for the colonoscopy procedure. It can also support the timely receipt of colonoscopy reports in primary care.

The colonoscopy report must be complete, including the colonoscopist's follow-up recommendation. After primary care clinicians receive and read colonoscopy reports, the result and appropriate follow up should be documented in the health record. Primary care clinicians need to be familiar with CRC screening and surveillance guidelines so that both colonoscopists and primary care clinicians actively ensure patient follow up. The table below summarizes the appropriate surveillance follow-up guidelines.[60]

Understanding colonoscopy quality measures is also important for primary care clinicians. The NCCRT published a report in 2010 on assessing the quality of colonoscopy services. See **Appendix C-14** for a list of the quality measures for colonoscopy reports.[92]

**Table 4. US Multi-society Task Force Recommendations for Post-Colonoscopy Follow-up in Average-Risk Adults with Normal Colonoscopy or Adneomas.[a,75]**

| Baseline Colonoscopy Finding | Recommended Interval for Surveillance Colonoscopy | Strength of Recommendation | Quality of Evidence |
|---|---|---|---|
| Normal | 10 years[b] | Strong | High |
| 1-2 tubular adenomas <10mm | 7-10 years[c] | Strong | Moderate |
| 3-4 tubular adenomas <10mm | 3-5 years | Weak | Very low |
| 5-10 tubular adenomas <10mm | 3 years | Strong | Moderate |
| Adenoma ≥ 10 mm | 3 years | Strong | High |
| Adenoma with tubulovillous or villous histology | 3 years[d] | Strong | Moderate |
| Adenoma with high-grade dysplasia | 3 years[d] | Strong | Moderate |
| >10 adenomas on single examination[e] | 1 year | Weak | Very low |
| Piecemeal resection of adenoma ≥ 20mm | 6 mo | Strong | Moderate[f] |

[a]All recommendations assume examination to cecum with bowel preparation adequate to detect lesions >5mm in size; recommendations do not apply to individuals with a hereditary CRC syndrome, personal history of inflammatory bowel disease, personal history of hereditary cancer syndrome, serrated polyposis syndrome, malignant polyp, personal history of CRC, or family history of CRC, and must be judiciously applied to such individuals, favoring the shortest indicated interval based on either history or polyp findings.

[b]Follow-up may be with colonoscopy or other screening modality for average-risk individuals.

[c]Patients with recommendations issued before 2020 for shorter than 7-to-10-year follow-up after diagnosis of 1-2 tubular adenomas may follow original recommendations. If feasible, physicians may re-evaluate patients previously recommended an interval shorter than 10 years and reasonably choose to provide an updated recommendation for 7-10-year follow-up, taking into account factors such as quality of baseline examination, polyp history, and patient preferences.

[d]Assumes high confidence of complete resection.

[e]Patients with >10 adenomas or lifetime >10 cumulative adenomas may need to be considered for genetic testing based on absolute/cumulative adenoma number, patient age, and other factors such as family history of CRC.

[f]See US Multi-Society Task Force recommendations for endoscopic removal of colorectal lesions.

## Establish a Medical Neighborhood

The creation of a medical neighborhood will be critical for coordinating the care of patients; the neighborhood will include the primary care clinician, gastroenterology or other specialty physicians, the facility, pathology, anesthesia, backup surgery, radiology, hospital, and possibly oncology.

A practice can utilize a physician champion as mentioned previously to line up the needed components. It is helpful to have a way to estimate the number of cancers found in a state or region so that practices can then negotiate with the hospitals and oncology centers. This is because most of the cancers found on screening are stage I, and if not picked up until later, are usually found at stage III or IV, and could be considered a greater financial liability for the hospital and oncology center.

Hospitals that are accredited by the American College of Surgeons Commission on Cancer program may have data on the number and stage of colon and rectal cancers treated in their institution. Such data can also stimulate collaboration.

Care coordination becomes increasingly important for patients who are diagnosed with colorectal cancer.

Practices should utilize existing local resources – state primary care associations, hospital affiliations, cancer coalitions, specialty advocacy organizations, health center-controlled networks and health plans, state and local health departments, academic medical centers, and legislative and political champions – to provide funding and to build networks to link care between primary care clinicians, specialty physicians, and health systems.

Some states may already receive funding through the CDC's Colorectal Cancer Control Program (CRCCP), which requires working with their own state comprehensive cancer control program and state cancer coalition. An advantage of working with cancer coalitions is that they can pull in nontraditional public health partners, such as insurers, employers, and large health systems, to try to reach as many people as possible who have not been screened. This collaboration can further improve links of care and ensure continuity among primary care clinicians, gastroenterologists, oncologists, radiation oncologists, and surgeons in underserved communities.

## Conclusion

The steps in this manual will help your practice implement an appropriate screening strategy for your patients, successfully navigate the process with tracking of results and follow-up, and help support well-functioning medical neighborhoods and effective care coordination between primary care and other specialty physicians. Our goal is to make a difference in the lives of patients by increasing colorectal cancer screening rates and ultimately decreasing colorectal cancer incidence and mortality around the country.

# CASE STUDIES

# 10 EXEMPLARY PRIMARY CARE PRACTICE CASE STUDIES

Real-world examples of colorectal cancer (CRC) screening improvements provide health systems with an opportunity to jumpstart their adoption of best practices and glean insight from lessons learned.

To augment the updated *Steps Guide*, in the summer of 2021 the ACS NCCRT reached out to ten diverse primary care health systems that had made achievements in increasing their CRC screening rates. The following ten case studies are based on interviews conducted to assess these health systems' key innovations and strategies implemented in their specific populations as well as lessons learned.* Much of the content is in their own words and the ACS NCCRT thanks them for sharing their stories.

The goal of the *Steps Guide* and these case studies is to provide practical approaches and guidance for primary care practices to apply these interventions as part of a comprehensive approach to increase CRC screening. The summary chart on the following page provides high level details for each health system and links to their in-depth summary. Within the summaries, example resources are linked and in the appendices.

*Many of the interventions documented were conducted before most health systems began implementing CRC screening for average risk patients at age 45, earlier than the previous recommendation to begin screening at age 50.

For questions or concerns, please reach out to the ACS NCCRT team at **nccrt@cancer.org**.

**Sources:**

American Cancer Society, 2023. Colorectal Cancer Facts and Figures. Accessed on 6/5/2023 from **https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2023.pdf**

# SUMMARY OF HEALTH CENTER INITIATIVES (CASE STUDIES)

### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Reducing client out-of-pocket costs
- Small media
- Navigator/Community Health Worker
- Automated campaigns
- Patient incentives

### Clinician/Staff Strategies

- Provider assessment & feedback
- Provider reminder or recall
- Provider education
- Provider incentives
- Care team/team-based approach
- Clinical champion
- HIT interventions dashboard
- Shared decision-making model
- Standing orders
- Follow up to abnormal (positive) FIT

### Reducing Structural Barriers

- Mailed FIT
- Transportation
- Community outreach
- Open scheduling
- Expanded office hours

| Organization | Overview | Pg |
|---|---|---|
| **Allegheny Health Network Premier Medical Associates**<br>*Pittsburgh, PA* | ■ Large Multi-specialty Physician Practice<br>■ Urban<br>■ EHR: Allscripts | 61 |
| **Coal Country Community Health Center**<br>*Beulah, ND* | ■ Federally Qualified Health Center<br>■ Rural<br>■ EHR: Epic | 65 |
| **East Boston Neighborhood Health Center**<br>*Boston, MA* | ■ Federally Qualified Health Center<br>■ Urban<br>■ EHR: Epic | 69 |
| **Family and Medical Counseling Service, Inc.**<br>*Washington, D.C.* | ■ Federally Qualified Health Center<br>■ Urban<br>■ EHR: eClinicalWorks | 72 |

| Organization | Overview | Pg |
|---|---|---|
| **Mercy Health System**<br>*Headquarters in St. Louis, MO* | ■ Large Health System<br>■ Urban, Suburban, Rural<br>■ EHR: Epic | 76 |
| **NOELA Community Health Center**<br>*New Orleans, LA* | ■ Federally Qualified Health Center<br>■ Urban<br>■ EHR: AthenaHealth | 80 |
| **North Hudson Community Action Corporation**<br>*Union City, NJ* | ■ Federally Qualified Health Center<br>■ Suburban<br>■ EHR: eClinicalWorks | 83 |
| **Sanford Health**<br>*Bismark, ND* | ■ Large Health System<br>■ Urban, Suburban, Rural<br>■ EHR: Epic | 86 |
| **Tiburcio Vasquez Health Center**<br>*Alameda County, CA* | ■ Federally Qualified Health Center<br>■ Suburban<br>■ EHR: OCHIN-Epic | 89 |
| **Zufall Health Community Health Center**<br>*Dover, NJ* | ■ Federally Qualified Health Center<br>■ Suburban<br>■ EHR: eClinicalWorks | 92 |

# CASE STUDY SPOTLIGHT

## Allegheny Health Network
## Premier Medical Associates

**Type**
Primary Care System

**Location**
Pittsburgh, PA

**EHR**
Allscripts

**81,000+**
patients

- 0.2% are best served in a language other than English
- 11% Black
- 0.8% (679 patients) Hispanic
- 1% (1,026 patients) of patients are uninsured

**100+**
providers

**24**
medical services and specialties

**10**
locations

### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Small media
- Navigator/Community Health Worker
- Automated campaigns

### Clinician/Staff Strategies

- Provider assessment & feedback
- Provider reminder or recall
- Provider education
- Care team/team-based approach
- Clinical champion
- HIT interventions Dashboard
- Shared decision-making model
- Follow up to abnormal (positive) FIT

### Reducing Structural Barriers

- Mailed FIT

## Background

Premier Medical Associates, an affiliate of the Allegheny Health Network (AHN), is the largest multi-specialty physician practice in the Greater Pittsburgh area. In 2012, AHN had a colorectal cancer (CRC) screening rate of 57.5% with a 15-20% mailed fecal immunochemical test (FIT) kit return rate. Many providers were only offering colonoscopies as well, believing them to be the "gold standard" of CRC screening.

## Results

Within 15 months of implementing changes, the practice increased its CRC screening rate to 75%. By 2019, AHN increased CRC screening rates to 88.7% through a combination of strategies, including a revised FIT kit mailing process (achieving a 90% mailed return rate) as well as the practice's efforts to follow up with patients with positive (abnormal) FIT results, AHN.

## Evidence-based Strategies and Innovations

AHN used a multipronged approach to increase CRC screening rates, including patient- and clinician/staff-focused strategies as well as reducing structural barriers through their revised mailed FIT program. Patient and provider education as well as reminders for both groups, a shared decision-making model, provider assessment and feedback, a FIT registry, and follow-up on positive abnormal test results are highlights from their success story.

In 2012, Dr. Francis Colangelo, the chief quality officer at the time, acting as a provider champion, brought in a nationally recognized clinical champion to educate providers on the importance of offering patients appropriate choices for screening. By sharing data on practice performance and developing routine processes for outreach, mailing and follow-up, the organization implemented a mailed FIT intervention with high rates of success. AHN provided the following strategies to increase CRC screening rates as well as lessons learned:

### Educate Providers to Offer Patients Choice

In 2012, Dr. Colangelo invited Dr. Richard Wender, ACS NCCRT chair at the time, to conduct grand rounds with 100 providers in the practice explaining the different screening modalities and the importance of offering patients choice in screening. They offered providers a new verbal script to use when offering patients CRC screening and explained the absolute need for the follow-up colonoscopy after positive or abnormal FIT results. Dr. Colangelo continues to be the clinical champion for this effort and continues to provide regular training to providers on offering patients choice. Examples of the scripts used to reinforce the need for colonoscopy after positive or abnormal FIT results are available in **Appendix CS01-1**.

### Be Transparent in Reporting Data

The practice began to transparently report monthly CRC screening rates in a visual display at provider meetings, listing each provider and how well their patient panel was doing on meeting the metric. The practice has transitioned to reporting CRC screening rates by office location instead of by provider, emphasizing the team-based nature of the improvement initiative. Examples of the current report of screening rates by office location and original provider-by-provider CRC Screening dashboard display are included as an attachment to this case study.

### Outreach to Existing Patients Turning 50* Each Month

Each month, the quality team pulls lists of average-risk patients who are newly turning 50 in the upcoming month (an average of 50-70 patients per month) and sends a tailored phone message about screening. The message alerts the patient that it is time to begin screening, that there are multiple ways for the individual to get screened, and that a kit will be mailed to their house that week for them to start screening. These patients are then added to the practice's FIT Registry for annual FIT screening. Increased or high-risk patients receive a recommendation to go straight to colonoscopy. The practice is now implementing plans to include patients aged 45-50 who have not been screened in such outreach.

* At the time this intervention was conducted, most major guidelines recommended individuals at average risk of CRC start screening at age 50.

### FIT Registry

The organization maintains a FIT registry within an Excel spreadsheet of all average-risk patients who have reached the initial age of screening and who choose to be screened with FIT, and on the 11-month anniversary of their prior test, the health center mails a FIT kit to them. Most of the patients return their FITs within a week or two. The registry contains nine years of data for patients whom they've been following for eight years now, and that's what has enabled the practice to achieve screening rates above 80% and to keep them above 80%. Patients who have a positive or abnormal FIT result are moved into the practice's Abnormal FIT Registry (see below).

### Abnormal FIT Registry

For patients who have a positive or abnormal finding on a FIT, the practice added an Alert to the EHR banner indicating "+FIT Test" in red text to grab the attention of the provider and address the issue. Providers offer these patients colonoscopy scheduling and follow-up with these patients every six months until the colonoscopy is completed. Once a colonoscopy is completed, patients are followed-up for colonoscopy screening at the recommended interval for their level of risk.

### Automated Robocall Reminders

The health system quality department runs monthly automated robocall campaigns just prior to the kits being mailed to patients. The calls are run via their EHR which delivers a recorded message to patients reminding them that their screening anniversary is coming up and that they'll be receiving a FIT kit in the mail from the health system. The quality team then mails out the FIT kits to all patients who are due for their screening that month.

### Exam Room Screening Reminder Posters

Every exam room has a locally created poster that provides education on the importance of CRC screening. An example poster is included as an attachment to this case study in **Appendix CS01-2**.

### Educating Providers on Timely Follow-up of Abnormal FIT Results

The practice makes an ongoing, concerted effort to remind providers that all positive or abnormal screening tests must be followed by colonoscopy. Examples of the scripts made available to providers are included in **Appendix CS01-1**.

### Messaging to Patients About Abnormal FIT Results

The practice provides the medical assistants and RNs with a script to use for patients who receive positive or abnormal FIT results and are reluctant to proceed with colonoscopy. Patients are reminded every 30 days to schedule their follow-up colonoscopy if necessary. Patients who still don't schedule the colonoscopy receive a mailed letter from their provider outlining the potential negative consequences of delaying follow-up.

## Tools Shared

- Examples of:
  - Script for providers for FIT – **Appendix CS01-1**.
  - Script used by MAs/RNs when contacting patients who had positive or abnormal FIT results and are reluctant to proceed with colonoscopy – **Appendix CS01-1**.
  - Mailed letter for monthly positive or abnormal FIT/colonoscopy procrastinators – **Appendix CS01-1**.
  - Robocall/text (sent one month before 50th birthday if patient has never been screened before) – **Appendix CS01-1**.
  - Example of provider-by-provider CRC screening dashboard display – **Appendix CS01-3**.
  - Screenshots of Abnormal FIT Alert in EHR and Abnormal FIT Registry – **Appendix CS01-4**.
- Exam Room Poster – **Appendix CS01-2**.

### Interviewee

**Frank Colangelo, MD, MS-HQS, FACP**
Vice President and Chief Quality Officer
Premier Medical Associates

# CASE STUDY SPOTLIGHT

## Coal Country Community Health Center

**Type**
Federally Qualified Health Center

**Location**
Beulah, ND

**EHR**
Epic

**8,685**
patients

**4**
locations

- 28.4% of patients at or below 200% Federal Poverty Guideline
- 0.5% of patients are best served in a language other than English
- 8.1% of patients are uninsured

### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Small media
- Navigator/Community Health Worker

### Clinician/Staff Strategies

- Provider reminder or recall
- Care team/team-based approach
- Clinical champion
- HIT interventions dashboard
- Shared decision-making model
- Follow up to abnormal (positive) FIT

### Reducing Structural Barriers

- Transportation
- Community outreach
- Expanded office hours

## Background

Coal Country Community Health Center (CCCHC) provides colorectal cancer (CRC) screenings for patients in rural and remote areas. These patients have unique challenges and access issues and in 2012, CCCHC had a CRC screening rate of 29%.

## Results

By January 2018, CCCHC had increased its CRC screening rate to 68% through the implementation of several innovative quality improvement projects. Their 2019 screening rate dipped to 56% but increased to 59% in 2020 despite challenges posed by the COVID-19 pandemic.

## Evidence-Based Strategies and Innovations

CCCHC saw opportunities to strengthen its collaborative relationship with the local critical access hospital and tertiary hospitals to increase screening rates, as well as make improvements to their own internal CRC screening process. For patients, they focused on education, reminders, small media, and navigation. With a clinical champion, they created a team-based approach, dashboards, reminders, shared decision-making, and improved process on follow-up after a positive or abnormal fecal immunochemical test (FIT). Lastly, they conducted community outreach, provided transportation to appointments, and expanded office hours to reduce structural barriers.

Furthermore, under the direction of Dr. Aaron Garman, Medical Director, the health center's healthcare delivery transformed from an acute care model, where they focused on sick visits, to a prevention and wellness model, where they are proactively working to keep their patients well. CCCHC shared the following solutions and lessons learned from their CRC screening interventions:

### Distributing FIT

The health center provides FITs to patients while they are in the practice. Patients are then able to return kits to the health center in-person or by mail.

### Referrals and Preferred Partnerships

- The health center has a strong relationship with the local critical access hospital in the area, which allows them to schedule colonoscopies relatively easily and have a seamless process for closing the referral loop. The critical access hospital has their own surgeon on staff, and the health center has a clinic in it. Before the patient leaves for the visit, they will have their colonoscopy appointment scheduled with the local critical access hospital.
- The health center also has an established relationship with each of the two tertiary hospitals about 80 miles away for patients who prefer to travel to one of the two facilities.
- The health center utilizes the same EHR as the critical access hospital and both tertiary hospitals, making it easy to share patient records.
- Incomplete referrals are sent from the medical records team to the nurse to perform follow-up. The reason is then documented in the EHR as to why the colonoscopy was not completed, canceled, or rescheduled.

### Existing Patient Outreach

The health center does a 100% recall for all patients who are not up to date on their CRC screening every six months. Quarterly reminders are also sent through the patient portal automatically for preventive screenings.

### Historical Test Result Data

When reviewing the medical record to see if a patient has completed their screening, any missing historical test records are requested from the entity that performed the screening. Once the historical results have been received, the medical records department sends the historical results to the nurse to update the medical record.

### EHR-based Best Practice Advisories

Within the EHR there are best practice advisories to guide the providers to perform preventive screenings. The health center can also submit requests to the EHR vendor to customize these alerts. The practice also uses order sets customized to the type of screening ordered.

### Three-Step Recall Process

The health center utilizes the dashboards within the EHR.

- When an order is noted as delinquent in the EHR, the health center first mails a letter to the patient. The practice then contacts the patient via phone if the screening has not been completed within two weeks, then lastly the practice sends another letter.
- The health center also uses text messages for reminders.
- Reminders are also sent through the patient portal via the EHR.

### Patient Education

- The health center uses the patient education module within the EHR to print education for patients. The practice also works with the North Dakota Colorectal Cancer Roundtable to develop messages and education for patients. Additionally, the health center works with other health centers and the state primary care associations in North and South Dakota to share patient education resources for CRC screenings.
- The health center provides services and education through numerous community health fairs.
- The health center uses social media platforms to provide education to the community.

### Structural Barriers

- The health center provides transportation services for patients to their practice. The practice and the critical care access hospital are working jointly to overcome patients' transportation barriers for colonoscopies.
- The health center provides after-hours services for patients unable to come between 8am–5pm.

## Outreach and Follow-up

- The health center uses a team-based approach with RN care coordinators to assist with closing loops and gaps in care.
- The day before the visit the care coordinator performs pre-visit planning and reviews the charts for any gaps in care. If any gaps are noted, it is communicated to the patient's care team via "huddle notes" within the EHR.
- During the visit, the care team reviews and provides the FIT if appropriate, along with education on how to complete the screening.
  - For normal FIT results, a letter is sent to the patient or a message is sent through the patient portal. All normal/negative results are automatically published to the patient portal.
  - The health center follows up with patients immediately upon receiving positive or abnormal FIT results. The patient is contacted by the nurse via phone and the care team determines if the patient must come in for a follow-up appointment. If the health center has been unsuccessful in reaching the patient by phone, a certified letter is mailed to the patient.
  - Kits that have not been returned are identified within the EHR as orders without results, and the nursing staff follows up. Positive or abnormal results are flagged to the provider and are scheduled for a follow-up appointment.
- If a colonoscopy is the appropriate screening method, the provider performs the history and physical at that visit to prevent the patient from having to return for another visit. The appointment is made for the patient's colonoscopy and the bowel prep instructions are given to the patient at that visit. A staff member from the critical access hospital performs a reminder call the day before the scheduled colonoscopy to review steps with the patient. After the colonoscopy, the results are sent back to the health center with the recommended screening frequency, the reason for increased screening frequency, and the health maintenance module within the EHR is updated.

## Navigation for Patients with Positive or Abnormal Results

The care coordinator for each care team navigates patients with positive or abnormal results. The care coordinator is also responsible for updating the patient's medical record if information was received by an interface, and the provider signs off on it.

### Interviewee

**Chastity Dolbec, BSN, RN**
Director of Patient Care and Innovation
Coal Country Community Health Center

# CASE STUDY SPOTLIGHT

## East Boston Neighborhood Health Center (EBNHC)

EAST BOSTON NEIGHBORHOOD HEALTH CENTER

**Type**
Federally Qualified Health Center

**Location**
Boston, MA

**EHR**
Epic

**80,744**
patients

- 87.5% of patients at or below 200% Federal Poverty Guideline
- 61.2% of patients are best served in a language other than English
- 20.6% of patients are uninsured

### Patient Strategies

- Patient education
- Small media
- Patient incentives

### Clinician/Staff Strategies

- Provider reminder or recall
- HIT interventions dashboard

## Background

In 2017, East Boston Neighborhood Health Center (EBNHC) set a goal to increase its colorectal cancer (CRC) screening rate from a baseline of 38.1%. Then, at the beginning of 2021, EBNHC also prioritized low rates of returned or successfully completed stool-based CRC screening tests (as many as 20% of returned tests had “inadequate” or “incomplete” results).

## Results

As a result of changes EBNHC increased their UDS CRC screening rate by more than 20 percentage points to 58.5% by 2019. Further work to improve fecal immunochemical test (FIT) completion reduced returned inadequate or incomplete tests from a rate of 20% in February 2021 to 11% by April 2021.

## Evidence-based Strategies and Innovations

To raise CRC screening rates, EBNHC used multiple strategies focused on patients and providers. They credit customization of patient education and patient incentives for FIT return as one part of their success story. Additionally, they achieved success by implementing provider reminders, a dashboard, and a health intervention technology (HIT) intervention to increase rates. EBNHC shared the following solutions and lessons learned from their CRC screening interventions:

### Educational Materials

EBNHC developed patient-friendly educational materials, including YouTube videos in English and Spanish and FIT instructions, such as step-by-step pictorial diagrams. QR codes that link to educational materials are also provided to patients in after-visit care summaries.

### Patient Incentives

The health center offers a $25 gift card raffle incentive to patients who return their completed FITs during the month of the raffle.

### FIT Kit Customization

The health center customized FIT kits to make them more patient-friendly in the following ways:

- Removing the pen/paper order form provided by the lab company and applying the sticker with the unique order identification number to the FIT; part of the FIT workflow is that the medical assistant enters the order identification number for the card into the electronic order when ordering the test.
- Inserting pictorial instructions along with QR Codes and links to patient instructional videos in English and Spanish.
- Inserting an incentive flyer on how to enter the raffle for a $25 gift card for returning completed kits to the lab during the month of the raffle.

### Patient Reminders

EBNHC created provider alerts within Epic Storyboard.

### HIT/Dashboard

- Created one-click pathway within Epic for ease of use for providers.
- Created report within EHR showing inadequate/incomplete tests using specified fields.

## Tools Shared

- Patient pictorial instruction sheet with QR codes to access the patient videos on YouTube – **Appendix CS03-1**.
- Incentive flyer – **Appendix CS03-2**.
- Listing of fields used from EHR to report on inadequate/incomplete tests – **Appendix CS03-3**.
- Screenshots of Provider Alert in Epic Storyboard and sample one-click order for FITs – **Appendix CS03-04**.
- Screenshot of after-visit summary from a test patient portal account that includes patient instructions for FITs – **Appendix CS03-5**.

## Interviewees

**Karin Leschly, MD**
Medical Director
East Boston Neighborhood Health Center

**Heidi Emerson, PhD, MPH**
Quality Improvement and Population Health Manager
East Boston Neighborhood Health Center

# CASE STUDY SPOTLIGHT

## Family and Medical Counseling Service (FMCS)

### Type
Federally Qualified Health Center

### Location
Washington, D.C.

### EHR
eClinicalWorks

**3,362**
patients

- 81.5% of patients at or below 200% Federal Poverty Guideline
- 1.3% of patients are best served in a language other than English
- 24.0% of patients are uninsured

### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Small media
- Navigator/Community Health Worker
- Automated campaigns

### Clinician/Staff Strategies

- Provider assessment & feedback
- Provider reminder or recall
- Care team/team-based approach
- HIT interventions dashboard
- Follow up to abnormal (positive) FIT

### Reducing Structural Barriers

- Mailed FIT
- Transportation

## Background

In 2017, Family and Medical Counseling Service, Inc. (FMCS) had a colorectal cancer (CRC) screening rate of 34.6%. FMCS faced process and capacity challenges with CRC screenings due to not having a dedicated staff person to assist with these efforts, including follow-up with patients.

## Results

By 2020, FMCS increased its CRC screening rate by 12 percentage points to 46.8%. The practice attributes its success in streamlining their processes to having a patient navigator dedicated to CRC screening efforts.

## Evidence-based Strategies and Innovations

FMCS used multiple strategies to increase their CRC screening rate. To address structural barriers, they used funding from the DC Primary Care association to provide transportation as well as a mailed fecal immunochemical test (FIT) campaign. Clinicians and patients received reminders, and a team-based approach was used as well as dashboards and a streamlined process for follow-up after positive or abnormal FITs. A variety of patient education was provided too, but their biggest change was hiring and utilizing a patient navigator to assist with CRC screening. The practice shared the following solutions and lessons learned from their CRC screening interventions:

### Patient Navigators Consistently Follow Through with Patients

- The practice hired a patient navigator to oversee CRC screening efforts. By having a dedicated patient navigator, the health center ensured consistent follow-through with patients for screening.
- The patient navigator provides education and instructions to patients on FIT kits and follows up with them to return the kits.

### Mailed FIT: Postage Issues

During the pandemic, the practice experienced issues with inconsistent postage on FIT kits mailed to patients that made it difficult to fully implement a mailed FIT campaign. Of the FIT kits distributed by mail, approximately 60% of patients returned their testing kits.

### Patient Screening Reminders

- The practice uses robo-calls through an automated system to provide reminder calls, texts, and emails for patients overdue for screening. These reminders continue until the screening is completed.
- After giving patients a FIT kit to take home, the navigator creates a “dummy” referral in the EHR and creates actions in the EHR to serve as reminders to follow up with patients to return the FIT kits.
- The practice schedules follow-up appointments with patients to return to the office within a couple of weeks and instructed patients to bring the completed kit with them for the return visit.
- When patients do not return the FITs during a return visit, providers receive notifications via telephone encounters and are encouraged to re-engage the patient at the next visit.

### Positive or Abnormal Results Follow-up

The patient navigator flags the result in the system and sends it to the provider as high priority. The provider then calls the patient with the results and alerts the patient navigator if a follow-up colonoscopy is needed. The navigator follows up with the patient and states “I am following up on the results that were shared with you by your doctor”.

### Colonoscopy Referral Follow-Through

- The patient navigator schedules the colonoscopy appointment for the patient. Two days before the appointment, the navigator conducts a reminder call. If transportation barriers are noted, the navigator works to set up transportation assistance. Once results are returned, they are attached to the order, and a note is entered in the referral/diagnostic imaging order stating, "the report is attached, please enter results". It is then assigned to the provider.
- If the patient does not show for their colonoscopy, the navigator tries to reach the patient three times. For those that remain unsuccessful, the navigator sends the order back to the provider, and in the results writes "scheduling unsuccessful".

### Lab Requisitions

To prevent discrepancies with specimens and orders, the patient navigator staples the lab requisition form to the shipping envelope and instructs patients to include their name and date of birth on the kit.

### Provider Prompts in the EHR

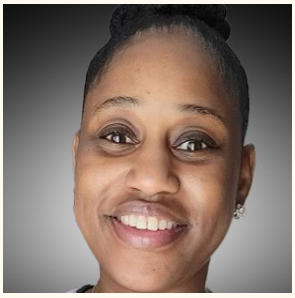
- **Clinical Decision Support System (CDSS) Alerts & Chart Reviews** – CDSS alerts providers and staff if the patient is due for a CRC screening. In addition, the medical assistants conduct chart reviews the day before the visit and will add a note if the patient is due for a screening.
- **Healthcare Effectiveness Data and Information Set (HEDIS) Dashboard** – allows providers to review their individual compliance rates with clinical quality measures. Providers can drill down to view which patients are non-compliant.
- Appropriately attaching results to diagnostic imaging orders is key for the practice to receive performance measure credit for performing the screening. The patient navigator worked to streamline this process and ensure that the proper dates were on the orders. This was a collaborative effort between the navigator, medical records, and medical assistants.

### Patient Education

Prior to the COVID-19 pandemic, the patient navigator provided American Cancer Society (ACS) pamphlets to patients and performed face-to-face education. During March, Colorectal Cancer Awareness Month, FMCS also set up a table in the lobby to provide educational talks about CRC. The practice also provides patient education via the patient portal. If the patient navigator was not able to perform in-person education, they would provide education via phone and send an ACS pamphlet via mail.

### Structural Barriers

- **Medical Transportation** – Through their partnership with the DC Primary Care Association, the health center received funds to assist some patients with transportation needs to consult appointments. Pre-COVID, the navigator also arranged for transportation for post-op procedures.
- **Courier** – The navigator sometimes picks up specimens directly from patients' homes.



## Interviewees

**Demetria A-T Premier, MSW**
Quality Improvement Health Information Management Coordinator
Family and Medical Counseling Service, Inc.

**Michael Serlin, MD**
Former Medical Director
Family and Medical Counseling Service, Inc.

**Marquita Iddirisu**
Former Patient Navigator
Family and Medical Counseling Service, Inc.

# CASE STUDY SPOTLIGHT

## Mercy Health System

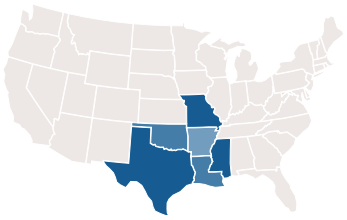
**Type**
Primary Care Practice

**Headquarters**
St. Louis, MO

**EHR**
Epic

**3,671,033**
outpatient visits in 2020

**Practices in**



### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Small media

### Clinician/Staff Strategies

- Provider reminder or recall
- Provider education
- Provider incentives
- Care team/team-based approach
- HIT interventions dashboard
- Shared decision-making model

### Reducing Structural Barriers

- Mailed FIT

## Background

Mercy Health System (MHS) examined their colorectal cancer (CRC) screening process and calculated it would need to recruit 32 providers to conduct screening colonoscopies full-time just to address the backlog of colonoscopies. To alleviate this backlog, they implemented a policy of offering fecal immunochemical tests (FITs) as the first line of screening for average-risk patients in what they called their “FIT first” campaign.

## Results

Eighty-five percent of MHS patients completed their CRC screening without needing a colonoscopy during the FIT first campaign. The cost savings and reduction in unnecessary burden on the health system were significant. By 2019, the health system had reached an overall CRC screening rate of 60% and increased that to 76% by 2021 among Medicare patients.

## Evidence-based Strategies and Innovations

MHS has taken a patient-centered approach to CRC screening, engaging in shared decision-making, while also training staff and providers on how to provide options to the patients. Providers and care teams worked together and received reminders, used an HL7 interface (data processing system) upgrade, and implemented a mailed FIT campaign to increase CRC screening rates.

At the beginning of this process, MHS found that their practices considered FITs easy to dismiss due to the lack of upfront financial reward and the required follow-up after a positive or abnormal test. The COVID-19 pandemic created an opportunity for the health system to use FITs as an appropriate option for CRC screening when screening colonoscopies were paused and the subsequent backlog of patients needing screening ensued. MHS shared the following solutions and lessons learned from the changes they made to their CRC screening strategy:

### Mailed FIT Kits

- Obtaining test results can be challenging when the intervention is led by a health system partner and not the practice. The health system partnered with a Medicare Advantage plan on a mailed FIT intervention where FIT kits were mailed directly by the health plan to beneficiaries, rather than distributed by providers to patients. The main challenge that the practice encountered with this intervention is that they were unable to successfully track and follow-up with patients at the system level on completion of the tests, results of the FITs, and follow-up of positive or abnormal results. While the health plan would send the results back to the primary care providers at the practice, there was often a lag of several months before the results were manually logged into the practice EHR. Since there was no mechanism to electronically transmit the results directly from the health plan to the practice EHR, the practice ran into challenges with reliably entering and tracking results. The health system found they require tighter control to ensure receipt of timely results to effectively follow-up with patients on their test results and ensure proper follow-up if needed.
- **Patient Education** – The FIT kit used by their lab (InSure® ONE™) is an at-home test kit that only requires water-based sampling of one bowel movement. The practice is currently going through the process of retooling and implementing new workflows for mailing these FIT kits and ensuring that patient education instructions are included in mailings to refer to the water-based method as opposed to their previous FIT that required the patient to also brush the stool.
- **"Freshness counts"** – The health system found it is necessary to ensure that specimens are sent to the lab before they expire and to be cognizant of expiration dates of test kits. Staff and providers need to communicate to patients the importance of timeliness in returning samples. If specimens are being sent or dropped off at the provider's office before being sent to the lab, they should be sent to the lab right away to ensure freshness. Labs will not process expired kits either.
    - Postal service issues – during the pandemic, it sometimes took two weeks or more for samples to reach the labs. If mailing specimens, they need to be sent as soon as possible since many samples expire within four to six weeks.

- Best practices/lessons learned:
  - Conduct pilot tests to work out potential kinks with mailed materials
  - Ensure return envelopes are pre-labeled and stamped with appropriate postage
  - Follow-up with patients should occur within a week of distributing test kits

### EHR Point of Care (POC) Prompts

The Encounter Guide EHR POC prompt provides alerts used by roomers to begin educating patients and start the conversation about CRC screening. The health system uses patient educational content from Healthwise in the EHR, which can be made available to patients as a printed handout and/or transmitted electronically via the patient portal. FIT kits are provided either during the visit or mailed to the patient.

### mt-sDNA (Cologuard) HL7 Interface

For patients whose health insurance covers Cologuard, the health system has a bi-directional interface with EPIC that enables them to order Cologuard and receive the results of the test through the interface. This has been a turnkey solution for the providers. Once the HL7 interface is established, the order gets sent directly to Exact Sciences (the maker of Cologuard) from the EHR, and Exact Sciences follows up with the patient. The resulting report comes back to the EHR electronically through the interface.

### Provider Incentives

In July 2021, MHS began a compensation incentive tied to quality achievements, which includes CRC screening as one of those measures. Since they still have colonoscopy backlogs, they are using this opportunity to drive “FIT first”.

### Provider/staff Education

MHS is now re-educating staff about the new FIT kit, realizing that the clinical teams, providers, and staff all need reassurance about test reliability and the differences in sample methodology. It is critical that patients hear consistent instructions from everyone that they interact within the health system.

### FIT First

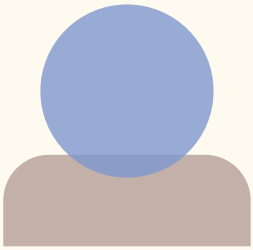
By leading with FITs first for average-risk patients and prioritizing patients with positive or abnormal results for colonoscopy, the health system is addressing what it sees as a myth of the reliability of testing options. The health system believes the message should be: “All tests are equally reliable if the tests are followed through” and still takes an informed and shared decision-making approach with patients. The health system also shares information with providers, called “Throw a FIT”, about cost-effectiveness of the stool-based tests to help reduce their bias towards colonoscopy for average risk patients.

## Tools Shared

- Encounter Guide – during the rooming process, if the patient is due for CRC screening, a point of care prompt will come up for the provider in the EHR – **Appendix CS05-1**.
- Sample letters, sample script for campaigns, telephone and text messaging campaigns – **Appendix CS05-2**.
- Information on how to provide patient-centered, cost-effective CRC options to patients in making the decisions ("Throw a FIT" provider training slides) – **Appendix CS05-3**.

### Interviewees

**James Rogers, MD, FACP**
Adult Primary Care and Medical Director
Mercy Health System



**Debra Barnhart**
Director of Operations
Mercy Health System

# CASE STUDY SPOTLIGHT

## NOELA Community Health Center – Mary Queen of Vietnam (MQVN) Community Development Corporation

### Type
Federally Qualified Health Center

### Location
New Orleans, LA

### EHR
Athena Health

**4,904**
patients

- 94.0% of patients at or below 200% Federal Poverty Guideline
- 63.2% of patients are best served in a language other than English
- 36.0% of patients are uninsured

### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Small media
- Navigator/Community Health Worker

### Clinician/Staff Strategies

- Provider assessment & feedback
- Provider reminder or recall
- Provider education
- Care team/team-based approach
- Clinical champion
- HIT interventions dashboard

### Reducing Structural Barriers

- Mailed FIT

## Background

NOELA's initial review of colorectal cancer (CRC) screening rates in 2013 revealed a rate of 3%, prompting them to make increasing CRC screening a priority. By 2014, NOELA started work with the American Cancer Society and signed the 80% by 2018 pledge (a commitment to strive toward reaching an 80% screening rate). In 2016, their rates had increased to 70.4% and they were working to further increase their rates.

## Results

NOELA's UDS CRC screening rate increased to 80% in 2018, achieving the above-mentioned goal. In 2019 their rate was 73.4% and in 2020 it was 75.5%, remaining consistently high across time, including during the COVID-19 pandemic.

## Evidence-based Strategies and Interventions

NOELA employed several different strategies to boost their already high CRC screening rates, including implementation of a mailed fecal immunochemical test (FIT) intervention, patient navigators educating patients about CRC screening, providing training to all staff on how to distribute FIT kits to patients, and use of provider dashboards to promote screening within the practice. NOELA provided the following solutions and lessons learned:

### Share Data and Feedback with all Staff

The quality improvement director runs monthly reports on the health center's CRC screening data and conducts provider feedback sessions. During the sessions, the staff review test results and ensure that patients are receiving appropriate follow-up. They also look at missed opportunity reports to understand the number of patients that have completed CRC screening and those that have not, and then try to focus on how to improve their screening rates.

- **CRC data and reports shared with all staff:** cancer screening rates comparison (year-to-date); CRC screening – monthly comparison; CRC screening – trailing year comparison; CRC screening – missed opportunity report; colonoscopy vs. FIT.
- **Data and reports shared with patient navigators:** CRC screening trend report; care coordination – client reminders/patient navigation; FITs distributed vs. FITs returned; FITs distributed tracker.
- **Data and reports shared with providers:** daily huddle notes; provider scorecard; cancer screening provider comparison; data discussed during QI meetings.

### Patient Navigators

- Navigators go through the registry of existing patients that are due for FIT and contact them by phone. If they have an upcoming appointment, the navigator informs the patient that during their upcoming appointment they can pick up an FIT kit.
- After distributing the FITs, the navigator calls the patient to remind them to bring back the test within a week or two of giving it out, and then reminds them monthly until the test is returned.
- NOELA found they have a better FIT return rate when the patient navigator distributes the FIT than when the provider gives it out. They found this had more to do with the follow up provided by the patient navigator handing it out as opposed to lack of a consistent follow up when the provider gives it out.

### Mailed FITs

During the height of the COVID-19 pandemic, patients often didn't want to come into the health center. When reaching out to remind patients, navigators would ask if patients preferred to pick up or receive mailed FIT kits. If mailed a kit, patients would either return them in the mail or bring them back to the health center, as most do not live very far away.

### Mail Postcards to Patients Who Don't Respond to Phone Calls

Reminder postcards are mailed to patients who are not available by phone, asking them to call to schedule an appointment. For patients reached by phone, if they are unable to come into the clinic, they're offered the opportunity to receive the FIT kit by mail.

### Train Clinical and Non-clinical Staff to Communicate with Patients About FIT

NOELA trained most staff in the clinic on how the test is performed. Whether it's front desk staff or medical assistants, they all know how to explain the process to patients. If the medical assistant did not cover it with the patient by the time the provider gets in the room, the provider will make the recommendation and then either the provider will give the FIT kit to the patient, or at checkout, they ask the front desk staff to explain to patients how to complete it before they leave. Most of the staff are familiar with the test, how it's conducted, and how to explain it to patients.

### More Visits per Year = Better Screening Percentage

NOELA found a strong correlation between the number of visits patients have per year, and whether they were up to date with their screenings or not. Patients who tend to complete the FIT kits are the ones who have at least three or more visits throughout the year.

**Interviewee**

**Keith Winfrey, MD**
Chief Medical Officer
New Orleans East Community Health Center

# CASE STUDY SPOTLIGHT

## North Hudson Community Action Corporation (NHCAC)

NORTH HUDSON COMMUNITY ACTION CORPORATION

**Type**
Federally Qualified Health Center

**Location**
Union City, NJ

**EHR**
eClinicalWorks

**58,896**
patients

- 96.6% of patients at or below 200% Federal Poverty Guideline
- 76.2% of patients are best served in a language other than English
- 46.3% of patients are uninsured

### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Reducing client out-of-pocket costs
- Navigator/Community Health Worker
- Automated campaigns

### Clinician/Staff Strategies

- Care team/team-based approach
- Standing orders
- Follow up to abnormal (positive) FIT

### Reducing Structural Barriers

- Mailed FIT
- Expanded office hours

## Background

In 2017, North Hudson Community Action Corporation (NHCAC) had a colorectal cancer (CRC) screening rate above 71.4%, higher than the national average for FQHCs. They still prioritized reaching a CRC screening rate of 80% or higher in their clinics, which serve over 50,000 predominantly Hispanic/Latino patients.

## Results

By 2018, NHCAC's UDS CRC screening rate increased to 87.1%. Like other health centers, the health center experienced a decline in their UDS CRC screening rates to 77.1% during the height of the COVID-19 pandemic in 2020. As of June 2021, the health center reported that their screening rate had started to improve again and was up to 82%.

## Evidence-based Strategies and Innovations

NHCAC prioritized increasing CRC screening rates by continually improving screening processes and addressing patient barriers to screening, including hesitancy to complete CRC screening. They provided patient education as well as funding for screening costs if needed. A team-based approach, standing orders, expanded hours, and a mailed fecal immunochemical test (FIT) campaign were also used to increase rates. The health center shared the following key interventions they implemented, and lessons learned:

### Outreach to Existing Patients/Patient Reminders

- A data analyst provides a list of patients reaching the initial age of screening in that year to patient navigators who conduct outreach to bring patients in for screening.
- The practice developed a Happy Birthday Letter to remind patients that they are due for CRC screening.

### Standing Orders

Standing orders are available so medical assistants can order the test for eligible patients without waiting for an order from a primary care clinician.

### Location of FIT/Guaiac-based Fecal Occult Blood Test (gFOBT)

Tests are kept in the clinical area for easy access. Medical assistants provide the education to the patients rather than the patients going to the lab.

### Mailed FIT/gFOBT

- The practice mails FIT/gFOBT to patients during telehealth visits with specific instructions on how to return the test. Patients return tests to the practice in-person, they do not mail tests back.
- The practice was able to utilize some of the American Rescue Plan (ARP) COVID-19 funding to assist with implementation.

### Test Affordability

For patients without health insurance who cannot afford a FIT, gFOBT is provided. The practice also offers charity care and the CDC-funded **NJ Cancer Education and Early Detection (NJCEED)** program provides free screenings to patients in need.

### Patient Education and Communication

- Most non-compliance arises from patients not wanting to perform the test, so the practice relies upon patient education to address patients' reluctance to screening.
- The practice utilizes the EHR to send out reminder letters, texts, calls, and campaigns. Patient education is sent through the patient portal.

### Team-based Approach

- Medical assistants perform chart scrubs the day before every patient visit. They also order the test where appropriate and educate the patient on the testing instructions.
- **Negative/normal FIT/gFOBT results** – once results are received, they're communicated to patients by the provider through the portal within two weeks.
- **Abnormal FIT/gFOBT results** – the provider signs off on any abnormal results within seven days with a plan of care and follow-up. The patient navigator reviews abnormal results and follows up with the patient.
- **Positive FIT/gFOBT results** – Patient navigators follow up with patients who have had positive results to schedule them for an appointment to review the results. Referral navigators follow up on referrals for patients for diagnostic colonoscopies. The referral navigators make appointments for the follow-up colonoscopy and assist patients with the process.

### Extended Office Hours

The practice has office hours until 7 p.m. some days and also provides services on Saturdays. This allows patients to return kits outside of normal business hours.

### Robo-calls

The practice uses an automated system to send robo-calls to patients overdue for returning lab tests.

## Tool Shared

Sample Happy Birthday letter – in English and in Spanish

## Interviewees

**Rita Knause, MD**
Chief Medical Officer
North Hudson Community Action Corporation

**Jeannette Sujovolsky, DO**
Director of Adult Medicine
North Hudson Community Action Corporation

**Nishie Perez, MA, BSN, RN**
Director QI/CRM, Medical Affairs Department
North Hudson Community Action Corporation

# CASE STUDY SPOTLIGHT

## Sanford Health

**Type**
Primary Care System

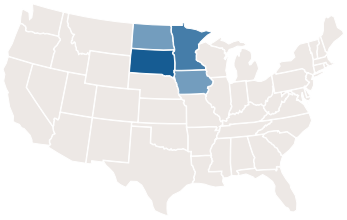
**Headquarters**
Bismarck, ND

**EHR**
Epic

**5.2M**
outpatient and clinic visits

**40%**
rural population

**Practices in**



### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Small media

### Clinician/Staff Strategies

- Provider education
- Shared decision-making model
- Follow up to abnormal (positive) FIT

### Reducing Structural Barriers

- Mailed FIT
- Transportation
- Open scheduling
- Expanded office hours

## Background

Sanford Health serves a large rural community with unique challenges related to accessing colorectal cancer (CRC) screenings. Patients may live 100+ miles away from their locations, making fecal immunochemical test (FIT) drop-off and colonoscopy appointments difficult. Furthermore, Sanford serves those on Native American Reservations where regular access to bathrooms is not guaranteed, so prep for colonoscopy may not be feasible.

## Results

As of June 2019, twenty-nine of Sanford Health's primary care clinics were exceeding the 80% CRC screening goal, with a system-wide screening rate of 78%, up 9.4 percentage points from 2015. CRC screening rates decreased in 2020 and 2021 due to challenges with COVID, but Sanford Health remains committed to working toward the 80% goal.

## Evidence-based Strategies and Innovations

Sanford Health has implemented several FIT and colonoscopy-focused innovations for increasing rural patients' access to CRC screenings. While using a shared decision-making tool, providers and patients were educated about "the best test is the test that gets completed", focusing on a grant-funded mailed FIT campaign. Patients were empowered to schedule their own colonoscopies and Sanford Health expanded hours and transportation assistance for those who required it. Sanford Health shared the following solutions and lessons learned from their CRC screening interventions:

### Provider and Patient Education

**The best test is the test that gets completed** – focusing on any screening test is better than not screening at all.

### Mailed FITs

The health system received a $10K grant from the North Dakota Department of Health Comprehensive Cancer Control Program to implement a pilot project to mail FIT kits to patients in rural and remote areas. The project involved contacting patients to see if they were interested in participating and mailing FIT kits to their homes.

- **Eliminates transportation barriers** by offering patients who live more than 100 miles from the practice the option of having FIT kits mailed to their homes.
- **Use self-addressed stamped envelopes** for FIT returns to minimize inconvenience and cost to patients.
- **Outreach phone calls to existing patients to assess readiness for intervention** – patients were called to see if they were interested in receiving a FIT by mail. Patients were informed that they were overdue for CRC screening, benefits of screening were explained, the test was described, and then they were asked if they'd be interested in receiving a FIT in the mail to complete the test at home and return it to the health center by mail.
- **Mail and track for follow-ups** – If the FIT was not returned within 30 days, the practice phoned the patient with a reminder to return the kit.

### Provide Transportation Assistance

For positive or abnormal FIT results requiring follow-up colonoscopy, the health system provides taxi vouchers, as well as occasional overnight lodging assistance to patients who can't get to their follow-up colonoscopy due to transportation barriers.

### Saturday Colonoscopy Screening Days

The practice has conducted several Saturday CRC screening day blitzes over the past few years that were both advertised and directly promoted with letter mailings to patients. They have conducted them in March for CRC awareness month and in November and December as well. They found that the November and December timeframe was much more effective, due to insurance coverage and meeting deductibles for the year. These colonoscopy screening events were so successful that they have increased the frequency from one Saturday in March the first year, to now conducting two dates in November and two in December each year.

### Use of a Shared Decision-making Communication Tool

The practice uses an internally developed shared decision-making tool to start the conversation between the staff and the patient about the three CRC screening test options they offer (FIT, mt-sDNA and colonoscopy). Patients are offered a one-page, pocket-card handout that describes available screening options. The shared decision-making tool is also available for patients to download from the patient portal.

### Enable Patients to Schedule Their Own Colonoscopy via the Patient Portal

The patient portal automatically displays an alert when patients are of age and overdue based on their screening schedule. Since the practice is part of an integrated health system, the patient can schedule their colonoscopy directly from the patient portal which is then triaged by an RN in the scheduling department. Patients are either scheduled for a procedure based on past history without having to get an order from their primary care physician or are scheduled for a gastroenterology consult. Staff encourage the use of the patient portal at every visit or have them sign up if they're not already connected.

## Tool Shared

Homegrown shared decision-making tool – **Appendix CS08-1**.

### Interviewee

**Stacey Will, MSB, BSN, RN**
Quality Improvement Advisor
Sanford Health

# CASE STUDY SPOTLIGHT

## Tiburcio Vasquez Health Center

**Type**
Federally Qualified Health Center

**Location**
Alameda County, CA

**EHR**
OCHIN-Epic

**27,492**
patients

- 92.0% of patients at or below 200% Federal Poverty Guideline
- 60.8% of patients are best served in a language other than English
- 28.0% of patients are uninsured

**4**
locations

Union City | Hayward | San Leandro | Fremont

### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Navigator/Community Health Worker

### Clinician/Staff Strategies

- Provider reminder or recall
- Care team/team-based approach

### Reducing Structural Barriers

- Open scheduling
- Expanded office hours

## Background

Tiburcio Vasquez Health Center (TVHC) placed a focus on increasing colorectal cancer (CRC) screening rates after identifying that in 2016 the health center's CRC screening rate was below the national average for Federally Qualified Health Centers (FQHCs).

## Results

Between 2017 and 2019, the practice increased CRC screening rates from 33% to 40%.

## Evidence-based Strategies and Innovations

TVHC used multiple strategies to increase their CRC screening rates, including reducing structural barriers by offering expanded office hours and mailed fecal immunochemical tests (FITs). All staff in the participating clinics were engaged in the CRC screening efforts and educated about the importance and handling of FITs. Patient education and reminders were also essential to success, as well as designating a Medical Assistant (MA) to assist in the process. TVHC shared the following solutions and lessons learned from their CRC screening interventions:

### Mailed FITs

- The practice has a dedicated MA who spends four hours per week on mailed FIT processes.
- TVHC adapted successes from different practices, such as putting labels on kits to remind the patient to add the date the sample was completed. The MA also sends reminders to patients to keep the kit in the bathroom for easier access.

### The Health Center Sought Ways to "Normalize Poop" with Staff

- TVHC allowed open dialogue with non-clinical staff to discuss concerns and provided education to them on the importance of accepting FIT kits.
- The front office staff were the ones receiving the FIT kits and had to get used to it. The message shared with them was, "This is something that can save someone's life". Providers and MAs normalized the process of FIT collection in their practice by creating a supportive and open environment.

### Patient Education and Communication

After-visit summaries provided to patients who take home a FIT include an illustrated, wordless instruction sheet developed by the Kaiser Permanente Center for Health Research. The practice then follows up with patients by text message. This is available in **Appendix CS09-4**.

### Birthday Card Reminder Campaign

- TVHC implemented a birthday reminder campaign for existing patients who have both a birthday and an upcoming appointment. They mail FIT kits to these patients and give them a choice to either return their completed kit by mail or bring it with them when they come in for their visit.
  - The key to success with this campaign is that patients are already making an investment in their health. Patients that received these reminders had been in for an appointment within the last 18 months and had an upcoming appointment in six weeks.
  - Patients who had not been in for a recent visit or did not have an upcoming appointment were much less likely to return a completed FIT.
- An alert is placed in the chart and during the reminder call for the visit. The MA encourages the patient to bring in the test or return it via mail.

### Addressing Structural Barriers

- In addition to offering same-day and urgent appointments, the practice also provides after-hours appointments, some Saturday appointments, a mobile van, and outdoor wellness clinics where patients can obtain FITs. They also implemented a "poop on-demand" option, which offers patients the opportunity to provide a stool sample for testing while in the office.
- One of the structural barriers the practice encountered was that patients didn't want to walk upstairs to the lab to drop off their completed FIT kits. Additionally, both the lab and post office would frequently reject mailed FIT kits from patients. To address this issue:
  - The health center worked with the lab supervisor to agree on a process where the patient returns the kit to the clinic's front desk staff, who then hand-deliver the specimens to the lab.
  - Part of normalizing the FIT kits with front office staff included providing them with gloves and having them agree to deliver the kits daily to the lab (sometimes several times a day). This not only assisted patients who were unable or unwilling to climb stairs, it also eliminated the barrier of both the lab and the post office rejecting mailed kits.

## Tools Shared

- Photo of FIT colon reminder – the graphic is stuck to all the computers in the adult medicine clinic as a reminder to check CRC screening status – **Appendix CS09-1**.
- Flyer promoting colorectal cancer screening to African American patients – **Appendix CS09-2**.
- Mailed FIT workflow (used by MAs until centralized care coordination staff are available), when order is sent it goes to a centralized work queue for mailing – **Appendix CS09-3**.
- Wordless FIT instructions for patients – the health center uses the Kaiser Permanente Center for Health Research wordless FIT instructions – **Appendix CS09-4**.

## Interviewees

**Blair Brown, MD**
Senior Director, Population Health and Quality Improvement
Tiburcio Vasquez Health Center

**Jessica Jamison, MPH**
Former Director, Patient and Community Engagement
Tiburcio Vasquez Health Center

# CASE STUDY SPOTLIGHT

## Zufall Health Community Health Centers

ZUFALL HEALTH COMMUNITY HEALTH CENTERS

**Type**
Federally Qualified Health Center

**Location**
Dover, NJ

**EHR**
eClinicalWorks

**41,497**
patients

- 87.9% of patients at or below 200% Federal Poverty Guideline
- 66.4% of patients are best served in a language other than English
- 51.6% of patients are uninsured

### Patient Strategies

- Patient reminder or recall/in reach
- Patient education
- Reducing client out-of-pocket costs
- Navigator/Community Health Worker
- Automated campaigns
- Patient incentives

### Clinician/Staff Strategies

- Provider reminder or recall
- Provider education
- HIT interventions dashboard
- Standing orders
- Follow up to abnormal (positive) FIT

### Background

In 2015, Zufall Health Community Health Centers' (Zufall Health's) colorectal cancer (CRC) screening UDS rate was 50%. Zufall Health prioritized CRC screening after engaging with the Screen NJ Initiative and identifying a burden on individual providers managing the entire CRC screening process on their own.

### Results

By employing CRC screening navigators as additional support for providers, completing follow-up colonoscopies, and provider feedback/assessments, the health center increased its UDS CRC screening rate to 65% in 2019.

## Evidence-based Strategies and Innovations

Zufall Health used multiple strategies to improve its CRC screening rates and processes. The health center credits employing six CRC screening navigators who dedicated r time to providing support to the practice in conducting outreach, education, and follow-up of patients due for CRC screening as essential to their success. Additional patient-focused strategies include patient education, reminders, reducing out-of-pocket costs, and patient incentives. Clinician and staff-focused strategies include educating staff and providers and using dashboards to track progress. The health center shared the following summary of solutions and lessons learned while improving CRC screening in their practices:

### CRC Screening Navigation

Over the last several years, Zufall Health has been funded to provide CRC screening and navigation at seven of their locations by **Screen NJ**, an initiative between Rutgers Cancer Institute of New Jersey and the New Jersey Department of Health to increase CRC screening rates. Zufall Health's six CRC screening navigators are medical assistants (MAs) who receive special training to conduct outreach, communicate with, and follow up with patients throughout all steps of the CRC screening process. The CRC screening navigators also work very closely with and provide additional support to the primary care providers. Navigators receive specialized training on the importance of CRC screening, current practice guidelines, health center screening rates, and practice workflow for ordering tests, communicating with patients and providers, and following up with patients with their test results.

### Reducing Patient Out-of-pocket Costs

The Screen NJ Initiative also helps subsidize the cost of FITs and colonoscopies so that the cost is not a burden to the patient.

### FIT Champions

The CRC screening navigators are empowered to remind providers about patients who are due for CRC screening. They reinforce the Clinical Decision Support System (CDSS) alerts in the EHR, which identify patients due for screening. They also remind providers to order the FIT or colonoscopy by entering the standing orders for the providers when rooming the patient.

The CRC screening navigators receive specialized training that enables them to speak with patients about the importance of CRC screening. When the provider meets with the patient, the educational message is reinforced, and that helps patients to better understand why they should complete the screening test.

### Peer Learning and Mentoring

The CRC screening navigators meet at least quarterly to discuss how best to encourage patients to return their FITs and follow through with colonoscopy if needed. The more experienced CRC screening navigators facilitate the discussions and are also champions within the practice to ensure that providers and front desk staff are aware of workflows for distributing and receiving FIT kits. The quality improvement process of using Plan-Do-Study-Act (PDSA) cycles of change for implementing evidence-based interventions is discussed. For example, screening navigators might volunteer to test the process of mailing FIT to patients that are due or overdue for screening. During these meetings, the team shares successes and ideas that have worked at their site for implementation at other sites.

### Dashboards

Quarterly reviews of the health center's CRC screening dashboards and providing shout-out "gold stars" to teams with the highest results helps to motivate providers and teams to outperform each other and continuously improve their outreach and follow up with patients to complete their screenings.

### Text and Voicemail Messaging Campaigns

Zufall Health uses the Luma Health text and voicemail messaging platform, coupled with an EHR-based patient registry, as an initial reminder to encourage patients to schedule their appointments for CRC screening. The messages lead with, "Our records show it is time for your colorectal cancer screening." By using an automated messaging campaign first, it helps reduce the number of calls that the CRC screening navigators need to make to follow up with patients who are due for screening but haven't yet scheduled their appointments.

### Front Desk Staff Training

The practice trains the front desk staff on how to greet and assist patients who bring completed kits back to the office and where to drop them off when returning them.

### Contactless FIT Drop-off Boxes

During the COVID-19 pandemic, Zufall Health set up several contactless drop-off boxes where patients can return their completed FIT without entering the building.

### Patient Incentives

The practice provides $10 gift cards to all patients who return their completed FITs to the practice. The CRC screening navigators promote incentives to patients when providing them with instructions about how to do the test.

### Positive FIT Dashboard

The focus of the Positive FIT dashboard is to enable follow-up with patients who have positive (or abnormal) FIT results. Within one week of receiving positive or abnormal FIT results, CRC screening navigators call patients and assist them in scheduling their follow-up colonoscopy.

## Tools Shared

- Contactless FIT drop-off box (photograph provided) – **Appendix CS10-1**.
- Sample positive FIT dashboard used for quality improvement – **Appendix CS10-2**.
- Standing order policy for MAs – **Appendix CS10-3**.
- PowerPoint for MA training – **Appendix CS10-4**.
- Sample patient text and voicemail reminders – **Appendix CS10-5**.
- Sample quarterly patient newsletter with an article about FIT incentive – **Appendix CS10-6**.

## Interviewees

**Rina Ramirez, MD**
Chief Medical Officer
Zufall Health Community Health Centers

**Kathleen Felezzola, RN**
Director of Nursing
Zufall Health Community Health Centers

**Kathy Orchen, PA, MPH, MS**
Quality Assurance Program Manager
Zufall Health Community Health Centers

# CASE STUDY APPENDICES

## CS01-1

### Script for providers:

I will agree to allow you to be screened with a FIT (or FIT-DNA) if you promise me that you will do a colonoscopy if the result is positive.

### Script for MA/RN contacting the patient with positive FIT result who is reluctant to proceed with diagnostic colonoscopy:

- Dr. _____ will be very concerned that you do not want to have the colonoscopy done. He/She thinks it is very important to do that.
- The colonoscopy is needed because a positive result on a FIT test can be the first warning sign that there is a polyp or colorectal cancer.
- Yes your hemorrhoids may have been bleeding, but you could also have a polyp or cancer. The only way to make sure you are OK is to have the colonoscopy done.
- No. We never order second FIT tests to make see if the bleeding has gone away. Every positive FIT needs a colonoscopy to rule out more serious causes of bleeding.
- I am going to let Dr. _____ know today that you do not want to do the test. He/She may reach out to you letting you know how important it is to get this done.

### Mailed letter for monthly positive FIT/colonoscopy procrastinators:

Dear _____

As your Primary Care Physician at Premier Medical Associates, I am writing to ask you to schedule a very important test.

Our records show that within the past month, you completed an at-home stool test for colorectal cancer screening which showed a positive result. As a result, I recommended that you have a colonoscopy. To date, our records show that you have not completed your colonoscopy, and as your doctor, I am very concerned.

A positive test result is sometimes a warning sign that a person has pre-cancerous colon polyps (growths) that need to be removed to prevent them from turning into colorectal cancer. Rarely, a positive test is a warning sign of early-stage colorectal cancer that needs to be taken care of promptly.

If our records are inaccurate and you have had a colonoscopy done, please contact your GI doctor and have them forward your results to our office. If you have not had a colonoscopy done, it is critical that you do so and I ask that you contact our office in the next 10 days, or as soon as possible, to schedule this test.

Let's face it, few people consider themselves at risk for cancer and these screenings are very easy to put off. For some reason, the idea of a colonoscopy itself is daunting. However, the reality is that colorectal cancer is the second leading cause of cancer-related deaths in Pennsylvania and the United States.

Most colorectal cancer-related deaths can be prevented. If detected early, this cancer has a 90% survival rate. Early detection can mean the difference between life and death. Our team at Premier Medical Associates stands by to assist you any way we can.

If you have questions about how this test is done, how it will be paid for, or any other concerns we can address or you or a member of your family as you follow through on this important test, please contact our GI nurse at 412-457-0427.

Sincerely, Dr. _____

## Robocall/text (sent 1 month before 50th birthday if a patient has never been screened before)

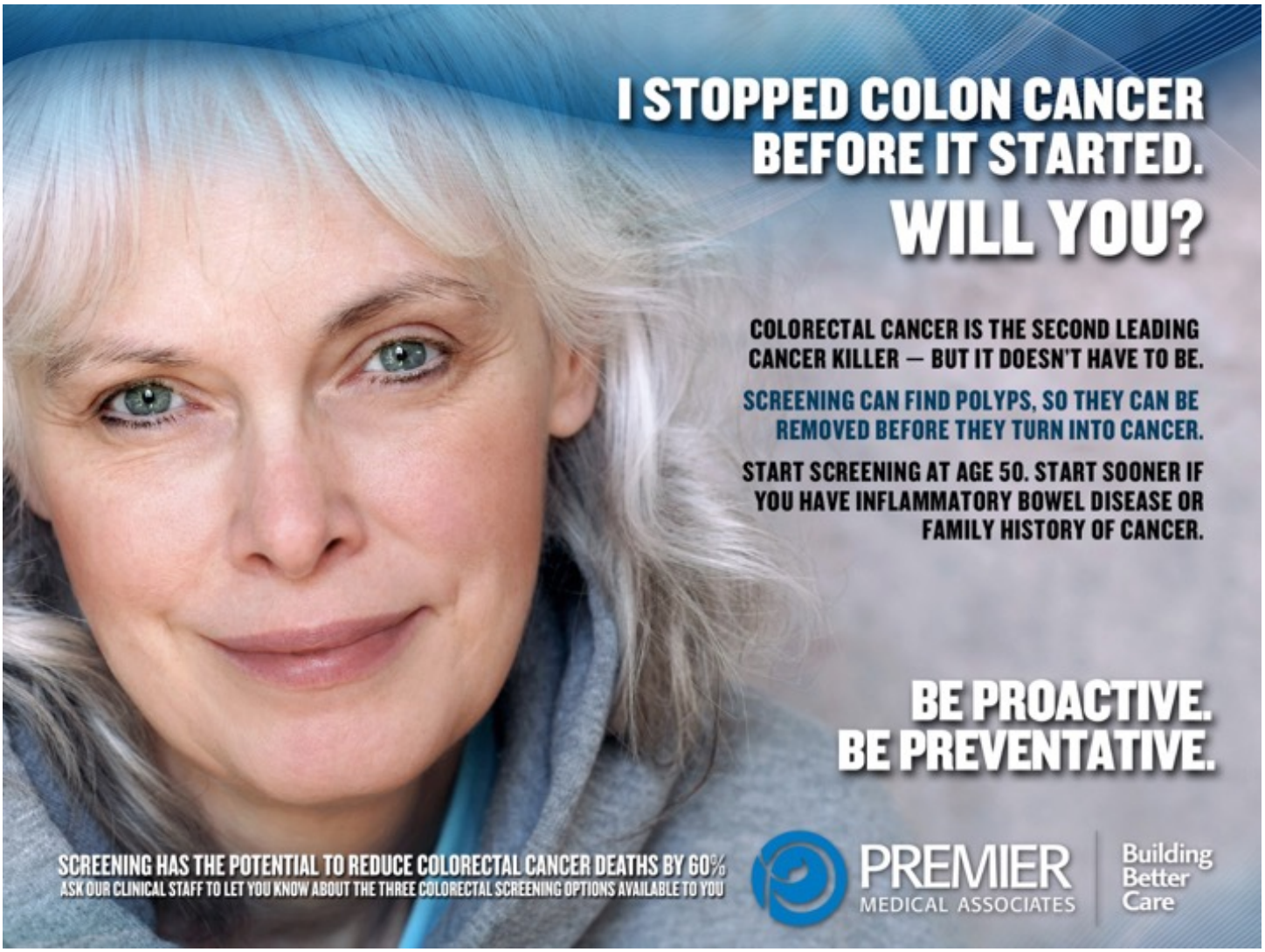
Happy 50th Birthday!

Colorectal cancer rates are increasing for the 50-54 year age group.

A colonoscopy isn't the only option for colorectal cancer screening. There are simple, affordable options, including tests that can be done at home. Talk to your doctor about which option is right for you. Ask which tests are covered by your health insurance.

# CS01-2

## Exam Room Poster – Allegheny Health Network / Premier Medical Associates



# CS01-3

## Examples of CRC Screening Dashboard Displays

**CRC Screening Rates by Office – Year ending 6/30/2020**

| Site of Care | Patient Count | Prior Report Screening Rate | Current Screening Rate | Trend |
|---|---|---|---|---|
| IM OMC | 2,607 | 86.5% | 86.1% | ↓ |
| FP Mon | 2,156 | 84.3% | 84.8% | ↑ |
| FP Irwin | 2,372 | 82.5% | 81.0% | ↓ |
| FP FH | 1,398 | 80.5% | 81.0% | ↑ |
| FP GM | 3,430 | 81.9% | 80.8% | ↓ |
| IM NV | 2,007 | 79.5% | 80.6% | ↑ |
| FP PH | 3,818 | 77.6% | 77.8% | ↑ |

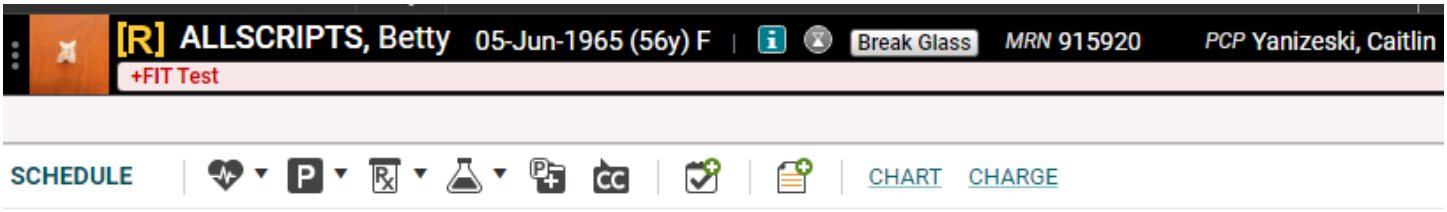
**Provider-by-provider CRC Screening Rates (original dashboard)**

| | 1/1/16 | 10/1/15 | 7/1/15 | 4/1/15 | 1/1/15 | 10/1/14 | 7/1/14 | 4/1/14 | target |
|---|---|---|---|---|---|---|---|---|---|
| Dr. Brown | 91.8 | 90.7 | 89.4 | 88.9 | 86.4 | 88 | 88.1 | 88.5 | 80 |
| Dr. White | 90.3 | 89 | 89.5 | 89.3 | 88.5 | 87.5 | 88.1 | 86.7 | 80 |
| Dr. Black | 89.9 | 88.7 | 87.3 | 84.8 | 86.2 | 83.1 | 83.6 | 80.1 | 80 |
| Dr. Blue | 88.8 | 86.8 | 84.2 | 80.9 | 79.4 | 75.2 | 73.2 | 71 | 80 |
| Dr. Green | 85.8 | 84.7 | 84.9 | 83.7 | 86 | 84.1 | 82 | 79 | 80 |
| Dr. Gold | 85.6 | 86.1 | 85.8 | 85.3 | 84.1 | 83.7 | 83.1 | 82.7 | 80 |
| Dr. Scarlett | 85.4 | 85.3 | 85.2 | 85.2 | 83.9 | 82.6 | 82.2 | 82.1 | 80 |
| Dr. Goldenrod | 84.6 | 86 | 83.5 | 81.2 | 80.7 | 77.8 | 78.9 | 78.2 | 80 |
| Dr. Olive | 83.9 | 82.5 | 83.7 | 82.7 | 82.7 | 82.5 | 83.1 | 82.4 | 80 |
| Dr. Forest | 83.3 | 82 | 82 | 80.1 | 80.1 | 79.2 | 80.2 | 78.6 | 80 |
| Dr. Cerulean | 83.1 | 83.5 | 82.9 | 82.6 | 83.8 | 82.2 | 81.1 | 79.9 | 80 |
| Dr. Periwinkle | 82.4 | 82.4 | 82.9 | 81.1 | 81.1 | 81.6 | 80 | 79.6 | 80 |
| Dr. Fushia | 82.3 | 79.5 | 76.3 | 73.2 | 75.8 | 74.7 | 75.3 | 72.9 | 80 |
| Dr. Mulberry | 80.8 | 79.4 | 79.1 | 80.3 | 76.5 | 71.3 | 66.3 | 61.8 | 80 |
| Dr. Sienna | 80 | 80 | 80.2 | 80.7 | 79.5 | 80.5 | 81.1 | 80.9 | 80 |
| Dr. Van Dyke | 76.6 | 77.1 | 75.7 | 73.2 | 73.2 | 74.7 | 74.5 | 74.8 | 80 |
| Dr. Umber | 76 | 75.2 | 75 | 77 | 77.1 | 77.7 | 76.5 | 76.9 | 80 |
| Dr. Gray | 75 | 72.9 | 73.9 | 72 | 70.5 | 69.5 | 68.6 | 68 | 80 |
| Dr. Maroon | 74.7 | 73.1 | 73 | 72.8 | 72.3 | 72.1 | 71.6 | 68.9 | 80 |
| Dr. Maize | 72.7 | 72.5 | 72.1 | 70.7 | 70.8 | 72.5 | 74.1 | 73.6 | 80 |
| Dr. Robin | 71.6 | 70.8 | 69.3 | 68 | 70.9 | 72.5 | 74 | 72 | 80 |
| Dr. Wisteria | 68.1 | 67.8 | 67.6 | 66.7 | 63.9 | 61 | 59.2 | 55.7 | 80 |
| Dr. Jazzberry | 65.8 | 63.5 | 61.3 | 60.1 | 59.2 | 59.4 | 59 | 58.8 | 80 |
| Dr. Cerise | 65.2 | 64.8 | 64.4 | 65.5 | 66 | 64.3 | 67.3 | 68.7 | 80 |

# CS01-4

## Positive FIT Alert in EHR and Positive FIT Registry Screenshots

**Positive FIT Alert in EHR (shown on Test Patient, Betty)**




**Positive FIT Registry**

This report is sent out weekly to providers for their patients who had a positive FIT Test

| Patient name | DOB | MRUN | Date of + FIT | Home office | Provider | Action taken | Patient mailing address |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

# CS03-1

## Patient pictorial instruction sheet




*Instructions have been modified by EBNHC. Courtesy of Kaiser Permanente Center for Health Research.*

## QR codes to access the patient videos on YouTube

QR Code

- ✓ Video English and Spanish
- ✓ Posted on YouTube
- ✓ QR code activated
- ✓ Language Specific QR code "activated" 6/1/2021 AVS
- ✓ Viewed (as of 6/3/21):
  - English = 275 views
  - Spanish = 150 views

ENGLISH

SCAN ME

https://www.youtube.com/watch?v=jXLIvgWNW1A

SPANISH

SCAN ME

https://www.youtube.com/watch?v=4PMxLj8Jwv4

EBNHC QI AND POPULATION HEALTH - DO NOT DISTRIBUTE WITHOUT PERMISSION 7

## CS03-2

### Incentive flyer

# CS03-3

## Listing of fields used from EHR to report on inadequate/incomplete tests

| Selected Columns | Width |
|---|---|
| MRN (EPT) [367] | 1440 |
| Patient DOB [54500] | 1440 |
| First Name [2208] | 2160 |
| Last Name [2209] | 2160 |
| Phone Number (EPT) [2245] | 1800 |
| Patient Preferred Language [1132] | 1440 |
| Patient Gender Identity [1938] | 1440 |
| Patient Address [15197] | 2880 |
| PCP [54502] | 1440 |
| PCP Department [4044] | 2160 |
| ORDERING PROVIDER [1150] | 3000 |
| Ordering Provider ID [42189] | 1080 |
| Ordering Provider NPI [84609] | 2000 |
| Order Date [1052] | 1080 |
| Order Patient DAT [34903] | 0 |
| Order Patient Internal ID [34904] | 0 |
| Age of Order [20195] | 1440 |
| Lab Order Status [51220] | 1440 |
| Order Status [51223] | 1900 |
| Comment Resuts [100811] | 1440 |
| Comment with cancellation [100810] | 0 |
| Order Patient Name and MRN [84521] | 0 |
| Order ID [52000] | 0 |
| ORDERS NEEDING COSIGN [20113] | 2880 |
| Cosigner User ID [4483] | 2700 |

# CS03-4

## Screenshots of Provider Alert in Epic Storyboard and sample one-click order for FIT kits

### Colorectal Cancer Screening

## Measure Description:

**Measure Description:** Percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer (in 2019).

**Numerator:** Patients with one or more screenings for colorectal cancer. Appropriate screenings are defined by any one of the following criteria:

- Fecal occult blood test (FOBT) during the measurement period.
- Fecal immunochemical test (FIT)-deoxyribonucleic acid (DNA) during the measurement period or the 2 years prior to the measurement period.
- Flexible sigmoidoscopy during the measurement period or the 4 years prior to the measurement period.
- Computerized tomography (CT) colonography during the measurement period or the 4 years prior to the measurement period.
- Colonoscopy during the measurement period or the 9 years prior to the measurement period.

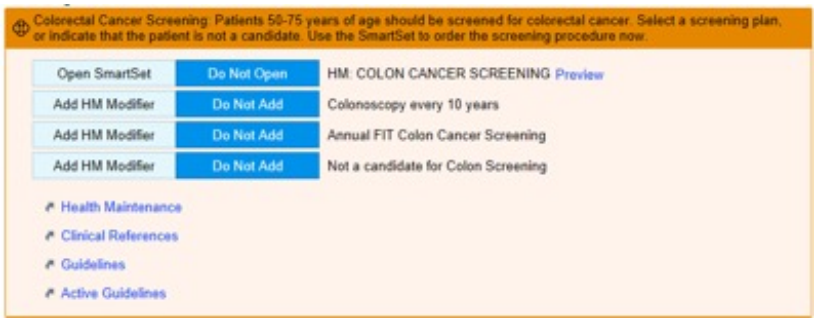
**Denominator:** Patients 50 through 75 years of age with a medical visit during the measurement period.

**Exclusions/Exceptions:**

- Numerator: Not applicable
- Denominator:
  - Patients with a diagnosis of colorectal cancer or a history of total colectomy.
  - Patients who were in hospice care during the measurement period.

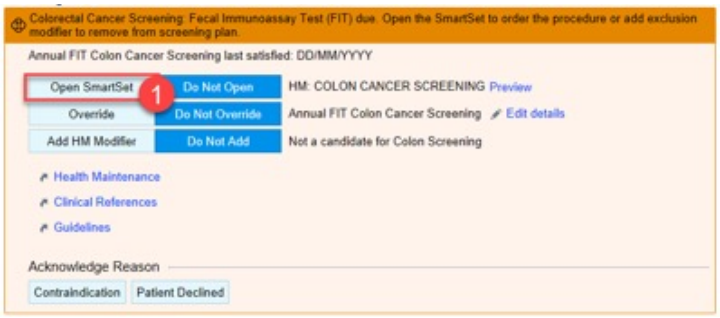
## Workflow:

When the patient turns 50 years of age the provider is prompted to select a Colorectal Cancer (CRC) Screening plan. Patients who are low risk: no family history of colorectal cancer, no prior history of colon polyps, and do NOT have a history of hemorrhoids and/or rectal bleeding are suitable for yearly FIT screening.

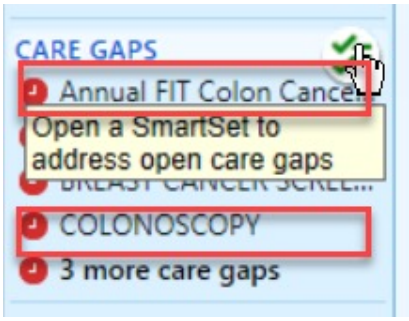


When the patient is due for Colorectal Cancer Screen:

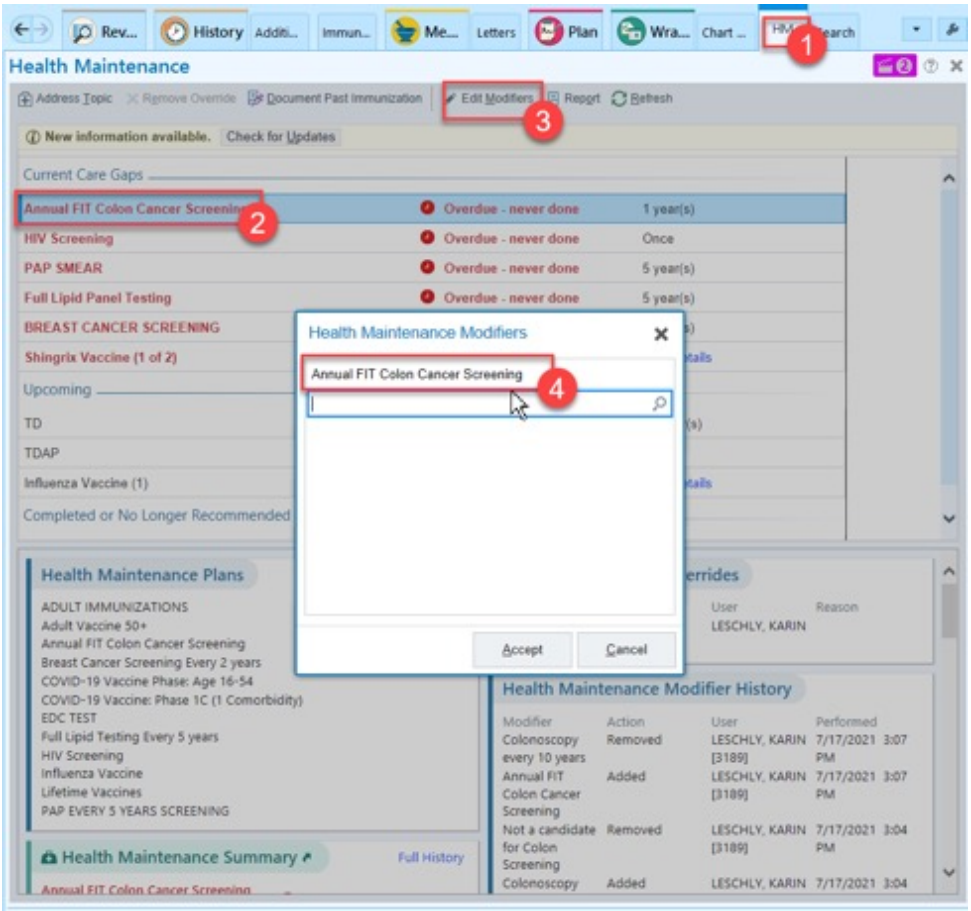
**MAs:** Order the FIT by opening the SmartSet on the Fecal Immunoassay Test (FIT) Best Practice Alert.



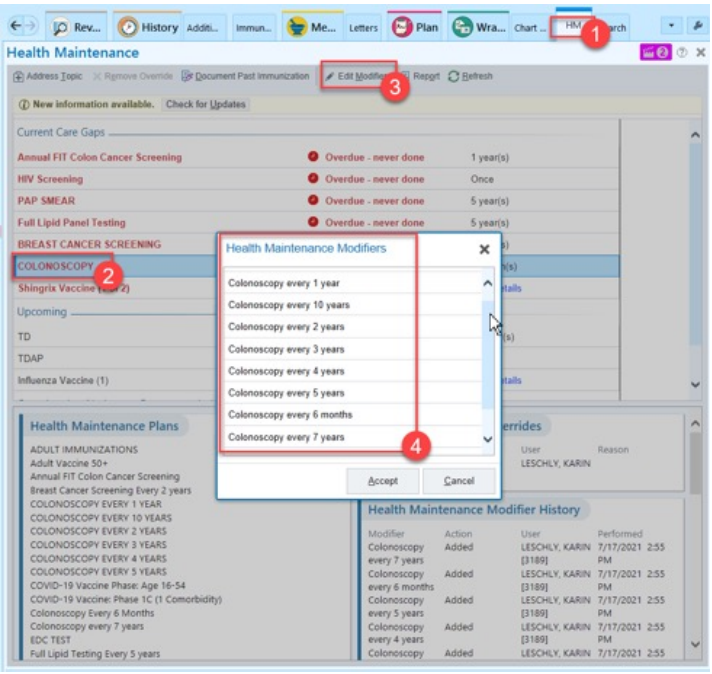

**Providers:** Order the FIT or Colonoscopy through the Care Gap SmartSet on StoryBoard.



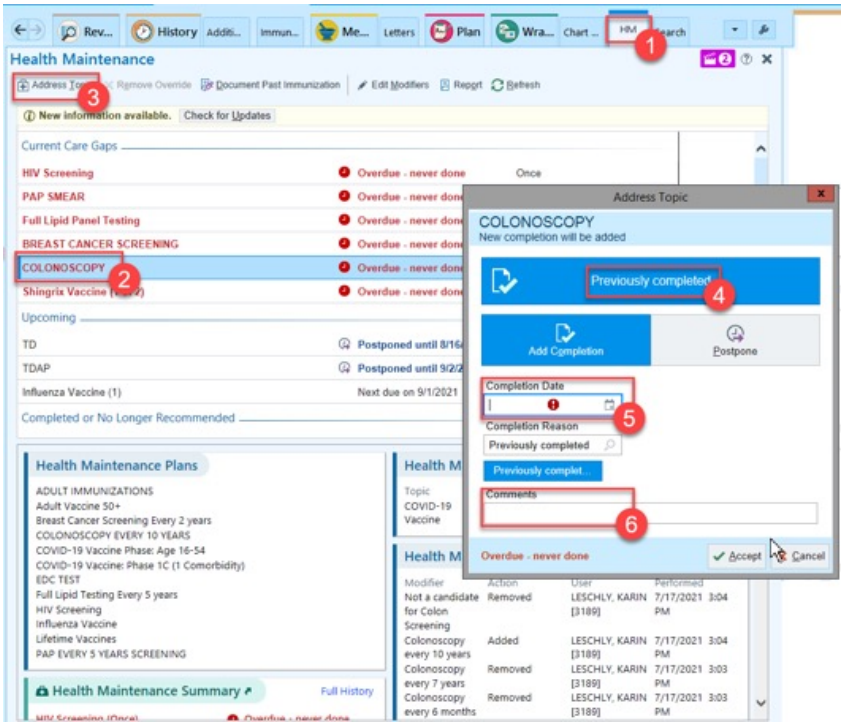

If the patient needs to be taken off the FIT Health Maintenance Topic, **Modify** the Annual FIT Colon Cancer Screen by removing it.



If the patient needs a colonoscopy at an interval other than 10 years **Modify** the Colonoscopy Health Maintenance Alert by selecting the appropriate Health Maintenance Modifier.




If the patient has had completed their Colonoscopy at an outside organization **Address** the Colonoscopy Health Maintenance Topic by entering the completion date. CareEverywhere FIT results are mapped.



# CS03-5

## Screenshot of after-visit summary from a test patient portal account that includes patient instructions for FITs

### AFTER VISIT SUMMARY

MRN: [redacted] 5/13/2021 Family Medicine 617-568-4800

### Today's Visit

You saw [redacted] MD on Thursday May 13, 2021.

Done Today
INSURE ONE FIT TESTING

### What's Next

You currently have no upcoming appointments scheduled.

### Your Medication List as of May 13, 2021 3:43 PM

Always use your most recent med list.

| | |
|---|---|
| **Benzoyl Peroxide** 5 % Liqd | wash face twice daily |
| **Clindamycin Phosphate** 1 % Gel | apply to face nighly |
| **Loratadine** 10 MG Tabs | 1 tablet daily as needed |
| **Norgestim-Eth Estrad Triphasic** 0.18/0.215/0.25 MG-35 MCG Tabs<br>Commonly known as: Ortho Tri-Cyclen (28) | Take 1 Tablet by mouth one time a day |
| **Sertraline HCl** 50 MG Tabs | Take 1 Tablet by mouth one time a day |

### FIT kit Instructions

ENGLISH SCAN ME

SPANISH SCAN ME

This document contains confidential information about your health and care. It is provided directly to you for your personal, private use only.

### Orders Placed Today

Normal Orders This Visit

INSURE ONE FIT TESTING [82274 CPT(R)]

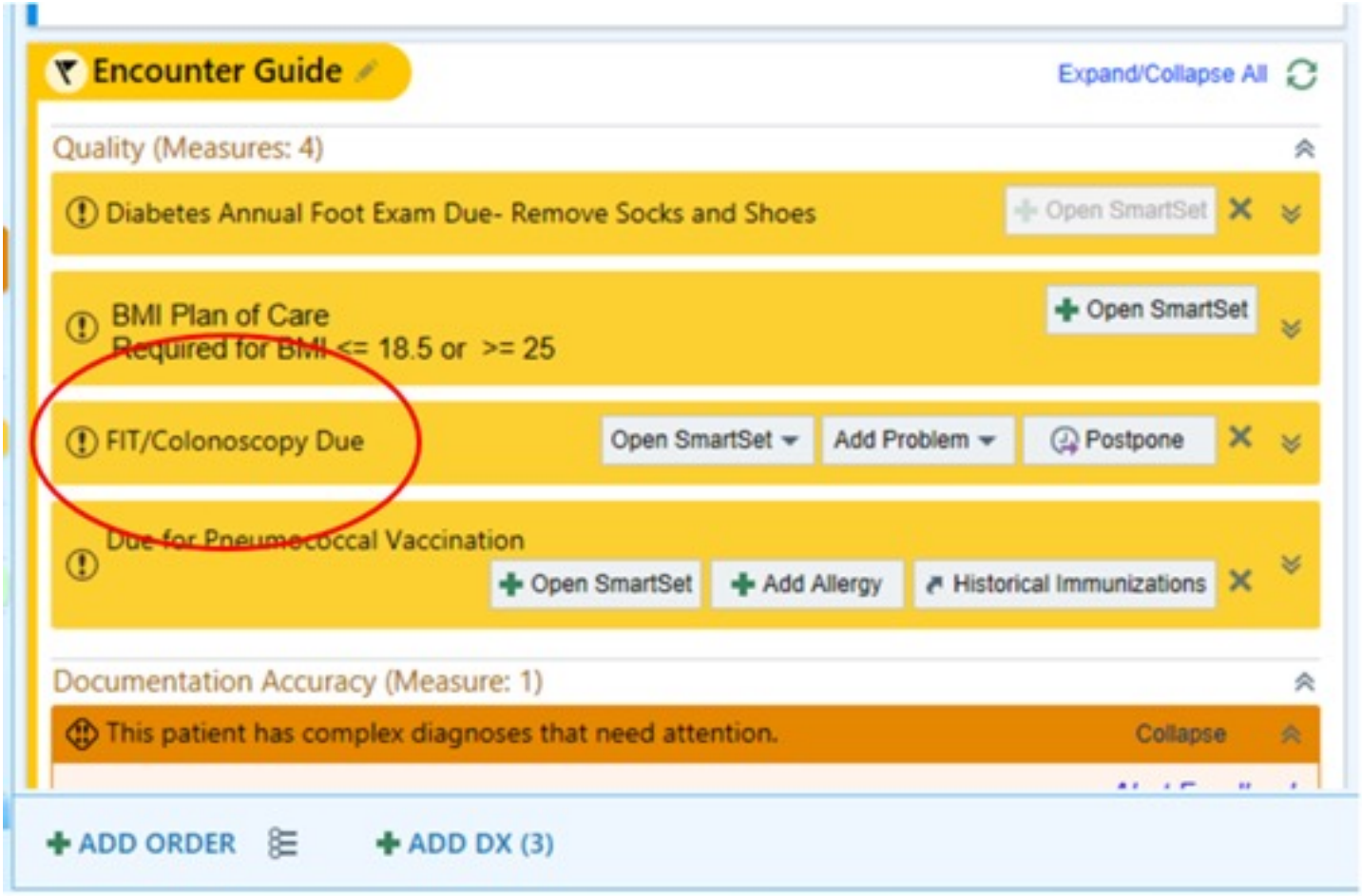
### Call 4 Health

If you are not feeling well after business hours, you can reach a nurse by calling 617-568-4800.

# CS05-1

## Encounter Guide Screenshot from Epic

**Point of Care Prompt Example used by Mercy Health System to alert provider that patient is due for Colonoscopy**



# CS05-2

## Normal FIT Patient Result Letter Template

[Date]

[First Name] [Last Name]

[Address]

[City,] [State] [ZIP]

Dear [First Name],

You recently completed a Fecal Immunochemical Test (FIT) to check for colorectal cancer. The results of your FIT test were **normal**, meaning there was no blood found in your stool at the time of the test.

**Next Steps**

Regular screenings can help protect you from colorectal cancer. The U.S. Preventative Services Task Force recommends screenings at ages 50 to 75. A screening colonoscopy for adults of average risk can be done every 10 years. Alternatively, a FIT test can be done yearly.

If you have a Mercy primary care provider, a copy of these results has been shared with them. *If you do not have a primary care provider, we can help you locate a Mercy physician. Visit Mercy.net to find a doctor.*

**Catch it Early**

Remember, although colorectal cancer can be deadly, it can be cured if caught early. Screening is key to early detection and prevention of cancer. To learn more about colorectal cancer screening tests, go to insert URL.

Congratulations on taking an important step in protecting your health!

Sincerely,

Your Mercy Care Team

## Abnormal FIT Patient Follow-up Letter Template

[Date]

[First Name] [Last Name]

[Address]

[City,] [State] [ZIP]

Dear [First Name],

You recently completed a Fecal Immunochemical Test (FIT) to check for colorectal cancer. The results of your test were abnormal, showing blood in your stool.

An abnormal result does not necessarily mean that you have colorectal cancer, but it does mean that additional testing is needed. Your doctor may recommend that you follow up with a colonoscopy to find the source of your bleeding and to determine if a polyp or cancer is present.

**Next Steps**

Schedule an appointment with your primary care provider and let them know that you tested positive for blood in your stool (FIT Test). If you have a Mercy primary care provider, a copy of these results has been shared with them. *If you do not have a primary care provider, we can help you locate a Mercy physician. Visit Mercy.net to find a doctor.*

**Learn More**

Remember, although colorectal cancer can be deadly, it can be cured if caught early. Screening is key to early detection and prevention of cancer.

A colonoscopy can protect your health. If colorectal cancer is caught early with a colonoscopy, 9 out of every 10 people with the disease can be cured. If you have colorectal cancer and do not get tested, you may miss out on the chance for early and more effective treatment.

To learn more about colonoscopy go to insert URL

Sincerely,

Your Mercy Care Team

## Script for Abnormal FIT Result

Hi [Patient Name],

This is [Caller's First Name]. I work with Dr. [PCP] at Mercy. You recently completed a Fecal Immunochemical Test (FIT) to check for colorectal cancer. The results of your test were abnormal, showing blood in your stool. Dr. [PCP] would like for you to schedule an appointment to discuss the next steps.

IS NOW A GOOD TIME TO SCHEDULE AN APPOINTMENT?

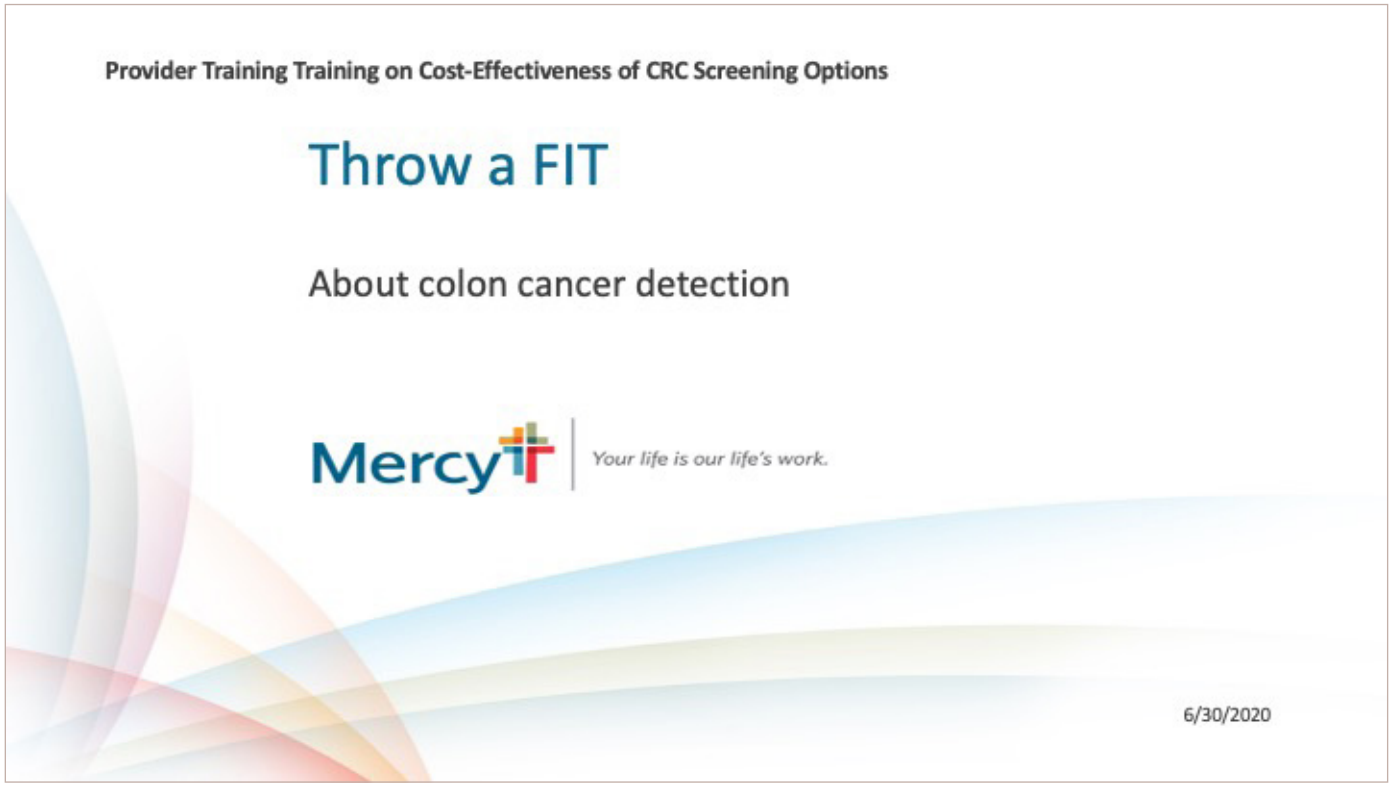
- **"Yes"** → (Book the appointment and confirm.) You are scheduled for _____ day and time with (doctor or APP name). He/she will have a copy of your results and a copy will also be mailed to you.
- **"No"** → I recommend that you call and schedule an appointment with Dr. (Mercy PCP's) office within the next two weeks. He/she will have a copy of your results and a copy will also be mailed to you.
- **"I'm no longer seeing Dr. [Mercy PCP]."** → Do you have a primary care provider?
  - **"Yes"** → Please share a copy of your results with your provider. A copy of your results will also be mailed to you. Call their office to schedule an appointment and to talk about your abnormal results and next steps.
  - **"No"** → Do you need help finding a Mercy primary care provider?
    - **"Yes"** → (Can look up providers with new patient appointments available. Book the appointment and confirm.) You are scheduled for _____ day and time with (doctor or APP name and address). He/she will have a copy of your results and a copy will also be mailed to you.
    - **"No"** → I recommend that you call and schedule an appointment with a primary care provider within the next two weeks. A copy of your results will also be mailed to you. Schedule an appointment to talk about your abnormal results and next steps.

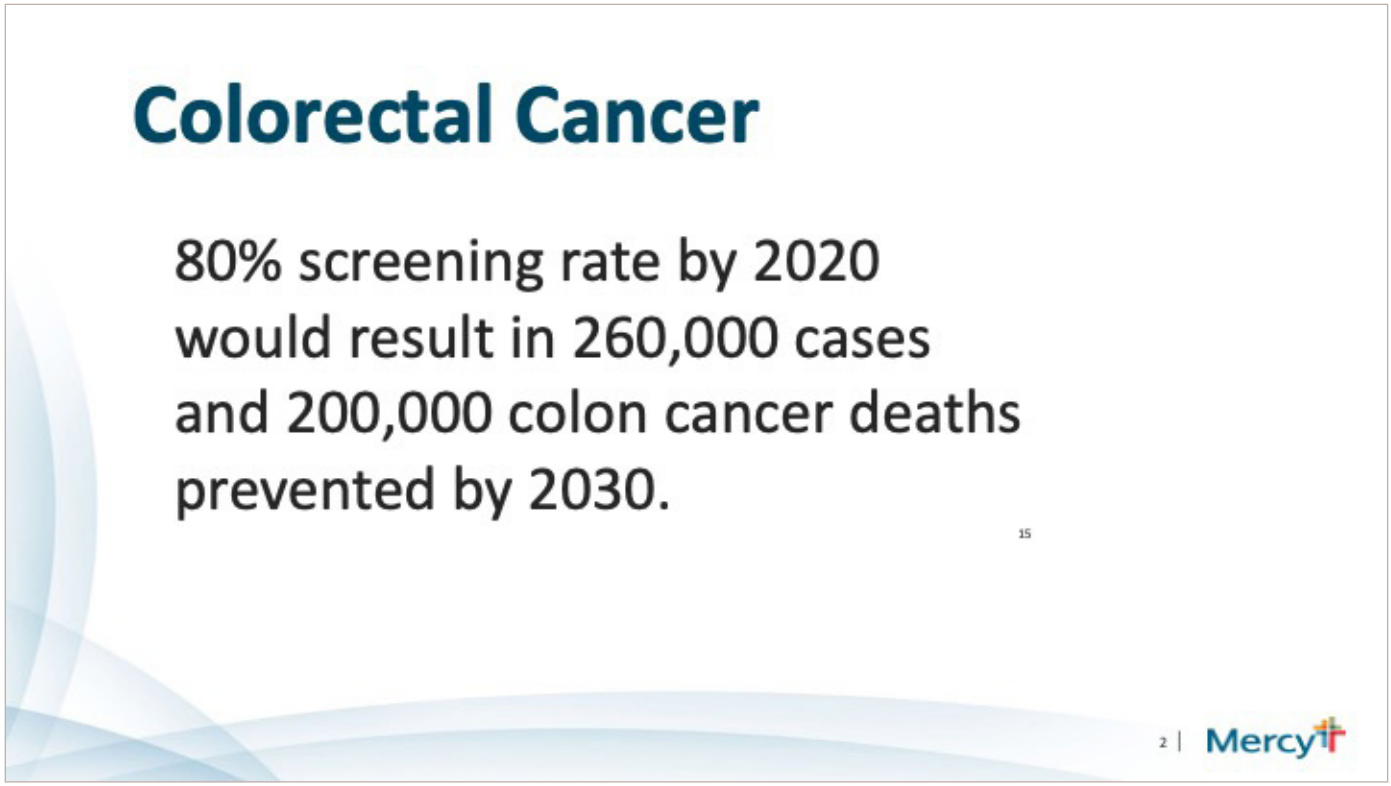
**Question and Answer**

- **"Why do I need to do this?"** OR **"Does this mean I have cancer?"** An abnormal result does not necessarily mean that you have colorectal cancer, but it does mean that additional testing is needed. Your doctor may recommend that you follow up with a colonoscopy to find the source of your bleeding, and to determine if a polyp or cancer is present. A colonoscopy can protect your health. If colorectal cancer is caught early with a colonoscopy, 9 out of every 10 people with the disease can be cured. If you have colorectal cancer and do not get tested, you may miss out on the chance for early and more effective treatment.
- **"Where can I learn more about a colonoscopy?"** To learn more about colonoscopy go to insert URL

## CS05-3

Information on how to provide patient-centered, cost-effective CRC options to patients in making the decisions ("Throw a FIT" provider training slides).



## Procedure "costs"

| Test | Prof MCR FEE | Prof Fee sch | Total Fee MCR/Fee |
|---|---|---|---|
| Colonoscopy 10 yrs | $308.63* | $1109* | 38.86/110.90* |
| Flex Sig 5 yrs | $158.57* | $324* | 31.74/64.80* |
| CT colonography 5 yrs | $117.75* | $462* | 23.55/92.40* |
| DNA stool 3 yrs | $508.87 | $1098 | 169.62/366 |
| FIT 1 yr | $18.05 | $66 | 18.05/66 |
| FOBT 1 yr | $15.92 | $66 | 15.92/66 |

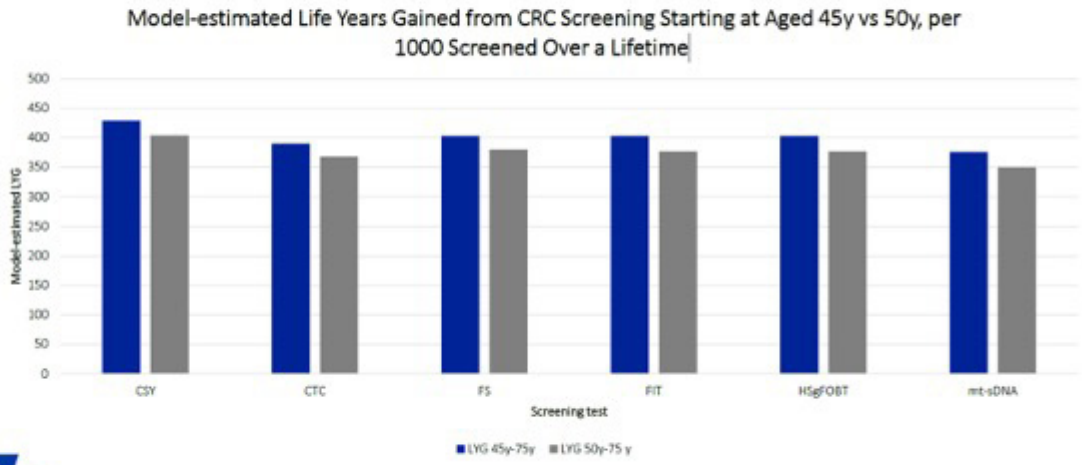
* Does not include facility fees

## The American Cancer Society Guidelines

- Any of the recommended screening options can be used.
  - Colonoscopy every 10 years
  - Flex sig every 5 years
  - CT colonography every 5
  - Multi-target stool DNA every 3 years
  - FIT or HSgFOBT annually

## Model-estimated Benefit CRC Screening by Starting Age

CSY – Colonoscopy
CTC – CT colonography
FS – Flexible Sig
FIT – fecal immunochemical
HSgFOBT – Guiacs
Mts-DNA - Cologuard




@RichWender

Source: Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA Cancer J Clin. 2018; 68: 000-000

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## Result of delays

Incidence rates are going up among patients 50 to 54.
Only 51% of patients 50 to 54 are up-to-date with screening.

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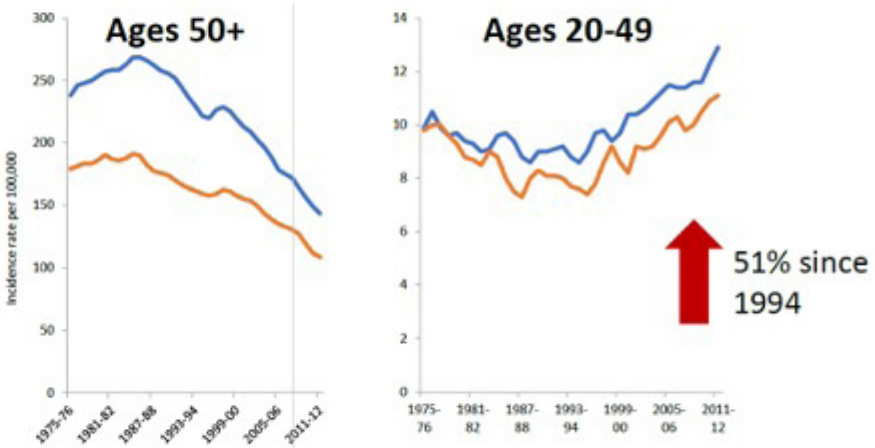
# Recent Developments in Colorectal Cancer Burden

Rising colorectal cancer incidence among people under age 50.[1]




@RichWender

1. Siegel et al. Colorectal Cancer Incidence Patterns in the United States, 1974-2013. J Natl Cancer Inst 2017;109.
SEER 9 delay-adjusted rates, 1975-2012; 2-year moving average.

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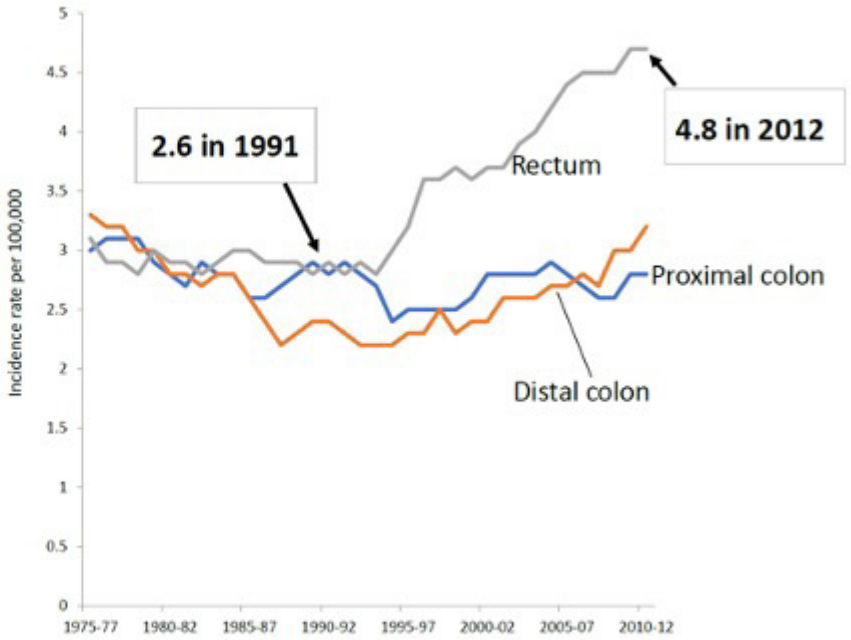
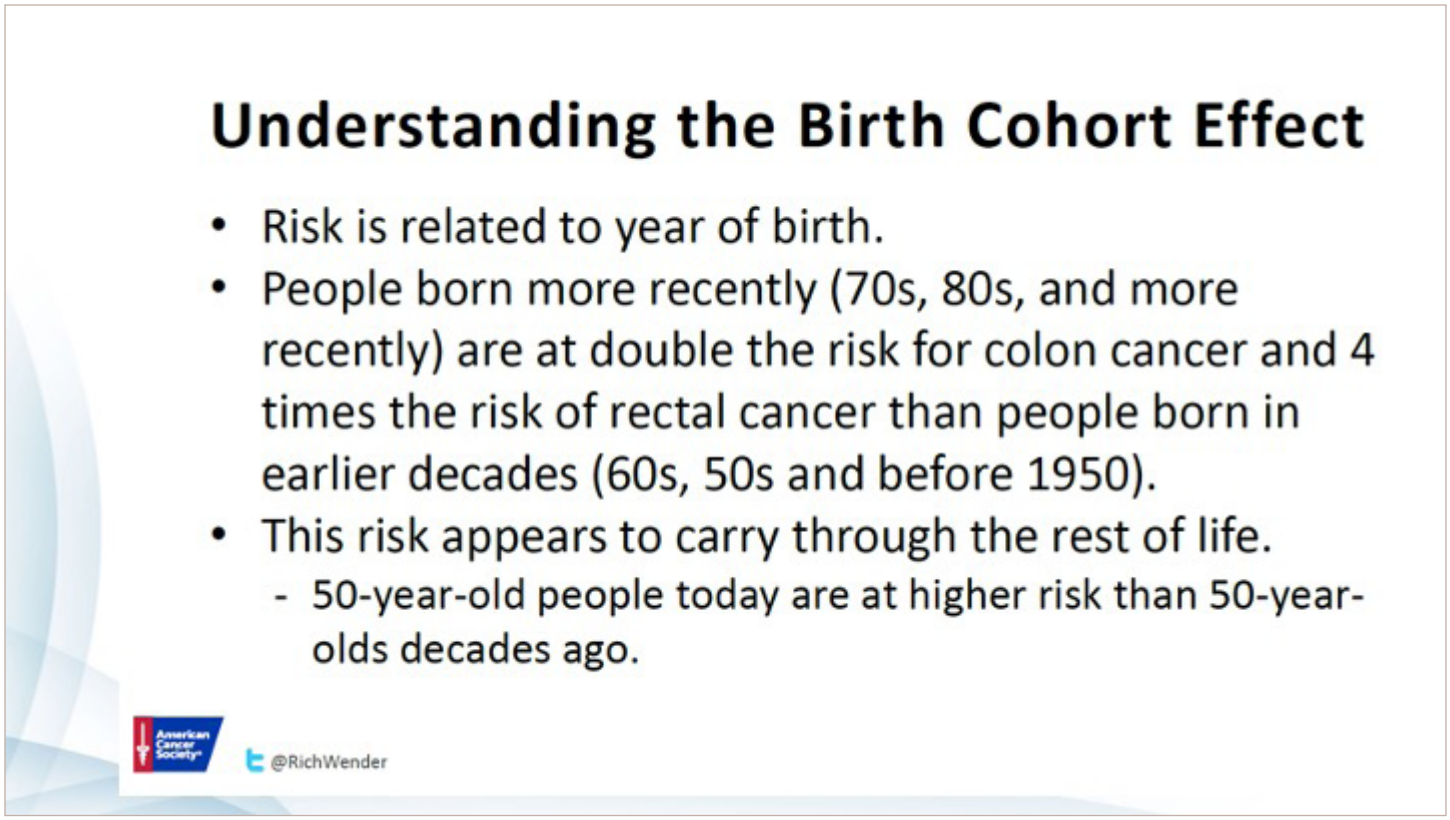
# Incidence Trend in <50 Years by Tumor Subsite

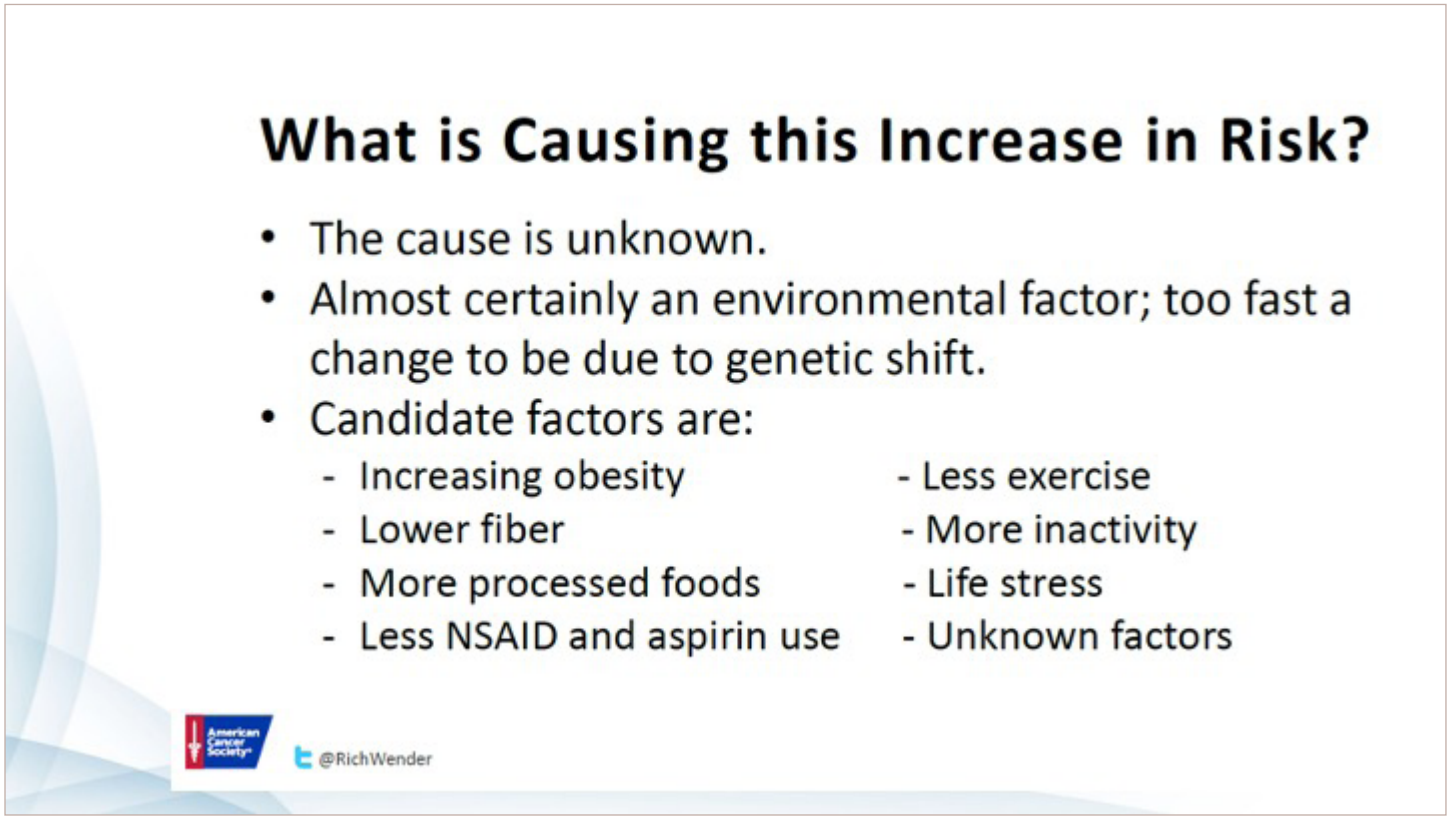



@RichWender

Source: SEER 9 delay-adjusted rates, 1975-2012; 3-year moving average.

68


Understanding the Birth Cohort Effect
• Risk is related to year of birth.
• People born more recently (70s, 80s, and more recently) are at double the risk for colon cancer and 4 times the risk of rectal cancer than people born in earlier decades (60s, 50s and before 1950).
• This risk appears to carry through the rest of life.
- 50-year-old people today are at higher risk than 50-year-olds decades ago.
@RichWender


What is Causing this Increase in Risk?
• The cause is unknown.
• Almost certainly an environmental factor; too fast a change to be due to genetic shift.
• Candidate factors are:
- Increasing obesity
- Lower fiber
- More processed foods
- Less NSAID and aspirin use
- Less exercise
- More inactivity
- Life stress
- Unknown factors
@RichWender

## Insurance Coverage Update

- Two large insurers are covering all screening options according to the ACS guideline:
  - Aetna
  - CareFirst
- Maine passed a bill in May requiring most insurers to cover screening beginning at age 45.
- Other states have laws linking coverage to ACS guidelines.
- **All insurers will cover annual FIT testing with follow-up colonoscopy.**

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## Colonoscopy and Stool Testing are Both Critical Strategies

Every system achieving 80% is relying on stool testing as well as colonoscopy.
Both approaches are critical.

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## Stool Blood Testing Remains Important in the "Age of Colonoscopy"

- Colonoscopy is now the most frequently used screening test for CRC.
- However, when provided annually to average-risk patients with appropriate follow-up, stool occult blood testing with high-sensitivity tests can provide similar reductions in mortality compared to colonoscopy and some reduction in incidence.

@RichWender

Source: Evaluating Test Strategies for Colorectal Cancer Screening: A Decision Analysis for the U.S. Preventive Services Task Force

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## We Must Ensure that Anyone Can Be Offered a Home Stool Blood Test

- Even if you recommend colonoscopy for all, some people won't get one, can't get one, or shouldn't get one.
- Using colonoscopy exclusively will, inevitably, lead to a screening gap.


@RichWender

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## Many Patients Prefer Home Stool Testing

| | |
|---|---|
| **Colonoscopy recommended:** | 38% completed colonoscopy |
| **FOBT recommended:** | 67% completed FOBT |
| **Colonoscopy or FOBT:** | 69% completed a test |

@RichWender

Source: Adherence to Colorectal Cancer Screening: A Randomized Clinical Trial of Competing Strategies

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## Fecal Immunochemical Tests (FITs) Should Replace Guaiac FOBT

FITs:

- Demonstrate superior sensitivity and specificity.
- Are specific for colon blood and are unaffected by diet or medications.
- Some can be developed by automated readers.
- Some improve patient participation in screening.

@RichWender

Sources: Allison JE, et.al. J Natl Cancer Inst. 2007; 191:1-9
Cole SR, et.al. J Med Screen. 2003; 10:117-122

## AMGA current counts

| AMGA Participant Service Area | Patient Count | Numerator | *Screening Rate | # Un-screened |
|---|---|---|---|---|
| Joplin | 11,720 | 5,955 | 50.81% | 5,765 |
| Fort Smith | 24,675 | 11,806 | 47.85% | 12,869 |
| East | 127,522 | 77,319 | 60.63% | 50,203 |
| Springfield | 66,754 | 43,828 | 65.66% | 22,926 |
| NWA | 25,775 | 16,735 | 64.93% | 9,040 |
| West | 57,331 | 33,728 | 58.83% | 23,603 |
| Mercy | 313,777 | 189,371 | 60.35% | 124,406 |

* AMGA excludes Sites of Care with <100 patients when drilling down. The overall Benchmark reports includes these so the numbers can vary between the two reports.

## Manpower Shortage

Skilled scopist = 1,728 – 2,106 year (1,917)

- 8-10 screenings/day
- 4.5 days/week
- 48 weeks/year

# of FTE's needed

- Close Gap to 80% screening = 32.44
- Rescope @ 10%/yr = 9.9

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## Colonoscopies for all? Practical Implications?

- Manpower shortage
- Cost of normal exams - Closing 80% gap
  - Cost net of FIT
    - MCR = $290.18
    - Fee = $1090.95
  - 75% of screening scopes = normal (ADR =25%)

Colonoscopy "cost" for normal

if MCR = $13,573,549.90

if Fee = $50,895,272.10

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## What do we want?

Lead with FIT complete with colonoscopy

Standardize

- Tools
- Capture
- Results

Centralize the Management to reduce clinic burden

Drive better rates and save lives

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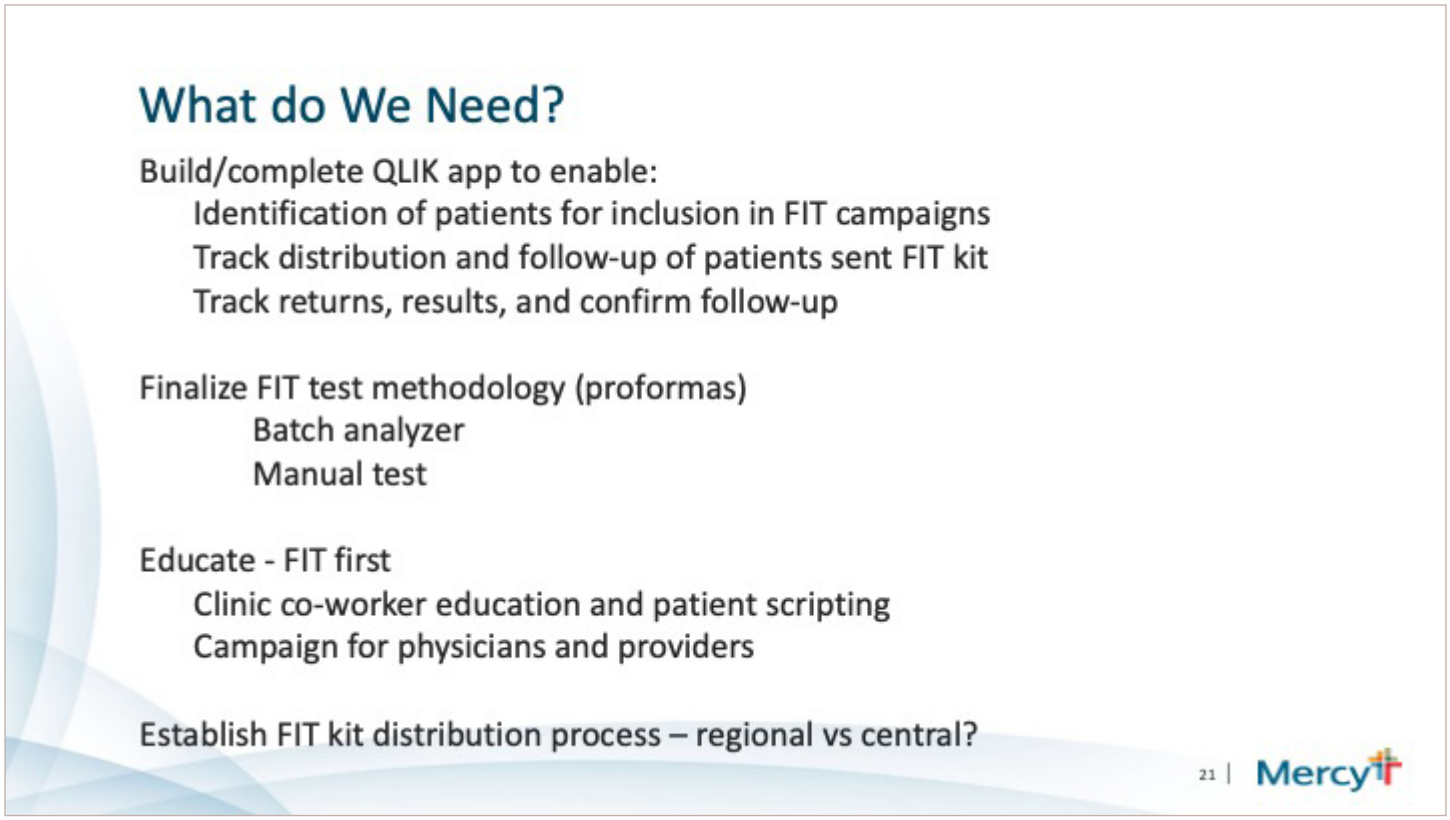

What do We Need?
Build/complete QLIK app to enable:
Identification of patients for inclusion in FIT campaigns
Track distribution and follow-up of patients sent FIT kit
Track returns, results, and confirm follow-up
Finalize FIT test methodology (proformas)
Batch analyzer
Manual test
Educate - FIT first
Clinic co-worker education and patient scripting
Campaign for physicians and providers
Establish FIT kit distribution process – regional vs central?
21 |
Mercy

# CS08-1

## Shared Decision-making Tool

## Choosing which colorectal cancer screening option is right for you

SANFORD HEALTH

**You** can make choices about your health. Screening for colorectal cancer is recommended for everyone between the ages of 50 to 75. Choosing to do screening can save your life. Your age and other health factors affect when and how you should be screened.

Use this tool to talk to your doctor about 3 screening options. Each column below outlines 1 way to do screening. Compare each option to choose which screening method is best for you. Remember, the **best** screening option is the one that gets done!

**Note: if you have a history of colorectal cancer or bowel disease, or have a close relative with colorectal cancer or polyps, a colonoscopy may be the best choice for you.**

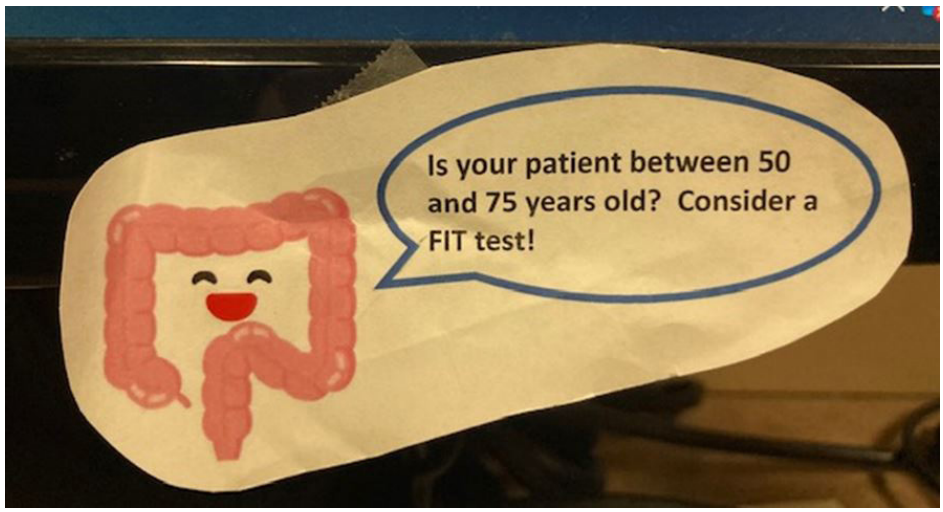
| | FIT | Cologuard FIT-DNA | Colonoscopy |
|---|---|---|---|
| **What is it?** | Fecal Immunochemical Test: Stool is checked for blood (not seen by the naked eye) by taking a sample and mailing it in. | Stool is checked for cancer markers and blood (not seen by the naked eye) by taking a sample and mailing it in. | A lighted scope with a camera is used to look at the colon and rectum. This finds tissues and cells that are not normal. |
| **Where is it done?** | You collect a sample at home and return test kit to lab or mail it back (often pre-paid postage is included). | A test kit will be mailed to your home. You will collect a sample and mail the test kit back (address label and postage stamp included). | Your provider will give this test at the hospital in a procedure room. Medicines will be given to you to provide comfort. |
| **How often?** | Completed every 1-year if normal. *If test is not normal, you will need a colonoscopy. | Completed every 3-years if normal. *If test is not normal, you will need a colonoscopy. | Completed every 10-years if normal. *May include a biopsy or polyp removal if needed. |
| **How do I get ready?** | No preparation or diet restrictions required. | No preparation or diet restrictions required. | Requires fasting and a cleansing of the colon with a laxative. |
| **What is the cost?** | Low Cost – check with your insurance (often covered). | Variable cost – Check with insurance (sometimes covered). | Higher cost – check with insurance (often covered if qualified). |

039051-00317 9/17

## CS09-1

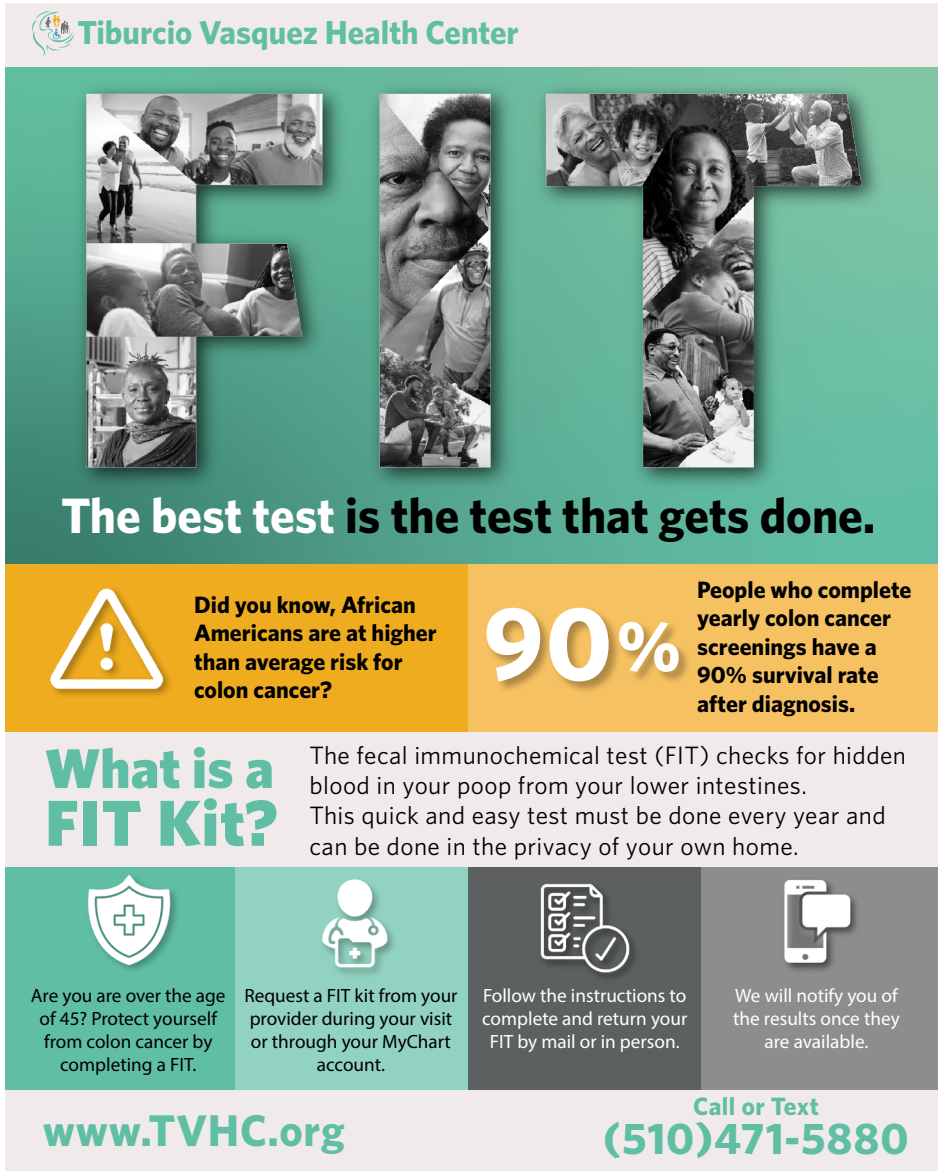
### FIT Colon Reminder

The graphic is stuck to all the computers in the adult medicine clinic as a reminder to check CRC screening status.




## CS09-2

Flyer promoting colorectal cancer screening to African American patients



## CS09-3

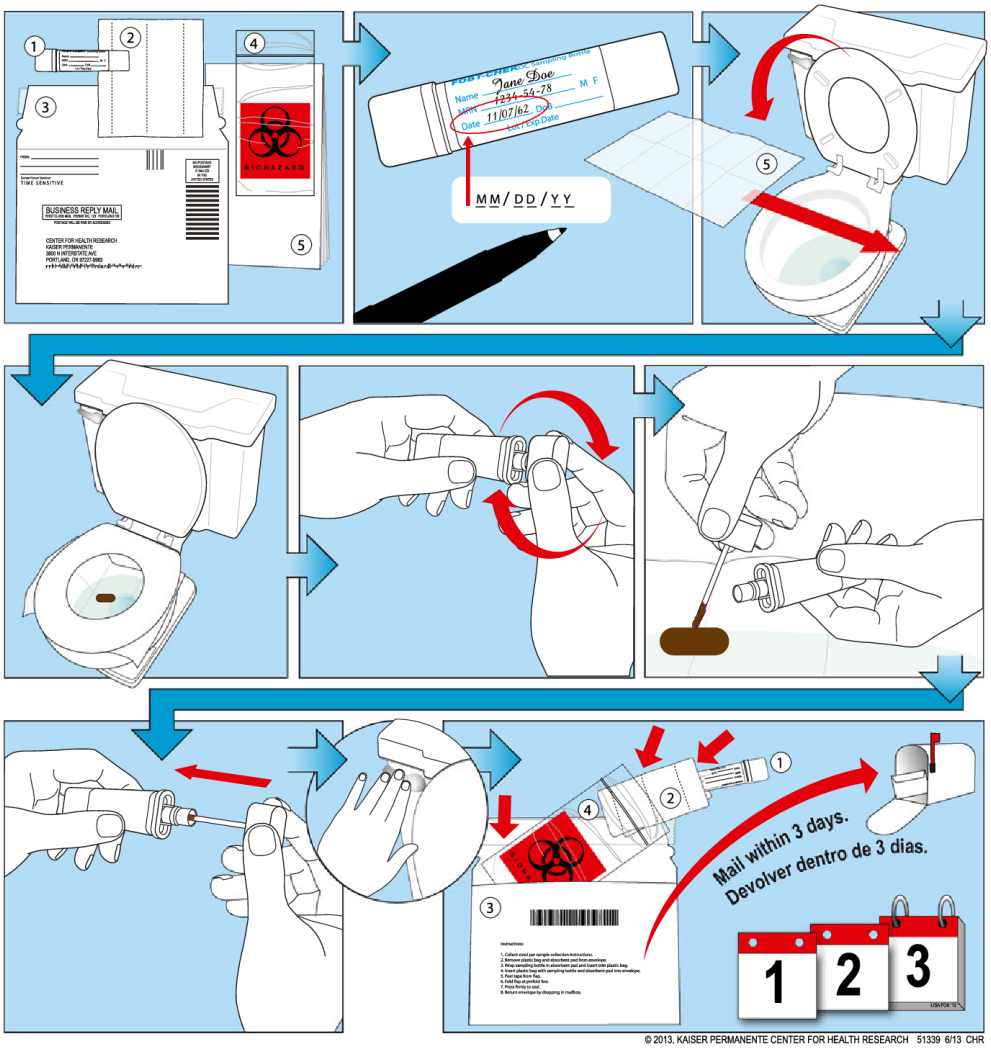
### Mailed FIT workflow (used by MAs until centralized care coordination staff are available)

When order is sent it goes to a centralized work queue for mailing.

## 21 – 75

21-65 w/ cervix: Cervical Cancer Screen (Pap)
40-74 w/ breasts: Breast Cancer Screen (Mammo)
45-75: Colorectal Cancer Screen (FIT)

- Review relevant tabs (labs, imaging, etc) in Epic, Care Everywhere & Patient Archive
- Search item name in Epic search bar (ex: pap, mammogram, FIT, etc)
- Document most recent result in Epic Care Gap tab
- If due, pend/send orders to PCP or schedule visit
- Update documentation in Epic & create recall apt for appropriate follow-up




## CS09-4

### Wordless FIT instructions for patients

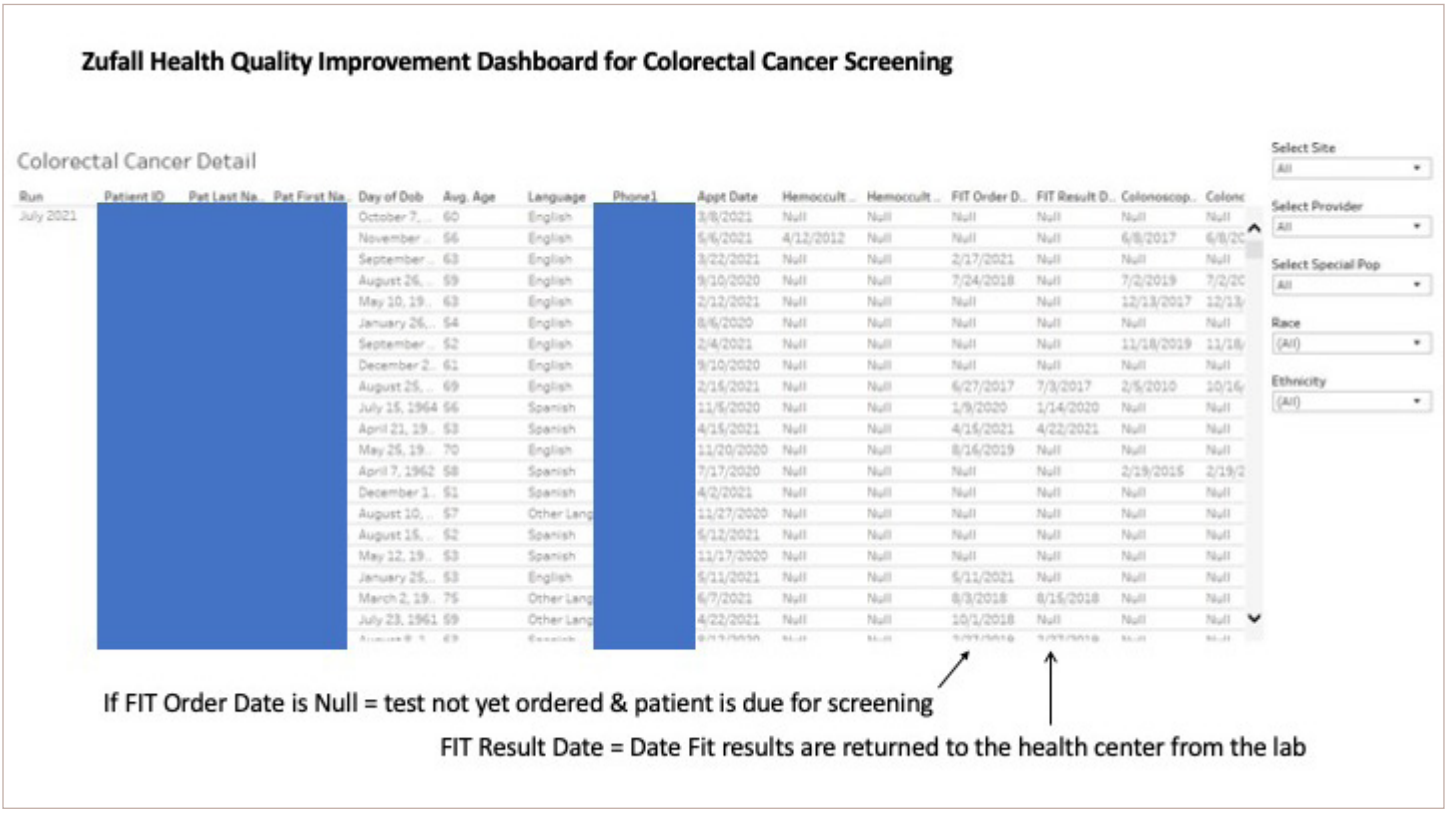
The health center uses the Kaiser Permanente Center for Health Research wordless FIT instructions.

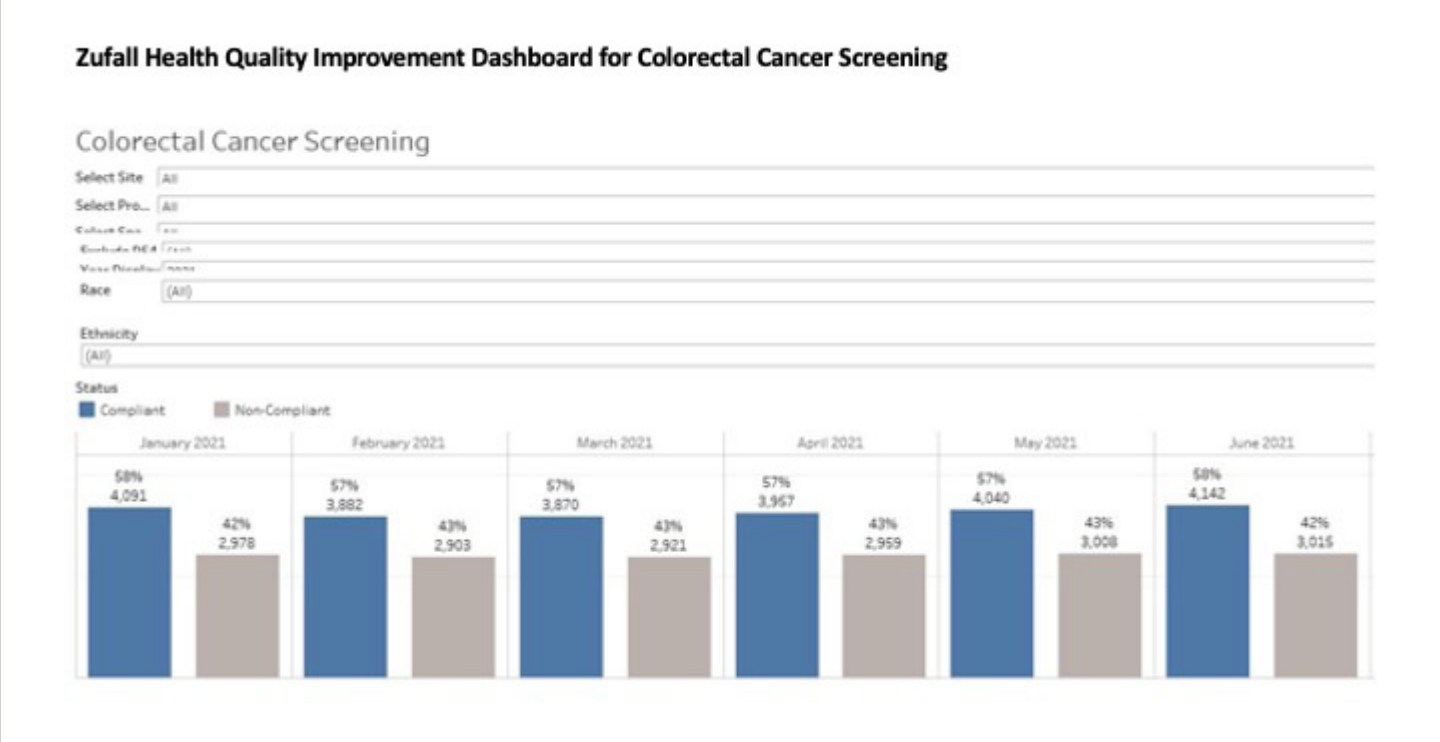
# CS10-1

## Contactless FIT drop-off box


# CS10-2

## Sample positive FIT dashboard used for quality improvement



# CS10-3

## Standing order policy for MAs

ZUFALL HEALTH

Standing Orders Policy

Reviewed 04/09/2021
Supersedes 05/12/2020
Page 3 of 6

**Colon Screening for Patients 45 and older (until 75)**
All patients 45 years and over need education on getting colon cancer screening, either with a FIT test annually or a colonoscopy every 3-10 years, depending on the risk of the patient and the results of previous colonoscopies. Patients, younger than 45, with specific health concerns, may be offered colon cancer screening.

To check if they have a colonoscopy in the chart, look under the DI tab and see if there is a colonoscopy result. Colonoscopy results should be attached to an order under DI for ease of locating the test and for reporting. If the report is not in DI, look under Patient Documents. If not on the chart but the patient says they had one, ask when and where they had their procedure and obtain consent for release of information. If it has been more than 10 years, they need to be screened again. If they cannot get the test result, advise them that they need to be screened again either with a FIT test or another colonoscopy.

- To order FIT, use the drop down menu under colon cancer screen in eCW to check off advice given.
- Then go to assessment, add Z12.11 and the order the *Fecal Immunochemical Test or FIT-FOBT IH (inhouse).
- If the provider agrees, discuss how to do the test with patient, including collecting the specimen and returning the cassette, at the end of the visit.

If the provider orders a GI consultation and colonoscopy instead, information regarding where and how to get the colonoscopy done will be given by the MA.

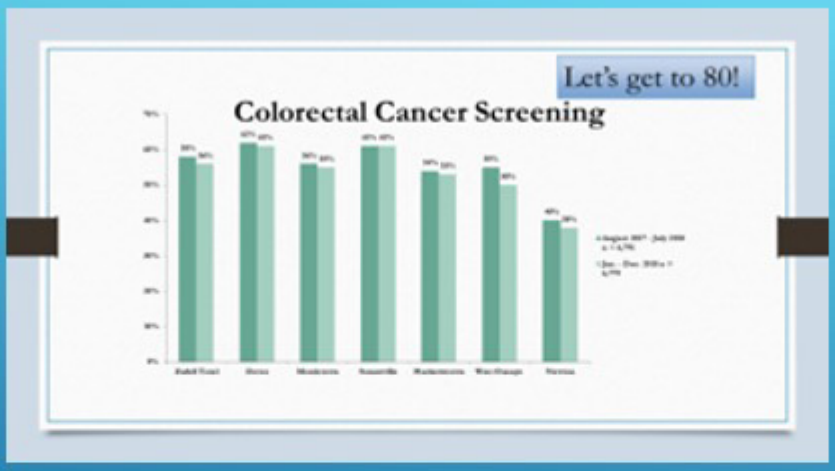
Please note that if a patient has a positive FIT test, the patient must get a colonoscopy. A repeat FIT test the following year is not indicated.

# CS10-4

## PowerPoint for MA training


- Navigator/Trainer
- Navigators at each site
- Identified GI specialists who will provide needed care to our patients who may have financial barriers to care.
- All Zufall team members including Providers and MA's who see the patients each and every day and can provide education and reinforce the importance of this screening to support this program

## WHO WILL MAKE THIS HAPPEN?




## CURRENT COLORECTAL SCREENING RATES BY SITE

- Patients between the ages of 45 and 75 years old who are screened using FIT (LabCorp) or FIT-FOBT (Insure FIT – inhouse) testing must be screened annually.
- Patients younger than 45 and between the ages of 76 and 85 will be screened at providers discretion based upon age and personal and/or family history.
- Patients who are screened using Colonoscopy must be screened every 10 years and do not need a FIT or FIT-FOBT testing in the interim unless deemed necessary by provider.
- If patient has been tested prior to becoming a Zufall Patient, please have patient sign release at first visit and request copies of any Colorectal screening results

## WHO SHOULD BE SCREENED?— COLORECTAL SCREENING

### Proposed Activities

- Provide FIT-FOBT tests to all of Zufall's eligible uninsured patients across all centers
- Conduct Patient Navigation to encourage return of tests
- Process the returned kits in house or prepare them for LabCorp
- Refer and navigate patients with positive result to colonoscopy services

### Expected Outcomes

- CRC screening rates increase across Zufall's sites
- Let's get to 80%!!!!


## COLORECTAL CANCER SCREENING

## Activity

- FIT tests will be distributed and returns will be tracked in Zufall's EMR by staff
- Timeline will be as follows:
  - FIT kits given at any visit
  - Navigator will follow up at 3 days, 7 days and 14 days
  - Navigator will confirm lab results or follow up to request lab results 5 days after FIT return/delivery to lab

## Outcome

- 5000 FIT kits will be distributed to our target patient population
- 3500 or more kits will be returned by our target population and processed

Review standing orders!

# FIT TEST DISTRIBUTION

## Activity

- Navigators will reach out to positive patients with follow-up reminders and assistance with further diagnostic testing, via phone and patient portal
- Zufall will provide 50 patients annually with $25 to eliminate the GI visit Copay
- Zufall will provide Financially indigent patients requiring colonoscopies with subsidies for up to $300 of copays

## Outcome

- An estimated 280 patients with positive FIT tests will have access to Colonoscopies


# FOLLOW UP

## EXPENSES TO BE CHARGED TO GRANT

- FIT TEST Kits (In House) – for uninsured patients -$8.00 annually
- FIT TEST (Lab Processing) – for both insured and uninsured - $20 annually
- Staff travel to Training
- Patient Incentives: $10. gift cards for purchase of groceries to incentivize medially indigent patients to conduct and return their FIT tests to Zufall's Screen NJ patient navigators

## BILLING

- All purchases/invoices related to the Screen NJ grant must have the following information noted on the PO
  - Date of purchase
  - Site
  - Screen NJ #658
- For example: ***01.31.2019DoverScreen NJ#658***


## TO ORDER FROM MCKESSON

- Product #1099224
- 90025 Collection Kit InSure® ONE™ Colorectal Cancer Screening Fecal Occult Blood Test (iFOB or FIT) Stool Sample CLIA Waived 25 Collection Kits


- For most of you—navigator responsibilities should account for 20% of your schedule or approximately 8 hours per week.
- Somerville: Due to the presence of CEED at your site, ScreenNJ Navigation should account for 10% or approximately 4 hours per week.
- Schedules for participating in the Screen NJ project will be unique to each site and must be arranged with your site manager and ensure appropriate staffing at all times for each site.

## HOW DOES THIS AFFECT YOUR SCHEDULE?

# CS10-5

## Sample patient text and voicemail reminders

**Text Message**

| | |
|---|---|
| English | Our records show it is time for your colorectal cancer screening. Please call {{FACILITY_TELEPHONE}} to schedule an appointment. |
| Spanish | Nuestros registros indican que es tiempo de hacer su examen para detección de cáncer de colon. Por favor llame al (telephone number in Spanish) para hacer su cita. |

**Voice Message**

| | |
|---|---|
| English | Our records show it is time for your colorectal cancer screening. Please call {{FACILITY_TELEPHONE}} to schedule an appointment. Once again, the telephone number is {{FACILITY_TELEPHONE}}. |
| Spanish | Nuestros registros indican que es tiempo de hacer su examen para detección de cáncer de colon. Por favor llame al (telephone number in Spanish) para hacer su cita. Otra vez, el número de teléfono es (telephone number in Spanish). |

# CS10-6

## Sample quarterly patient newsletter with article about FIT incentive

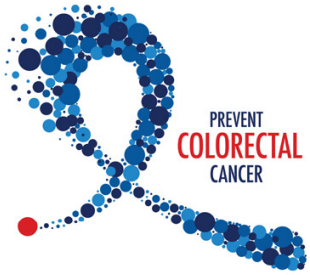
March 2021

# This Month at Zufall

## 1 New Guidelines for Colorectal Cancer Screening

New guidelines from the American Cancer Society recommend that people at average risk of colorectal cancer start regular screening at age 45. Colorectal cancer is the third most common cancer in the United States. Screening is important because it can find cancer at an early stage when treatment works best. Two tests are available for screening:

- Fecal Immunochemical Test (FIT) - Looks for hidden blood in the stool, can be done at home, and should be done every year.
- Colonoscopy - Finds abnormal growths that can be removed before they turn into cancer. It is performed by a doctor and should be done every 5 to 10 years depending on your risk factors.




Talk to your provider about which test is right for you. For more information, visit http://bit.ly/2Mqgtjo.

## 2 Eat Less Salt for a Healthier Heart

A diet high in salt (also called sodium) can lead to high blood pressure and other serious illnesses. The American Heart Association recommends less than 2,300 milligrams, or a total of one teaspoon of salt, each day. Here are some ways to help you use less salt:

- Eat more fresh foods and fewer processed foods.
- Read food labels and choose "low sodium" or "no sodium" options.
- Cook fresh meals at home using little or no salt.
- Drain and rinse vegetables canned in salted water.
- Flavor foods with salt-free seasonings to enjoy strong flavors.

Zufall's Supplemental Nutrition Assistance Program Education (SNAP-Ed) team can help you choose healthier food options for good heart health. SNAP-Ed is a nutrition and physical activity program that teaches N.J. residents how to make healthy, budget-friendly food choices and lead more active lives. Virtual classes are free and open to the public. Learn more about SNAP-Ed classes: http://bit.ly/3spvxNm.

## 3 Free COVID Testing Still Available

Zufall is offering COVID testing at scheduled, off-site events in Morris and Sussex counties. Testing is available in Morris County at St. Margaret of Scotland Church in Morristown and Casa Puerto Rico in Dover. In Sussex County, residents can obtain tests at three alternating public sites in Augusta, Newton, and Sparta. You do not need to be a Zufall patient to get tested at these locations. Register for an appointment online at http://bit.ly/3ozafLl. Walk-ins are welcome.

Established patients can also get tested at most Zufall medical locations. Call to make an appointment: http://bit.ly/2U4KPJi.

All COVID testing will be a nasal swab. Rapid testing is NOT available. There is no charge for COVID testing. LabCorp bills insurers directly. If you're uninsured, the federal CARES Act will cover the fee. However, if your employer requires regular, repeat testing, you may not be covered.

**Enrollment for health insurance has been extended through May 15. Visit www.getcovered.nj.gov. Need help? Call the Zufall Insurance Enrollment Hotline at 973-891-3425.**

ZUFALL HEALTH COMMUNITY HEALTH CENTERS

zufallhealth.org

Follow us on:

marzo 2021

# en Zufall

## Detección


información, visite http://bit.ly/3qzpvsb.

## ebas de COVID tuitas, Aún onibles

de COVID en eventos programados fuera s en los condados de Morris y Sussex. ponibles en el condado de Morris en la Scotland en Morristown y en Casa Puerto ondado de Sussex, los residentes pueden tres sitios públicos alternos en Augusta, es necesario ser paciente de Zufall para estos lugares. Regístrese en línea para ly/3ozafLl. Las personas sin cita son

cidos también pueden hacerse la prueba en aciones médicas de Zufall. Llame para hacer 2U4KPJi.

son administradas con un hisopo nasal. O están disponibles. No hay cargo por LabCorp factura directamente a los ene seguro, la ley federal CARES cubrirá la su empleador requiere pruebas periódicas que no esté cubierto.

clases virtuales son gratuitas y abiertas al público. Obtenga más información sobre las clases de SNAP-Ed: http://bit.ly/3spvxNm.

**La inscripción abierta para el Seguro de Salud se ha extendido hasta el 15 de mayo. Visite www.getcovered.nj.gov. Necesita ayuda? Llame a la línea directa de Inscripción al Seguro de Salud de Zufall (973) 891-3425.**

ZUFALL HEALTH COMMUNITY HEALTH CENTERS

zufallhealth.org

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| # | Reference | Annotated Bibliography Category |
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# APPENDICES

# APPENDIX A-1
# COLORECTAL CANCER SCREENING RATE MEASURES

Centers for Disease Control and Prevention. Measuring Breast, Cervical and Colorectal Cancer Screening Rates in Health System Clinics: Guidance Document. March 2018. **https://www.cdc.gov/cancer/nbccedp/pdf/measuring-cancer-screening-rates-508.pdf**

| Measure | Reporting Period | Performance Measure | Numerator | Denominator | Appropriate Screening Definition |
|---|---|---|---|---|---|
| **Government Performance and Results Act (GPRA) used by Indian Health Service** | July 1 to June 30 | Proportion of clinically appropriate patients ages 50 to 75 who have received colorectal screening | Patients who have had any colorectal cancer screening | American Indian/Alaska Native patients ages 50 to 75, with at least two clinics visits in the past three years<br><br>Exclusions: documented history of colorectal cancer or total colectomy | Fecal occult blood test (FOBT) or Fecal Immunochemical Test (FIT) during report period; Flexible Sigmoidoscopy in past 5 years; Colonoscopy in past 10 years |
| **Health Care Effectiveness Data and Information Set (HEDIS)** | January 1 to December 31; measures reported to NCQA in June | Percentage of adults ages 50 to 75 who had appropriate screening for colorectal cancer | Patients in the denominator who received one or more screenings for colorectal cancer | All patients 51 to 75 years of age as of December 31 during the measurement year<br><br>Exclusions: Colorectal cancer or total colectomy | FOBT during the measurement year; flexible sigmoidoscopy during the measurement year or the four years prior to the measurement year; colonoscopy during the measurement year or the nine years prior to the measurement year; computerized tomography (CT) colonography during the measurement year or the four years prior to the measurement year; fecal immunochemical test (FIT)-DNA test (Cologuard®) during the measurement year or the two years prior to the measurement year |

| Measure | Reporting Period | Performance Measure | Numerator | Denominator | Appropriate Screening Definition |
|---|---|---|---|---|---|
| **Uniform Data System (UDS)** | January 1 to December 31; measures reported to HRSA in February | Percentage of patients ages 50 to 75 who had appropriate screening for colorectal cancer | Number of active patients 51 to 74 years of age who have received appropriate colorectal cancer screening | Number of patients who were 51 to 74 years of age at some point during the measurement year, who had at least one medical visit during the reporting year<br><br>Exclusions: Have or have had colorectal cancer | Guaiac-based FOBT, or FIT, during the measurement year; flexible sigmoidoscopy during measurement year or previous four years; colonoscopy during measurement year or previous nine years |
| **National Quality Forum (NQF)-Endorsed Measure** | January 1 to December 31 | Percentage of adults ages 50 to 75 years who had appropriate screening for colorectal cancer | Number of patients with one or more screenings for colorectal cancer | Number of patients 51 to 75 years of age with a visit during the measurement year<br><br>Exclusions: Colorectal cancer or total colectomy | FOBT, including FIT, during the measurement year; Flexible Sigmoidoscopy during the measurement year or the four years prior to the measurement year; colonoscopy during the measurement year or the nine years prior to the measurement year |

[1] **National Committee for Quality Assurance (NCQA)**

[2] **Health Resources and Services Administration (HRSA)**

# APPENDIX A-2

## Calculating CRC Screening Rates for Community Health Centers using the Health Resources Services Administration (HRSA) Universal Data System (UDS) Specifications

Community Health Centers (CHCs) report CRC screening rates annually using Universal Data System (UDS) specifications. CHCs have the option of reporting on screening for their entire patient population as a denominator (referred to as the "universe") using Health Information Technology (HIT)/EHR reporting or selecting a scientifically drawn random sample to review manually. If the CHC cannot report on the universe (or chooses not to), then they must report with a random sample. While the random sample option is permitted, the full EHR or HIT system reporting is preferred. One useful tool to help collect and identify sources of data is the **Collect Health System Data Work Sheet**[15] in **Appendix A-2.1**. **Chart Audit Sample Template**[15] is available in **Appendix A-2.2**.

Appropriate screening defined by UDS Health Center Data Reporting Requirements[13]:

- Colonoscopy conducted during the reporting year or previous nine years (total = 10 years)
- Flexible sigmoidoscopy conducted during reporting year or previous four years (total = 5 years)
- Computerized tomography (CT) colonography conducted during the reporting year or previous four years (total=5 years)
- Multitarget Stool DNA (mt-sDNA): Fecal immunochemical test-deoxyribonucleic acid during the reporting year or previous two years (total=3 years)
- High sensitivity Guaiac-based fecal occult blood test (HSgFOBT) or immunochemical-based fecal occult blood test (iFOBT, commonly referred to as "FIT") during the reporting year.

Data for this measure may be obtained from EITHER:

A. **EHR/HIT Reporting on the entire population ("universe")** – The number will include the total number of CHC patients who fit the criteria (i.e., the number of patients who were 50 through 74 years of age at some point during the measurement year, who had at least one medical visit during the reporting year).

OR

B. **Scientific random sampling** – This will be a scientifically drawn sample of 70 patient health records selected from all patients who fit the criteria. The sample must be drawn from the entire patient population identified as the universe. See the UDS Manual **Appendix C** or **Appendix A-3** of this manual for a detailed description of how to perform the random sampling.[13]

Use a review of a sample of charts in lieu of full-denominator reporting from an EHR if:[1]

- the EHR does not include a minimum of 80% of health center patients who meet the criteria for inclusion in the denominator,
- the EHR does not exclude every clinic health center patient who meets one or more exclusion criteria exclusion from the denominator,
- the required data were not collected from the patient as part of the visit or searchable in discrete data fields at the time of the visit,
- the EHR has not been in place long enough to be able to find the data required in prior year's activities.

The process to calculate the screening rate is influenced by the specific type and version of the EHR. Please refer to **Appendix B-1** and **B-2** for **examples of entering data into a searchable field** in 2 separate EHR Systems. (NextGen and eClinicalWorks). For additional website resources on the electronic health record, see the **annotated bibliography** in **Appendix D**.

## Calculate the Baseline Screening Rate

The HRSA formula for calculating the screening rate is:

- **Denominator:** Number of patients 50 through 74 years of age with a medical visit during the measurement period
- **Denominator Exclusions:**
  - Patients with a diagnosis of colorectal cancer or a history of total colectomy
  - Patients who were in hospice care during the measurement period
  - Patients aged 66 or older who were living long-term in an institution for more than 90 days during the measurements period
  - Patients aged 66 and older with an advanced illness and frailty
- **Numerator:** Number in the denominator with one or more screenings for colorectal cancer. The UDS definition of screening includes patients who have received any of the following13:
  - Colonoscopy conducted during the reporting year or previous nine years (total = 10 years)
  - Flexible sigmoidoscopy conducted during reporting year or previous four years (total = 5 years)
  - Computerized tomography (CT) colonography conducted during the reporting year or previous four years (total=5 years)
  - Multitarget Stool DNA (mt-sDNA): Fecal immunochemical test-deoxyribonucleic acid during the reporting year or previous two years (total=3 years)
  - High sensitivity Guaiac-based fecal occult blood test (HSgFOBT) or immunochemical-based fecal occult blood test (iFOBT, commonly referred to as "FIT") during the reporting year.[2]

[1] Page 84 of: **https://bphc.hrsa.gov/sites/default/files/bphc/datareporting/pdf/2021-uds-manual.pdf**

[2] Page 101 (Reporting Considerations) of: **https://bphc.hrsa.gov/sites/default/files/bphc/datareporting/pdf/2021-uds-manual.pdf**

# APPENDIX A-2.1

## Collect Health System Data Worksheet

| Data | Data Source | Notes |
|---|---|---|
| Most recent colorectal cancer (CRC) screening rates—that is, the percentage of eligible patients screened in a specific time period. | | |
| Percentage of eligible patients screened with high-sensitivity fecal occult blood test (FOBT) or fecal immunochemical test (FIT) in a specific time period. | | |
| Percentage of eligible patients screened with multi-target stool DNA test (mt-sDNA) in a specific time period. | | |
| Percentage of eligible patients screened with colonoscopy in a specific time period. | | |
| Percentage of eligible patients screened with CT colonography in a specific time period. | | |
| Percentage of eligible patients screened with sigmoidoscopy in a specific time period. | | |

Original Source: Centers for Disease Control and Prevention. Increasing Colorectal Cancer Screening: An Action Guide for Working with Health Systems. Atlanta: Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2013. Updated based on May 2021 USPSTF Guidelines.

# APPENDIX A-2.2

## Chart Audit Sample Template

| | | | HSgFOBT/FIT | | Colonoscopy | | | |
|---|---|---|---|---|---|---|---|---|
| Name/ID | Visit Date (MM/DD/YY) | Risk (Avg/Inc/High) | Completed (Y/N) (MM/DD/YY) | Result | Ordered (Y/N) (MM/DD/YY) | Completed (Y/N) (MM/DD/YY) | Result | Diagnosis |
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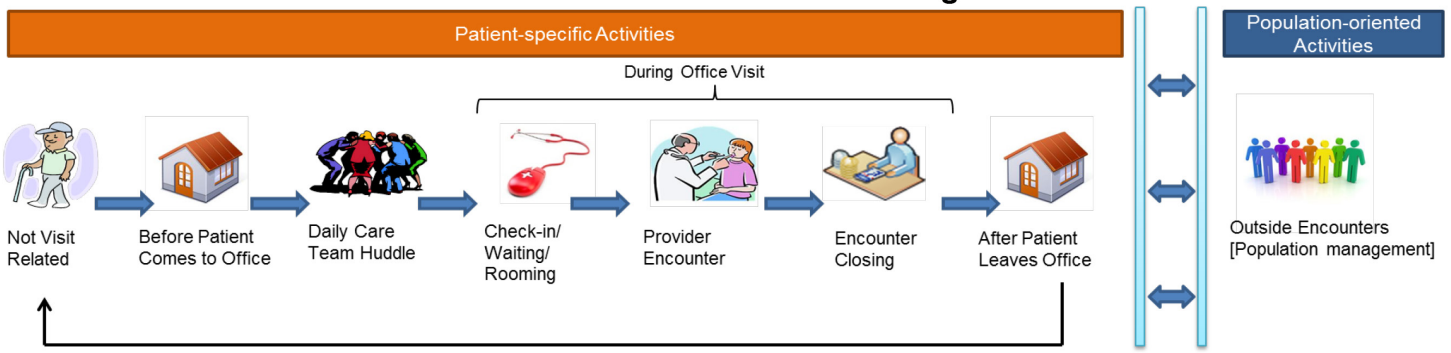
# APPENDIX A-3.1

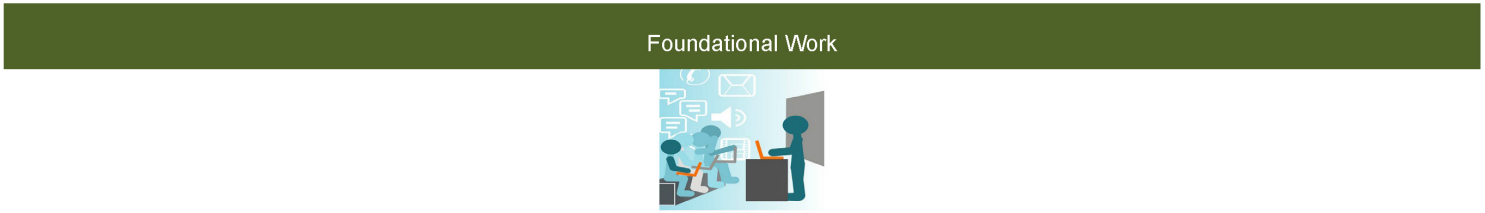
## Ambulatory CDS/QI Worksheet (Simplified Version)

### What Are We Trying To Improve? How Are We Doing Today?

| | |
|---|---|
| **Target** | **12/2020 goal set to achieve 60% by 6//30/2021** |
| **Current Performance on Target** | **Baseline in 1/1/2020 was ___ 4/2021 TY 43.5%** |

### Performance Drivers for this Target:




"Activities that are foundational to current patient-specific and population management activities and/or planned enhancements - e.g., staff training, policies and procedures, EHR tool development, etc."

## CDS/QI Approach Summary[1] - EBIs of Patient & Provider Reminders

| | Not Visit Related | Before Patient Comes to Office | Daily Care Team Huddle | Check-in/ Waiting/ Rooming | Provider Encounter | Encounter Closing | After Patient Leaves Office | Outside Encounters [Population management] | Foundational Work |
|---|---|---|---|---|---|---|---|---|---|
| **Current Information flow** | Pt phone number is wrong; in the wrong spot – gets error message when trying to contact patient | Medical Assistants do phone call reminders to patients to come in for screening | | Education/reminders within the clinic – posters with reminders about screening; also in bathrooms; flyers on doors – ask dr. about getting stool test; also in patient rooms | Reviews patients' preventive needs (Azara; preventive section, in med hx; some using CDSS); discuss options – for FIT – pick up/get at lab with blood work (on 1st floor of clinic), if colonoscopy, gets referral | | | Pull list from Azara of who's coming in the week before | $ to do the text messages; comes out of health center's budget; can be a barrier ($0.10/message) |
| **Potential Enhancements** | Review standard language in eCW for CRC campaign; revise text messages if needed (who will do? Alex/Dr. R./ Dr. C.; see what's available)<br><br>Review Messenger templates in eCW | Text campaign will automate text reminders to patients to come in for screening | | | Consider utilizing CDSS practice-configured alerts in right chart panel; can review how to add to right chart panel.<br><br>Associate orders or order set to alerts. | | If patient does not return the FIT, how do you f/up with them? | | Training for staff on use of practice-configured alerts<br><br>Inform front desk staff of reminder campaign and that patients will be calling in to schedule appts for screening; what information does front desk need to assist patients? |

[1]This table contains an overview of details documented on subsequent pages in this worksheet

# APPENDIX A-3.2

2020

# Partner Clinic Readiness Assessment Toolkit

WEST VIRGINIA PROGRAM TO INCREASE COLORECTAL CANCER SCREENING
WEST VIRGINIA UNIVERSITY CANCER PREVENTION & CONTROL

## Contents

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## Process Overview

The West Virginia Program to Increase Colorectal Cancer Screening (WV PICCS) will pursue a three-tiered approach to assessing each partner clinic's readiness to engage in the initiative.

Both qualitative and quantitative data points will be collected over a four-month onboarding period with partner clinics. Surveys will be administered, for the most part, through the Qualtrics platform. Two validated tools, the Organizational Readiness for Implementing Change (ORIC) measure and the Readiness Thinking Tool, will be used to collect data points related to perceived clinic readiness from various parties at each clinic. A Health Information Technology (HIT) Survey and a Colorectal Cancer (CRC) Screening Clinic Workflow and Processes Survey will provide the context needed to facilitate more in-depth semi-structured interviews with key informants. An environmental scan will help the WV PICCS team visually understand workflow strengths and weaknesses and identify potential avenues growth. Finally, CRC screening data points will be collected to establish a baseline from which to assess the effectiveness of interventions.

Most baseline assessment activities will be completed within the four-month onboarding period. Two exceptions will include the ORIC measure for all clinic staff and providers and the Readiness Thinking Tool (Tier III). The ORIC measure for all staff and providers will be administered after the initial WV PICCS training which will occur approximately 6 months after a clinic partnership begins. The Readiness Thinking Tool will be used before implementing any evidence-based intervention (EBI) throughout the implementation phase.

After Tier I and Tier II assessments are completed, WV PICCS staff will synthesize the findings and present each clinic with an Initial Assessment Report to facilitate the beginning of implementation activities. In addition, Tier I and Tier II assessments will be used to develop CDC Implementation Plans for each clinic by December 2020.

## Tiered Approach to Readiness Assessments

### Tier I

1. **HIT Survey.**[1] The person completing this survey will work closely with their clinic's electronic health record (EHR) for quality improvement. The survey will collect basic information on the EHR, staff capabilities, and functions that are needed to participate in WV PICCS (see Appendix A).
2. **Environmental Scan.** During the initial site visit, WV PICCS staff will conduct an environmental scan to assess interior, exterior, and digital features of the clinic. Due to COVID-19, this initial environmental scan may need to be delayed until in-person meetings are permitted (see Appendix B).
3. **CRC Screening Clinic Workflow and Processes Survey.** The person completing this survey will have a strong knowledge of clinic workflow and practices. The survey will be used to acquire an overall understanding of current practices, policies, and workflow related to CRC screening. This information will provide important background needed to facilitate key informant interviews (see Appendix C).
4. **COVID-19 Impact Survey.** The person completing this survey will have a strong knowledge of clinic workflow and organizational practices. The survey will be used to assess the effect of COVID-19 on clinic operations and specifically CRC screening initiatives (see Appendix D).

### Tier II

5. **HIT Site Visit.** The WV PICCS HIT Team will visit each clinic and meet with designated staff to assess EHR capabilities and staff skills. Information gathered from the HIT Survey will provide the background needed to facilitate a productive site visit and overall HIT assessment process.
6. **Key Informant Interviews.** WV PICCS staff will interview at least four individuals at each clinic site. These key informants will come from different staffing categories including administrative/clerical, leadership, clinical support, and providers. The interview questions were designed to understand workflow, processes, motivation, and clinic culture. The interviews will be used to clarify answers from the CRC Screening Clinic Workflow and Processes Survey (see Appendix E).
7. **Baseline CRC Screening Rates and Patient Characteristics Survey.** The person completing this survey will be able to pull data from their clinic's EHR. The survey will be used to collect baseline CRC screening rates, CRC screening test completion/return rates, and patient characteristics (i.e. sex, nationality/ethnicity, and insurance status). The ability to accurately pull these reports will be assessed and facilitated during the HIT assessment process (see Appendix F).

### Tier III

8. **ORIC.**[2] After the conclusion of the initial WV PICCS staff and provider training session, participants will be asked to complete the ORIC measure to assess perceived clinic readiness to participate in WV PICCS. (see Appendix G).
9. **Readiness Thinking Tool.**[3] This survey will be administered to all clinic CRC team members prior to implementing EBI throughout the implementation phase. (see Appendix H).

## Readiness Assessment Timeline

The Readiness Assessment Timeline outlines the assessment activities each partner clinic will complete each month during the onboarding process.

**Tier I**
(Months 1-2)

- HIT Survey (Qualtrics)
- Environment Scan (In-Person)
- CRC Screening Clinic Workflow and Processes Survey (Qualtrics)
- COVID-19 Impact Survey (Qualtrics)

**Tier II**
(Months 2-4)

- HIT Site Visit (In-Person or Video Conferencing)
- Key Informant Interviews (In-Person or Video Conferencing)
- Baseline CRC Screening Rates and Patient Characteristics Survey (Qualtrics)

**Reporting**
(Months 5-6)

- Initial Assessment Report (Partner Clinic Report)
- Implementation Plan (CDC Report)

**Tier III**
(Months 6 & Beyond)

- ORIC (In-Person or Qualtrics)
- Readiness Thinking Tool (In-Person or Qualtrics)

# References

1. WVU Office of Health Services Research. (2020).
2. Shea CM, Jacobs SR, Esserman DA, Bruce K, Weiner BJ. Organizational readiness for implementing change: A psychometric assessment of a new measure. Implementation science. 2014 Dec;9(1):1-5.
3. Capacity Building Center for States. (2019). Change and implementation readiness assessment tool. Washington, DC: Children's Bureau, Administration for
4. Children and Families, U.S. Department of Health and Human Services.

## Readiness Assessment Tools

### Appendix A
HIT Survey

# WVPICCS Health Information Technology Assessment

Start of Block: Default Question Block

Q1
**WV Program to Increase Colorectal Cancer Screening Health Information Technology Assessment**
The following questions are about the use of electronic health records (EHRs) in relation to colorectal cancer screening and data use. Please complete these questions to the best of your ability, and consult with other members of your practice as needed.

Thank you sincerely for your time and partnership. The West Virginia Program to Increase Colorectal Cancer Screening (WV PICCS) values working with you.

Page Break

Q2 Please note the name of your health system or practice:

_____

Q3 Please note the name(s) and title(s) of the individual(s) completing this survey:

_____

_____

_____

_____

_____

Page Break

Q4 Please provide the following information about the EHR currently used:

Q5 Name of the EHR

_____

Q6 How long your practice has used the EHR (in years and months)

_____

Page Break

Q7 Who at your practice is responsible for reviewing reports from the EHR? (Please list the job title(s) of those involved.)

_____

_____

_____

_____

_____

Q8 Does your practice currently use the clinical data associated with UDS, PQRS, NQF, and/or other reporting bodies to plan and implement quality improvement activities for colorectal cancer?

- ○ Yes
- ○ No

Page Break

Q9 Which of the following areas does your practice have experience modifying in the EHR? (Please check all that apply.)
For the areas that your practice doesn't have experience modifying in the EHR, please list the barriers.

- ☐ Data collection forms/templates _____
- ☐ Reporting _____
- ☐ Patient reminders _____
- ☐ Provider alerts _____
- ☐ Ability to create mailing lists/labels for patient reminders _____
- ☐ None of the above

Page Break

Q10 Is your EHR set-up to provide a list of patients age 51-74 who are not up-to-date on their colorectal cancer screenings?

- ○ Yes
- ○ No, but that feature can be programmed with current staff and resources
- ○ No, but that feature can be programmed if additional resources were available
- ○ No, cannot be generated

Q11 If you would like to provide more information on whether your EHR is set-up to provide a list of patients age 51-74 who are not up-to-date on their colorectal cancer screenings, and if that feature is used, please do so here.

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Page Break

Q12 Is your EHR set-up to alert providers, medical assistants, or other staff that a patient is due or past due for colorectal cancer screening?

- ○ Yes
- ○ No, but that feature can be programmed with current staff and resources
- ○ No, but that feature can be programmed if additional resources were available
- ○ No, cannot be generated

Q13 If you would like to provide more information on whether your EHR is set-up to alert providers, medical assistants, or other staff that a patient is due or past due for colorectal cancer screenings, and/or whether those features are used, please do so here.

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Page Break

2

Q14 How actively used is the alert for due or past due colorectal cancer screenings?

- ○ Not at all used / Not activated
- ○ Sporadically used
- ○ Generally used among the health care team
- ○ Consistently used across the health care team / Standard operating procedure
- ○ Unsure

Q15 If you would like to provide more information on how actively the alert for due or past due colorectal cancer screenings is use, please do so here.

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Page Break

Q16
Does the EHR allow for the documentation of which colorectal cancer screening test has been referred by the provider (i.e., immunofecal occult blood test, sigmoidoscopy, colonoscopy, etc.)?

- ○ Yes, in discrete fields
- ○ Yes, in text box
- ○ No
- ○ Unsure

---

Q17 If you would like to provide more information on whether your EHR allows for the documentation of which colorectal cancer screening test has been referred by the provider (i.e., immunofecal occult blood test, sigmoidoscopy, colonoscopy, etc.), please do so here.

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Page Break

Q18 Is your EHR set-up to capture family and personal history of colorectal cancer?

- ○ Yes, in discrete fields
- ○ Yes, in text box
- ○ No, but that feature can be programmed with current staff and resources
- ○ No, but that feature can be programmed if additional resources were available
- ○ No, cannot be generated

Q19 If you would like to provide more information on whether your EHR is set-up to capture family and personal history of colorectal cancer, please do so here.

_____

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Page Break

Q20
Does the EHR allow you to run colorectal cancer screening rates by provider?

- ○ Yes
- ○ No
- ○ Unsure

Q21 Can your health system, without assistance, run these reports?

- ○ Yes
- ○ No

Q22 If you would like to provide more information on whether your EHR allows you to run colorectal cancer screening reports by provider, please do so here.

_____

_____

_____

_____

_____

Page Break

2

Q23 Do patient EHR charts indicate if a provider has recommended colorectal cancer screening and the patient declined?

- ○ Yes, in discrete fields
- ○ Yes, in text box
- ○ No, but that feature can be programmed with current staff and resources
- ○ No, but that feature can be programmed if additional resources were available
- ○ No, cannot be generated

Q24 Do patient EHR charts indicate if a provider has recommended colorectal cancer screening and the patient deferred a response (wants to think it over)?

- ○ Yes, in discrete fields
- ○ Yes, in text box
- ○ No, but that feature can be programmed with current staff and resources
- ○ No, but that feature can be programmed if additional resources were available
- ○ No, cannot be generated

Page Break

Q25 Please describe the office flow of how colorectal screening results are entered into the EHR. Please include descriptions as applicable of manual data entry, upload of scanned documents, and import of electronic data.

_____

_____

_____

_____

_____

Page Break

2

Q26 The WV Program to Increase Colorectal Cancer Screening aims to be an asset to your practice's ability to increase colorectal cancer screenings and best serve your patient population. Please provide any additional information on needs your organization may have for colorectal cancer screening reporting, tracking, and analytics so that we can best partner with you.

_____

_____

_____

_____

_____

End of Block: Default Question Block

## Appendix B

### Environmental Scan

| PRE-SITE VISIT | | |
|---|---|---|
| **QUESTION** | **Y OR N** | **DETAILS** |
| Site has a social media profile. If yes, which sites? | | |
| Do the social media outlets provide any public health information? If so, what topics are being informed? | | |
| Site has a website. If yes, are hours, location(s) and contact information provided? | | |
| Website provides public health information. If so, what topics are being informed? | | |
| **SITE VISIT - EXTERIOR** | | |
| **NOTE: Take photographs of exterior and interior of the clinic during the site visit.** | | |
| Site has easy access to parking. | | |
| Parking spots are a reasonable walking distance from entry. | | |
| Site has accessibility to individuals with disabilities (i.e. parking, wheelchair entrance, etc.) | | |
| Site entrance is clearly visible. | | |
| Valet service is available. | | |
| **SITE VISIT – INTERIOR** | | |
| Site has a waiting room/lobby. | | |
| The lobby has TV screen(s), kiosk or video monitor(s). If so, which kind(s)? | | |
| Lobby has public health information displayed. If so, are there brochures, posters or both? | | |
| Lobby has colorectal cancer/screening information displayed. If so, are there brochures, posters or both? | | |
| Public health information is displayed in other locations throughout the clinic. If so, please list areas. | | |
| The clinic hours are clearly posted. | | |
| There is a reception desk with a receptionist available. | | |
| Do the exam rooms have any public health information displayed? If so, are there brochures, posters or both? | | |
| Restrooms display any public health information? If so, please describe the type of publications displayed | | |
| Are the CRC test kits physically located in the clinic area? | | |
| Does the patient receive any form of tangible reminders when they exit their appointments? | | |

Appendix C

CRC Screening Clinic Workflow and Processes Survey

# WV PICCS: CRC Screening Clinic Workflow and Processes (Baseline)

Start of Block: Default Question Block

Q1 This survey will collect your clinic's current colorectal cancer (CRC) screening practices and workflow.

The person(s) completing this assessment should have knowledge of clinic workflow and practices. It will take approximately 30 minutes to complete.

A separate assessment will need to be completed for each clinic participating in WV PICCS.

End of Block: Default Question Block

Start of Block: Block 1

Q2 The questions in this section collect information regarding CRC screening administration at your clinic (5 total).

Q3 Does your clinic have CRC screening standing orders?

- ○ Yes (1)
- ○ No (2)

*Display This Question:*

*If Does your clinic have CRC screening standing orders? = Yes*

Q4 Describe your CRC screening standing orders.

_____

_____

_____

_____

_____

*Display This Question:*

*If Does your clinic have CRC screening standing orders? = No*

Q5 Describe any challenges your clinic may have in establishing CRC screening standing orders.

_____

_____

_____

_____

_____

Q6 Identify the person identified as your clinic's CRC screening champion. Provide name and title/role.

_____

_____

_____

2

Q7 Select all of the CRC screening methods used by your clinic.

- [ ] FIT (1)
- [ ] FIT-DNA (Cologuard) (2)
- [ ] FOBT (3)
- [ ] Colonoscopy (4)

Q8 Which screening method do you use the most in your clinic?

- ○ FIT (1)
- ○ FIT-DNA (2)
- ○ FOBT (3)
- ○ Colonoscopy (4)

End of Block: Block 1

Start of Block: Block 2

Q9 The questions in this section collect information related to patient encounters (5 total).

Q10 Describe your clinic's patient encounter workflow (i.e. triage, staff members involved, etc.)

Q11 Which staff members are responsible for assessing CRC screening eligibility?
When does this assessment occur?

Q12 Who discusses CRC screening with the patients?
How is CRC screening presented to the patient?

Q13 Who orders CRC screening for the patient?
How does this occur?

_____

_____

_____

_____

Q14 Describe any CRC screening educational materials given to your patients and/or on display.

_____

_____

_____

_____

_____

End of Block: Block 2

Start of Block: Block 3

Q15 This section of questions collects information on your CRC screening tracking processes (9 total).

Q16 Who is responsible for tracking if and when a stool-based test (i.e. FIT) is returned? Describe this process.

_____

_____

_____

_____

Q17 Who is responsible for tracking if and when a colonoscopy is completed? Describe this process.

Q18 How are positive or negative results documented and how are patients notified?

Q19 Describe the process for working with patients to schedule follow-up testing after a positive FIT.

Q20 How do you work with patients that do not show up for follow-up testing?

_____

_____

_____

_____

_____

Q21 How do you assist patients that are uninsured and unable to afford follow-up testing?

_____

_____

_____

_____

_____

Q22 Does your clinic have a patient navigator?

- ○ Yes (1)
- ○ No (2)

Q23 Describe the role of a patient navigator in your clinic.

2

_____

_____

_____

Q24 How many fulltime patient navigators does your clinic employ?

_____

End of Block: Block 3

Start of Block: Block 4

Q25 This final section of questions will collect information on your current CRC practices (4-8 total).

Q26 Does your clinic engage in provider assessment and feedback for CRC screening?

- Yes (1)
- No (2)

*Display This Question:*

*If Does your clinic engage in provider assessment and feedback for CRC screening? = Yes*

Q27 Describe your provider assessment and feedback process.

_____

_____

_____

_____

Q28 Does your clinic use provider reminders for CRC screening?

- ○ Yes (1)
- ○ No (2)

*Display This Question:*

*If Does your clinic use provider reminders for CRC screening? = Yes*

Q29 Describe your provider reminder process.

_____

_____

_____

_____

_____

Q30 Does your clinic use patient reminders for CRC screening?

- ○ Yes (1)
- ○ No (2)

*Display This Question:*

*If Does your clinic use patient reminders for CRC screening? = Yes*

2

Q31 Describe your clinic's use of patient reminders.

_____

_____

_____

_____

_____

Q32 Does your clinic actively seek to reduce structural barriers to CRC screening?

- Yes (1)
- No (2)

*Display This Question:*

*If Does your clinic actively seek to reduce structural barriers to CRC screening? = Yes*

Q33 Describe patient barriers to CRC screening and how your clinic tries to reduce them.

_____

_____

_____

_____

_____

End of Block: Block 4

Appendix D

COVID-19 Impact Survey

# WV PICCS: COVID-19 Impact

Start of Block: Default Question Block

Q1 This survey will collect information how COVID-19 has affected your clinic with a specific emphasis on colorectal cancer (CRC) screening.

The person(s) completing this assessment should have knowledge of clinic workflow and operations. It will take approximately 5-10 minutes to complete.

A separate assessment will need to be completed for each clinic participating in WV PICCS.

End of Block: Default Question Block

Start of Block: Block 1

Q2 Over the past 12 months, due to COVID-19, have you had to close or reduced your clinic hours?

- ○ Yes, closed (at least a full week or more) (1)
- ○ Yes, reduced hours (2)
- ○ Yes, closed and reduced hours (3)
- ○ No, clinic did not close or reduce hours (4)

*Display This Question:*

*If Over the past 12 months, due to COVID-19, have you had to close or reduced your clinic hours? = Yes, closed (at least a full week or more)*

*Or Over the past 12 months, due to COVID-19, have you had to close or reduced your clinic hours? = Yes, closed and reduced hours*

2

Q3 Number of weeks your clinic was closed

_____

*Display This Question:*

*If Over the past 12 months, due to COVID-19, have you had to close or reduced your clinic hours? = Yes, reduced hours*

*Or Over the past 12 months, due to COVID-19, have you had to close or reduced your clinic hours? = Yes, closed and reduced hours*

Q4 Number of clinic hours reduced per week

_____

*Display This Question:*

*If Over the past 12 months, due to COVID-19, have you had to close or reduced your clinic hours? = Yes, reduced hours*

*Or Over the past 12 months, due to COVID-19, have you had to close or reduced your clinic hours? = Yes, closed and reduced hours*

Q5 Number of weeks clinic has operated with reduced hours

_____

End of Block: Block 1

Start of Block: Block 2

Q6 In the past 12 months, has COVID-19 negatively impacted your clinic's delivery of CRC screening and diagnostic services?

- ○ Yes (1)
- ○ No (2)

2

*Display This Question:*

*If In the past 12 months, has COVID-19 negatively impacted your clinic's delivery of CRC screening a... = Yes*

Q7 Indicate if any of these situations has occurred in your clinic over the past 12 months. Type Y (yes) or N (no) for each question.

- Visits were limited to only sick patients, with limited or preventative care available (1) _____
- Visits were limited to those at high risk for CRC or with symptoms of CRC (2) _____
- Visits were telemedicine/telehealth only (3) _____
- Could not refer average risk patients for screening colonoscopies due to limited availability of endoscopic services (4) _____
- Could not refer patients with abnormal or positive fecal test results for follow-up due to limited availability of endoscopic services (5) _____
- Patients cancelled or did not schedule appointments due to fear of COVID-19 (6) _____
- Patients fearful of getting COVID-19 (7) _____

*Display This Question:*

*If In the past 12 months, has COVID-19 negatively impacted your clinic's delivery of CRC screening a... = Yes*

Q8 Please provide any additional information on how COVID-19 has affected your clinic's CRC screening services.

_____

_____

_____

2

End of Block: Block 2

Start of Block: Block 3

Q9 Over the past 12 months, has COVID-19 negatively impacted your clinic's implementation of of evidence-based interventions (EBIs) or patient navigation activities for CRC screening?

- Yes (1)
- No (2)

*Display This Question:*

*If Over the past 12 months, has COVID-19 negatively impacted your clinic's implementation of of evid... = Yes*

Q10 Indicate if any of these situations has occurred in your clinic over the past 12 months. Type Y (yes) or N (no) for each question.

- COVID-19 negatively affected PATIENT REMINDERS for CRC screening (1)
- COVID-19 negatively affected PROVIDER REMINDERS for CRC screening (2)
- COVID-19 negatively affected PROVIDER ASSESSMENT & FEEDBACK for CRC screening (3)
- COVID-19 negatively affected REDUCING STRUCTURAL BARRIERS for CRC screening (4)
- COVID-19 negatively affected PATIENT NAVIGATION for CRC screening (5)

End of Block: Block 3

Start of Block: Block 4

Q11 Please provide any additional information that may help us understand the impact COVID-19 has had on your clinic.

_____

_____

_____

_____

_____

End of Block: Block 4

# Appendix E

Key Informant Interview Guide

**Administrative/Clerical Questions**

1. Describe your position at CLINIC.
    - What are some of the primary tasks/duties that you complete each day?
        - Describe the workflow for these primary tasks.
    - How would you describe your average daily workload?
2. Describe your role, if any, in improving the quality of patient care at CLINIC.
    - Why do you feel this way?
3. Describe a quality improvement change that has been made at CLINIC in the past.
    - Describe how you were or were not able to contribute to this process.
    - How do you think this process of change could be improved in the future?
4. Describe some of the ways you could support a colorectal cancer screening quality improvement initiative at CLINIC.
    - Do you feel like your contribution would be important?
    - What would be some challenges to assisting?

Main goals: Understanding process/workflow, work volume, perception of inclusion/value/participation

**Leadership Questions**

1. Describe your role at CLINIC.
    - What is your role, if any, in improving the quality of patient care?
2. Describe a quality improvement change that has been made at CLINIC in the past.
    - What were the strengths and weaknesses of this process?
    - Who was involved in this process?
    - How could this process be improved in the future?
3. Describe CLINIC'S process for prioritizing quality improvement initiatives.
    - What are some of CLINIC's current quality improvement priorities?
    - Describe the resources you need to successfully complete these initiatives.
    - Do you feel you are well positioned to undertake a quality improvement initiative now?
        - Why or why not?
4. Describe some of the ways you could support a colorectal cancer screening quality improvement initiative at CLINIC.
    - Do you feel like your contribution would be important?
    - What would be some challenges to assisting?
    - Describe the resources you need to successfully complete this initiative.

Main goals: Views on quality improvement, approach to change, prioritization of QI, personal role in QI, capacity for QI

**Clinical Staff Questions**

1. Describe your position at CLINIC.
    - What are some of the primary tasks/duties that you complete each day?
        - Describe the workflow for these primary tasks.
    - How would you describe your average daily workload?
2. Describe your role, if any, in working with patients to satisfy quality measures.
    - How important is your role in ensuring patients satisfy quality measures?
3. Describe how you approach conversations about colorectal cancer screening with your patients.
    - How do patients typically respond to these conversations?
    - What are some of the challenges you have in getting patients to complete colorectal cancer screening?
    - Do you have any suggestions to improve colorectal cancer screening rates at CLINIC?
4. Describe a quality improvement change that has been made at CLINIC in the past.
    - Describe how you were or were not able to contribute to this process.
    - How do you think this process of change could be improved in the future?
5. Describe some of the ways you could support a colorectal cancer screening quality improvement initiative at CLINIC.
    - Do you feel like your contribution would be important?
    - What would be some challenges to assisting?
    - Describe the resources you need to successfully complete this initiative.
    - Describe any EHR-related changes that you feel could help or improve a colorectal cancer screening initiative.

Main goals: Understanding process/workflow, work volume, perception of inclusion/value/participation, colorectal cancer screening specific processes/approaches

**Provider Questions**

1. Describe your role at CLINIC.
    - How would you describe your average daily workload?
        - Approximately how many patients do you see on an average day in the clinic?
        - How much time do you spend on documenting patient encounters?
            - Do you feel that CLINIC's EHR is user-friendly and helps you in this documentation process?
                - ✓ Why or why not?
    - Describe the workflow for patient appointments.
2. How do you encourage patients to satisfy quality measures?
    - Do you feel that patients are responsive to these approaches?
        - Could these approaches be improved?
            - Why or why not?

3. Describe how you approach conversations about colorectal cancer screening with your patients.
    - How do patients typically respond to these conversations?
    - What are some of the challenges you have in getting patients to complete colorectal cancer screening?
    - Do you have any suggestions to improve colorectal cancer screening rates at CLINIC?
4. Describe a quality improvement change that has been made at CLINIC in the past.
    - Describe how you were or were not able to contribute to this process.
    - How do you think this process of change could be improved in the future?
5. Describe some of the ways you could support a colorectal cancer screening quality improvement initiative at CLINIC.
    - Do you feel like your contribution would be important?
    - What would be some challenges to assisting?
    - Describe the resources you need to successfully complete this initiative.
    - Describe any EHR-related changes that you feel could help or improve a colorectal cancer screening initiative.

Main goals: Understanding process/workflow, work volume, perception of inclusion/value/participation, colorectal cancer screening specific processes/approaches

Appendix F

Baseline CRC Screening Rates and Patient Characteristics Survey

# WV PICCS: Baseline CRC Screening Rates and Patient Characteristics

Start of Block: Default Question Block

Q1 This survey will be used to collect CRC screening rate information and patient characteristics for your clinic.

The person(s) completing this assessment should feel comfortable pulling this data from your electronic health records system.

If your health system has more than one clinic participating in WV PICCS, patient characteristics and CRC screening rates for each clinic can be entered on this survey.

Q2 Person Completing this Report

_____

Q3 Health System Name

_____

Q4 Number of Health System Clinics (include all sites - not just those participating in WV PICCS)

_____

Q5 Number of Health System Providers (not just for participating clinic)

_____

Q6 Data Source

- ○ Chart Review Only (1)
- ○ Electronic Health Records (EHR) Only (2)
- ○ Both (3)

*Display This Question:*

*If Data Source != Electronic Health Records (EHR) Only*

Q7 Percent of Charts Reviewed for CRC Rate

_____

*Display This Question:*

*If Data Source != Electronic Health Records (EHR) Only*

Q8 Did you use random or systematic sampling for the chart review?

- ○ Systematic (1)
- ○ Random (2)
- ○ Not Sure (3)

*Display This Question:*

*If Data Source != Chart Review Only*

Q9 Electronic Health Record (EHR) Name

_____

Q10 Provide the following data points for your clinic. The reporting date range is January 1 - December 31, 2020.

Q11 Clinic 1: CRC Screening Rate Information

- Clinic Name (2) _____
- Numerator (3) _____
- Denominator (4) _____
- Percentage (5) _____
- Measure Used (UDS, HEDIS, Practice Analytics) (6)

_____

Q12 Clinic 1: Patient Characteristics

- Total Number of Clinic Patients (3) _____
- Total Number of Clinic Patients, Aged 50-75 (4) _____
- Total Number of WOMEN, 50-75 (5) _____
- Total Number of MEN, 50-75 (6) _____
- Total Number of UNINSURED, 50-75 (7) _____
- Total Number HISPANIC, 50-75 (10) _____
- Total Number WHITE, 50-75 (11) _____
- Total Number BLACK, 50-75 (12) _____
- Total Number ASIAN, 50-75 (13) _____
- Total Number PACIFIC ISLANDER, 50-75 (14) _____
- Total Number AMERICAN INDIAN, 50-75 (15) _____
- Total Number MORE THAN ONE RACE, 50-75 (2) _____

2

Q13 Clinic 1: CRC Tests Ordered & Completed

- ○ Number of Screening Colonoscopies Ordered (2)
  _____
- ○ Number of Screening Colonoscopies Completed (3)
  _____
- ○ Number of FIT (stool-based tests) Ordered (4)
  _____
- ○ Number of FIT (stool-based tests) Completed (5)
  _____
- ○ Number of Diagnostic (follow-up) Colonoscopies Ordered (7)
  _____
- ○ Number of Diagnostic (follow-up) Colonoscopies Completed (8)
  _____

Q14 Clinic 1: Number of Providers

_____

Q15 Do you have another clinic that you need to add?

- ○ Yes (5)
- ○ No (6)

*Skip To: Q30 If Do you have another clinic that you need to add? = No*

Q16 Clinic 2: CRC Screening Rate Information

- Clinic Name (2) _____
- Numerator (3) _____
- Denominator (4) _____
- Percentage (5) _____
- Measure Used (UDS, HEDIS, Practice Analytics) (6)

_____

Q17 Clinic 2: Patient Characteristics

- Total Number of Clinic Patients (3) _____
- Total Number of Clinic Patients, Aged 50-75 (4) _____
- Total Number of WOMEN, 50-75 (5) _____
- Total Number of MEN, 50-75 (6) _____
- Total Number of UNINSURED, 50-75 (7) _____
- Total Number HISPANIC, 50-75 (10) _____
- Total Number WHITE, 50-75 (11) _____
- Total Number BLACK, 50-75 (12) _____
- Total Number ASIAN, 50-75 (13) _____
- Total Number PACIFIC ISLANDER, 50-75 (14) _____
- Total Number AMERICAN INDIAN, 50-75 (15) _____
- Total Number MORE THAN ONE RACE, 50-75 (2) _____

2

Q18 Clinic 2: CRC Tests Ordered & Completed

- ○ Number of Screening Colonoscopies Ordered (2)
  _____
- ○ Number of Screening Colonoscopies Completed (3)
  _____
- ○ Number of FIT (stool-based tests) Ordered (4)
  _____
- ○ Number of FIT (stool-based tests) Completed (5)
  _____
- ○ Number of Diagnostic (follow-up) Colonoscopies Ordered (7)
  _____
- ○ Number of Diagnostic (follow-up) Colonoscopies Completed (8)
  _____

Q19 Clinic 2: Number of Providers

_____

Q20 Do you have another clinic that you need to add?

- ○ Yes (5)
- ○ No (6)

*Skip To: Q30 If Do you have another clinic that you need to add? = No*

Q21 Clinic 3: CRC Screening Rate Information

- Clinic Name (2) _____
- Numerator (3) _____
- Denominator (4) _____
- Percentage (5) _____
- Measure Used (UDS, HEDIS, Practice Analytics) (6)

_____

Q22 Clinic 3: Patient Characteristics

- Total Number of Clinic Patients (3) _____
- Total Number of Clinic Patients, Aged 50-75 (4) _____
- Total Number of WOMEN, 50-75 (5) _____
- Total Number of MEN, 50-75 (6) _____
- Total Number of UNINSURED, 50-75 (7) _____
- Total Number HISPANIC, 50-75 (10) _____
- Total Number WHITE, 50-75 (11) _____
- Total Number BLACK, 50-75 (12) _____
- Total Number ASIAN, 50-75 (13) _____
- Total Number PACIFIC ISLANDER, 50-75 (14) _____
- Total Number AMERICAN INDIAN, 50-75 (15) _____
- Total Number MORE THAN ONE RACE, 50-75 (2) _____

Q23 Clinic 3: CRC Tests Ordered & Completed

- ○ Number of Screening Colonoscopies Ordered (2)
  _____
- ○ Number of Screening Colonoscopies Completed (3)
  _____
- ○ Number of FIT (stool-based tests) Ordered (4)
  _____
- ○ Number of FIT (stool-based tests) Completed (5)
  _____
- ○ Number of Diagnostic (follow-up) Colonoscopies Ordered (7)
  _____
- ○ Number of Diagnostic (follow-up) Colonoscopies Completed (8)
  _____

Q24 Clinic 3: Number of Providers

_____

Q25 Do you have another clinic that you need to add?

- ○ Yes (5)
- ○ No (6)

*Skip To: Q30 If Do you have another clinic that you need to add? = No*

Q26 Clinic 4: CRC Screening Rate Information

- Clinic Name (2) _____
- Numerator (3) _____
- Denominator (4) _____
- Percentage (5) _____
- Measure Used (UDS, HEDIS, Practice Analytics) (6)

_____

Q27 Clinic 4: Patient Characteristics

- Total Number of Clinic Patients (3) _____
- Total Number of Clinic Patients, Aged 50-75 (4) _____
- Total Number of WOMEN, 50-75 (5) _____
- Total Number of MEN, 50-75 (6) _____
- Total Number of UNINSURED, 50-75 (7) _____
- Total Number HISPANIC, 50-75 (10) _____
- Total Number WHITE, 50-75 (11) _____
- Total Number BLACK, 50-75 (12) _____
- Total Number ASIAN, 50-75 (13) _____
- Total Number PACIFIC ISLANDER, 50-75 (14) _____
- Total Number AMERICAN INDIAN, 50-75 (15) _____
- Total Number MORE THAN ONE RACE, 50-75 (2) _____

Q28 Clinic 4: CRC Tests Ordered & Completed

- Number of Screening Colonoscopies Ordered (2) _____
- Number of Screening Colonoscopies Completed (3) _____
- Number of FIT (stool-based tests) Ordered (4) _____
- Number of FIT (stool-based tests) Completed (5) _____
- Number of Diagnostic (follow-up) Colonoscopies Ordered (7) _____
- Number of Diagnostic (follow-up) Colonoscopies Completed (8) _____

Q29 Clinic 4: Number of Providers

_____

Q30 How confident are you in the accuracy of the data provided?

- Not Confident (4)
- Somewhat Confident (5)
- Very Confident (6)

2

Q31 Are there known unresolved problems with the CRC data provided?

- ○ Yes (1)
- ○ No (2)
- ○ Unknown (3)

*Display This Question:*

*If Are there known unresolved problems with the CRC data provided? = Yes*

Q32 Please explain the unresolved problem with the CRC data provided.

_____

_____

_____

_____

_____

End of Block: Default Question Block

Appendix G

ORIC

# WV PICCS: Organizational Readiness for Implementing Change (ORIC)

Start of Block: Default Question Block

Q1 This survey is used to collect information about clinic readiness to undertake colorectal cancer screening improvement initiatives with WV PICCS. It will be completed by staff and providers who participate in initial WV PICCS training. The assessment will take approximately 5 minutes to complete.

Q2 Health System/Clinic

_____

Q3 Role/Position

_____

End of Block: Default Question Block

Start of Block: Block 1

2

Q4 People who work here feel confident that the organization can get people invested in implementing this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

Q5 People who work here are committed to implementing this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

2

Q6 People who work here feel confident that they can keep track of progress in implementing this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

Q7 People who work here will do whatever it takes to implement this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

2

Q8 People who work here feel confident that the organization can support people as they adjust to this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

Q9 People who work here want to implement this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

2

Q10 People who work here feel confident that they can keep the momentum going in implementing this change.

- ○ Disagree (1)
- ○ Somewhat Disagree (2)
- ○ Neither Agree or Disagree (3)
- ○ Somewhat Agree (4)
- ○ Agree (5)

---

Q11 People who work here feel confident that they can handle the challenges that might arise in implementing this change.

- ○ Disagree (1)
- ○ Somewhat Disagree (2)
- ○ Neither Agree or Disagree (3)
- ○ Somewhat Agree (4)
- ○ Agree (5)

---

2

Q12 People who work here are determined to implement this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

Q13 People who work here feel confident that they can coordinate tasks so that implementation goes smoothly.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

2

Q14 People who work here are motivated to implement this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

---

Q15 People who work here feel confident that they can manage the politics of implementing this change.

- Disagree (1)
- Somewhat Disagree (2)
- Neither Agree or Disagree (3)
- Somewhat Agree (4)
- Agree (5)

End of Block: Block 1

Appendix H

Readiness Thinking Tool

# WV PICCS: Readiness Thinking Tool

Start of Block: Default Question Block

Q1 This survey is used to collect information about clinic readiness to undertake specific colorectal cancer screening improvement initiatives with WV PICCS. The assessment will take approximately 5 minutes to complete.

End of Block: Default Question Block

Start of Block: Block 1

Q2 Clinic Name

_____

Q3 Role/Position

_____

Q4 Date Completed

_____

2

Q5 Describe the evidence-based intervention (EBI) your clinic will implement.

_____

End of Block: Block 1

Start of Block: Block 2

Q6 This innovation seems better than what we are currently doing.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

Q7 This innovation fits with how we do things.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

2

Q8 This innovation seems simple to use.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q9 This innovation can be tested and experimented with.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q10 We have the ability to see that this innovation is leading to outcomes.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

2

Q11 This innovation has a high level of importance compared to other things we do.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

End of Block: Block 2

Start of Block: Block 3

Q12 We have sufficient abilities to do the innovation.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

Q13 There is a well-connected person who supports and models this innovation.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

2

Q14 We have the necessary supports, processes, and resources to enable this innovation.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q15 We have the necessary relationships between organizations that support this innovation.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q16 We have the necessary relationships within the clinic to support this innovation.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

End of Block: Block 3

---

Start of Block: Block 4

2

Q17 We have clear norms and values of how we do things here.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q18 People have a strong sense/feeling of being a part of this clinic.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q19 Our clinic is open to change in general.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

2

Q20 Our clinic has the ability to acquire and allocate resources including time, money, effort, and technology.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q21 Our clinic has effective leaders.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q22 Our clinic has effective communication and teamwork.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

2

Q23 Our clinic has enough of the right people to get things done.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

---

Q24 Our clinic has the ability to plan, implement, and evaluate.

- Disagree (1)
- Partially Agree (2)
- Strongly Agree (3)
- Unsure (4)

End of Block: Block 4

# APPENDIX A-3.3

## NY State Clinic Readiness Assessment Tool

### Introduction:

Clinics should complete this assessment tool to the best of their ability. This survey is one component of the clinic assessment process and your responses will be reviewed with the project team during assessment meetings. The information provided in this survey will set the stage for ongoing communication and discussion as we work with you to understand your processes and build improvement plans. Questions or clarifications can be addressed to your project manager.

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Section 9: COVID-19 Impact on Colorectal Cancer Screening . . . . . 15
Section 10: Other . . . . . 16

### Section 1: General Clinic Information

| Question | | Answer |
|---|---|---|
| 1 | FQHC/Health System Name | |
| 2 | Clinic Name | |
| 3 | Clinic Location (city, ZIP code) | |
| 4 | Name/title of key contact for project | |
| 5 | Email address of key contact | |
| 6 | Telephone number of key contact | |
| 7 | Name/title of individual completing assessment (IF DIFFERENT FROM KEY CONTACT) | |
| 8 | Email address of individual completing assessment | |
| 9 | Telephone number of individual completing assessment | |

## Section 2: Clinic and Patient Characteristics

| Question | | Answer | |
|---|---|---|---|
| 1 | Total number of clinic sites in the health system that provide primary care services (do not include school-based health clinics) | | |
| 2 | Number of staff by category at the clinic and FQHC/Health System level | **Clinic Level** | **FQHC/Health System Level** |
| | Primary Care Clinical Providers (MD/DO, NP, PA) | | |
| | Nursing (RN, LPN, APN) | | |
| | Medical Office Assistants | | |
| | Community Health Workers | | |
| | Patient Navigators | | |
| | Health Information Technology specialists (or some other identifier) | | |
| | Administrative | | |
| | Clerical | | |
| | Other | | |
| 3 | Please provide NPI#s used for billing along with billing addresses. This will be used to support health plan engagement, specifically Medicaid Managed Care plans, in this work. | | |
| 4 | Percent of patients less than 200% of the federal poverty limit | | |
| 5 | Percent of patients best served in a language other than English | | |
| 6 | Patient Population Characteristics: | | |
| | Total # of clinic patients that had at least one visit in the last year (all ages): | | |
| | Total # of clinic patients 50-75 that had at least one visit in the last year: | | |
| | Of the patients 50-75 with at least one visit in the prior year: | | |
| | % of patients, Men | | |
| | % of patients, Women | | |
| | % of patients, uninsured | | |
| | % of patients, Hispanic | | |
| | % of patients, Non-Hispanic | | |
| | % of patients, white | | |
| | % of patients, Black/AA | | |
| | % of patients, Asian | | |
| | % of patients, Native Hawaiian/Pacific Islander | | |
| | % of patients, American Indian/Alaska Native | | |
| | % of patients, more than one race | | |

## Section 3: Quality Improvement (QI) Structure and Priorities

| | Question | Answer |
|---|---|---|
| 1 | Please briefly describe the clinic or center's QI structure. If the QI structure is at the FQHC/ Health System level, please note that and describe. | |
| 2 | How experienced is your clinic staff with QI efforts?<br><br>*Select One:* | ☐ Highly - we have a QI Team, and clinic QI plan<br>☐ Fairly - we know about QI, but do not formally work on it<br>☐ Not very experienced - we don't know much about QI and do not work on it |
| 3 | Prior to the start of this work, has your clinic:<br><br>*Select all that apply:* | ☐ Used HIT to perform data analytics and reporting to monitor and improve the colorectal cancer screening rate<br>☐ Had a QI team or other clinic staff focused improvement efforts on screening |
| 4 | What are your other current and planned quality improvement initiatives? | |

## Section 4: Colorectal Cancer Screening Workflow

| | Question | Answer |
|---|---|---|
| 1 | Does your clinic follow a set of colorectal cancer screening guidelines? | ☐ Yes<br>☐ No |
| 2 | (If yes) Which guidelines does your clinic follow?<br><br>*Select all that apply* | ☐ USPSTF<br>☐ ACS<br>☐ Other, please describe |
| 3 | Does your clinic have an established workflow, process or protocol for colorectal cancer screening | ☐ Yes<br>☐ No (skip to question #9) |
| 4 | (If yes) Is that process documented? | ☐ Yes (please share workflow, skip to question #6)<br>☐ No |
| 5 | If the process is not documented or you are unable to share please provide a brief description of the current workflow, process, or protocol. | |
| 6 | Are there any concerns or issues with the current colorectal cancer workflow that you would like to address? | |

| Question | | Answer |
|---|---|---|
| 7 | When are staff educated about colorectal cancer screening policies and/or processes?<br><br>*Select all that apply* | ☐ At orientation<br>☐ Annually<br>☐ When they change<br>☐ Staff are not educated about colorectal cancer screening policies and/or processes<br>☐ Other |
| 8 | How often are colorectal cancer screening protocols reviewed and updated?<br><br>*Select One:* | ☐ Annually<br>☐ Every 2 years<br>☐ Every 5 years<br>☐ Other |
| 9 | Does your clinic have a standing order for fecal screening test kits? | ☐ Yes<br>☐ No |
| 10 | Does your clinic have a clinical champion for cancer screening? | ☐ Yes<br>☐ No (skip to question #12) |
| 11 | If yes, please select which activities the clinical champion engages in to promote colorectal cancer screening.<br><br>*Select all that apply* | ☐ Sets clear expectations to staff regarding implementation<br>☐ Actively and enthusiastically promotes value of the innovation<br>☐ Discusses barriers, answers questions with other physicians<br>☐ Communicates strategies/challenges with leadership<br>☐ Shows appreciation for the efforts and contributions of others<br>☐ Refers patients into the program to set an example<br>☐ Keeps the project a priority and protects its resources<br>☐ Ensures that the innovation is implemented in the face of organizational inertia or resistance<br>☐ Other |
| 12 | What screening modalities does your clinic recommend?<br><br>*Select all that apply* | ☐ High sensitivity guaiac Fecal Occult Blood test (gFOBT)<br>☐ Fecal Immunochemical Test (FIT or iFOBT)<br>☐ FIT-DNA (Cologuard®)<br>☐ Colonoscopy |
| 13 | Indicate which colorectal cancer screening modality was most frequently used by the clinic during the prior year.<br><br>*Select One* | ☐ High sensitivity gFOBT<br>☐ FIT/iFOBT<br>☐ FIT-DNA (Cologuard®)<br>☐ Colonoscopy |
| 14 | Please describe if screening modality varies by provider, patient preferences and/or any recent changes due to the impact of COVID. | |
| 15 | Name(s) of high sensitivity FOBT or iFOBT/FIT used | |
| 16 | Does the clinic offer free fecal test kits? | ☐ Yes<br>☐ No |
| 17 | What staff roles are responsible for identifying patients that are due for screening?<br><br>*Select all that apply* | ☐ Clerical<br>☐ Medical Assistants<br>☐ Nursing<br>☐ Clinical Providers<br>☐ Other (please specify) |

| Question | | Answer |
|---|---|---|
| 18 | What staff roles are responsible for discussing the importance and need for colorectal cancer screening with patients? | ☐ Clerical<br>☐ Medical Assistants<br>☐ Nursing<br>☐ Clinical Providers<br>☐ Other (please specify) |
| 19 | Is a colorectal cancer risk assessment completed for patients?<br><br>*Select all that apply* | ☐ No (skip to question #22)<br>☐ Yes, for all adult patients<br>☐ Yes, when they turn 50<br>☐ Yes, during annual physical<br>☐ Yes, at other interval |
| 20 | If a risk assessment is done, please select the factors hat are included in the clinic's assessment.<br><br>*Select all that apply* | ☐ Age<br>☐ Symptoms<br>☐ Increased or High-Risk Factors<br>☐ Family history of adenoma/colorectal cancer<br>☐ Other (describe) |
| 21 | If your clinic uses a specific risk assessment tool, is it embedded in your electronic health record (EHR)? | ☐ Yes<br>☐ No |
| 22 | What staff roles are responsible for placing orders for colorectal cancer screening tests?<br><br>*Select all that apply* | ☐ Clerical<br>☐ Medical Assistants<br>☐ Nursing<br>☐ Clinical Providers<br>☐ Other (please specify) |
| 23 | Does your clinic have a defined or documented colorectal cancer screening patient education protocol/process that educates patients about the importance of colorectal cancer screening, screening options and the screening process? | ☐ Yes<br>☐ No |
| 24 | How do patients receive fecal screening test kits?<br><br>*Select all that apply* | ☐ Kits are available in-patient rooms and given to patient at time of appointment<br>☐ Patient visits lab to pick up<br>☐ Kit is mailed to patient<br>☐ Other (please describe) |
| 25 | Where do patients return their fecal screening test kits?<br><br>*Select all that apply* | ☐ Mail to the clinic<br>☐ Drop off at the clinic<br>☐ Mail to a lab<br>☐ Other (please describe) |
| 26 | How are kit distributions and returns tracked? | |
| 27 | Do clinical staff contact patient to prompt them to complete fecal screening test kits? | ☐ Yes<br>☐ No (skip to question #28) |
| 28 | If yes, at what intervals? | |
| 29 | Do clinic staff have a role to assist patients in completing colonoscopy referrals? | ☐ Yes<br>☐ No (skip to question # 31) |

| Question | | Answer | |
|---|---|---|---|
| 30 | If yes, what roles do they have?<br><br>*Select all that apply* | ☐ Scheduling referral appointment<br>☐ Reminding patient to attend referral appointment<br>☐ Assisting patient to obtain endoscopy preparation items<br>☐ Assisting the patient to attend the appointment (e.g. arranging rides, childcare, eldercare, etc..)<br>☐ Educating patients on colonoscopy process (prep, and next steps) | |
| 31 | How are colonoscopy referrals tracked? | | |
| 32 | In a typical year how many GI/endoscopy practices do you regularly refer patients to for colorectal cancer screening? | | |
| 33 | What is the approximate percent of colorectal cancer screening reports returned from the GI/ endoscopy practice to the clinic? | | |
| 34 | Is there a standard process in place for your clinic to obtain endoscopy and lab reports/ results?<br><br>*Select One* | ☐ No process (skip to question #36)<br>☐ Informal process<br>☐ Formal process | |
| 35 | Please describe the process. | | |
| 36 | How are patients provided colorectal cancer screening results, both normal and abnormal?<br><br>*Check Box (check all that apply)* | ☐ No (skip to question #39)<br>☐ Yes, but only for positive screening results<br>☐ Yes, for all results | |
| 37 | How are patients provided colorectal cancer screening results, both normal and abnormal?<br><br>*Check Box (check all that apply)* | **Normal** | **Abnormal** |
| | In person appointment | ☐ | ☐ |
| | Phone Call | ☐ | ☐ |
| | Results are mailed | ☐ | ☐ |
| | Patient portal alert | ☐ | ☐ |
| | Other | ☐ | ☐ |
| 38 | Are the communication of results to the patient documented in the EHR? | ☐ Yes<br>☐ No | |
| 39 | What is the follow-up process for contacting patients who have not returned their fecal test kit or completed their colonoscopy referral? | | |
| 40 | How do you track when patients are due for rescreening? | | |
| 41 | Does your rescreening process differ from the initial screening process? For example, if a patient previously completed a take home fecal test kit, do you have a process for mailing them a new one? | ☐ Yes, please describe:<br>☐ No | |

| | Question | Answer |
|---|---|---|
| 42 | If a patient reports that they are up to date with screening, do you attempt to verify that information with the reported service provider?<br><br>*Select One* | ☐ Yes, the majority of the time.<br>☐ Yes, only for select providers<br>☐ No |
| 43 | Do you collect documentation that the screening occurred from that service provider? If yes, please describe efforts to collect documentation. | ☐ Yes, please describe:<br>☐ No (skip to next section) |
| 44 | Is this information captured in the HIT system? If yes, please describe. | ☐ Yes<br>☐ No |

## Section 5: Evidence Based Interventions (EBIs) and Supportive Strategies to Promote Colorectal Cancer Screening

| | Question | Answer |
|---|---|---|
| | **Provider Assessment and Feedback** | |
| | **Provider assessment and feedback interventions both evaluate provider performance in delivering or offering screening to patients (assessment) and present providers with information about their performance in providing screening services (feedback). Feedback may describe the performance of a group of providers or an individual provider and may be compared with a clinic goal or standard.** | |
| 1 | Does your clinic use provider assessment and feedback to improve colorectal cancer screening rates?<br><br>*Select One* | ☐ Yes<br>☐ No (skip to question #7) |
| 2 | What forms of Provider Assessment and Feedback does the clinic use?<br><br>*Select all that apply* | ☐ Individual provider/care team reports<br>☐ Clinic level reports<br>☐ Center level reports |
| 3 | Who are reports provided to?<br><br>*Select all that apply* | ☐ C-Suite<br>☐ Clinicians<br>☐ Administrative staff<br>☐ Nursing staff<br>☐ All staff<br>☐ Other (specify) |
| 4 | If reports are generated at the individual provider or care team level and shared beyond those individuals, are providers identified or deidentified?<br><br>*Select One* | ☐ Identified<br>☐ De-identified |
| 5 | Where or in what format are reports shared?<br><br>*Select all that apply* | ☐ Provider meetings<br>☐ E-mail<br>☐ Quarterly reports<br>☐ Embedded in other communications (specify)<br>☐ Other (specify) |

| Question | | Answer |
|---|---|---|
| 6 | How often are feedback reports shared?<br><br>*Select all that apply* | ☐ Monthly<br>☐ Quarterly<br>☐ Semiannually<br>☐ Annually |
| **Provider Reminders** | | |
| **Reminders inform health care providers it is time for a patient's cancer screening test or that the patient is overdue for screening. The reminders can be provided in different ways, such as alerts in patient charts or by e-mail.** | | |
| 7 | Does your clinic use provider reminders for colorectal cancer screening? | ☐ Yes<br>☐ No (skip to question #12) |
| 8 | What form of provider reminders does the clinic use for colorectal cancer screening?<br><br>*Select all that apply* | ☐ EHR alert<br>☐ Paper notes (skip to question #12)<br>☐ Pre visit planning (skip to question #12)<br>☐ Other (specify) (skip to question #12) |
| 9 | If provider reminders are in the EHR does the provider need to actively close and document the patient response or can it just be ignored?<br><br>*Select One* | ☐ Required active response to stop alert<br>☐ Alert stops if ignored |
| 10 | Is the patient response documented in the EHR? | ☐ Yes<br>☐ No |
| 11 | If provider reminders are in the EHR can the nurse, MA or other staff manage them? | ☐ Yes<br>☐ No |
| **Patient Reminders** | | |
| **Patient reminders are written (letter, postcard, email) or telephone messages (including automated messages) advising people that they are due for screening. These interventions can be untailored to address the overall target population or tailored with the intent to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment.** | | |
| 12 | Does your clinic use patient reminders to let patients know they are due or past due for colorectal cancer screening? | ☐ Yes<br>☐ No (skip to question #15) |
| 13 | (If yes) What form of patient reminders does the clinic use for colorectal cancer screening?<br><br>*Select all that apply* | ☐ Mail<br>☐ Phone<br>☐ Patient portal<br>☐ E-mail<br>☐ Text message<br>☐ Automated calls<br>☐ Communications from patient navigators or community health workers<br>☐ Other |
| 14 | Please describe the patient reminder process (e.g., patients are called 2 x, then one letter, each instance one week apart) | |

| Question | | Answer |
|---|---|---|
| **Structural Barrier Reduction** | | |
| **Structural barriers are non-economic burdens or obstacles that make it difficult for people to access cancer screening. Interventions designed to reduce these barriers may facilitate access to cancer screening.** | | |
| 15 | Does your clinic have structural barrier reduction in place to make it easier for patients to access colorectal cancer screening? | ☐ Yes<br>☐ No (skip to question #18) |
| 16 | Does your clinic do any of the following activities to reduce structural barriers?<br><br>*Select all that apply* | ☐ Reducing time or distance between service delivery settings and target populations<br>☐ Modifying hours of service to meet patient needs<br>☐ Offering services in alternative or non-clinical settings<br>☐ Eliminating or simplifying procedures and other obstacles<br>☐ Other (specify) |
| 17 | Please provide brief details about the barrier reduction activities checked in the above question. | |
| **Financial Barrier Reduction** | | |
| **Interventions to reduce patient out-of-pocket costs attempt to minimize or remove economic barriers that make it difficult for patients to access cancer screening services. Costs can be reduced through a variety of approaches, including vouchers, reimbursements, reduction in co-pays, or adjustments in federal or state insurance coverage.** | | |
| 18 | Does your clinic offer financial barrier reductions? | ☐ Yes<br>☐ No (skip to question #20) |
| 19 | (If Yes) Does you clinic provide any of the following?<br><br>*Select all that apply* | ☐ Reduction in co-pays<br>☐ Sliding fee scale<br>☐ Participate in Cancer Services Program<br>☐ Voucher for colonoscopy prep items<br>☐ Other (specify) |
| **Education** | | |
| **Group and one-on-one education convey information on indications for, benefits of, and ways to overcome barriers to screening with the goal of informing, encouraging, and motivating participants to seek recommended screening.**<br><br>**Group education is usually conducted by health professionals or by trained lay people who use presentations or other teaching aids in a lecture or interactive format, and often incorporate role modeling or other methods. One-on-one education is typically delivered by healthcare workers or other health professionals, lay health advisors, or volunteers to individual patients, and are conducted by telephone or in person in medical, community, worksite or household settings.** | | |
| 20 | *Does your clinic provide verbal colorectal cancer screening education?* | ☐ Yes<br>☐ No (skip to question #22) |
| 21 | (If yes) Do your clinic staff utilize:<br><br>*Select all that apply* | ☐ One-on-one education<br>☐ Group education<br>☐ On-line educational resources (FIT instruction videos, colonoscopy education videos, colorectal cancer organizational education such as NCCRT, ACS, health plans, CBOs, etc... |

| | Question | Answer |
|---|---|---|
| **Small Media** | | |
| **Small media include videos and printed materials such as letters, brochures, and newsletters. These materials can be used to inform and motivate people to be screened for cancer. They can provide information tailored to specific individuals or targeted to general audiences.** | | |
| 22 | Does your clinic use small media to promote colorectal cancer screening? | ☐ Yes<br>☐ No (skip to question #24) |
| 23 | Small Media - Please describe what the clinic uses for small media to promote colorectal cancer screening?<br><br>*Select all that apply* | ☐ Letters<br>☐ Brochures<br>☐ Newsletters<br>☐ Other (specify) |
| **Patient Navigation and Community Health Workers** | | |
| 24 | Does your clinic have Community Health Workers (CHW) or Patient Navigators (PN) on staff?<br><br>*Select One* | ☐ Yes, CHWs (answer question #25, skip #26)<br>☐ Yes, PNs (answer question #26, skip #25)<br>☐ Yes, both CHWs and PNs<br>☐ No (skip to question #27) |
| 25 | (If Yes) What role do your CHWs have in the cancer screening process?<br><br>*Select all that apply* | ☐ Not used for colorectal cancer screening<br>☐ One on one education<br>☐ Group education<br>☐ Patient reminders<br>☐ Other specify |
| 26 | (If yes) What role do your PNs have in the cancer screening process?<br><br>*Select all that apply* | ☐ Not used for colorectal cancer screenings<br>☐ Used for barrier assessment and reduction<br>☐ Appointment scheduling<br>☐ Patient reminders<br>☐ Navigation for colorectal cancer diagnostic services<br>☐ Other (specify) |
| **EBI Assessment** | | |
| 27 | If your clinic has ever implemented provider assessment and feedback, provider reminders, patient reminders, reducing structural barriers or supportive strategies to increase colorectal cancer screening, has any sort of assessment or evaluation of their impact been conducted? | ☐ Yes<br>☐ No (skip to next section) |
| 28 | If yes, please briefly describe your findings | |

## Section 6: Barriers

| Question | | Answer | | | | |
|---|---|---|---|---|---|---|
| | | Not Important | Low Importance | Neutral | Moderate Importance | Very Important |
| 1 | **Patient Related Barriers:** In your opinion, how important are each of the following as potential barriers to increasing the cancer screening rate in your clinic? | | | | | |
| | Patient fear of screening procedure | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Patient fear of screening results | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Patient lack of insurance/procedure costs | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Language barriers | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Lack of transportation | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Patient embarrassment | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Patients do not follow through with recommendations | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Patient co-morbidities | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Religious barriers | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Cultural custom barriers | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2 | **System Related Barriers:** Please identify by importance how each of the following system-related barriers impact your clinic (or clinic's colorectal cancer screening rates). | | | | | |
| | Not having enough time to discuss colorectal cancer screening with patients | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Not enough time or capacity to discuss colorectal cancer screening completion (take home test instructions or colonoscopy prep) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Inability to track down date and results of prior screenings | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Long delay in scheduling screening procedures | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Remembering to make screening recommendations | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Managing concurrent care provided by specialist (GI) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Delay in receiving screening results from specialists | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Shortage of trained providers to conduct screening | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Organizational focus on efforts other than screening | ☐ | ☐ | ☐ | ☐ | ☐ |
| | Lack of full-time commitment to quality improvement efforts | ☐ | ☐ | ☐ | ☐ | ☐ |

| | Question | Answer |
|---|---|---|
| 3 | What sources are utilized to identify patient and/or system barriers to colorectal cancer screening? | |
| 4 | Are you able to identify patient population characteristics (e.g. economic status/race/gender) of those patients who are not up to date with colorectal cancer screening? | |
| 5 | Please identify any additional system barriers not noted, including insurance, billing, laboratory delays or other gaps in patients completing a colorectal cancer screening or delivering test results to patient | |
| 6 | Have you used Patient and Family Advisory Council feedback into your QI Initiatives? | ☐ Yes<br>☐ No<br>☐ Not Applicable |
| 7 | Please describe | |

## Section 7: Health Information Technology (HIT)/Data/Reporting

| | Question | Answer |
|---|---|---|
| 1 | Has the clinic fully transitioned from paper charts to EHR (if no, describe) | ☐ Yes<br>☐ No |
| 2 | What EHR does the clinic use? | |
| 3 | Do all clinics in the health system use the same EHR? (If no, describe) | ☐ Yes<br>☐ No |
| 4 | How long has your clinic used your current EHR? | Numeric Field (X Years, X Months) |
| 5 | Does your clinic plan to change EHRs in the next 2 years? | ☐ Yes<br>☐ No |
| 6 | What other data systems are used to support care management? | |
| 7 | Is the clinic connected to the HIE/QE in the region? If yes, what is the name(s) of the HIE? | ☐ Yes<br>☐ No |
| 8 | How does your organization host the EHR?<br><br>*Select One* | ☐ In-house, on internal servers<br>☐ Hosted externally, not Internet/web based<br>☐ Hosted externally to organization, Internet/web based<br>☐ Other<br>☐ Don't know |
| 9 | What colorectal cancer screening data elements are captured in structured fields?<br><br>*Select all that apply* | ☐ Distribution of fecal screening kits<br>☐ Referral to GI<br>☐ Date of distribution or referral<br>☐ Date for scheduled colonoscopy<br>☐ Date of test completion<br>☐ Type of test<br>☐ Results of test<br>☐ Other |

| Question | | Answer | | |
|---|---|---|---|---|
| 10 | Does your clinic currently use any of the following data reports from the EHR or another clinic data system to support colorectal cancer screening | **Yes** | **No** | **Not Available** |
| | List of patients not up-to-date on cancer screening | ☐ | ☐ | ☐ |
| | Patient visit planning report | ☐ | ☐ | ☐ |
| | Referral management report | ☐ | ☐ | ☐ |
| | Colorectal cancer screening rates | ☐ | ☐ | ☐ |
| | Patient Reminders | ☐ | ☐ | ☐ |
| | Other | ☐ | ☐ | ☐ |
| 11 | Who (staff role) is responsible for generating colorectal cancer reports?<br>*Select all that apply* | ☐ Clerical<br>☐ Medical Assistants<br>☐ Nursing<br>☐ Clinical Providers<br>☐ Other (please specify) | | |
| 12 | Can reports be exported?<br>*Select One* | ☐ Yes<br>☐ No<br>☐ Don't Know/ not sure | | |
| 13 | Can EHR reports be added/modified by clinic staff or only by the EHR vendor?<br>*Select all that apply* | ☐ FQHC staff<br>☐ EHR Vendor | | |
| 14 | Can EHR alerts and reminders be added/ modified by clinic staff or only by the EHR vendor?<br>*Select all that apply* | ☐ FQHC staff<br>☐ EHR Vendor | | |
| 15 | If there are modifications required (e.g. adding customized reports) to the EHR, is there a cost associated with this?<br>*Select One* | ☐ Yes<br>☐ No<br>☐ Don't know/not sure | | |
| 16 | Are colorectal cancer screening documentation practices standardized across the clinic?<br>*Select One* | ☐ Yes, for all<br>☐ Yes, for most<br>☐ No, only for some<br>☐ No, everyone has their own documentation process. | | |
| 17 | What method is used to record colorectal cancer screening results in the EHR?<br>*Select all that apply* | ☐ Automatically pushed in from lab or endoscopy center<br>☐ Manually entered<br>☐ Other | | |
| 18 | Does your clinic conduct routine data validation on data generated by your EHR?<br>*Select One* | ☐ Yes<br>☐ No (skip to Section 8)<br>☐ Not sure/don't know (skip to section 8) | | |

| Question | | Answer |
|---|---|---|
| 19 | If yes, is it conducted for colorectal cancer screening reporting?<br><br>*Select One* | ☐ Yes<br>☐ No (skip to Section 8)<br>☐ Not sure/don't know (skip to Section 8) |
| 20 | If yes, how often is this done? | |

## Section 8: Colorectal Cancer Screening Rate

| Question | | Answer |
|---|---|---|
| 1 | **Pre-COVID Data:** | |
| | Colorectal cancers screening rate for December 2019 trailing year? | |
| | Colorectal cancer numerator | |
| | Colorectal cancer denominator | |
| 2 | **Baseline Data:** | |
| | Colorectal cancer screening rate for June 2020 trailing year? | |
| | Colorectal cancer numerator | |
| | Colorectal cancer denominator | |
| 3 | Where did you pull the numerator and denominator from?<br><br>*Select all that apply* | ☐ EHR<br>☐ Ancillary data system<br>☐ Other (Free Text) |
| 4 | Colorectal cancer screening measure<br><br>*Select One* | ☐ UDS<br>☐ NQF<br>☐ HEDIS<br>☐ QPP-MIPS<br>☐ Other (Free Text) |
| 5 | How confident are you in the accuracy of the colorectal cancer data generated by your EHR?<br><br>*Select One* | ☐ Not Confident<br>☐ Somewhat Confident<br>☐ Mostly Confident<br>☐ Highly Confident |
| 6 | If the answer to the above question is a 1 or 2 please describe the known issues and any efforts to address the problems. | |
| 7 | During the baseline measurement period (June 2020 TY) what was the number of tests below that were ordered and completed? | |
| | Fecal screening test kits | / |
| | Screening Colonoscopy | / |
| | Colorectal Cancer Screening via other methods | / |
| | Follow-up Colonoscopy | / |

| | Question | Answer |
|---|---|---|
| 8 | Colorectal cancer screening rate target for June 2021. Target rate should be ambitious but realistic and achievable. | |

## Section 9: COVID-19 Impact on Colorectal Cancer Screening

| | Question | Answer |
|---|---|---|
| 1 | Did COVID-19 cause your clinic to close or reduce the number of hours open?<br><br>*Select all that apply* | ☐ Yes, closed (answer Question 2)<br>☐ Yes, reduced hours/days (answer Question 3)<br>☐ No, clinic did not close or reduce hours/day (proceed to Question 4) |
| 2 | If fully closed for 1 week or more, how many weeks was the clinic closed because of COVID-19? | # of weeks _____ |
| 3 | If reduced hours/days… | |
| | What was the typical number of hours the clinic was open per week prior to COVID-19. | # of hours each week _____ |
| | Number of hours the clinic reduced due to COVID-19. Provide a weekly estimate. | # of hours each week _____ |
| | Number of weeks the clinic operated at the above reduced time. | # of weeks _____ |
| 4 | Did COVID-19 negatively impact the clinic's delivery of colorectal cancer screening and/or diagnostic services? | ☐ Yes (proceed to Question 5)<br>☐ No (proceed to Question 6) |
| 5 | Clinic visits were limited to sick patients, with limited or no preventive care available. | ☐ Yes<br>☐ No |
| | Clinic visits were limited to patients at high risk or with symptoms for colorectal cancer. | ☐ Yes<br>☐ No |
| | Clinic visits were restricted to telehealth/ telemedicine only. | ☐ Yes<br>☐ No |
| | Clinic could not refer average risk patients for colonoscopy due to limited availability of endoscopic services. | ☐ Yes<br>☐ No |
| | Clinic could not refer patients with positive or abnormal fecal test results for follow-up colonoscopies due to limited availability of endoscopic services. | ☐ Yes<br>☐ No |
| | Patients canceled or did not schedule appointments due to COVID concerns. | ☐ Yes<br>☐ No |
| | Patients were fearful of getting COVID-19. | ☐ Yes<br>☐ No |
| | COVID-19 negatively impacted the clinic's delivery of colorectal cancer screening and/or diagnostic services that cannot be categorized in the above options. | ☐ Yes<br>☐ No |

| Question | | Answer |
|---|---|---|
| 6 | Did COVID-19 negatively impact the clinic's implementation of evidence-based interventions (EBIs) for colorectal cancer screening? | ☐ Yes (proceed to Question 7)<br>☐ No (proceed to Question 8) |
| 7 | Did COVID-19 negatively impact patient reminders? | ☐ Yes<br>☐ No |
| | Did COVID-19 negatively impact provider reminders? | ☐ Yes<br>☐ No |
| | Did COVID-19 negatively impact provider assessment and feedback? | ☐ Yes<br>☐ No |
| | Did COVID-19 negatively impact reduction of structural barriers? | ☐ Yes<br>☐ No |
| | Did COVID-19 negatively impact implementation of patient navigation? | ☐ Yes<br>☐ No |
| 8 | Additional comments related to impact of COVID-19 on colorectal cancer screening? | |

## Section 10: Other

| Question | | Answer |
|---|---|---|
| 1 | In the past 2 years have you worked with partner organizations to support colorectal cancer screening? | |
| 2 | Please note any particular areas or strategies you would like to focus your colorectal cancer screening improvement work on? | |
| 3 | Is there any additional information that you think would be helpful to share with us regarding your screening process or screening rates? | |

# APPENDIX A-3.4

## Assess Your Progress Worksheet

**Instructions:** Work with stakeholders and health systems to answer the following questions. Use a separate work sheet for each system.

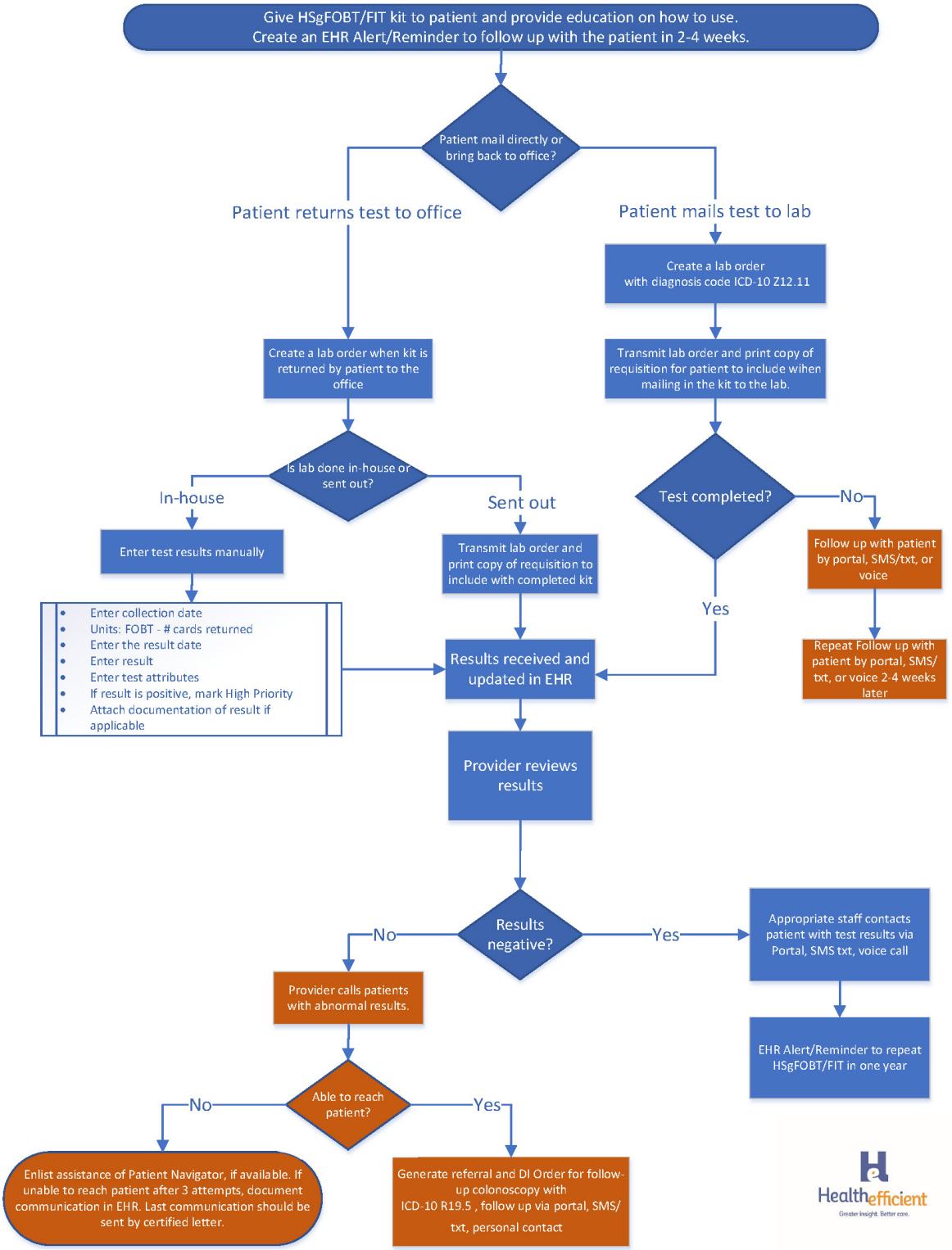
| | Assess Your Relationship with the Health System | Answers and Plans for Change |
|---|---|---|
| 1 | Has the action plan been completed? If not, why? | |
| 2 | Are you in contact with your health system champion regularly? How do you communicate (in person, by phone, by email)? Is your contact method effective? | |
| 3 | Are problems identified and resolved quickly and effectively? | |
| 4 | Do you have other questions or concerns? | |

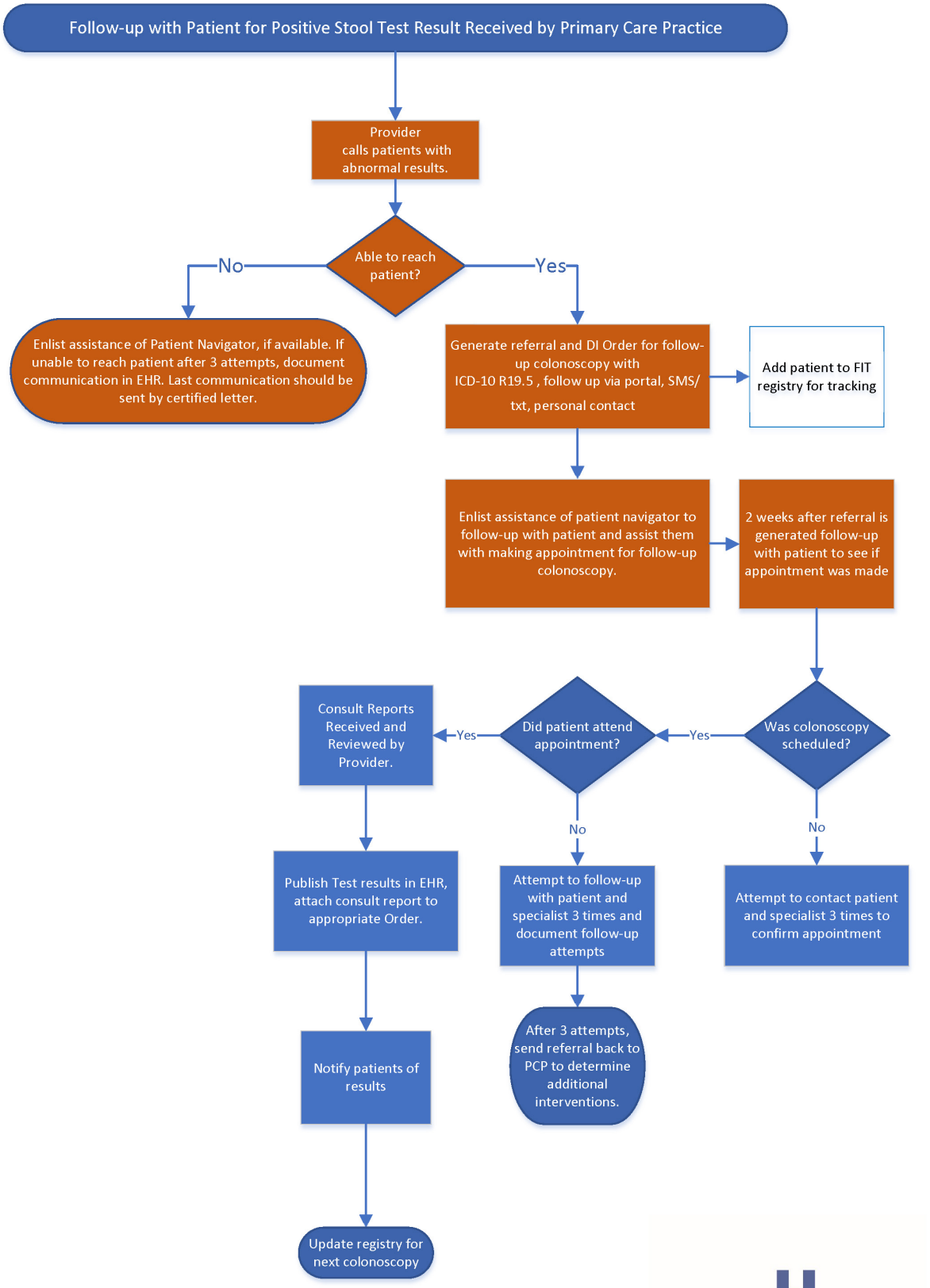
| | Assess the Health System's Efforts to Improve CRC Screening Rates | Answers and Plans for Change |
|---|---|---|
| 1 | Have all specific tasks, timelines, and responsibilities been carried out? | |
| 2 | Are relevant data being collected? | |
| 3 | Does the system need to make adjustments? Have solutions been identified or carried out? | |
| 4 | Is information about progress and any needed adjustments being communicated to key stakeholders? | |
| 5 | Do you have other questions or concerns? | |

Source: Centers for Disease Control and Prevention. Increasing Colorectal Cancer Screening: An Action Guide for Working with Health Systems. Atlanta: Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2013.

# APPENDIX A-4

## Workflows for HSgFOBT/FIT

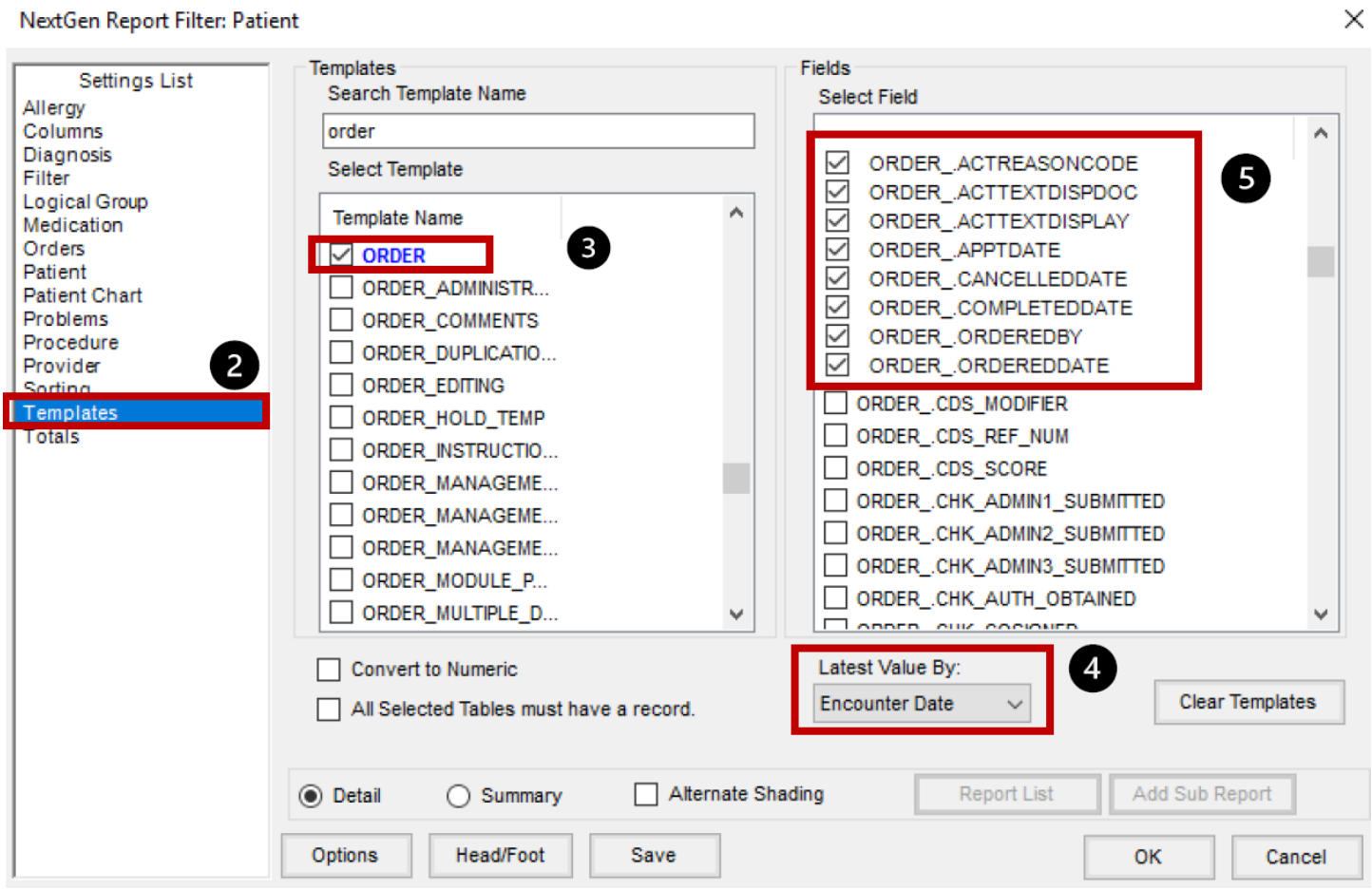



Follow-up with Patient for Positive Stool Test Result Received by Primary Care Practice
Provider calls patients with abnormal results.
Able to reach patient?
No
Yes
Enlist assistance of Patient Navigator, if available. If unable to reach patient after 3 attempts, document communication in EHR. Last communication should be sent by certified letter.
Generate referral and DI Order for follow-up colonoscopy with ICD-10 R19.5 , follow up via portal, SMS/ txt, personal contact
Add patient to FIT registry for tracking
Enlist assistance of patient navigator to follow-up with patient and assist them with making appointment for follow-up colonoscopy.
2 weeks after referral is generated follow-up with patient to see if appointment was made
Was colonoscopy scheduled?
Yes
Did patient attend appointment?
Yes
Consult Reports Received and Reviewed by Provider.
No
Attempt to contact patient and specialist 3 times to confirm appointment
No
Attempt to follow-up with patient and specialist 3 times and document follow-up attempts
After 3 attempts, send referral back to PCP to determine additional interventions.
Publish Test results in EHR, attach consult report to appropriate Order.
Notify patients of results
Update registry for next colonoscopy
Healthefficient
Greater insight. Better care.

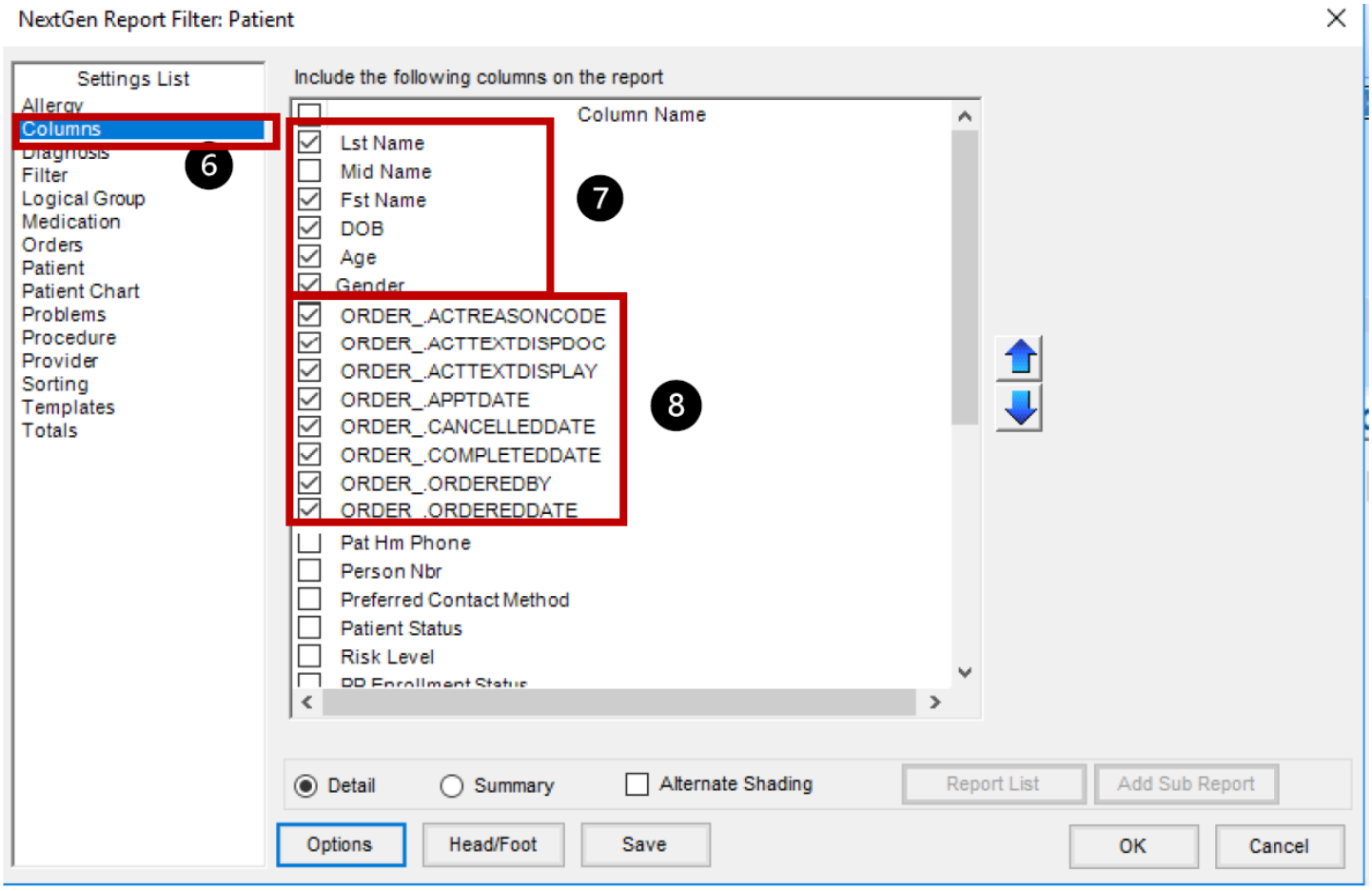
# APPENDIX B-1
# NEXTGEN SCREENSHOTS

## Colonoscopy Protocol Report Build Tool

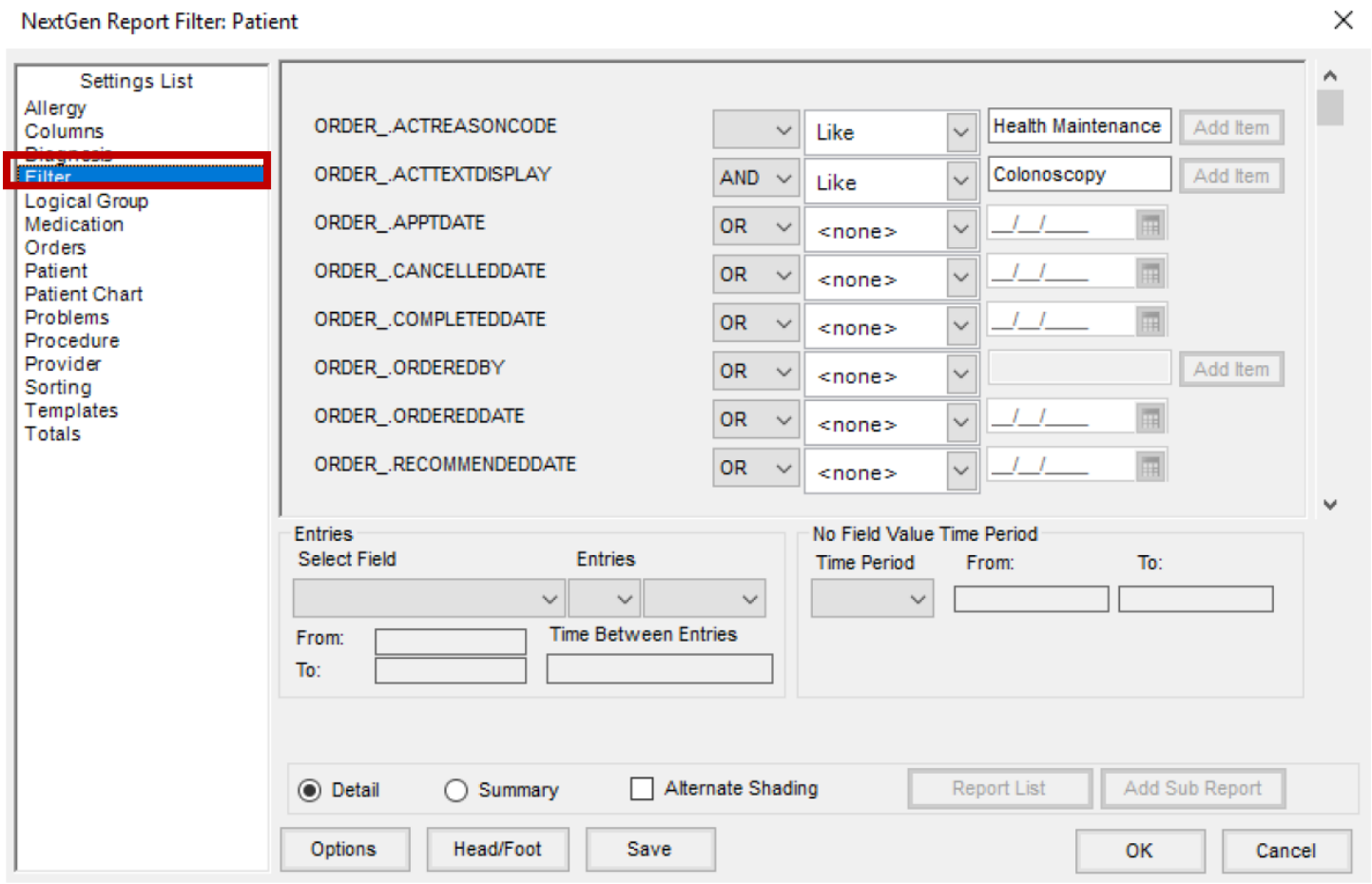
1. NextGen EHR > File > Reports > Generate Report > by Practice
2. Select “Templates” in Settings List
3. Select “Order”
4. Select L*atest Value By* – “Encounter Date”
5. Select listed fields to pull for the report



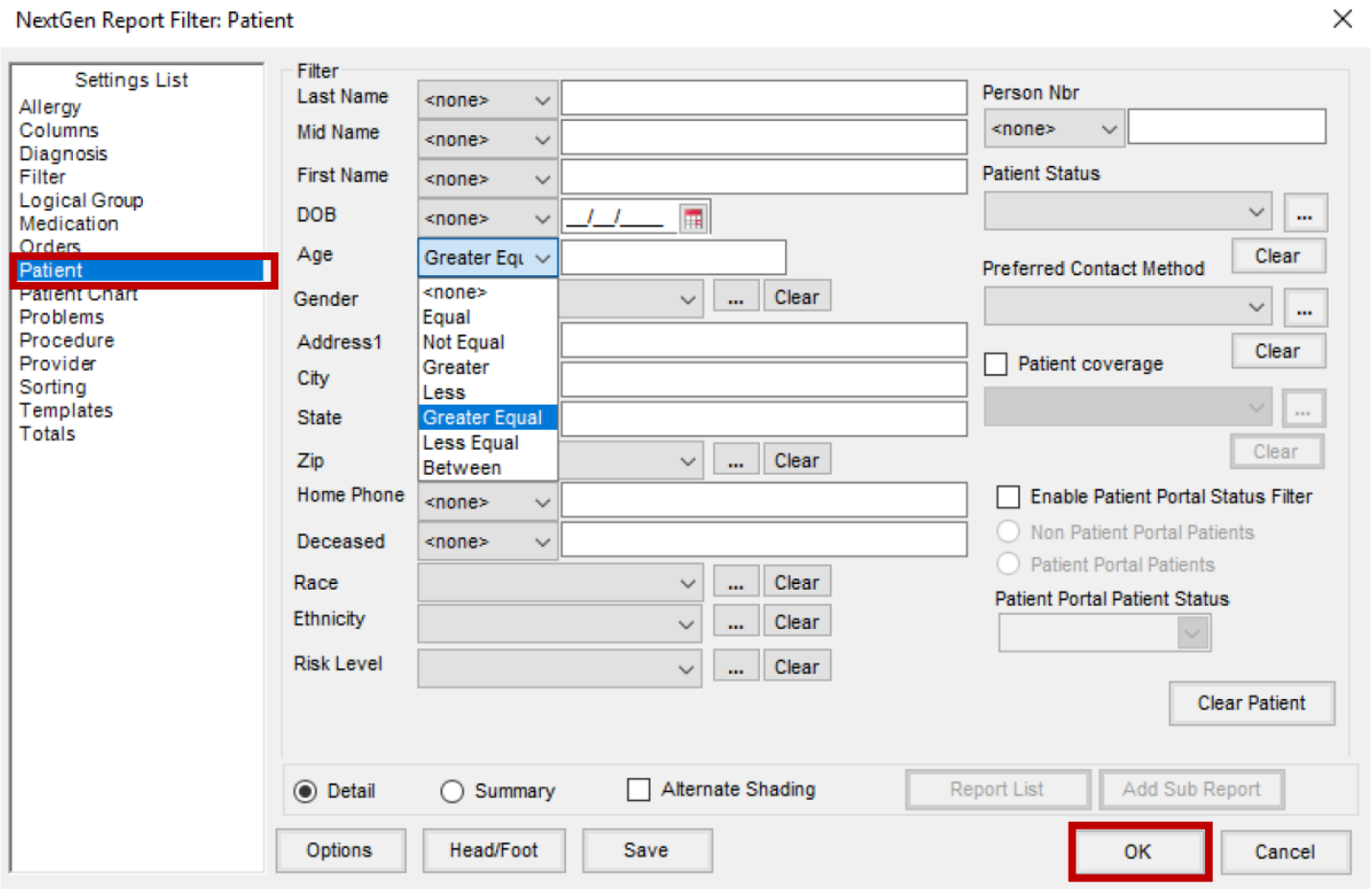
6. Select “Columns” in Settings List
7. Select desired column names for report
8. Select field order for the report



9. Select Filter from Settings List
10. Select “Like” for order_.actReasonCode
11. Enter “Health Maintenance” in description box
12. Select “Like for order_.actTextDisplay
13. Enter “Colonoscopy” in description Box
14. Change all other filters to OR

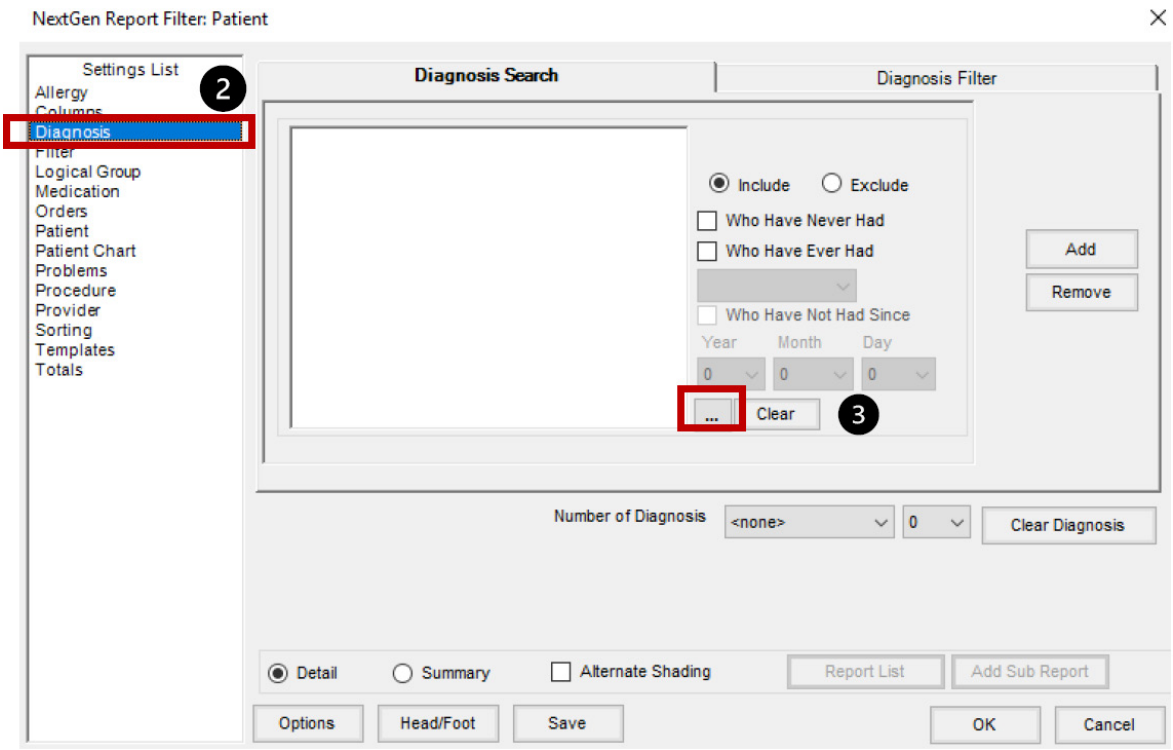


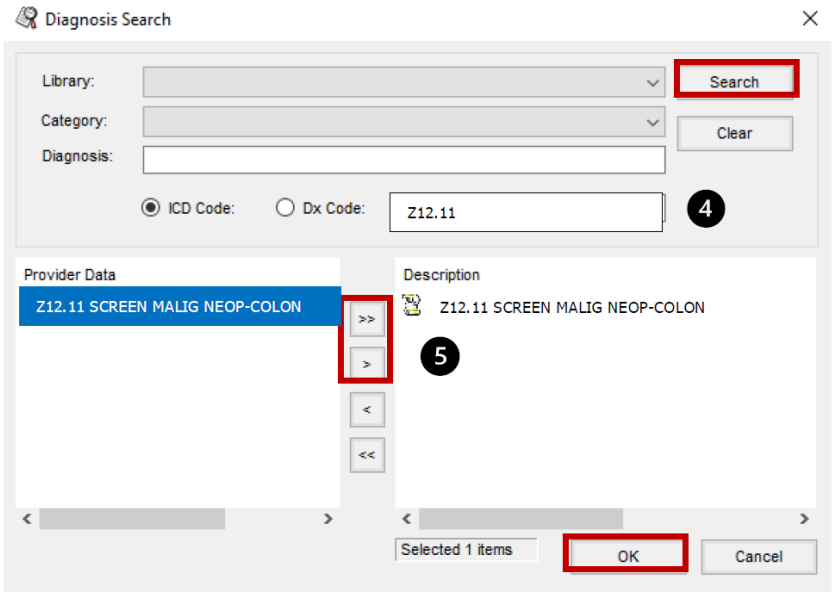
15. Select “Patient” in Settings List
16. Add any filters desired from available listing.
17. Add any additional Settings List filter to apply to report as desired
18. Select “OK” to generate report on screen



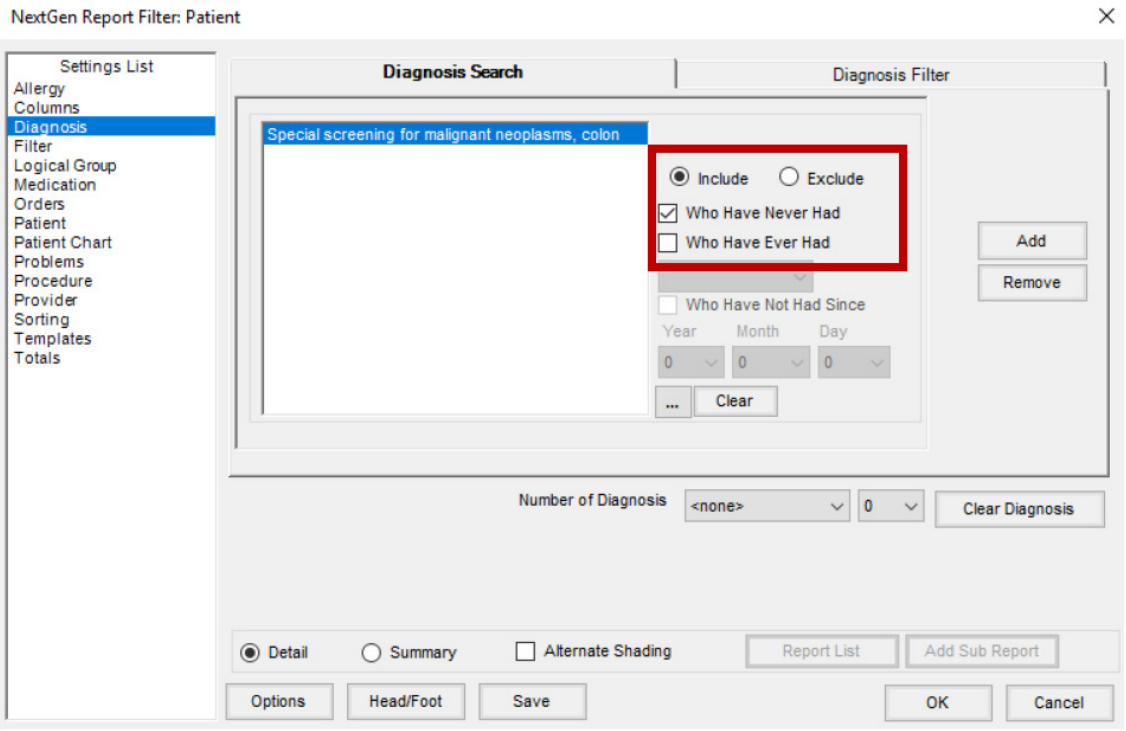
# EHR Diagnosis Report Screening for Colon Malignancy (ICD 9 V76.51, ICD10 Z12.11)

1. NextGen EHR > File > Reports > Generate Report > By Practice
2. Select “Diagnosis” in Settings List
3. Select ellipsis to open diagnosis search box
4. Enter appropriate diagnosis in open box and select “Search”
5. Use arrows in center to move desired data to description box
6. Select “OK”

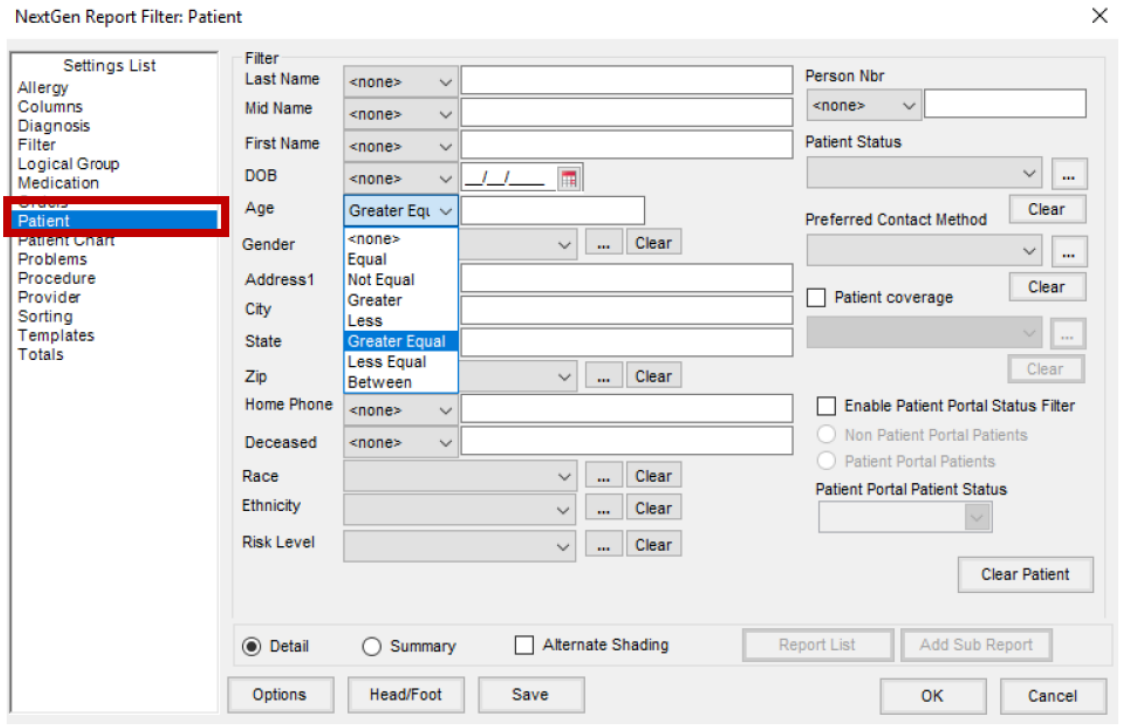


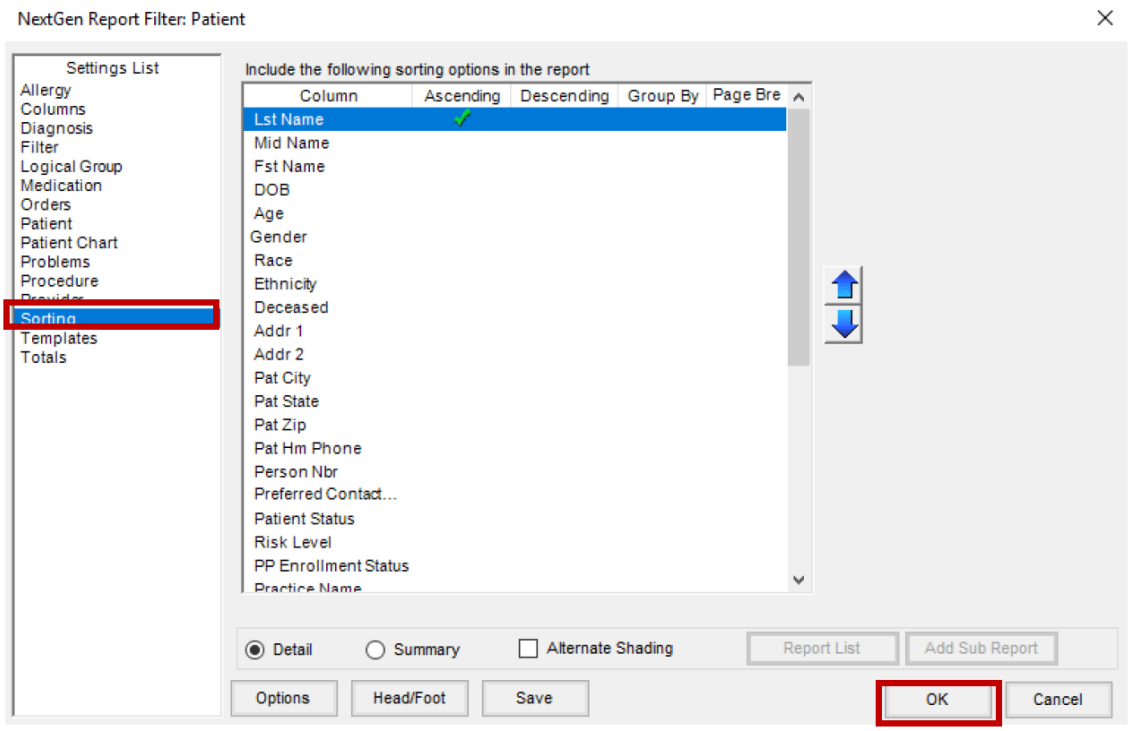
7. Check box to include patients “Who Have Never Had”. Other options are available depending upon desired report.




8. Select “Patient” in Settings List
9. Select any desired Patient filters for report generation



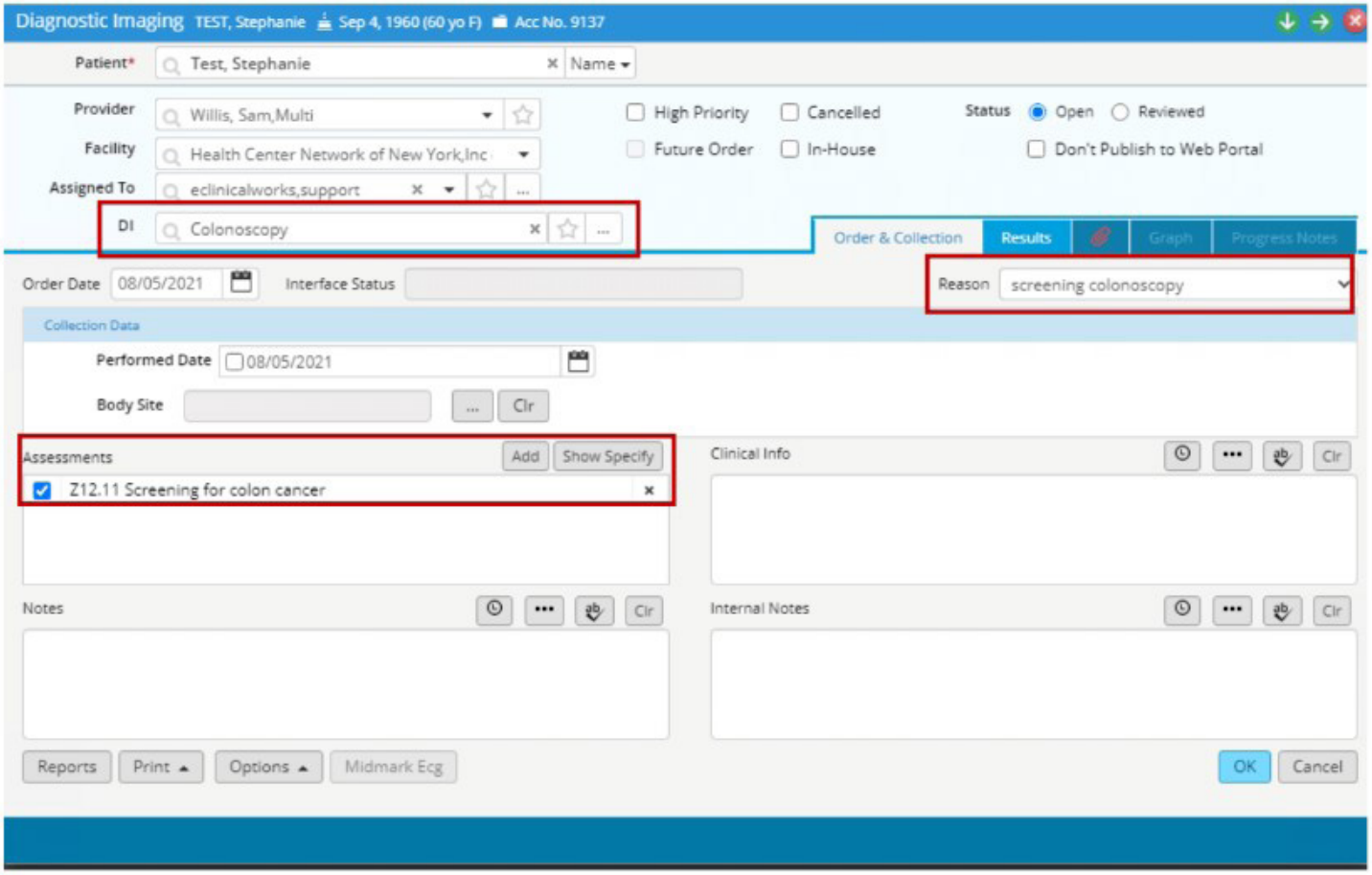
10. Select “Sorting” in Settings List
11. Indicate desired sort for the report generation
12. Add any additional filters from Settings list as desired
13. Select “OK” to generate report on screen



# APPENDIX B-2
# ECLINICALWORKS SCREEN SHOTS

## Order Colonoscopy through Diagnostic Imaging eCW v11

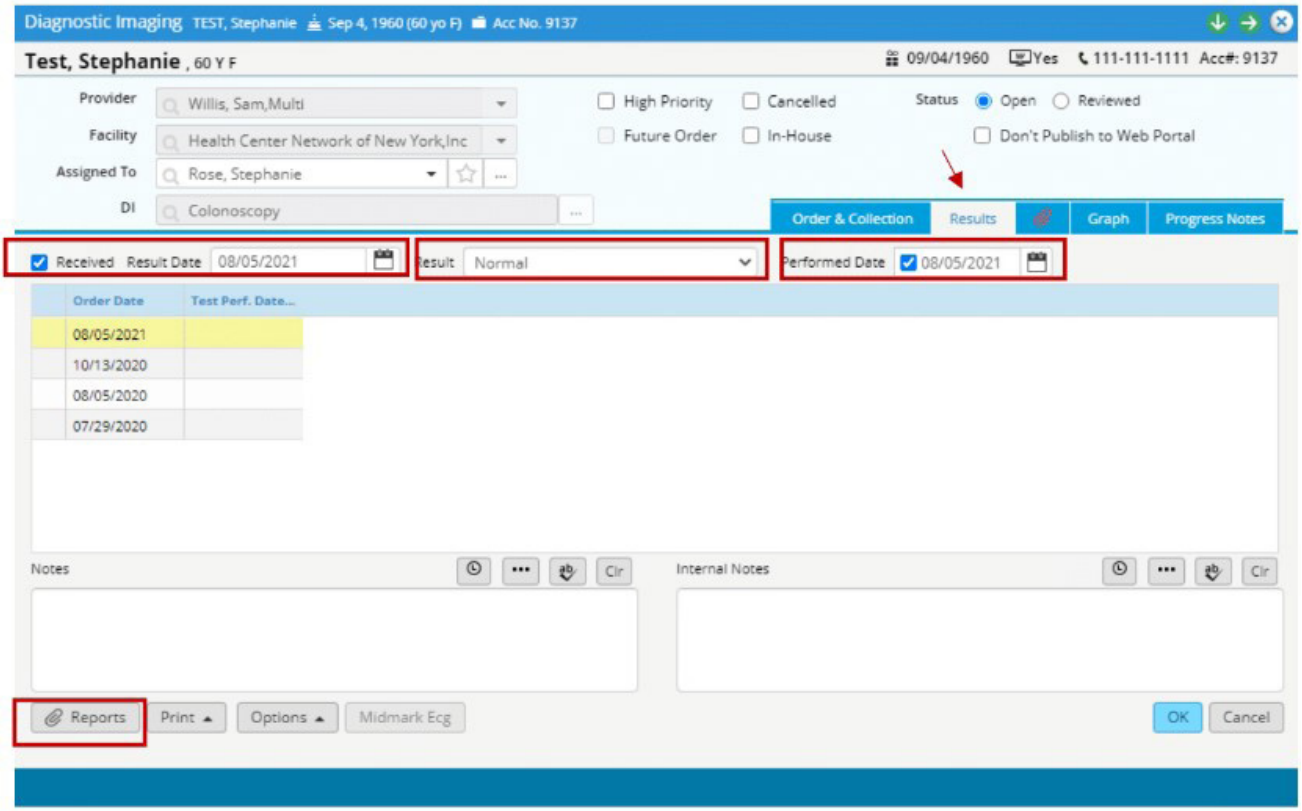
1. Access Diagnostic Imaging (DI) from the Patient Hub or Progress Note
2. Select Colonoscopy in the DI test name field
3. Enter the Reason in the Reason field
4. Select Add and search for the Diagnosis Code to add to the Assessment field




Note: Creating a DI order for colonoscopy is important to satisfy CDS and quality measures. Organizations may create a referral in addition to the DI order but it does not satisfy CDSS alerts.

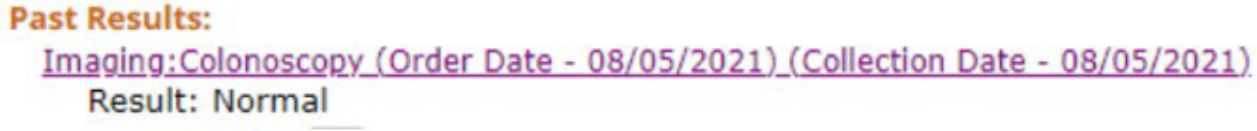
# Colonoscopy Results Received

1. Close the loop/complete the DI order for the colonoscopy once the report is received
2. Open the outstanding DI Order for the patient and click on the Results tab
3. Check the “Received” Box, select the “Result Date” and the “Performed Date”
4. Attach the paper report by clicking on the Reports button and add the scanned document. (This will display a paperclip icon and makes it easy to see the result was received for this test)
5. If support staff are entering the received date and attaching the report, route the Open DI with the attached document to the provider by changing the Assigned To field to the provider’s name.



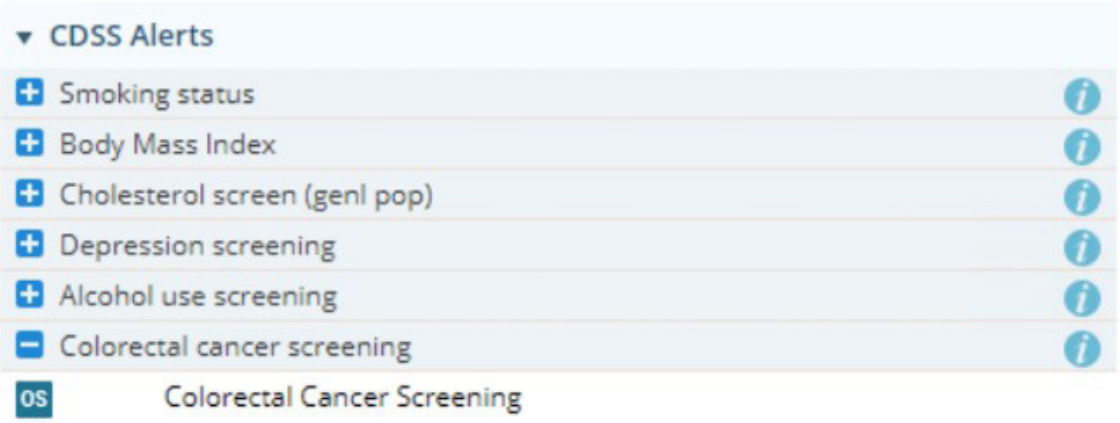

6. Once the Provider review the colonoscopy report, they will update the Result Drop down and mark the DI order as Reviewed
7. Recommended: All results should be published to the patient portal. Ensure the “Don’t Publish to Web Portal” checkbox is unchecked.

The completed DI order can be added to the next Progress note from the DRTLA tab

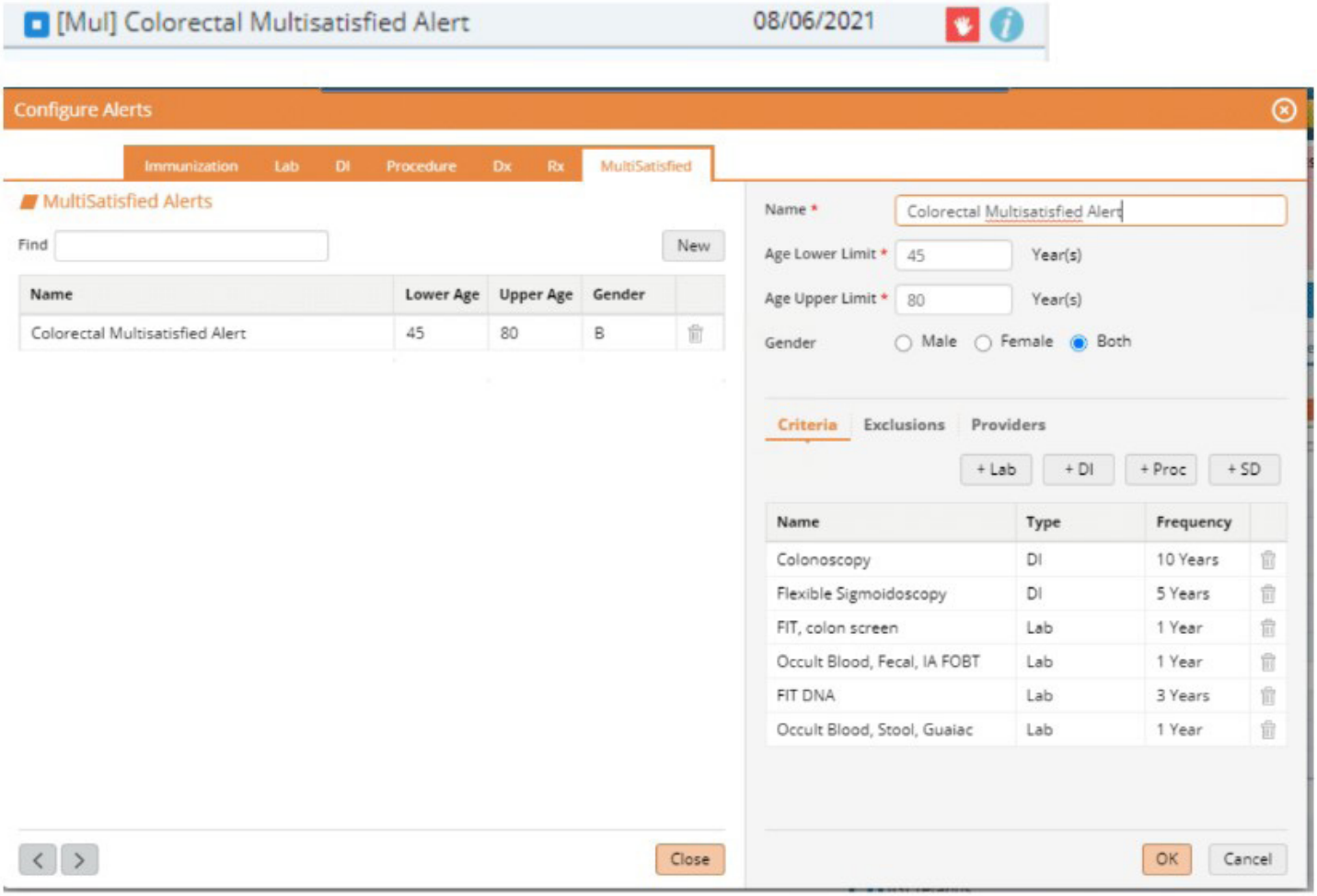



# Clinical Decision Support Alerts

You can attach a quick (single order) Order Set to the colorectal cancer screening CDSS Alert. This allows users to quickly place the DI order with a single click when the see the alert.



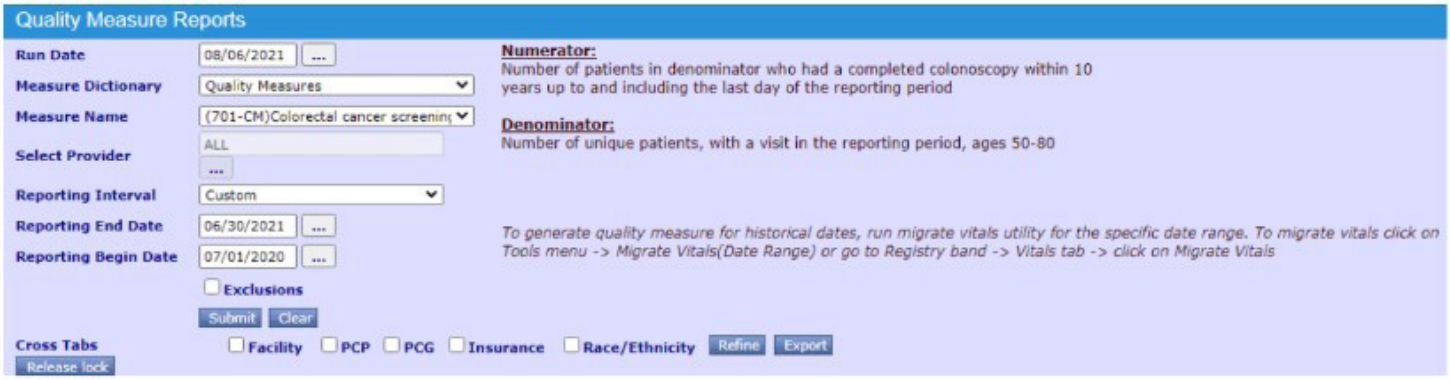

You can also create a Practice Alert that takes into consideration all various options that can be used for colorectal screening and the appropriate timeframes. Contact eCW Support to turn on the item key for MultiSatisfied Alert.



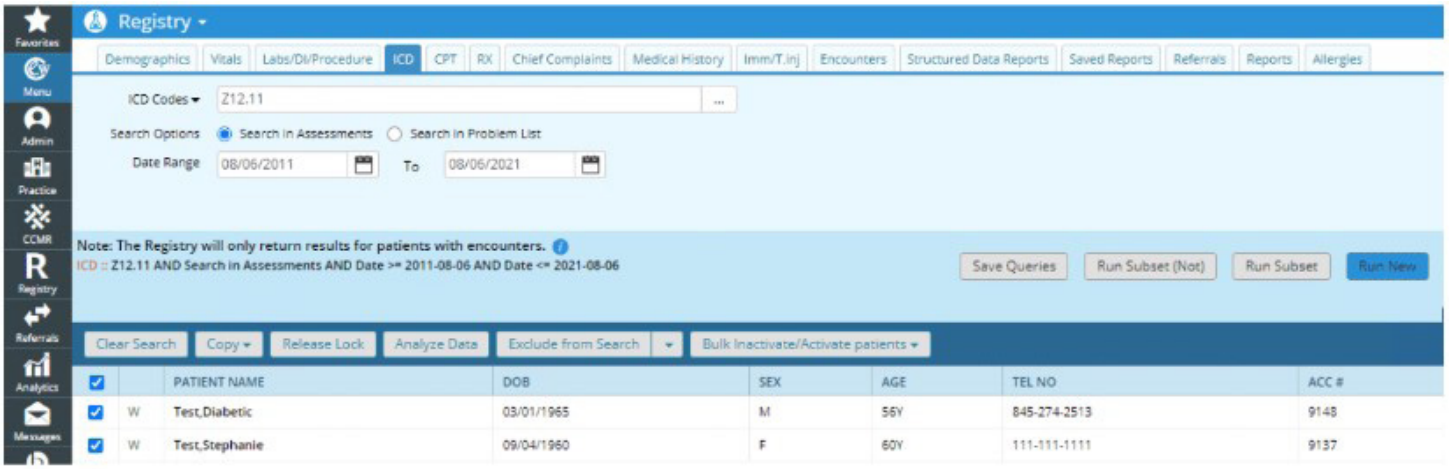
# Colorectal Screening Reports

You can create/access colorectal cancer screening reports from a variety of options

1. **HEDIS Dashboards** (Optional module for additional cost, however, this simplifies the reporting and allows you to quickly access patient details)
2. **EBO UDS Reports** (contact eCW Support to install latest version)
3. **Registry Quality Measure Reports** (Registry icon > Quality Measure Reports > Colorectal Cancer Screening) Provides aggregate reports




4. **Registry Reports** (Registry Icon > Registry) – create your own list of patients that have had a particular colorectal cancer screening or are due for a screening.



# APPENDIX C-1

## Sample Screening Policy Template
(Adapted from the New Hampshire Colorectal Cancer Screening Program)

EXAMPLE OF "SCREENING POLICY"

**XYZ Primary Care Practice**

### Colorectal Cancer Screening (CRCS) Initiative

Effective Date: Last Reviewed:

Function: Last Revised:

### Authorization:

Could be signed by Medical Director or committee

**I. Purpose** – Evidence shows that screening asymptomatic patients ages 45 and above can prevent colorectal cancer, as well as detect it at an early and curative stage, resulting in decreased morbidity and mortality rates. Colorectal cancer is the second leading cause of cancer deaths in the United States. In keeping with XYZ Primary Care Practice's philosophy that good information leads to good decisions and that we are a clinically integrated system of providers, we will implement a process for a consistent and comprehensive colorectal cancer screening program.

**II. Reference** – The XYZ Committee has carefully considered several standards to use in the colorectal cancer screening program. The United States Preventive Services Task Force (USPSTF), US Multi--Society Task Force, and American Cancer Society guidelines were chosen because they were most appropriate and widely accepted. Therefore, our staff will follow these colorectal cancer screening (CRCS) guidelines to ensure best practices for our patients.

**III. Responsibility** – It is the responsibility of all staff members to be familiar with the initiative, and to develop a practice based process for chart review, data abstraction, and accurate data entry and patient education for CRCS.

**IV. Procedure, Data Abstraction and Reporting** – refer to current performance measure stewards for applicable practice/population – e.g., **National Committee for Quality Assurance (NCQA) for HEDIS**, and the **HRSA Uniform Data Set (UDS)** which is used to assess federally-qualified community health center (FQHC) performance. Both the HEDIS and UDS performance measures are aligned to the **same electronic clinical quality measure (eCQM)**.

**V. Additional Data for Medical Review and Quality Audit** (See attachment 1)

## ATTACHMENT 1 (CRCS Initiative)

### ADDITIONAL DATA FOR MEDICAL REVIEW OR QUALITY AUDIT

Patient risk information is essential for appropriate screening and surveillance. An additional data field that includes ICD-10 code risk information may enhance the management of patients whose plan of care includes a higher frequency or earlier starting age for surveillance.

| ICD-10-CM Codes | Diagnosis |
|---|---|
| Z80.0 | Family history of malignant neoplasm of digestive organs |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z86.010 | History of colon polyps |
| | Malignant neoplasm of: |
| C18.0<br>C18.2<br>C18.4<br>C18.6<br>C18.7<br>C18.8<br>C18.9 | Cecum<br>Ascending colon<br>Transverse colon<br>Descending colon<br>Sigmoid colon<br>Overlapping sites of colon<br>Colon, unspecified |
| C20 | Malignant neoplasm of the rectum |
| | Secondary malignant neoplasm of: |
| C78.4<br>C78.5 | Small intestine<br>Large intestine and rectum |
| | Benign neoplasm of: |
| D13.2<br>D13.3<br>D13.39 | Duodenum<br>Unspecified part of small intestine<br>Other parts of small intestine |
| D01.0 | Carcinoma in situ of colon |
| | Neoplasm of uncertain behavior of: |
| D37.2<br>D37.4<br>D37.5 | Small intestine<br>Colon<br>Rectum |
| K51.* | Ulcerative colitis |
| K52.89<br>K52.9 | Other specified noninfective gastroenteritis and colitis<br>Other noninfective gastroenteritis and colitis, unspecified |
| K62.0<br>K62.1 | Anal polyp<br>Rectal polyp |

# APPENDIX C-2

Guidelines from the American Cancer Society, the US Preventive Services Task Force, and others recommend Fecal Immunochemical Tests (FIT), High-Sensitivity Fecal Occult Blood Tests (HS-gFOBT) and FIT-DNA testing as options for colorectal cancer (CRC) screening in men and women at average risk for developing colorectal cancer.

This document provides state-of-the-science information about these tests.

American Cancer Society

***Clinician's Reference***

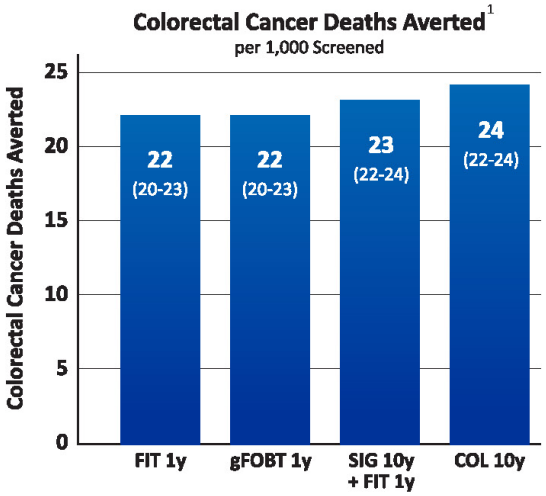
## STOOL-BASED TESTS FOR COLORECTAL CANCER SCREENING

80% IN EVERY COMMUNITY

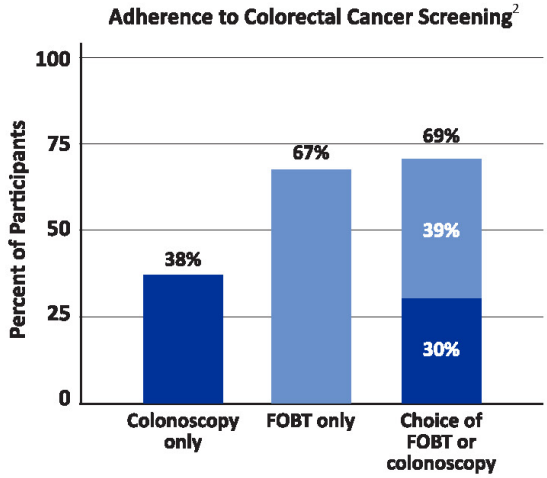
The number of colorectal cancer cases is dropping thanks to screening.
We are helping save lives.
We can save more.

## The following factors make stool tests a good option for colorectal cancer screening

- Colorectal cancer screening with guaiac-based FOBT has been shown to decrease both incidence and mortality in randomized controlled trials.
- Modeling studies suggest that lives saved through a high quality stool-based screening program are nearly the same as with a high quality colonoscopy-based screening program when strict adherence to screening and needed follow up occurs at recommended intervals over a lifetime.




- All patients should be aware that stool tests are a recommended screening option, along with invasive exams like colonoscopy. When given a choice, a significant number of patients prefer stool tests. In addition, access to colonoscopy and other invasive tests may be limited or non-existent for many patients.




### IMPLEMENTING HIGH QUALITY STOOL-BASED SCREENING PROGRAMS

Use stool tests only for **average risk patients** (no personal or family history of CRC, adenomas, or genetic syndromes). High risk patients should have colonoscopy screening.

Use only high-sensitivity fecal immunochemical (FIT), guaiac-based FOBTs (such as Hemoccult II Sensa), or FIT-DNA tests. Hemoccult II and generic guaiac-based tests are far less sensitive and should not be used for CRC screening.

Stool samples obtained by digital rectal exam (DRE) have low sensitivity for cancer (missing 19 of 21 cancers in one study with guaic-based FOBT) and should never be used for CRC screening.

All patients who have an abnormal stool test must follow up with colonoscopy.

Use reminder and recall systems for health care providers and EHRs to improve the delivery of CRC screening.

High sensitivity gFOBT and FIT should be repeated annually; FIT-DNA tests should be repeated every 3 years based on current screening guidelines.

Development of the Clinician's Reference was supported, in part, by the American Cancer Society and Centers for Disease Control and Prevention comprehensive cancer control technical assistance and training cooperative agreement #5NU38DP004969.

## Three types of stool tests are available – FIT, guaiac-based FOBT, and FIT-DNA

**Fecal Immunochemical Tests (FITs)** look for hidden blood in the stool and are specific for human blood while older guaiac-based tests (gFOBTs) are not. Unlike gFOBT, FIT results are not impacted by food or medication. There is evidence that patient adherence with FIT may be higher than with gFOBT possibly because no dietary and medication restrictions are required before collecting samples, or because some brands of FIT require collection of only 1 or 2 specimens for a completed test. It is important to note that not all FITs are equally effective. As of July 2016, there are 26 FDA-cleared FITs available for purchase in the US, however most do not have published data on their performance for detection of cancer. To assist with choosing a FIT for use in your setting, the table below includes FITs that have published data on sensitivity and specificity for cancer.

| FIT BRAND NAME | MANUFACTURER | SENSITIVITY FOR CANCER†,‡ | SPECIFICITY FOR CANCER†,‡ | NUMBER OF STOOL SAMPLES |
|---|---|---|---|---|
| **Automated (non-CLIA waived) FITs** | | | | |
| OC Auto-FIT* | Polymedco | 65%-92.3%[3,4] | 87.2%-95.5%[3,4] | 1 |
| **CLIA-waived FITs** | | | | |
| OC-Light iFOB Test (also called OC Light S FIT) | Polymedco | 78.6%-97.0%[3,4] | 88.0%-92.8%[3,4] | 1 |
| QuickVue iFOB | Quidel | 91.9%[5] | 74.9%[5] | 1 |
| Hemosure One-Step iFOB Test | Hemosure, Inc. | 54.5%[3] | 90.5%[3] | 1 or 2 |
| InSure FIT | Clinical Genomics | 75.0%[6] | 96.6%[6] | 2 |
| Hemoccult-ICT | Beckman Coulter | 23.2%-81.8%[3] | 95.8%-96.9%[3] | 2 or 3 |

*Used with OC-Sensor DIANA and OC-Auto Micro 80 automated analyzers.

†Detection limits for cancer vary across FIT brand and by study such that direct comparison between FIT brands is not possible.

‡Cited studies should be interpreted in the full context of the published literature given variation in study size and quality.

**Guaiac-based FOBTs (gFOBTs)** have been the most common form of stool tests used in the US prior to FIT becoming widely available. Modern high-sensitivity tests have much higher cancer and adenoma detection rates than older tests, resulting in fewer missed cancers. Hemoccult II SENSA is the only test in this category for which published performance data is available. Screening guidelines now specify that only high-sensitivity forms of guaiac-based tests should be used for colorectal cancer screening. **Hemoccult II and similar older guaiac-based tests should not be used for colorectal cancer screening.**

| GFOBT BRAND NAME | MANUFACTURER | SENSITIVITY FOR CANCER | SPECIFICITY FOR CANCER | NUMBER OF STOOL SAMPLES |
|---|---|---|---|---|
| Hemoccult II SENSA | Beckman Coulter | 61.5%-79.4%[4] | 86.7%-96.4%[4] | 3 |

**FIT-DNA** is a stool test that looks for increased levels of altered DNA biomarkers that are released into the stool as cells from colorectal cancer and adenomas degenerate. Cologuard is the only stool DNA test currently marketed in the US and combines testing for these DNA biomarkers with a high-quality FIT (a "FIT-DNA" test).

| FIT-DNA BRAND NAME | MANUFACTURER | SENSITIVITY FOR CANCER | SPECIFICITY FOR CANCER | NUMBER OF STOOL SAMPLES |
|---|---|---|---|---|
| Cologuard | Exact Sciences | 92.3%[7] | 89.8%[7] | 1 |

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Visit **nccrt.org** or **cancer.org/colonmd** to find additional clinical practice tools and learn more about 80% in Every Community, the national initiative to reach colorectal cancer screening rates of 80% and higher across the US.

View the NCCRT June 2016 Implementing FIT webinar: **http://nccrt.org/webinars**

80% IN EVERY COMMUNITY

NATIONAL Colorectal Cancer ROUNDTABLE

American Cancer Society

cancer.org | 1.800.227.2345

# APPENDIX C-3

## Standard Gastroenterology History and Physical Form with Labs (Operation Access)

**Gastroenterology H&P with labs – complete and fax with patient referral to (***) ***-******

| | | | |
|---|---|---|---|
| Name | Sex | Age | Date of Birth / / |
| Address | Day Phone | | Eve Phone |
| | Language | | |
| Emergency Contact Name | Phone Number | | |
| Referring Physician | Phone Number | | |

| | |
|---|---|
| Procedure requested: | Indication: |
| Abnormal creatinine? | Cardiac disease (if yes, list)? |
| Patient has escort home? Yes No | |
| On Anti-platelet or anti-coagulation (if so, which ones?) | |
| Drug or alcohol abuse currently? | |

| |
|---|
| CC / HPI |

| | |
|---|---|
| PMH | Allergies |
| | Medications |
| SH | FH ( include any GI or liver cancers) |

| | | | | |
|---|---|---|---|---|
| **Physical Exam** - Pulse | | BP | Weight | |
| Cardiac | | Pulm | Abd | |
| **Labs:** | | | | |
| WBC | Hgb | Platelets | PT/INR | PTT |
| Other labs or studies (attach): | | | | |

# APPENDIX C-4

Appendix C:4 Direct Endoscopy Referral (New York Citywide Colon Cancer Control Coalition)

## Direct Referral For Screening Colonoscopy

Physicians: Fill out this form to determine if your patient is a good candidate for direct referral for colonoscopy.

For patients who **are good candidates**:

1. Fax this form to a participating endoscopist (see reverse for referral sites).
2. Provide patient with a copy of this form and the endoscopist's contact information.
3. Instruct patient to call the referral site to schedule their procedure and to receive bowel preparation instructions.

Refer patients who **are not good candidates** to a GI specialist for assessment prior to colonoscopy.

Date of Referral: _____/_____/_____

**Patient Information or Label:**

Name: _____

DOB: _____

Patient BMI: _____

Address: _____

_____

Phone: _____

Mobile: _____

Insurance Carrier: _____

Policy ID#: _____

**Reason for procedure:**

☐ Asymptomatic person age 45* years and older
☐ Asymptomatic person with positive stool-based screening test
☐ Asymptomatic person at high risk
  ☐ First degree relative with colon cancer or adenomatous polyps
  ☐ Personal history of colon cancer or adenomatous polyps (Most recent exam: _____/_____/_____)

**Medical History:** Check "yes" or "no" for each item below. If "yes" is selected for any of the items below, the patient may not be a good candidate for direct referral. Consult with a GI specialist.

| Is the patient... | Yes | No | Notes: |
|---|---|---|---|
| Age 75 or older? | | | |
| Under treatment for heart failure or valve-related concerns? | | | |
| Under treatment for advanced kidney, liver or lung disease? | | | |
| On anti-platelet or anticoagulation medication (including over-the-counter medication such as aspirin) and cannot safely stop it for one week? | | | |
| Under active treatment for acute diverticulitis? | | | |
| Pregnant or possibly pregnant? | | | |
| **Does the patient have...** | **Yes** | **No** | **Notes:** |
| Hematochezia or iron-deficiency anemia? | | | |
| A pacemaker or automatic implantable cardioverter or defibrillator? | | | |
| Inflammatory bowel disease (ulcerative colitis or Crohn's disease)? | | | |
| A history of severe cardiac/pulmonary/renal/hepatic disease requiring oxygen supplementation or causing high risk for sedation/anesthesia complications? | | | |
| A history of endocarditis, rheumatic fever or intravascular prosthesis? | | | |
| A history of difficult, incomplete or poorly prepped colonoscopy? | | | |
| A history of difficulty with previous sedation/anesthesia? | | | |
| A history of sleep apnea? | | | |

**Is the patient on medication for diabetes?** ☐ Yes ☐ No

**If yes:** Request a morning appointment. Advise patient on how much and when to take their diabetes medications to avoid hypoglycemia while on clear liquid bowel preparation and during procedure.

**Is the patient allergic to LATEX?** ☐ Yes ☐ No

**Is the patient allergic to any MEDICATION?** ☐ Yes ☐ No

List: _____

_____

**Please list all medications and OTC supplements below (attach additional sheets as necessary):**

Medication: _____ Dose: _____
Medication: _____ Dose: _____
Medication: _____ Dose: _____
Medication: _____ Dose: _____

**Please note any other relevant medical/surgical history:**

☐ Abdominal/pelvic surgery
☐ Abdominal/pelvic radiation
Other, please list: _____

_____

_____

**Assessment: This patient is a good candidate for a direct referral for colonoscopy. ☐ Yes ☐ No**

Physician Signature: _____ Physician Name (Print): _____

Office Phone: _____ Office Fax: _____

Office Address: _____

Preferred method to send results? ☐ PHONE ☐ FAX ☐ MAIL

## TO THE PATIENT:

You have been directly referred by your physician (health care provider) for a colonoscopy. Your provider will forward this form to the doctor who will perform your colonoscopy (an endoscopist) and give you their contact information. Call the endoscopist's office to schedule your colonoscopy and to receive instructions about:

1. How to take bowel preparation medication before the colonoscopy
2. How to adjust your diet before the colonoscopy
3. How to adjust your medications before the colonoscopy

## RESOURCES FOR UNINSURED AND UNDERINSURED PATIENTS:

If you do not have health insurance or if your current health insurance plan does not cover a screening colonoscopy, call **311** and ask about how to find a low-cost screening.

## *PAYMENT:

Most insurance plans including Medicaid and Medicare cover colon cancer screenings starting at age 50. If you are between ages 45 and 49, coverage for screening varies. Consult with your provider about your colon cancer risk and with your insurance plan about coverage before your screening test. If you do not have insurance, you may be eligible for low-cost or no-cost coverage. You can also get free in-person assistance when signing up for a plan. Call **311** or text "CoveredNYC" to 877877.

12.19

NYC Health

New York Citywide Colon Cancer Control Coalition

# APPENDIX C-5.1

## Sample Colonoscopy Appointment Letters in English (Operation Access)

<Date>
<First Name> <Last Name>
<Address>
<City>, <State> <ZIP Code>

Dear <First Name>:

We are glad to inform you that you have been scheduled for a consult with **<Dr Practice>**.

Date and Time: **<Procedure Appt Date English>** at **<Procedure Time>** – **Please arrive 15 minutes early**.

Address: **<Hospital or Procedure Address>**

**IMPORTANT:**
*****Follow the instructions included with this letter starting the day before your appt*****

1. Bring **this letter and photo identification** to your appointment.
2. Bring **all of the medications** you take regularly and show them to the doctor.
3. If you got any radiology procedure done (Ultrasounds, CT Scans, or X Rays), **please obtain and bring the reports and images** to your consult. The doctor may need these images and reports to diagnose you and decide on your treatment.
4. There are a limited number of available appointments. If you arrive late or miss your consult, we cannot guarantee that it can be rescheduled. Call us at least **48 hours** prior to the consult if you need to cancel.
5. Please **call us after the appointment** to inform me of the outcome and future appointments.
6. The doctor and the hospital have offered to donate this service to you. If you are asked to make a payment, **do not pay**. Instead, request that a bill be mailed to you. When you receive the bill, **do not pay**. Send me a copy of the bill.

Please call me if you have any questions or concerns.

Sincerely,

**<Primary Case Mgr>, <Primary Title>**
**Phone: <Primary Phone>**
**e-mail: <Primary Email>**

**INFORMATION FOR REGISTRATION:**

If you have any questions, please call us at (***)***-**** or the phone number listed above. Also please call us if you have scheduled the patient for surgery, so that we can ensure that the hospital codes the patient correctly as a non-billing case. Thank you!

# APPENDIX C-5.2

## Sample Colonoscopy Appointment Letters in Spanish (Operation Access)

<Date>
<First Name> <Last Name>
<Address>
<City>, <State> <ZIP Code>

Estimad <EndOfWordGenderSpanish> <First Name>:

Tenemos el gusto de informarle que se le ha programado un procedimiento con **<Dr Practice>**.

Fecha y Hora: **<Procedure Appt Date Spanish>** a las **<Procedure Appt Time Spanish>** – **Por favor llegue 15 minutos antes de la cita.**

Dirección: **<Hospital or Procedure Address>**

**IMPORTANTE:**
*****Sigue las instrucciones incluidas con esta carta, comenzando el día antes de su procedimiento*****

1. Lleve **esta carta y su identificación con foto** a su cita.
2. Traiga todos **los medicamentos** que toma regularmente y muéstreselos al doctor.
3. Si tuvo un procedimiento radiológico (ultrasonido, CT Scan o Rayos X), **por favor obtenga estos reportes e imágenes y tráigalos a su consulta**. Su doctor necesitará los imágenes y reportes para darle el diagnóstico más apropiado y decidir su tratamiento.
4. El programa tiene un número limitado de consultas disponibles. Si usted llega tarde o pierde su cita, no podemos garantizar de que sea reprogramada. **Llámenos con 48 horas de anticipación** si necesita cancelar.
5. Por favor **llámenos después de su cita** para informarnos de los resultados y de citas futuras.
6. Su doctor y el hospital ofrecieron donarle este servicio. Si le piden hacer un pago, **no pague**. En vez de pagar, pida que la factura sea enviada por correo. Cuando recibe esa factura, **no la pague**, mándeme una copia.

Por favor llámeme si tiene preguntas.

Sinceramente,

**<Primary Case Mgr>, <Primary Title>**
**Phone: <Primary Phone>**
**e-mail: <Primary Email>**

**INFORMATION FOR REGISTRATION:**

If you have any questions, please call us at (***)***-**** or the phone number listed above. Also please call us if you have scheduled the patient for surgery, so that we can ensure that the hospital codes the patient correctly as a non-billing case. Thank you!

# APPENDIX C-6

## Colonoscopy Preparation Navigator Checklists (Fair Haven CHC)

| Colonoscopy Screening | 1st Meeting | |
|---|---|---|
| Name: | | |
| Address: | | |
| Email: | | |
| Telephone #1: | Always attempt to get two phone numbers | |
| Telephone #2: | | |
| Referring clinician/address: | | |
| **Initial face-to-face meeting (1-5 weeks before appointment)** | **Date** | |
| ■ Discussion of importance of colonoscopy | | |
| ■ Provide educational literature? | | |
| **Does patient meet screening criteria?** | **Yes/No** | |
| >50 yrs old and >10 yrs since last colonoscopy | | |
| >40, first degree relative colon Ca and >5 yrs since last colonoscopy | | |
| Proven adenomatous polyp, >5 yrs since last colonoscopy | | |
| **Medication Review** | **STOP Date** | **Don't STOP** |
| ■ Aspirin, Plavix (clopidogrel) *need MD clearance, ideally stop 5 days<br>Plavix (clopidogrel)<br>Effient | | |
| ■ Coumadin (warfarin) *need MD clearance, ideally stop 4 days<br>Xarelto | | |
| ■ Diabetes meds<br>Metformin, Januvia, glyburide *need MD clearance, usually hold oral agent morning of test<br>Insulin *need MD clearance, usually half dose insulin night before and morning of test | | |
| ■ Anti-hypertensives (BP meds) | | **X** |
| ■ Iron and iron-containing vitamins | **1 week before** | |
| ■ ALL other meds can be held on the day of appointment | | |
| ■ Patient given written instructions about medications? (Yes/No) | | |
| **Bowel Prep** | | |
| ■ Provide copy of bowel prep in native language | | |
| ■ Review bowel prep (in native language, if possible) | | |
| ■ Review with patient specific times to take laxatives | | |
| ■ Review with patient "Clear liquid diet"; provide patient with diet list | | |

| Colonoscopy Screening | 1st Meeting |
|---|---|
| **Appointment** | |
| ■ Date and arrival time | |
| ■ Estimated departure time (usually ~3 hrs after arrival) | |
| ■ Appointment card given to patient? | |
| **Transportation** | |
| ■ Review need for driver (if public transportation, must be accompanied) | |
| ■ Patient's transportation plans (who, how): | |
| Name: Phone: | |

| Colonoscopy Screening<br>Second face-to-face meeting mandatory if initial meeting >5 weeks before colonoscopy | 1-3 Weeks Before |
|---|---|
| **Bowel Prep** | |
| ■ Provide copy of bowel prep in native language | |
| ■ Review bowel prep (in native language, if possible) | |
| ■ Review with patient specific times to take laxatives | |
| ■ Review with patient "Clear liquid diet," provide patient with diet list | |
| **Appointment** | |
| ■ Date and arrival time | |
| ■ Estimated departure time (usually ~3 hrs after arrival) | |
| ■ Appointment card given to patient? | |
| **Transportation** | |
| ■ Review need for driver (if public transportation, must be accompanied) | |
| ■ Patient's transportation plans (who, how): | |
| Name: Phone: | |

| Screening Colonoscopy – Telephone Calls | 1-3 Weeks Before |
|---|---|
| **One week before appointment** | |
| ■ Remind patient of date and arrival time | |
| ■ Confirm transportation plans | |
| ■ Brief review of bowel prep | |
| ■ Review clear liquid diet | |
| ■ Review medication list | |

| Screening Colonoscopy – Telephone Calls | 1-3 Weeks Before |
|---|---|
| **One day before appointment** | |
| ■ Ask how prep is going | |
| ■ Remind importance of increased fluids – **Must drink "beyond thirst"; at least extra ½ gallon over 24 hours** | |
| ■ Remind importance of two doses of prep, separated by at least 4-6 hours | |
| **Record of additional phone calls** | **Date** |
| Patient concern/question:<br><br>Resolution: | |
| Patient concern/question:<br><br>Resolution: | |

# APPENDIX C-7.1

fluFIT fluFOBT

## HOW TO DO IT
## 5 Simple Steps

Setting up a FLU-FIT or FLU-FOBT Program is not hard, but it does require some careful planning and staff training before you start.

### 1. Put Together Your FLU-FIT or FLU-FOBT Team

**Select a FLU-FIT or FLU-FOBT Champion to coordinate your efforts**

This will usually be a nurse or other member of the medical team who works closely with the manager of your clinical site.

**Select your FLU-FIT or FLU-FOBT Team Members and Staffing Levels**

FLU-FIT and FLU-FOBT team members can be medical assistants or other health workers who enjoy working with patients and who can be trained to provide flu shots and/or FIT/FOBT kits to patients.

Depending on your setup, you may have each team member carry out all aspects of the FLU-FIT or FLU-FOBT process with patients, or you may divide up the tasks.

To implement a FLU-FIT or FLU-FOBT process, you may need to adjust your staffing levels. If you have a high volume clinical site, you may need to assign one or more additional persons above what you usually need for flu shot season to help assess patient eligibility and dispense FIT kits.

**Help your FLU-FIT or FLU-FOBT Team to be Successful**

To make sure that the process runs smoothly, start your planning process early, and involve your team members in the planning process.

Once you have settled on the details of your program and who will be involved, set up a date for a final training session. Usually this training should take place one or two weeks before the start of your Program. See link about Training

Team members should arrive before the flu shot line opens to check their supplies and systems for assessing patient eligibility, and providing FIT/FOBT. Assign at least one experienced team member who knows all aspects of the program to be on hand each day to help supervise and offer guidance to team members who are less experienced. Develop a coverage system for lunch breaks and a back-up plan to solve logistical challenges as they arise.

## 2. Choose Times and Places for FLU-FIT or FLU-FOBT and Advertise Them

**When to Start**

The best time to start a FLU-FIT or FLU-FOBT Program is at the time when you usually begin dispensing flu shots. The first several days and weeks of flu shot activities can be busy, but this is also the time when you have the opportunity to reach the largest number of patients who may be due for colorectal cancer screening with FIT or FOBT.

**Where to do it**

You can do FLU-FIT or FLU-FOBT Programs wherever you provide flu shots, but the approach used may differ depending on the nature of your venue, your available resources, and your relationships with your patients.

FLU-FIT and FLU-FOBT Programs are easiest to implement within integrated healthcare settings. For example, in settings with immediate access to documentation about prior screening history and with systems to provide test results to primary care physicians and to refer patients with abnormal tests to get follow-up.

FLU-FIT and FLU-FOBT Programs can be implemented during dedicated “FLU-FOBT Clinics” or integrated with routine primary care office visits.

FLU-FIT and FLU-FOBT Programs can be implemented outside of integrated healthcare settings, such as in commercial pharmacies or in non-clinical community health settings, but the logistics of doing this successfully are more complex, because of payment, processing, and test reporting issues.

**Advertise it**

The first step is to meet with the people who work within your organization,including managers and all of your staff members, and inform them that you are doing a FLU-FIT or FLU-FOBT Program so they can be ready to support you and so they can help you reach out to your patients.

How you announce the Program to your patients depends on your resources. If you are in a primary care setting, you may choose to pass out flyers to your patients announcing the FLU-FIT or FLU-FOBT Program dates, send postcards, provide an automated phone call announcement, or place information about the program on your website or in a clinic newsletter.

Important information to give to patients can include the following:

- Dates and Times of your Program
- Who should come in for their flu shot
- Explain that patients aged 50-75 who come in for flu shots will be offered a home colorectal cancer screening kit if they are due
- Provide a motivational message, such as “Yearly Prevention Saves Lives”

## 3. Patient Flow and Line Management Plan

**Offer FIT/FOBT in line BEFORE giving the flu shot**

Planning patient flow issues in advance will help your Program run smoothly. In busy settings, there may be a FLU-FIT or FLU-FOBT line. When there is a line, the most efficient way to reach everyone who needs colorectal cancer screening is usually to provide FIT/FOBT before providing flu shots. Waiting until after giving flu shots to offer FIT/FOBT may be less efficient, since patients usually expect to leave immediately after getting their flu shot.

**Assessing eligibility for FLU and FIT/FOBT**

Most experienced flu shot clinics already have established protocols for screening for patients with allergies to egg or poultry products or other contraindications to flu shots. Guidelines for providing flu shots are provided here

Annual FIT/FOBT should be considered for all adults between the ages of 50 and 75. Patients who have had a colonoscopy in the last 10 years will not usually need to get annual FIT/FOBT. Patients with other colorectal cancer screening tests, such as flexible sigmoidoscopy or barium enema usually can still benefit from annual FIT/FOBT.

Therefore, the goal is to offer FIT/FOBT to the following patients:

- Age 50-75
- No colonoscopy in the last 10 years
- No FIT/FOBT in the last year

In many cases, this information can be found in electronic medical records or in a health maintenance log sheet in the patient's paper medical chart. Team members who are unfamiliar with where to find this information may need training from a physician or clinic manager.

When information about colorectal cancer screening is not available in the medical record, you can ask patients between the ages of 50 and 75 to tell you if they did a home stool test for colorectal cancer screening in the last year or a colonoscopy in the last 10 years, and offer FIT/FOBT who are due for screening based on their answers.

If there is both no information in the medical record and patients are uncertain about when they had their last tests, you may still consider offering FIT/FOBT if it seems possible that they have not had testing in the recommended time intervals.

One time-saving approach for clinics with electronic health records is to print out a list of patients who are due for FIT/FOBT at the beginning of the flu shot season, and use it as a reference to select appropriate patients for FIT/FOBT as they come in for their flu shots.

## 4. Develop Systems to Support Follow-Up of FIT/FOBT Kits Dispensed

**Consider ease of test completion when selecting a FIT or FOBT kit**

There are many FIT and FOBT tests kits on the market. When possible, select a test kit that does not require the patient to restrict their diet or medication regimen for several days before they collect their specimen. It is easiest for patients to complete a test that they can take home and complete without special preparation or delay.

**Provide clear instructions for completing and returning kits**

Most test kits come with manufacturer-recommended instructions, and they can be given to patients as part of the FIT/FOBT kit.

You may want to insert additional instructions (such as multilingual instructions, simpler instructions for low literacy patients, a special reminders to date the kit when completed, and/or a phone number to call if they have questions) if you believe this would be helpful.

**Provide a return envelope for kits to be mailed back to your clinic or to the lab**

Most test kits come with return envelopes to allow kits to be mailed back to your clinic or laboratory. Providing envelopes with paid postage will increase your return rates on FIT/FOBT kits dispensed.

**Provide a return envelope for kits to be mailed back to your clinic or to the lab**

Most test kits come with return envelopes to allow kits to be mailed back to your clinic or laboratory. Providing envelopes with paid postage will increase your return rates on FIT/FOBT kits dispensed.

**Reminder phone calls or postcards to encourage test completion by those who are given FIT or FOBT**

Typically, less than 50% of people who are given FIT/FOBT kits will return them without reminders. Providing reminders within 2 or 3 weeks of providing patients with a home FIT/FOBT kit can increase return rates.

**Assist patients with abnormal FIT or FOBT results to get colonoscopy and additional treatment when needed**

Develop a system for FIT/FOBT results to get to both the patient and their primary care physician.

Patients with normal FIT/FOBT test results should receive the message that this is good news and that they should repeat the test in a year. Their primary care clinicians should also receive these results.

Patients with abnormal FIT/FOBT test results should be called and told that they require colonoscopy to check for polyps or cancer. Their primary care clinician should also be called with this message so they can assist with arranging a colonoscopy for the patient.

Keep a log of patients with abnormal test results and check it periodically to verify that everyone on the list has gotten needed follow-up.

## 5. Final Preparations

**Gather Your Supplies Well in Advance**

Order flu shots and FIT/FOBT Kits with Return Envelopes/Stamps

Written patient education materials, posters, and algorithms for your team can be downloaded from this website, edited for use in your patient population and printed up for your use link to materials

**Two Weeks Before FLU/FIT or FLU-FOBT Activities Start**

Recheck to be sure you have all your supplies

Do a walkthrough with your FLU-FIT Team

Consider doing a role play with your FLU-FIT Team, checking your workflow and procedures for providing flu shots and FIT/FOBT kits

**Your first day of your FLU-FIT or FLU-FOBT Program**

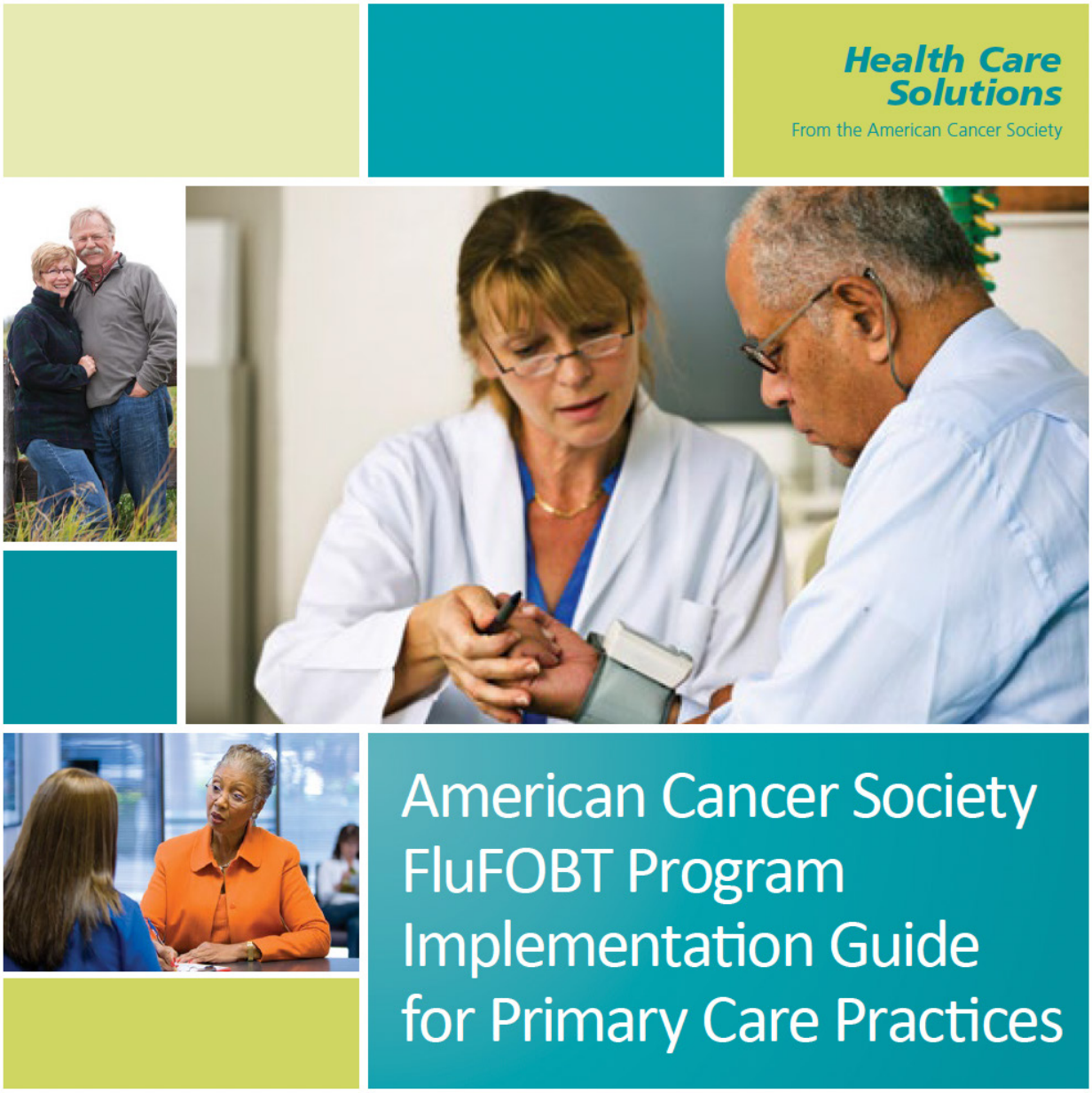
Whatever happens on the first day, don't give up – FLU-FIT and FLU-FOBT programs get easier with experience.

Congratulate yourselves for getting to this point!!!

**For more information or questions about FLU-FIT and FLU-FOBT Programs, visit www.flufit.org or contact:**

Michael Potter, MD
Department of Family and Community Medicine
University of California, San Francisco
San Francisco, CA 94143-0900
Email: potterm@fcm.ucsf.edu

# APPENDIX C-7.2



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## Acknowledgments

The American Cancer Society would like to thank Michael Potter, MD, former National Colorectal Cancer Roundtable (NCCRT) Steering Committee member and current chair of the NCCRT Professional Education and Practice Task Group, and his colleagues (at UCSF, the San Francisco Department of Public Health, and Kariser Permanente) and funders (the American Cancer Society, the Centers for Disease Control and Prevention, and the National Cancer Institute), for developing and demonstrating the effectiveness of FLuFOBT interventions. This guide is based with permission on the work of Michael Potter, MD. We thank FluFOBT Project Coordinators La Phengrasamy, MPH, (at San Francisco Department of Public Health);Vicky Gomez MPH, (formerly at Kaiser Permanente Division of Research in Oakland, CA); and Tina Yu (now at UCSF School of Medicine) for developing and field-testing many of the program materials and procedures included in this implementation guide. We would also like to thank Holly Wolf, PhD, MSPH, NCCRT Steering Committee member and chair of the NCCRT Policy Action Task Group, and her colleagues at the Colorado Colorectal Screening Program for organizing FluFOBT.org website materials into a model implementation guide.

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# FluFOBT Program Implementation Guide for Primary Care Practices

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## Introduction

The American Cancer Society FluFOBT Program (the Program) is intended to assist community health centers in increasing colorectal cancer (CRC) screening. It has been demonstrated in the medical literature that offering and providing take-home fecal occult blood tests and fecal immunochemical tests (FOBTs and FITs) to patients at the time of their annual flu shot increases CRC screening rates.[1,2,4]

Colorectal cancer (CRC) is the third leading cause of cancer death among both men and women separately in the United States (US).[8] An estimated 136,830 cases of colon and rectal cancer are expected to occur in 2014, with an estimated 50,310 deaths.

In 2010, 59.1% of adults 50 years of age and older reported use of either an FOBT or an endoscopy test within recommended time intervals. However, rates remain substantially lower in uninsured individuals and those with lower socioeconomic status.

Compelling data from the Centers for Disease Control and Prevention (CDC) suggest that CRC screening reduces the incidence and mortality from colorectal cancer. The CDC detailed a study concerning CRC screening data gathered from the 2002-2010 Behavioral Risk Factor Surveillance System surveys, in addition to incidence and mortality data gathered from the United States Cancer Statistics. Significant findings from this study were: CRC incidence and mortality rates declined 13% and 12% (approximately 66,000 cases and 32,000 deaths) respectively from 2003 to 2007, and screening prevented approximately half of the expected CRC cases (33,000) and deaths (16,000) during this same time frame.[6,7] Those screened for CRC increased 20% from 2002 to 2010. This study demonstrates that prevention and early detection of CRC through screening can decrease the incidence of and mortality from this disease.[7] However, in 2010 one in three adults between 50 and 75 years of age were still not up-to-date with screening recommendations.[6]

The American Cancer Society has developed this implementation guide to include:

- Background and evidenced-based information/education regarding the ACS FluFOBT Program and the benefits of FluFOBT
- Patient eligibility criteria for colorectal cancer screening
- Patient education about colorectal cancer and the importance of screening
- Steps to setting up a FluFOBT program in your health center
- Staff training regarding the implementation of the ACS FluFOBT Program for your center
- Tracking tools to manage your FluFOBT Program

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## Background Information and Education

### FluFOBT Background

The ACS FluFOBT Program is an efficient and effective way to increase colorectal cancer screening. When patients go for their annual flu shot, health center staff provide either a take-home fecal occult blood test (FOBT) kit or fecal immunochemical (FIT) kit to those who are also due for colorectal cancer screening. Patients due for colorectal cancer screening through FOBT or FIT are men and women 50 years of age and older who have not had an FOBT or FIT in the past year or a colonoscopy in the past 10 years. The ACS FluFOBT Program is a population-based intervention that has been shown to increase screening rates in community health centers.[1,3,4]

An FOBT or FIT is a stool-based colorectal cancer screening test, for average risk patients 50 years of age and older, that must be done annually to be effective.[8] There are two types of stool tests currently used for colorectal cancer screening, the guaiac-based FOBT and the immunochemical FOBT, more commonly known as a FIT. The Program will refer to both tests more broadly as FOBTs. Either a high-sensitivity guaiac-based FOBT or a FIT is appropriate for the ACS FluFOBT Program.

Colorectal cancer or adenomatous polyps often result in small amounts of blood in the stool. This blood is usually not visible to the naked eye (therefore described as "occult" or hidden). FOBT can detect these trace amounts of blood. The patient completes the FOBT by collecting a stool sample in the privacy of their home and returning the test to their doctor's office (or sending the kit to the lab) for processing. If the test indicates that blood is present a colonoscopy is needed to determine the source of the bleeding. **It is imperative that every patient with a positive FOBT result gets a colonoscopy to determine the source of the positive finding and to rule out cancer.**

Clinics can use this guide as a resource to plan and implement the ACS FluFOBT Program.

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## Why Have a FluFOBT Program?

### Some Reasons to Try!

**1. Annual colorectal cancer screening tests are underused:**
Colorectal cancer is the third leading cause of cancer death among both men and women in the United States, but most of these deaths could be prevented with routine screening. The least invasive, least expensive form of screening involves annual home stool tests, using either guiaic-based fecal occult blood tests (FOBT) or fecal immunochemical tests (FIT). If done yearly and with appropriate follow-up, FIT or FOBT can find some polyps (which, when removed, can prevent cancer), or catch cancer early when it can often be treated successfully. Modelling studies have found that high-quality colorectal cancer screening programs that emphasize the use of FIT and FOBT as initial screening tests can be similarly effective at saving lives to programs that emphasize more invasive tests, such as colonoscopy.

**2. Annual flu shot activities are an opportunity to reach many people who need colorectal cancer screening:**
Each fall, millions of Americans get flu shots. Many of these people are also at risk for colorectal cancer. Annual flu shot campaigns are an opportunity to reach this at-risk group with screening.

**3. FOBT kits can be given to patients by flu shot clinic staff:**
Many flu shot campaigns are run by nurses, pharmacists, or medical assistants. A prepared health care team can develop simple systems to provide a home FOBT or FIT kit to all eligible patients and in doing so can free up time for busy providers to address other pressing health concerns.

**4. FluFOBT programs increase colorectal cancer screening rates:**
FluFOBT programs have resulted in major improvement in colorectal cancer screening rates in a variety of clinical settings. The program can be implemented and sustained with limited resources. In addition, FOBT and FIT screening methods are well-accepted by patients, and lead to higher screening rates.

**5. FluFOBT programs can be a first step toward other innovative, preventive health and screening programs:**
Success with FluFOBT programs can lead to other practice innovations. For example, once the health center has a successful FluFOBT program, they may decide to add other services to flu shot activities, such as mammogram or smoking cessation referrals.

**6. FluFOBT programs can help health centers meet important performance goals:**
Beginning in 2012, the Health Resources and Services Administration (HRSA) added a colorectal cancer screening measure to the Clinical Quality Core Measure Set of performance measures (the Uniform Data System or UDS) annually tracked and reported by health centers. FluFOBT programs support the health center in meeting HRSA performance measures and Patient-Centered Medical Home standards.

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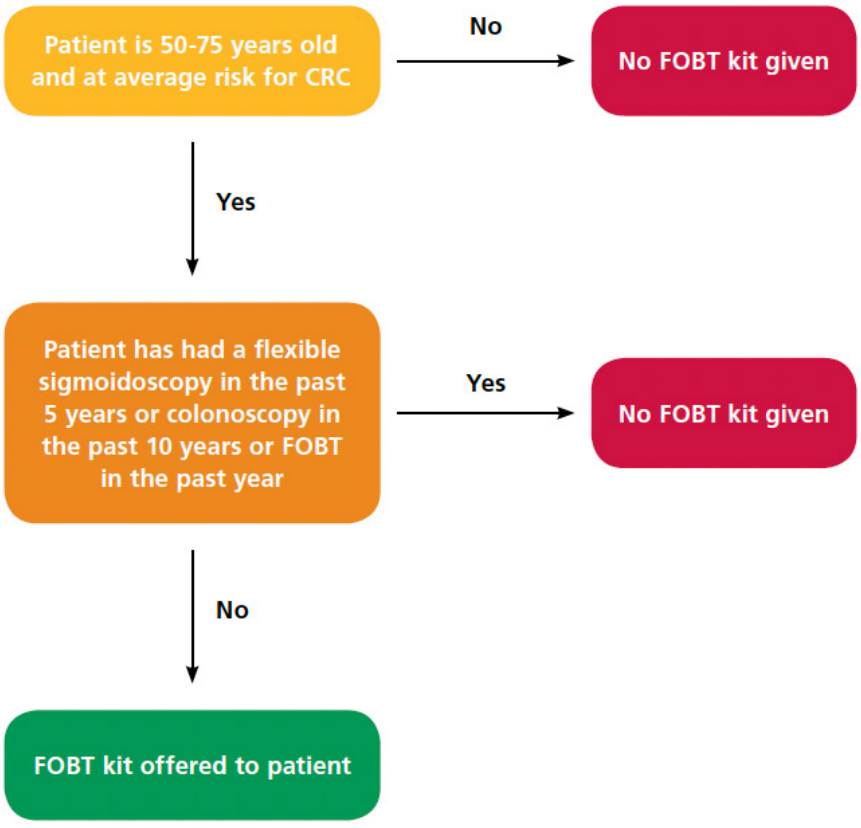
## Colorectal Cancer Screening Eligibility

HRSA's UDS measure requires health centers to report on colorectal cancer screening among patients between 50 and 75 years of age. To improve screening rates in their UDS reporting, clinics will give FOBT kits to all eligible average-risk patients coming in for their flu vaccine who are in this age range and have not been screened for colorectal cancer via colonoscopy in the past 10 years or FOBT in the past year. If there is a positive FOBT result, the patient will need a colonoscopy as part of the post-screening diagnostic process.

### When to offer an FOBT kit:



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# Colorectal Cancer Screening Recommendations

The following is based on recommendations for colorectal cancer early detection from the American Cancer Society and the US Preventive Services Task Force (USPSTF). More information can be found at cancer.org/colonmd.

## American Cancer Society Recommendations

Average-risk patients 50 years of age and older should be routinely screened for colorectal cancer. There are several screening tests for colorectal cancer, which when done at recommended intervals are effective at reducing colon cancer mortality, including:

- Colonoscopy every 10 years
- FOBT or FIT every year
- Flexible sigmoidoscopy every five years
- Double-contrast barium enema every five years
- CT colonography (virtual colonoscopy) every five years
- Stool DNA test

## US Preventive Services Task Force Recommendations

The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults beginning at 50 years of age and continuing until 75 years of age.

- Colonoscopy every 10 years
- FOBT or FIT every year
- Flexible sigmoidoscopy every five years, preferably with FOBT every three years

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There is no evidence that stool samples obtained from asymptomatic patients on digital rectal examination can be used to detect colorectal cancer, and neither the American Cancer Society nor the USPSTF guidelines endorse this form of testing. Therefore, all FOBT (whether guaiac or immunochemical) should be performed on specimens collected at home, and according to manufacturers' test instructions.

**If the result of an FOBT is positive, a colonoscopy should be done.**

The ACS FluFOBT Program is primarily an outreach service for average-risk patients. Health centers should develop both population screening programs (such as FluFOBT) for average-risk patients AND tailored approaches to identify and refer increased-risk or high-risk patients.

For complete information on colorectal cancer screening recommendations, including guidelines for higher-risk patients, refer to Appendix B: Colorectal Cancer Screening Recommendations for People at Increased or High Risk.

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## Patient Education

### Colorectal Cancer and FOBT: Facts and Talking Points to Use with Patients

**Facts about colorectal cancer and screening:**

- Colorectal cancer is the third leading cause of cancer death among both men and women in the United States.
- More than 50,000 Americans die of colorectal cancer each year.
- Finding polyps; finding cancer early, called early detection; and treatment can save lives.
- Seven out of 10 people diagnosed with colorectal cancer have no symptoms.
- Colorectal cancer is often preventable with testing, often called screening, of people who have no symptoms. Note: patients may understand the terms "test" or "testing" more easily than the word "screening."
- There are more than one million colorectal cancer survivors in the United States.
- Colorectal cancer screening is recommended for adults 50 years of age and older.

**Facts about FOBT and FIT kits:**

- These tests work by detecting small, invisible amounts of blood that can come from colon polyps or early colorectal cancer.
- If done every year, they can help find polyps and cancers before they become life threatening.
- Studies have shown that if done correctly and with proper follow-up, screening with high-quality FOBT can be similarly effective to colonoscopy for preventing deaths from colorectal cancer.
- The tests are done at home and returned to the health center or mailed into the lab.
- If the FOBT results are positive, people need to get a colonoscopy.
- If your patients choose to get FOBT, they need to do it every year, just like a flu shot
- Each patient should receive clear instructions about the test that you provide. (See the flufit.org website for test instructions and videos on multiple tests and in a variety of languages.)

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**Talking Points for Use with Patients:**

- We have something extra to offer you today!
- It looks like you are due for a home colon test.
- Testing for colon cancer (also called screening) can save lives.
- Just like a flu shot, all our doctors and nurses recommend home colon tests every year.
- It's easy – you can do it in the privacy of your home and bring it back or mail it in.

**Reminders after Giving the Kit to Patients:**

- Put the kit in the bathroom so it will be there when you need to use it.
- Try to complete the kit in the next few days if possible.
- Write the collection dates on each completed kit.
- Mail the kit in or bring it to the health center as soon as possible after you finish collecting the stool.
- Call us if you have a problem with the kit.
- Talk to your doctor if you have any other questions about FOBT.

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# How to Set Up Your FluFOBT Program

Setting up a FluFOBT program is not hard, but it does require some careful planning and staff training before you start.

## 1. Put your FluFOBT team together.

**Select a FluFOBT champion to coordinate your efforts.**
This will usually be a nurse or other member of the medical team who works closely with the clinicians and the manager of your health center.

**Select your FluFOBT team members and staffing levels.**
FluFOBT team members can be nurses, medical assistants, or other health workers who enjoy working with patients and who can be trained to provide flu shots and/or FOBT kits to patients. Also include staff members who can help track kit return rates and monitor project data.

Depending on your setup, you may have each team member carry out all aspects of the FluFOBT process with patients (e.g., give flu shots, assess FOBT eligibility, provide patient education, and distribute FOBT kits), or you may divide up the tasks.

To implement a FluFOBT program, you may need to adjust your staffing levels. If you have a high-volume clinical site, you may need to assign one or more additional people in addition to what you usually need for flu shot season to help assess patient eligibility and dispense FOBT kits.

**Help your FluFOBT team to be successful.**
To make sure that the program runs smoothly, start your planning process early, and involve your team members in the planning process.

Once you have settled on the details of your program and who will be involved, set a date for a final walkthrough and training session. This session should take place one or two weeks before the start of your program.

The walkthrough and training should include checking supplies and systems for assessing patient eligibility and providing FOBT. Assign at least one experienced team member who knows all aspects of the program to be on hand each day both during designated flu shot clinics and during routine clinic appointments when a flu shot might be given (to help supervise and offer guidance to team members who are less experienced). Develop a coverage system for lunch breaks and a backup plan to solve logistical challenges as they arise.

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## 2. Choose times and places for FluFOBT, and advertise them.

**When to Start**
The best time to start a FluFOBT program is when you usually begin dispensing flu shots. The first several days and weeks of flu shot activities can be busy, but this is also the time when you have the opportunity to reach the largest number of patients who may be due for colorectal cancer screening.

**Where to Do It**
You can do FluFOBT programs wherever you provide flu shots, but the approach used may differ depending on the nature of your venue, your available resources, and your relationships with your patients.

FluFOBT programs are easiest to implement within integrated health care settings. For example, you could have them in settings with immediate access to documentation about prior screening history and with systems to provide test results to primary care clinicians and to refer every patient with a positive test result to get follow-up.

FluFOBT programs can be implemented during dedicated flu shot clinics or integrated within routine primary care office visits.

**Advertise it.**
The first step is to meet with the people who work within your organization, including clinicians, managers, and all of your staff members, and inform them that you are doing a FluFOBT program so they can be ready to support you and help you reach out to patients.

How you announce the program to your patients depends on your resources. You may choose to pass out flyers announcing the FluFOBT program dates, send postcards, provide an automated phone call announcement, or place information about the program on your website or in a health center newsletter.

Important information to give to patients can include the following:

- Dates and times of your program
- Who should come in for their flu shot
- Explain that patients between 50 and 75 years of age who come in for flu shots will be offered a home colorectal cancer screening kit if they are eligible.
- Provide a motivational message such as "Colon cancer screening can save lives!"

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## 3. Design Patient-flow and Line-management Plan

**Offer FluFOBT before giving flu shot.**
Planning patient-flow issues in advance will help your program run smoothly. In busy settings, there may be a FluFOBT line. When there is a line, the most efficient way to reach everyone who needs colorectal cancer screening is usually to provide FOBT before providing flu shots. Waiting until after giving flu shots to offer FOBT may be less efficient, since patients usually expect to leave immediately after getting their flu shot.

**Assess eligibility for flu and FOBT.**
Most experienced flu shot clinics already have established protocols for screening patients with allergies to egg or poultry products or other contraindications to flu shots.

Annual FOBT should be considered for all adults 50 to 75 years of age. Patients who have had a colonoscopy in the past 10 years will not need to get annual FOBT.

Therefore, the goal is to offer FOBT to the following patients:

- Between 50 and 75 years of age
- No colonoscopy in the past 10 years
- No FOBT in the past year

For patients who are registered users of your health center, this information may be found in electronic health records or in a health maintenance log sheet in the patient's paper medical chart. Team members who are unfamiliar with where to find this information may need training from a physician or clinic manager.

When information about colorectal cancer screening is not available in the medical record, you can ask patients 50 to 75 years of age to tell you if they did a home stool test for colorectal cancer screening in the past year or a colonoscopy in the past 10 years, and offer FOBT to those who are due for screening based on their answers.

If there is no information in the medical record and patients are uncertain about when they had their last tests, you may still consider offering FOBT if it seems possible that they have not had testing in the recommended time intervals, or these patients can be referred to a clinician to clarify their screening status. Many patients who are older than 75 years of age may still benefit from screening. These patients should discuss the benefits and limitations of screening (based on their overall health status) with their clinician.

One time-saving approach for clinics with electronic health records is to print out a list of registered patients who are due for FOBT at the beginning of the flu shot season, and use it as a reference to select appropriate patients for FOBT as they come in for their flu shots.

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## 4. Develop systems to support follow-up of dispensed FOBT kits.

**In addition to selecting a high-sensitivity guaiac-based test or FIT, consider ease of test completion when selecting an FOBT kit.**
There are many FIT and FOBT kits on the market. When possible, select a kit that does not require the patient to restrict their diet or medication regimen for several days before they collect their specimen. It is easiest for patients to complete a test that they can take home and complete without special preparation or delay (see Appendix E).

Ideally, use kits that will be processed in a lab that can link results directly to the health center's electronic health record to facilitate project evaluation.

**Provide clear instructions for completing and returning kits.**
Most test kits come with manufacturers' recommended instructions, and they can be given to patients as part of the FOBT kit.

Depending on the needs of your patient population, you may want to include additional instructions (such as multilingual instructions, simpler instructions for low-literacy patients, a special reminder to date the kit when completed, and/or a phone number to call if they have questions).

**Provide a return envelope for kits to be mailed back to your clinic or to the lab.**
Most test kits come with return envelopes to allow the kits to be mailed back to your clinic for processing.

If patients will be allowed to mail kits back, providing postage-paid envelopes will increase your return rates on dispensed FOBT kits.

**Strongly consider reminder phone calls and/or postcards to encourage test completion by those who are given FOBT kits.**
Typically, less than 50% of people who are given FOBT kits will return them without reminders. Providing reminders within two weeks of providing patients with a home FOBT kit can increase return rates. Telephone reminders may lead to a higher return rate than mailed reminders although both increase return rates. Send reminders two weeks after dispensing the test if the kit has not been returned within that amount of time.

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**Assist patients with a positive FOBT result get a colonoscopy. A positive FOBT should not simply be repeated; every positive test requires a follow-up colonoscopy. Health center staff and clinicians should also be prepared to coordinate access to any treatment needed as a result of colonoscopy findings.**
Develop a system to get both normal and positive FOBT results to both the patient and their primary care physician.

Patients with normal FOBT results should receive the message that this is good news and that they should repeat the test in a year. Their primary care clinicians should also receive these results.

Patients with positive FOBT results should be called and told that they must have a colonoscopy to check for polyps or cancer. Primary care clinicians should also be alerted of all positive FOBT results so they can provide patients with an appointment or referral for a diagnostic colonoscopy.

**Keep a log of patients with positive test results, and check it periodically to verify that everyone on the list has gotten needed follow-up.**

**Be familiar with treatment resources in your community to determine a path to treatment in the rare cases where cancer or other major problems are found through screening and follow-up exams.**

## 5. Implement Your Program: Final Preparations

**Gather your supplies well in advance.**
Order flu vaccine and FOBT kits with return envelopes and/or stamps.

Written patient education materials, posters, and algorithms for your team are available for duplication in this implementation guide or downloadable from FluFOBT.org. Identify materials suitable for your patient population (language, reading level) in the weeks before beginning your FluFOBT program. If you have specific needs in this area, talk with your local American Cancer Society representative for assistance.

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**Two Weeks before FluFOBT Activities Start**
Re-check to be sure you have all your supplies.

Do a walkthrough with your FluFOBT team.

Consider doing a role play with your FluFOBT team, checking your workflow and procedures for providing flu shots, colorectal cancer screening information, and FOBT kits.

**First Day of Your FluFOBT Program**
Whatever happens on the first day, don't give up – FluFOBT programs get easier with experience.

**FluFOBT Checklist** (See Appendix F)

**Congratulate yourselves for getting to this point!**

American Cancer Society
FluFOBT Program Implementation Guide for Primary Care Practices

Health Care Solutions
From the American Cancer Society

# Staff Training for Your FluFOBT Program

Setting up a FluFOBT program requires training for the staff who will be interacting directly with your patients. The training that you provide will depend on the way you organize your program and the type of staff who are involved.

For example, if your health center is already experienced in providing FOBT kits to patients without a doctor's order, your team may not need very much training at all. However, if your team has never provided FOBT kits in the past, more training will be needed.

## The Five Key Elements to Include in Your Training(s):

### 1. Information about the importance of both flu shots and colorectal cancer screening, including the need for both to be repeated annually

Your staff should know a few facts about flu shots and colorectal cancer screening:

**Facts about flu and flu shots:**

- Flu is often mild, but can be a very serious illness.
- The CDC estimates that between 3,000 and 49,000 Americans die of complications from the flu each year.
- Flu shots are one of the best tools to prevent people from getting the flu.
- Flu shots are safe when administered as directed.
- Flu shots do not cause the flu.
- Flu shots are recommended for everyone over 6 months of age

*More information about flu and flu shots can be found on the CDC's seasonal flu website at cdc.gov/flu/index.htm.*

American Cancer Society
# FluFOBT Program Implementation Guide for Primary Care Practices

**Health Care Solutions**
From the American Cancer Society

**Facts about colorectal cancer and screening:**

- Colorectal cancer is the third leading cause of cancer death among men and women in the United States.
- More than 50,000 Americans die of colorectal cancer each year.
- Early detection and treatment can save lives.
- There are more than one million colorectal cancer survivors in the United States.
- Colorectal cancer screening is recommended for people between 50 and 75 years of age.

*More information about colorectal cancer and colorectal cancer screening can be found on the American Cancer Society website at cancer.org/colonmd.*

## 2. Information about how to organize your workflow efficiently

- In most clinical settings, it is best to offer FOBT before the administration of flu shots.
- It is also important to give consideration to how your space is organized so that it will be comfortable for patients and staff.
- If you have a busy, high-volume setting, you will want to have someone dedicated to managing the flu shot line to keep things running smoothly.
- You may also want to set up a separate station for FOBT kits several feet in front of the station where flu shots are being offered.
- If you are providing the FluFOBT program during primary care visits, or in a lower-volume setting with limited space, you may want to provide FOBT kits and flu shots together at the same clinic station.
- Make sure to select all of your patient education materials in advance, and have your work stations well stocked with FOBT kits and flu shots so that your team is well prepared.

American Cancer Society
# FluFOBT Program Implementation Guide for Primary Care Practices

Health Care Solutions
From the American Cancer Society

### 3. Assess eligibility for flu shots and FOBT without waiting for a doctor's order.

The CDC has developed detailed free training programs for health professionals and clinic staff who provide flu shots. These can be accessed at cdc.gov/flu/index.htm.

Patients are eligible for colorectal cancer screening with FOBT if they are between 50 and 75 years of age and also have had:

- ✓ No FIT or FOBT in the past year
- ✓ No colonoscopy in the past 10 years
- ✓ No personal history of Crohn's disease or ulcerative colitis*
- ✓ No personal or family history of colorectal cancer or adenomatous polyps*

** Patients with these risk factors and those over 75 years of age should be referred to a clinician to discuss colorectal screening.*

All patients with a positive FOBT should be referred for colonoscopy to check for polyps or cancer.

Eligibility for FOBT may be determined by reviewing clinic charts or your electronic health record.

- One time-saving approach for clinics with electronic health records is to print out a list of patients who are due for FOBT at the beginning of the flu shot season, and use it as a quick reference to select appropriate patients for FOBT as they come in for their flu shots.
- When clinic charts or electronic health records are not available, the clinic staff can ask the patient about prior FOBT and colonoscopy procedures.
- As long as the patient is reasonably certain that they have not completed a recent FOBT kit and that they have not had a colonoscopy in the past 10 years, it is reasonable to offer an FOBT kit with their flu shot.

### 4. Talking to patients about FOBT and how to complete the test

Colorectal cancer screening is a serious topic, but patients are usually receptive to hearing about it, especially when the conversation is kept simple and light. What you say to patients will depend on how your FluFOBT program is set up and what type of kit you provide to patients.

- Effective points to make to patients may include phrases like this:
  - We have something extra to offer you today!
  - It looks like you are due for a home colon test.
  - Colon cancer testing can save lives.

American Cancer Society
FluFOBT Program Implementation Guide for Primary Care Practices

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From the American Cancer Society

- Just like the flu shot, all our doctors and nurses recommend home colon tests.
- It's very easy and you can do it in the privacy of your home and mail it in.
- We'll make sure the results get to your doctor.

- Patients who accept the kit should be given additional written material and instructions.
- If the patient is unfamiliar with FOBT, it can be useful to take a moment to show them the kit and offer simple instructions with a visual aid or a brief instructional video.

### 5. Information about how to record your work and provide follow-up of FOBT kits provided to patients

For tracking purposes, you will want to keep a record of which patients were given FOBT (see Appendix H).

- This information can be recorded on a log sheet where flu shots are also recorded.
- This list can be useful to determine test return rates and to provide reminders to patients who have not yet returned their kits.
- The log sheet can also be used to gather information to track and arrange follow-up of positive test results.

## Summary

Although often a preventable disease, colorectal cancer (CRC) is the third leading cause of cancer death among men and women in the United States.[5] In addition, while unpredictable, flu-associated deaths in the US range from 3,000 to 49,000 people per year.[5] Screening for CRC and vaccination for flu both help reduce the incidence of these conditions. Research has demonstrated that a FluFOBT program is an efficient and effective way to increase colorectal cancer screening, which can improve screening rates in a variety of settings.[1,2,4] FluFOBT programs reach many patients who otherwise may not have an opportunity to receive screening.

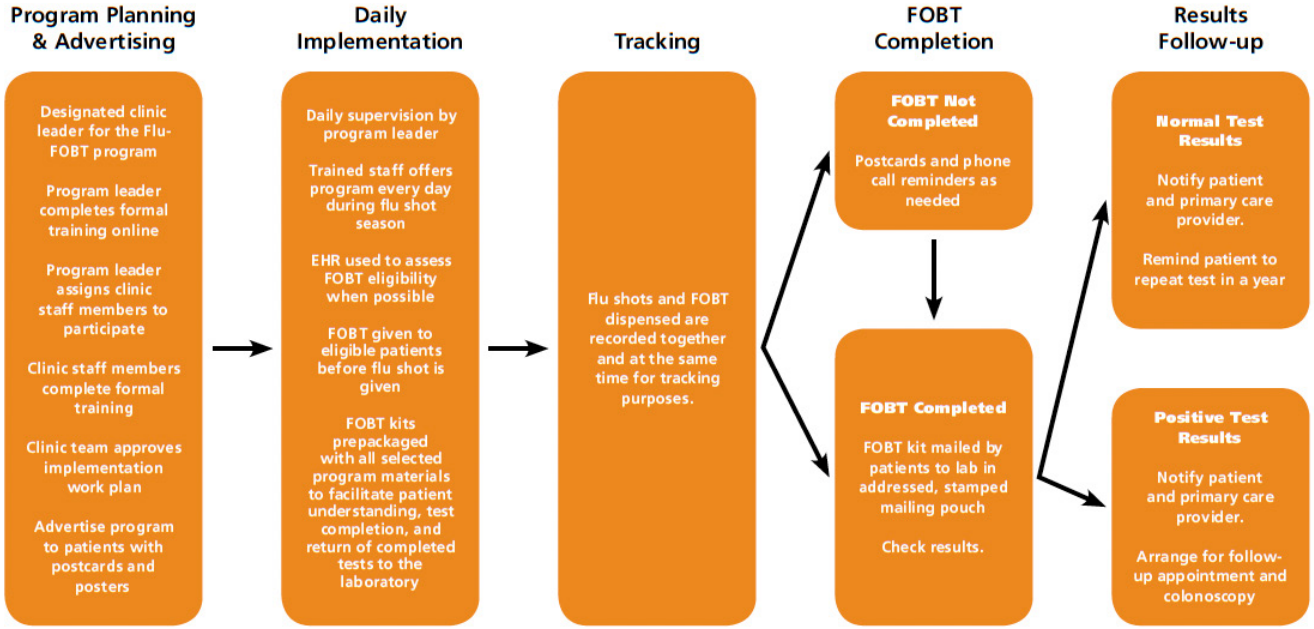
This implementation guide will assist your health center in setting up and implementing your FluFOBT program easily and successfully. If you have any questions or concerns about the program, please refer to cancer.org/flufobt or contact your local American Cancer Society representative.

# Appendix A:
## FluFOBT Components and Logic Model

**GOAL:** Increase colorectal cancer screening rates by offering home FOBT to eligible patients during annual flu shot activities.

**CORE FUNCTIONAL COMPONENT:** Standing orders to allow non-physician clinic staff to offer flu shots and FOBT together to any clinic patient or health care client 50 to 75 years of age who is seen during flu shot season.

**TARGET CLINICAL SETTINGS AND POPULATIONS:** Community health centers, pharmacies, managed care organizations, and other health care settings where flu shots are provided and where FOBT is offered for average risk colorectal cancer screening




### Sample Program Implementation Materials

- Mailed FluFOBT program announcements
- Clinic posters to advertise FluFOBT program
- Algorithm for FluFOBT program patient flow
- Algorithm to use EHR to assess FOBT eligibility
- Script to introduce/explain FOBT with flu shots to patients
- Visual aids to use when offering FOBT to patients
- Multilingual materials to explain why FOBT is important
- Multilingual FOBT completion instructions
- Multilingual video instructions
- Preaddressed FOBT mailing pouches
- Prestamped FOBT mailing pouches
- FluFOBT log sheet to record flu shots and FOBT dispensed

# Appendix B:
## Colorectal Cancer Screening Recommendations for People at Increased or High Risk

Individuals at increased or high risk of colorectal cancer should begin colorectal cancer screening before 50 years of age or be screened more often. The following conditions make the risk higher than average:

- A personal history of colorectal cancer or adenomatous polyps
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- A strong family history of colorectal cancer or polyps
- A known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or hereditary non-polyposis colon cancer (HNPCC)

The table below suggests screening guidelines for those with *increased or high risk* of colorectal cancer based on specific risk factors. Some people may have more than one risk factor.

**American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in People at Increased Risk or at High Risk**

**INCREASED RISK – Patients With a History of Polyps on Prior Colonoscopy**

| Risk Category | Age to Begin | Recommended Test(s) | Comment |
|---|---|---|---|
| People with small rectal hyperplastic polyps | Same as those at average risk | Colonoscopy, or other screening options at same intervals as for those at average risk | Those with hyperplastic polyposis syndrome are at increased risk for adenomatous polyps and cancer and should have more intensive follow-up. |
| People with 1 or 2 small (less than 1 cm) tubular adenomas with low-grade dysplasia | 5 to 10 years after the polyps are removed | Colonoscopy | Time between tests should be based on other factors such as prior colonoscopy findings, family history, and patient and doctor preferences. |
| People with 3 to 10 adenomas, or a large (1 cm +) adenoma, or any adenomas with high-grade dysplasia or villous features | 3 years after the polyps are removed | Colonoscopy | Adenomas must have been completely removed. If colonoscopy is normal or shows only 1 or 2 small tubular adenomas with low-grade dysplasia, future colonoscopies can be done every 5 years. |
| People with more than 10 adenomas on a single exam | Within 3 years after the polyps are removed | Colonoscopy | Doctor should consider possibility of genetic syndrome (such as FAP or HNPCC). |
| People with sessile adenomas that are removed in pieces | 2 to 6 months after adenoma removal | Colonoscopy | If entire adenoma has been removed, further testing should be based on doctor's judgment. |

## American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in People at Increased Risk or at High Risk – Continued

### INCREASED RISK – Patients With Colorectal Cancer

| Risk Category | Age to Begin | Recommended Test(s) | Comment |
|---|---|---|---|
| People diagnosed with colon or rectal cancer | At time of colorectal surgery, or can be 3 to 6 months later if person doesn't have cancer spread that can't be removed | Colonoscopy to view entire colon and remove all polyps | If the tumor presses on the colon/rectum and prevents colonoscopy, CT colonoscopy (with IV contrast) or DCBE may be done to look at the rest of the colon. |
| People who have had colon or rectal cancer removed by surgery | Within 1 year after cancer resection (or 1 year after colonoscopy to make sure the rest of the colon/rectum was clear) | Colonoscopy | If normal, repeat exam in 3 years. If normal then, repeat exam every 5 years. Time between tests may be shorter if polyps are found or there is reason to suspect HNPCC. After low anterior resection for rectal cancer, exams of the rectum may be done every 3 to 6 months for the first 2 to 3 years to look for signs of recurrence. |
| Colorectal cancer or adenomatous polyps in any first-degree relative before age 60, or in 2 or more first-degree relatives at any age (if not a hereditary syndrome) | Age 40, or 10 years before the youngest case in the immediate family, whichever is earlier | Colonoscopy | Every 5 years |
| Colorectal cancer or adenomatous polyps in any first-degree relative age 60 or older, or in at least 2 second-degree relatives at any age | Age 40 | Same options as for those at average risk. | Same intervals as for those at average risk. |

### HIGH RISK

| Risk Category | Age to Begin | Recommended Test(s) | Comment |
|---|---|---|---|
| Familial adenomatous polyposis (FAP) diagnosed by genetic testing, or suspected FAP without genetic testing | Age 10 to 12 | Yearly flexible sigmoidoscopy to look for signs of FAP; counseling to consider genetic testing if it hasn't been done | If genetic test is positive, removal of colon (colectomy) should be considered. |
| Hereditary non-polyposis colon cancer (HNPCC), or at increased risk of HNPCC based on family history without genetic testing | Age 20 to 25 years, or 10 years before the youngest case in the immediate family | Colonoscopy every 1 to 2 years; counseling to consider genetic testing if it hasn't been done | Genetic testing should be offered to first-degree relatives of people found to have HNPCC mutations by genetic tests. It should also be offered if 1 of the first 3 of the modified Bethesda criteria is met.[1] |
| Inflammatory bowel disease:<br>- Chronic ulcerative colitis<br>- Crohn's disease | Cancer risk begins to be significant 8 years after the onset of pancolitis (involvement of entire large intestine), or 12-15 years after the onset of left-sided colitis. | Colonoscopy every 1 to 2 years with biopsies for dysplasia | These people are best referred to a center with experience in the surveillance and management of inflammatory bowel disease. |

# Appendix C:

## Clinician's Reference: Fecal Occult Blood Testing (FOBT) for Colorectal Cancer Screening

### CLINICIAN'S REFERENCE: FECAL OCCULT BLOOD TESTING (FOBT) FOR COLORECTAL CANCER SCREENING

**Guidelines from the American Cancer Society, the US Preventive Services Task Force, and others recommend high-sensitivity fecal occult blood tests (FOBT) as one option for colorectal cancer screening. This document provides state-of-the-science information about guaiac-based FOBT and fecal immunochemical tests (FIT).**

- Colorectal cancer screening with FOBT has been shown to decrease both incidence and mortality in randomized controlled trials.
- High-sensitivity FOBT detects colorectal cancer at relatively high rates.
- Modeling studies suggest that the years of life saved through a high-quality FOBT screening program are essentially the same as with a high-quality colonoscopy-based screening program.
- Access to colonoscopy and other invasive tests may be limited or non-existent for many patients. In addition, some adults prefer less invasive tests.

**All of these elements make FOBT a reasonable choice for patients.**

**Recent advances in stool blood screening include the emergence of new tests and improved understanding of the impact of quality factors on testing outcomes.**

**Two main types of FOBT are available – guaiac-based FOBT and FIT.**

**Guaiac-based FOBTs** are the most common form of stool tests used in the US. Modern high-sensitivity forms of the guaiac-based test (such as Hemoccult Sensa) have much higher cancer and adenoma detection rates* than older tests (Hemoccult II and others).

| Guaiac-based FOBT version | Sensitivity for cancer | Sensitivity for adenomas |
|---|---|---|
| Hemoccult Sensa (high-sensitivity) | 50% – 79% | 21% – 35% |
| Hemoccult II | 13% – 50% | 8 % – 20% |

**These differences are so significant that screening guidelines now specify that only high-sensitivity forms of guaiac-based tests (like Hemoccult Sensa) should be used for colorectal cancer screening. Hemoccult II and similar older guaiac-based tests should no longer be used for colorectal cancer screening.**

**FITs** also look for hidden blood in the stool, but these tests are specific for human blood and guaiac-based tests are not. There are many brands of FIT sold in the US, and there is no consensus that one brand is superior to another. There is evidence that patient adherence with FIT may be higher than with guaiac FOBT; this may be a result of preparation needed by patients (no dietary and medication restrictions, only 1 or 2 specimens required with some brands).

| FIT and guaiac-based FOBT | Sensitivity for cancer | Sensitivity for adenomas |
|---|---|---|
| Immunochemical tests (FIT) | 55% – 100% | 15% – 44% |
| High-sensitivity guaiac-based FOBT (Hemoccult Sensa) | 50% – 79% | 21% – 35% |

**When done correctly FIT and high-sensitivity guaiac-based FOBT have similar performance*; both are significantly better than Hemoccult II and similar older tests.**

*Sensitivities cited are based on review of studies that used colonoscopy as the reference standard to determine FOBT performance characteristics.

National Colorectal Cancer Roundtable

American Cancer Society

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## Clinician's Reference: Fecal Occult Blood Testing (FOBT) for Colorectal Cancer Screening

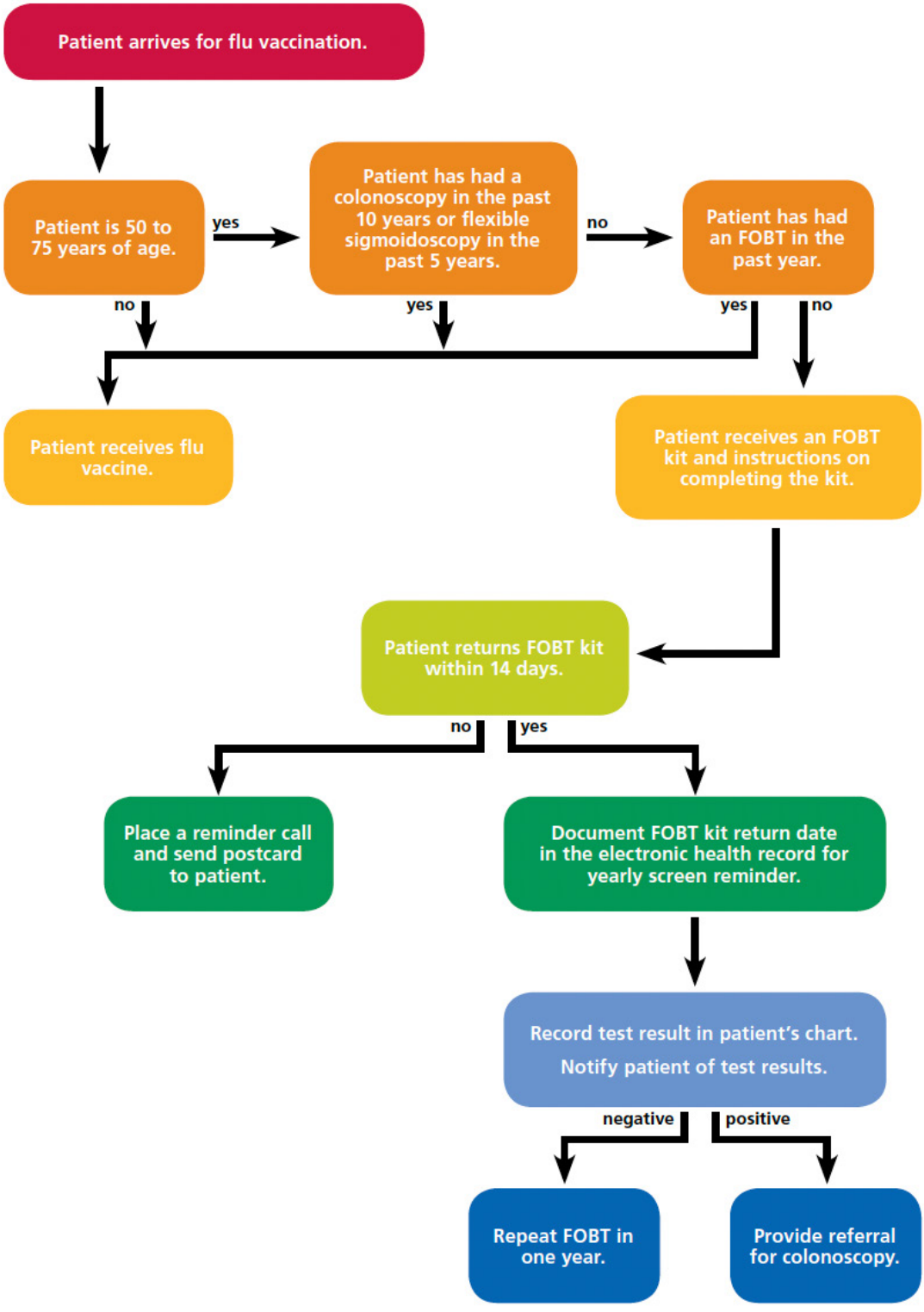
**The American Cancer Society, the US Preventive Services Task Force, and other organizations endorse the use of either a high-sensitivity guaiac-based fecal occult blood test (FOBT) or a fecal immunochemical test (FIT) for screening, within the context of a high-quality stool-based screening.**

**Characteristics of high-quality stool-based screening programs**

| *High-quality programs* | *Rationale* |
|---|---|
| Use only high-sensitivity guaiac-based FOBTs (such as Hemoccult Sensa) or fecal immunochemical tests (FIT). | Sensitivity for cancer is 2-3 times higher with FIT or high-sensitivity guaiac tests when compared to older stool guaiac-based tests (such as Hemoccult II) in most studies. |
| Eliminate the use of Hemoccult II and other older forms of guaiac-based FOBT. | Sensitivity for cancer is less than 25% in many studies of Hemoccult II (compared to sensitivity of >50% for FIT and high-sensitivity guaiac-based tests) |
| Never use in-office FOBT at the time of digital rectal exam as a screening test for colorectal cancer. | Studies have shown that a guaiac-based FOBT obtained on a single stool sample obtained at the time of in-office digital rectal exam may miss up to 95% of cancers and significant adenomas. There is no evidence that this would be an appropriate method for collection of stool for FIT either. |
| Perform tests only on stool specimens collected by patients at their home; the number of specimens to be collected and the collection process should follow manufacturers' recommendations. | Studies that demonstrated decreases in incidence and mortality with FOBT screening utilized home collection and analysis of specimens based on manufacturers' instructions. |
| Repeat stool tests annually. | One-time FIT or high-sensitivity guaiac tests may miss up to 50% of cancers (and a higher proportion of adenomas). Annual testing significantly improves lesion detection over time. |
| Follow-up all patients who have a positive stool test with colonoscopy. | Stool-based screening results in decreased incidence and mortality only when screen-detected abnormalities are assessed and managed appropriately. |

**For additional information, please visit nccrt.org/about/provider-education/crc-clinician-guide/ and cancer.org/colonmd.**

# Appendix D:
## FluFOBT Flow Chart

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# Appendix E:
## FOBT and FIT Brands

**The American Cancer Society and the National Colorectal Cancer Roundtable do not endorse any FIT or FOBT brand or product.** However, we do encourage the use of high-sensitivity tests to detect blood in the stool, per consensus guidelines. There are a number of FOBT and FIT brands available. For your convenience, we are listing websites from a few brands that are widely used in the United States. All of the brands listed are effective, but they differ somewhat in how they must be handled and processed. The websites listed all include information for health professionals and instructions for patients. For specific questions about individual tests, we recommend that you contact the manufacturers directly.

*Inclusion on this list does not imply endorsement by the American Cancer Society.*

- **Hemoccult Sensa (Beckman Coulter):** This is a high-sensitivity guaiac-based FOBT kit that requires samples from three consecutive bowel movements collected after dietary and medication restrictions. Each stool specimen is collected by using a collection stick to take samples from two different areas of stool from each bowel movement. The stool should be collected before it comes into contact with the toilet water. It is manually developed either in your clinic or in your clinic laboratory.
  - https://www.beckmancoulter.com/wsrportal/wsrportal.portal?_nfpb=true&_windowLabel=UCM_RENDERER&_urlType=render&wlpUCM_RENDERER_path=%2Fwsr%2Fdiagnostics%2Fclinical-products%2Frapid-diagnostics%2Fhemoccult-sensa%2Findex.htm
- **Hemoccult ICT (Beckman Coulter):** This is an FIT kit that usually requires two stool samples and does not require any dietary or medication restrictions. Each stool specimen is collected by using a collection stick to take samples from two different areas of stool from each bowel movement. The stool should be collected before it comes into contact with the toilet water. It is manually developed either in your clinic or clinic laboratory.
  - https://www.beckmancoulter.com/wsrportal/wsrportal/wsr/diagnostics/clinical-products/rapid-diagnostics/hemoccult-ict/index.htm?i=395067#2/10//0/25/1/0/
- **InSure FIT (Quest Laboratories):** This test requires two stool samples and does not require any dietary or medication restrictions. It uses a collection method that involves the use of two long brushes to simplify stool collection. The brush is used to collect a sample of stool and toilet water, which is then placed on a collection card. The InSure test kits come in versions that can be sent to a commercial laboratory for automated development or that that can be developed on site by in your clinic or clinic laboratory.
  - http://www.insuretest.com/index.php
- **OC FIT-Check (Polymedco):** This test can be provided as a one- or two-sample kit. The collection method involves poking the stool with a probe and placing the collection probe into a small tube, which is mailed into the laboratory. The stool is probed before it comes into contact with the toilet water. The OC FIT-Check test kits come in versions that can be sent to a hospital laboratory for automated development or that can be developed on site by in your clinic or clinic laboratory.
  - http://www.polymedco.com/

# Appendix F:
## Checklist for Running a FluFOBT Program

### Assemble your team and involve everyone in the planning process.

Designate a champion/coordinator.

Select team members.

- Clinicians
- Medical assistants
- Nurses
- Health workers who can be trained to provide flu shots and FOBT kits

Plan specific roles and tasks for each member of the team.

### Plan and implement your program.

Staff Training

- Educate staff on facts regarding the flu shots and colorectal cancer screening.
- Help them understand that flu shots and FOBT are both needed annually so they understand that this is a logical connection.
- Help familiarize them with the procedure of completing the FOBT kit that they will distribute to patients.
- Make sure they are comfortable with explaining the procedure of completing the FOBT kit to patients.
- Organize and practice the workflow until it runs smoothly.
- Help familiarize staff with eligibility and tracking practices.

Patient Flow

- Decide which staff will work with flu shot only-patients and FluFOBT patients.
- Determine how patients will be guided to the flu shot-only versus the FluFOBT areas.
- Provide the FOBT kits before providing flu shots.

Assessing Eligibility

- Have eligibility algorithm (provided earlier in this guide) posted.
- Develop a system for easy access to patient records/electronic health record.
- Consider offering FOBT if it seems possible that the patient may not have received screening in the recommended intervals.

### Designate dates, times, and locations.

Advertise, advertise, advertise. It will increase acceptance if patients know ahead of time that both a flu shot and a colorectal cancer screening test will be offered this year.

### Develop systems to support tracking and follow-up.

Develop log sheets.

Develop tracking sheets for positive and negative FOBT results

- Enter positive or negative result.
- Notify patient and doctor whether positive or negative.
- If negative, remind them to come in again next year.
- If positive, help make an appointment or referral to colonoscopy.
- Track, encourage, and assist colonoscopy completion.

### Finish preparations for your FluFOBT program.

- Gather an ample supply of flu vaccine and FOBT kits with return envelopes/stamps.
- Gather ample patient education materials/directions for FOBT.

### Don't forget REMINDER CALLS and/or postcards to patients to return their FOBT kits if they have not done so within two weeks.

# Appendix G:
## Action Plan Guideline (Sample)

### Overview Action Plan Activities Checklist for FluFOBT Program Activities

*(See Checklist for Running a FluFOBT Program, Appendix F, page 27.)*

| Action Item | Staff Responsible | Date to Be Completed | Notes | Complete |
|---|---|---|---|---|
| Identify clinic staff lead. | | | | |
| Identify clinic support staff. | | | | |
| Identify staff who will provide patient information, assess patient project eligibility, and distribute FOBT/FIT kits. | | | | |
| Identify staff responsible for tracking kit returns, as well as processing and reporting results. | | | | |
| Identify staff responsible for a reminder system for kits that are not returned (calls, postcards). | | | | |
| Plan for and conduct staff training (dates and impact on schedules). | | | | |
| Purchase flu vaccines. | | | | |
| Purchase FOBT/FIT kits.<br>• Identify the FOBT/FIT test brand that will be used. | | | | |
| Identify/prepare/print/order patient education materials:<br>• Prepare patient selling/talking points utilizing the materials found on FluFOBT.org.<br>• Prepare educational materials: (1) hard-copy handouts in needed languages; and (2) verbal scripts. Consider reading levels of materials.<br>• Make sure that test kit manufacturers' instructions are culturally and reading-level appropriate for your patient population, or prepare a written explanation for patients of how to complete and return the test kit and when to return the kit, in all needed languages (request assistance from Society if needed).<br>• Create or adapt existing reminder postcard in needed languages.<br>• Prepare a script for the follow-up phone call. | | | | |

| Action Item | Staff Responsible | Date to Be Completed | Notes | Complete |
|---|---|---|---|---|
| Identify/print/order promotional materials for use in the clinic setting (refer to FluFOBT.org website):<br>• Create or adapt posters/clinic materials in needed languages.<br>• Identify where materials will be posted.<br>• Decide if additional venues for FluFOBT promotion, outside of the clinic setting, are needed. | | | | |
| Prepare protocol for determining patient eligibility for this intervention:<br>• Define patient risk assessment (average risk versus high risk).<br>• Utilize patient eligibility algorithm. (Society resource) | | | | |
| Develop clinic flow plan for implementing FluFOBT:<br>• Select an FOBT/FIT kit storage area easily accessible when flu vaccinations are given.<br>• Decide if project log sheets (flu vaccination, FOBT/FIT kit distribution, and tracking form) will be kept in hard copies or through EHRs.<br>• Identify staff person(s) who will collect and document program data.<br>• Determine if alert should be placed in EHR to signify pilot participant.<br>• Assure a process is in place to close the "testing/results loop" (test order entered; patient returns completed kits to the clinic; clinic sends to lab; lab returns results to the clinic; patient is informed of results); consider patients in for flu shot only vs. other reasons who also (by the way) want a flu shot and are eligible for FOBT kit. | | | | |
| Create a process for tracking kit returns, processing and reporting results:<br>• Decide how follow-up will be documented in the EHR.<br>• Describe how patient will be informed of results.<br>• For patients with a positive result, develop a follow-up plan for referral to diagnostic follow-up (colonoscopy). | | | | |

| Action Item | Staff Responsible | Date to Be Completed | Notes | Complete |
|---|---|---|---|---|
| Create a reminder system process for patients who do not return kits:<br>• Verify patient's mailing address and phone number that are on file.<br>• Document if the patient is comfortable in having a message left on an answering machine.<br>• Consider asking patients to self-address a HIPPA-compliant fold-over postcard reminder that can be mailed to them if their kit is not returned within 2 weeks.<br>• Review log sheets weekly to assure patients are returning test kits within 2 weeks after receiving them.<br>• Call the patient if the kit is not returned after 2 weeks.<br>• If a call is not possible, send a postcard to the patient if kit is not returned within the 2-week timeframe.<br>• Identify a protocol for "lost to follow-up" when a patient does not return a kit, after multiple contacts. | | | | |
| Determine process for collecting input from frontline clinic staff and patients on what is working – and not working – with regard to program implementation and follow-up:<br>• Modify processes as needed based on staff and patient input. | | | | |
| Provide ongoing technical assistance once flu vaccination season begins:<br>• Hold a conference call or brief meeting after 1 full week of FluFOBT implementation to assess needs or any process changes.<br>• Determine how frequently the staff lead(s) would like to hold conference calls and/or have site visits or additional training. | | | | |

# Appendix H:
## FluFOBT Tracking Tools

### Telephone Script

Hello. This is **<Member Name>** calling from **<Health Center Name>.**

Our records indicate you have received an FOBT kit that has not yet been returned. Please complete your FOBT kit, and mail it back to us.

An FOBT kit screens for evidence of blood in your stool, which can be an early sign of colon cancer. Finding colon cancer early is key to saving lives.

If you would like another FOBT kit mailed to you, please press one now.

### Sample Reminder Postcard *(visit FluFOBT.org for current materials)*


**Greetings from [name of health care facility]!**

**When you came in to get your flu shot, we gave you a home colon cancer screening test kit. If you already completed it, thank you!**

**If you haven't done your home colon stool test yet, please do so and send it back to us as soon as possible.**

**Thank you very much!**

**[Insert signature of the patient's PCP or of the medical director of the clinic here]**

**[Insert Clinic Address and Logo here**

# Appendix I:
## Elements of a Successful FluFOBT Program

**Clinics should:**

- Conduct regular staff meetings about the program, particularly to make sure providers are all on board.
- Utilize the medical assistants (MAs) and nurses to the fullest extent possible for identifying eligible patients, providing education, and implementing standing orders for FOBT tests.
- Confirm the standing orders policy well in advance of the initiative. If necessary, additional training should be provided to medical assistants/nurses to ensure they feel empowered to educate patients and distribute FOBT kits. Determine how to best utilize the EHR to generate lists of eligible patients in advance.
- If implementing a flu shot clinic, ensure all participating staff have been trained on the FOBT/FIT kit and that there are sufficient staff to provide FOBT/FIT kits.
- Flu shot visits are short: it may be more efficient to have a staff member other than the nurse offer the FOBT kit and provide instructions.
- Track the FOBT kit return rate.
- Consider reminder phone calls in place of or in addition to mailed reminders if the kit is not returned within two weeks. This ensures that time is spent only on those who need a reminder.
- Ensure colonoscopy follow-up of all positive FOBT results.

# Appendix J:
## Advertising

Sample Patient Education Poster
*(visit FluFOBT.Org and cancer.org/flufobt for current materials)*

# References


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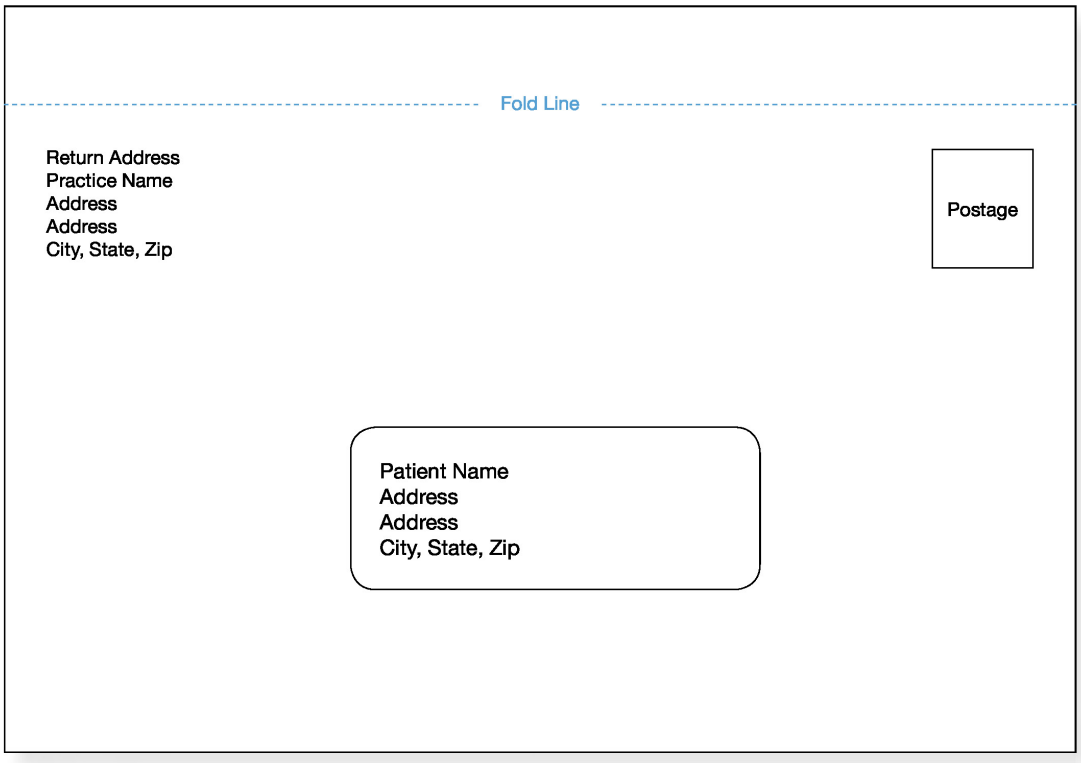
# APPENDIX C-8

## INSTITUTE PATIENT REMINDERS (LETTERS, POSTCARDS, AND TELEPHONE SCRIPTS)

- HIPAA-compliant letters and telephone messages can be modified for your specific clinic's needs. There should be three scripts:
  1. A reminder to come in for testing;
  2. A reminder to send in FOBT/FIT cards;
  3. A notification of negative CRC screening results

## TOOL L: SAMPLE HIPAA-COMPLIANT POSTCARDS

Outside of Card



# APPENDIX C-9

## TIME FOR TEST

Inside of Card

Fold Line

Dear _____ ,

It's time for your annual colorectal cancer screening test.

For people over age 50, this simple test saves lives.

Colorectal cancer is a 100% curable cancer when found in the early stages. Having a stool test every year can help find colorectal cancer early.

Remember to have this test every year. Follow up with your doctor any time you have bleeding from your bottom more than once, bloody stools, or a change in bowel habits.

Please call _____ to see your provider and pick up your stool test kit.

Sincerely,

Your healthcare provider
Address
City, State, Zip
Office Main Phone Number

# APPENDIX C-10

## REMINDER TO RETURN TEST

Inside of Card

Fold Line

Dear _____ ,

On your last visit to your healthcare provider, _____ , you were given a test to screen for colorectal cancer.

At this time, we have not received your test back in the mail.

Colorectal cancer is a 100% curable cancer when found in the early stages. Simple tests like having a stool test every year can help find cancer early.

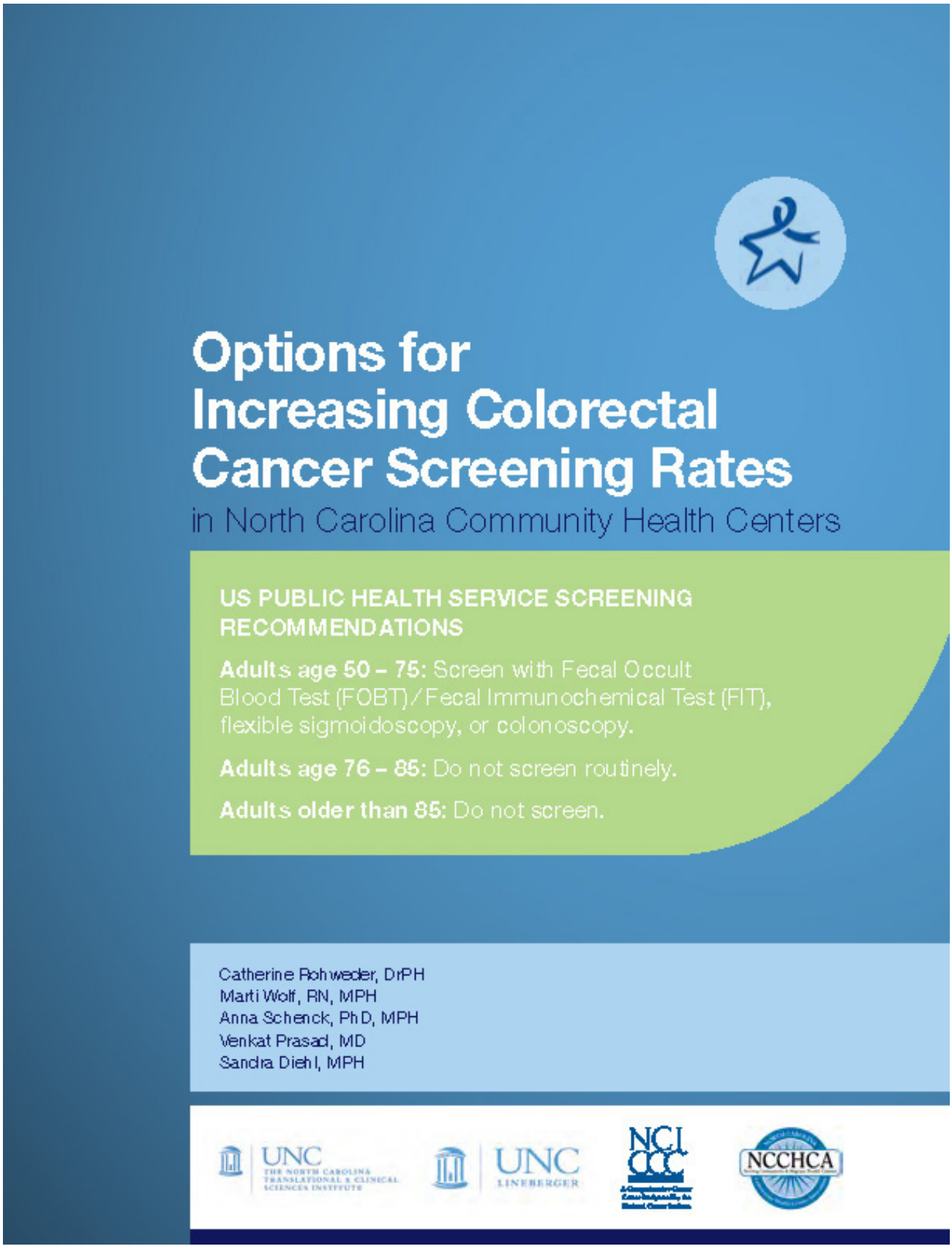
Please return your completed test kit to us as soon as possible.

If you have any questions about your test, please call _____ at _____ .

Sincerely,

Your healthcare provider
Address
City, State, Zip
Office Main Phone Number

# APPENDIX C-11



## The contents of this toolkit are adapted from the following resource:

Sarfaty, Mona. How to Increase Colorectal Cancer Screening Rates in Practice: A Primary Care Clinician's Evidence-Based Toolbox and Guide 2008. Eds. Karen Peterson and Richard Wender. Atlanta: The American Cancer Society, the National Colorectal Cancer Roundtable and Thomas Jefferson University 2006, Revised 2008.

**http://www.cancer.org/acs/groups/content/documents/document/acspc-024588.pdf**

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Rohweder C, Wolf M, Schenck A, Prasad V, Diehl S. Options for Increasing Colorectal Cancer Screening Rates in North Carolina Community Health Centers. Chapel Hill, NC: UNC Lineberger Comprehensive Cancer Center, January 2011.

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# Introduction

**In North Carolina in 2007, there were 4,100 new cases of colon/rectal cancer and 1,590 deaths.**[1, 2]

## WHY SCREEN FOR COLORECTAL CANCER?

- Colorectal cancer is the nation's second leading cause of mortality for cancers affecting both sexes.[3]
- Screening prevents colorectal cancer and reduces mortality.[4-6]
- The long period of transformation from adenomatous polyp to malignancy (5-15 years) gives clinicians a window of opportunity to help their patients prevent colorectal cancer.
- Screening for colorectal cancer is less costly than cancer treatment.
- Colorectal cancer screening rates will be a required element in the Universal Data System.

**Community Health Centers should recommend and offer colorectal cancer screening because their goal is to provide preventive care!**

## HOW CAN THIS GUIDE HELP IMPROVE SCREENING RATES?

- This guide provides tools for delivering colorectal cancer screening recommendations.
- This guide provides guidelines for administrators of CHCs to support screening practices.
- Incorporating these systems changes can help achieve the goal of increasing the national colorectal cancer screening rate from 47% in 2005 to 75% by 2015, as established by the American Cancer Society.[7]

This guide presents three Essential Elements for improving screening rates:

1. Support Screening in Your Clinic Environment
2. Make Your Recommendation
3. Use An Office Reminder System

A brief overview of each Essential Element follows with concrete strategies and tools to facilitate their adoption in North Carolina Community Health Center settings.

# Essential Element #1:
## Support Screening in Your Clinic Environment

### CONDUCT A CLINIC ASSESSMENT

A self-assessment survey such as the one in Tool A can be used to identify necessary resources and mechanisms that are already in place in the practice site and where there might be gaps. This exercise will make it easier to determine which tools in this guide should be implemented.

### TOOL A: SELF-ASSESSMENT SURVEY

| Yes | No | Medical Records |
|---|---|---|
| ☐ | ☐ | 1. Do patient charts indicate current CRC screening status? |
| ☐ | ☐ | 2. Do patient charts indicate method and date of last screening? |
| ☐ | ☐ | 3. Do patient charts indicate high-risk status due to family history? |
| ☐ | ☐ | 4. Does your medical record system have the capacity to provide a list of patients ages 50-75 who are not up to date on their screening? |

| Yes | No | Staff Roles |
|---|---|---|
| ☐ | ☐ | 5. Is there a designated staff member who *provides information* to patients about CRC screening? |
| ☐ | ☐ | 6. Is there a designated staff member who *recommends* CRC screening to patients? |
| ☐ | ☐ | 7. Is there a designated staff member who *follows up* with patients who agree to be tested? |

| Yes | No | Resources |
|---|---|---|
| ☐ | ☐ | 8. Are the PHS Clinical Practice Guidelines for CRC screening easily available for clinician reference? |
| ☐ | ☐ | 9. Does your clinic have free materials available to patients on CRC screening? |

| Yes | No | Follow-Up |
|---|---|---|
| ☐ | ☐ | 10. Does your clinic have a process for following up with patients who have not returned their FOBT/FIT kit cards? |
| ☐ | ☐ | 11. Does your clinic have a process for receiving and documenting test results for patients who choose flexible sigmoidoscopy or colonoscopy? |

| Yes | No | Billing |
|---|---|---|
| ☐ | ☐ | 12. Has your clinic's financial administrator identified health plan coverage, diagnosis, and billing codes for CRC screening? |

## IMPLEMENT CHANGES TO PATIENT VISITS

The clinic's environment, systems, and patient-provider communication can be enhanced to promote colorectal cancer screening.

### TOOL B: RECOMMENDED PATIENT VISIT PRACTICES

#### In the waiting room and exam room:

- Place informative and attractive office posters or fliers in the waiting room to educate about clinic policy and in exam rooms to cue action.
- Offer educational materials, instructional materials, and reminder tools to suit your clinic population.

#### At lab or triage area:

- Ask patients about family history and previous screening.
- Tag chart if patients are eligible for screening.
- Give standing orders for FOBT/FIT cards to average risk patients who are not up to date with screening.

#### During the exam:

- Reinforce message for CRC screening and discuss best option for patients (FOBT/FIT, colonoscopy, flexible sigmoidoscopy).

#### At checkout:

- Schedule screening before the patients leave the office.
- Program patient reminders into the electronic medical record or have patients fill out reminder cards.

#### After the visit:

- Call patients to remind them of their colonoscopy/flexible sigmoidoscopy appointments.
- Contact patients who do not return FOBT/FIT cards or keep their colonoscopy/flexible sigmoidoscopy appointments.

## DETERMINE INDIVIDUAL RISK LEVEL

- The U.S. Preventive Services Task Force recognizes two risk levels: average and higher than average, according to personal history and family history.
- Guidelines suggest that if an individual is high-risk, screening before age 50 with a colonoscopy is reasonable.[8] Since risk changes over time, an assessment, such as the one in Tool C, should be repeated annually.[9]
- Use algorithms such as the one in Tool D to quickly determine which tests are appropriate for the patient's risk level.

## TOOL C: ANNUAL ASSESSMENT TO DETERMINE RISK

These are questions you can ask patients in order to place them in the average-risk or high-risk categories. Then, follow the algorithm in Tool D.

- Have you ever had inflammatory bowel disease (Crohn's disease, ulcerative colitis)?
- Have you ever had a colon polyp?
  - A polyp is an abnormal growth in the inner lining of the colon. These can be harmless (benign), a sign of cancer (precancerous), or diagnosed as cancer (malignant).
- Has any member of your family had colorectal cancer?
- Has any member of your family had a colon polyp?

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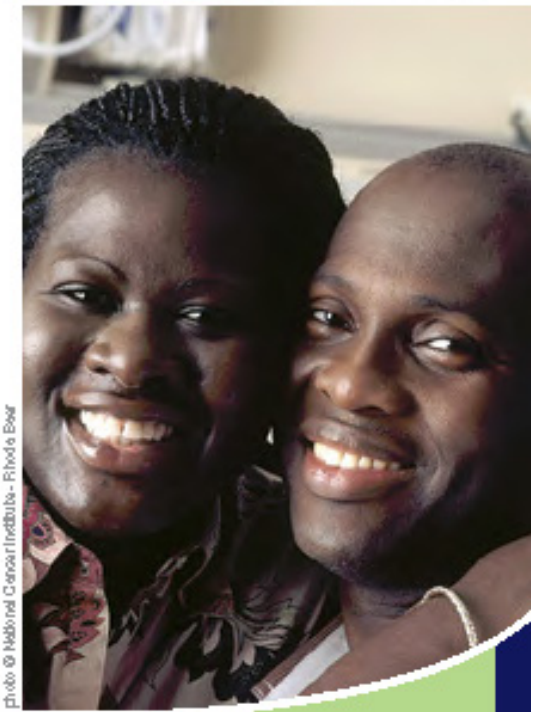

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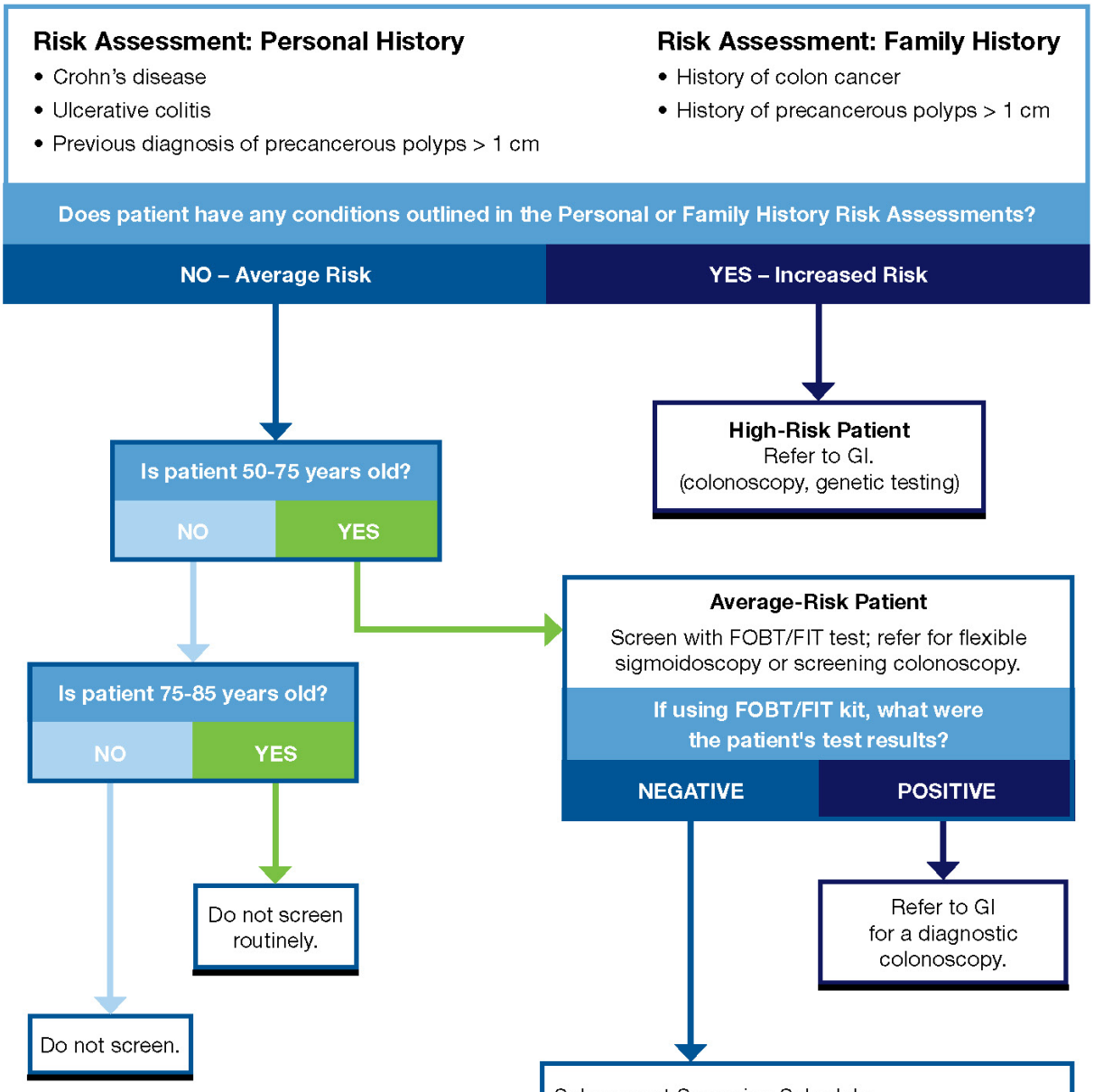
## TOOL D: SAMPLE SCREENING ALGORITHM



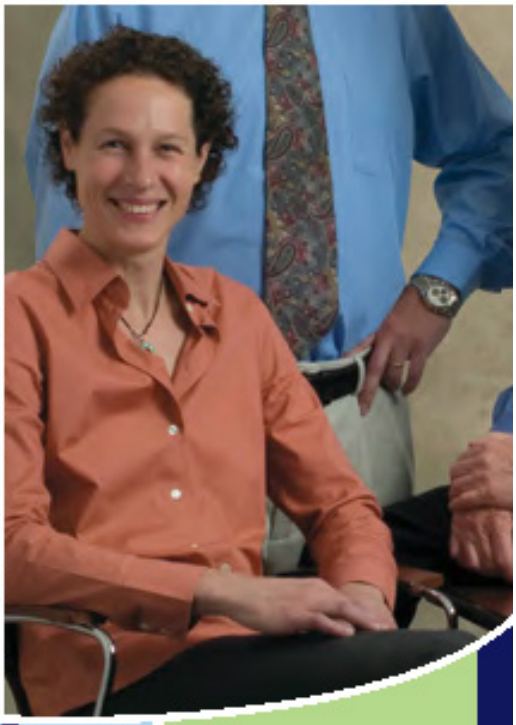

*Note: In addition to the U.S. Preventive Services Task Force's recommendations outlined above, other guidelines exist as well. See Appendix B for the American Cancer Society's recommendations or visit: www.cancer.org/Healthy/FindCancer Early/CancerScreeningGuidelines*

## IMPLEMENT UNIVERSAL RECOMMENDATION FOR FOBT/FIT

- In a 2004 study, the CDC concluded that there is sufficient capacity to screen the entire eligible population of the nation within one year using FOBT, backed up by colonoscopy for those who screen positive.[10]
- Community Health Centers are well-positioned to increase overall screening rates by recommending the FOBT/FIT kit and using standing orders to ensure that all eligible patients are screened.

## TOOL E: SAMPLE STANDING ORDER FOR FECAL OCCULT BLOOD TESTING

1. Determine that patients are 50 years of age or older and not in a high-risk category.
2. Establish that patients have not had FOBT or FIT in previous 12 months, colonoscopy in last 10 years, or sigmoidoscopy in last 5 years.
3. Offer FOBT/FIT colorectal cancer screening to patients along with routine lab work.
4. Provide patients the FOBT/FIT kit and instructions for performing and returning the test.
5. Record information in FOBT/FIT tracking log.
6. Follow up on return of FOBT/FIT kit. Ensure that provider and patients are notified of test results and that follow-up is scheduled as needed.



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## USE HIGH-SENSITIVITY FOBT OR FIT

- Traditional stool guaiac tests such as the Hemoccult IITM should be replaced with higher sensitivity tests such as the Hemoccult SENSATM or a fecal immunochemical test (FIT).[11-13]
- Although the FIT is more expensive, there may be advantages to using it, such as the elimination of dietary restrictions and fewer samples needed (for some kits).

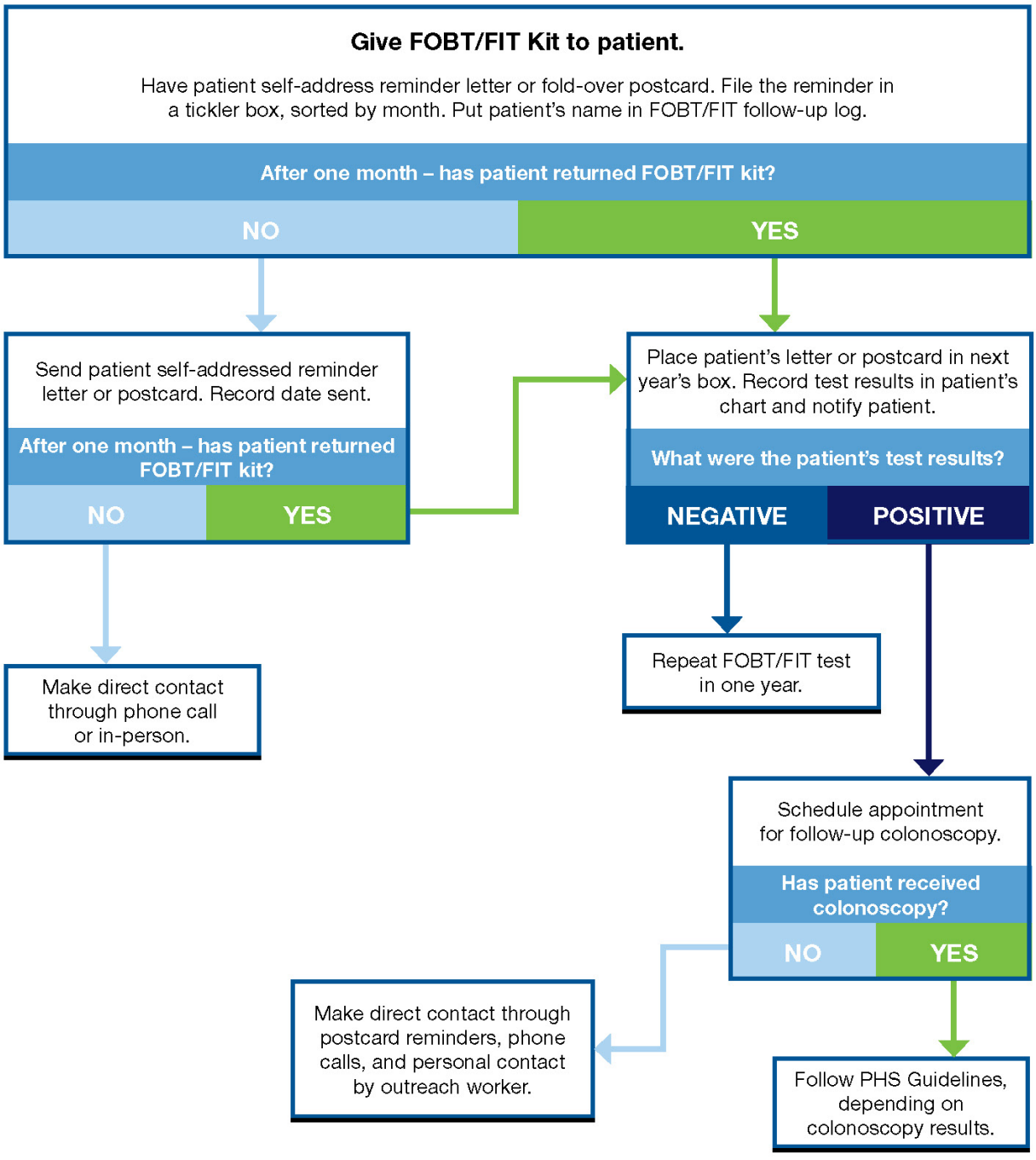
## KNOW YOUR PATIENT'S INSURANCE COVERAGE

- North Carolina state law mandates that health benefit plans provide coverage for colorectal cancer exams and laboratory tests.[14]
- Medicare reimburses for PHS-recommended screenings.
  - Medicare beneficiaries 50 years and older will be reimbursed for an annual stool test, a flexible sigmoidoscopy every 4 years (once every 10 years post colonoscopy), and a screening colonoscopy every 10 years (2 years at high risk).[15]
- Medicare beneficiaries can receive any of these screening tests without a deductible or co-pay.[16]

## *DO NOT* PERFORM DIGITAL RECTAL EXAMS

- Digital rectal exams (DRE) have not been found to be effective in detecting bleeding from colorectal polyps or cancers and should not be used to replace the at-home FOBT/FIT.[17, 18]
- Clinicians may continue to perform the exam for other purposes (such as prostate exams) but should not use the DRE as a screening method for colorectal cancer.

## TOOL F: SAMPLE FOBT/FIT POLICY IN FLOW CHART FORM



## *DO NOT* REPEAT POSITIVE FOBT/FIT

- All patients with a positive stool test for occult blood require colonoscopy follow-up.

## ARRANGE FREE OR LOW-COST COLONOSCOPIES FOR PATIENTS WITH POSITIVE FOBT/FIT

- Some CHCs have been able to arrange formal written agreements with local or regional gastroenterologists to provide affordable colonoscopies.
- Other CHC providers have informal verbal agreements with colleagues in their geographic area to perform colonoscopies for uninsured patients with a positive FOBT/FIT.
- The best argument for providing this service is that gastroenterologists will receive very few referrals on an annual basis from CHCs. In a study in High Point, NC approximately 200 people, most of whom were uninsured, were screened with a take-home stool test and only four (2%) required a follow-up colonoscopy for a positive result.[10]
- Encourage patients and physicians to request a discount from the gastroenterologists or to explore payment plan options.
- With healthcare reforms scheduled to take place in 2014, more CHC patients will have insurance to cover follow-up colonoscopies.

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# Essential Element #2:
## Make Your Recommendation

### RECOMMEND SCREENING FOR ALL ELIGIBLE PATIENTS

- One fact that has remained consistent from community to community is the influence of a physician's recommendation on the cancer screening decisions of their patients.
- Provider recommendation is the leading predictor of patient screening behavior.[20-24]
- To prevent and reduce mortality, the recommendation must include a referral for colonoscopy when other screening tests are positive.

### USE AN OPPORTUNISTIC APPROACH

- While many physicians prefer to give recommendations for cancer screening at the time of the annual checkup, this approach will not reach all the patients in the practice who need screening.
- An alternate approach is to recommend screening at all types of visits. This is generally referred to as an "opportunistic approach" or a "global approach." The opportunistic approach means recommending screening far more frequently.
- Given the many demands on a practitioner's time, an opportunistic approach will only work when office systems function automatically to get a recommendation to every appropriate patient – even if the clinician is not immediately involved.
- An opportunistic approach is not the same thing as conducting a single sample FOBT in the office as a screening test, which is ineffective.[17, 18]

photo ©National Cancer Institute - Rhoda Baer

## ASSESS PATIENT'S SCREENING PREFERENCE

A process of shared decision-making involving the clinician and patient should occur. For average and high-risk patients, the conversations could go something like this:

### TOOL G1: AVERAGE-RISK COUNSELING SCRIPT

"I would like you to be screened for colorectal cancer because it is recommended for everyone between the ages of 50 and 75. There are two ways you can get screened — you can either do a take-home test (FOBT/FIT) or we can refer you for an internal exam (either flexible sigmoidoscopy or colonoscopy).

The take-home test (FOBT/FIT) looks for blood in your stool. With this test, we can detect cancer at an early stage without the risks of a medical procedure. You'll need a colonoscopy if you have an abnormal finding on the FOBT/FIT. A colonoscopy is when the doctor looks at the inside of your intestine with a small camera.

A colonoscopy (or flexible sigmoidoscopy) allows us to find and remove growths (polyps) in your bowel. By removing these colon polyps, we can decrease your chance of developing cancer. The two main risks are accidentally puncturing your intestine (bowel perforation) and complications from pain medication (anesthesia). Both of these risks are rare.

The least expensive option for most patients is the take-home stool test. If you have Medicare, there is no cost to you for any of these tests. If your test result is positive, then our clinic will work with you to arrange for a follow-up colonoscopy. Results of the colonoscopy will help us know if there is cancer so that you can receive treatment."

### TOOL G2: HIGH-RISK COUNSELING SCRIPT

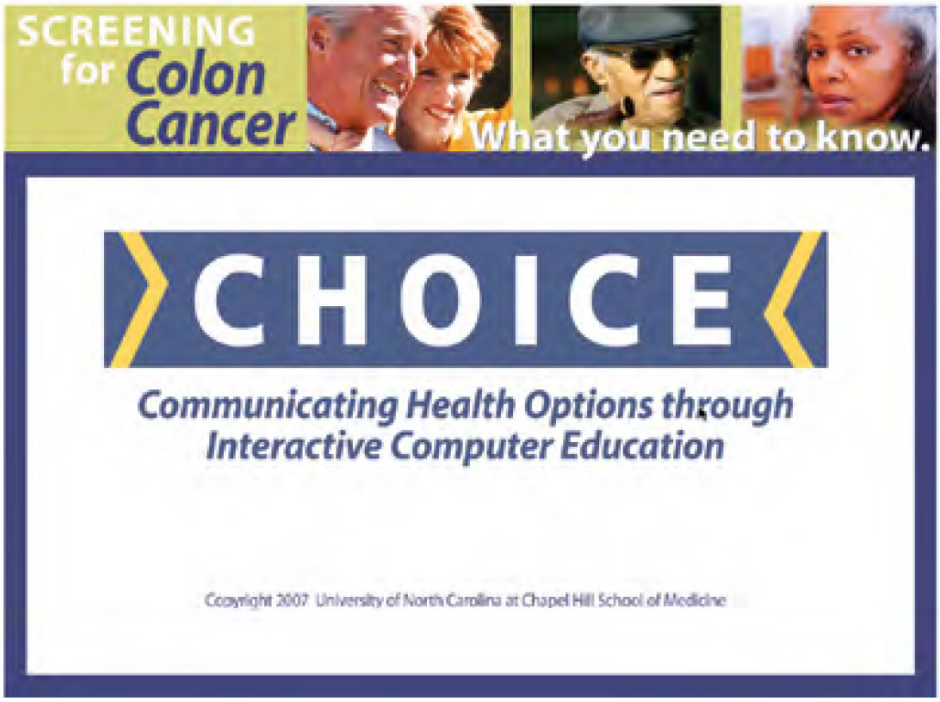
"Because you are high-risk (state the risk factors), I recommend that you have a colonoscopy. A colonoscopy is when the doctor looks at the inside of your intestine with a small camera. Results of the colonoscopy will help us figure out if you have precancerous growths or cancer, and treatment can be planned accordingly." (If uninsured or cost is an issue): "I realize this procedure costs a lot of money, but I feel this is a very important test for you to have. We'll work with the referral coordinator to get an appointment and talk about payment options."

## USE DECISION AIDS AND OTHER PATIENT MATERIALS

Decision aids help undecided patients identify screening and treatment preferences. One web-based tool, Screening for Colon Cancer: What you Need to Know, is free and can be accessed at: **http://decisionsupport.unc.edu/CHOICE6/entry.php?ac=89309**

### TOOL H: DECISION AID

This decision aid helps average-risk patients determine if they are ready for screening and if so, which type of screening they prefer. Individuals can view it at home or Community Health Centers can play it in a private alcove or waiting room. Persons who view this decision aid should not have previously been diagnosed with colorectal cancer or adenomatous polyps (**http://decisionsupport.unc.edu/CHOICE6/choice6.htm, accessed 4/29/10**).

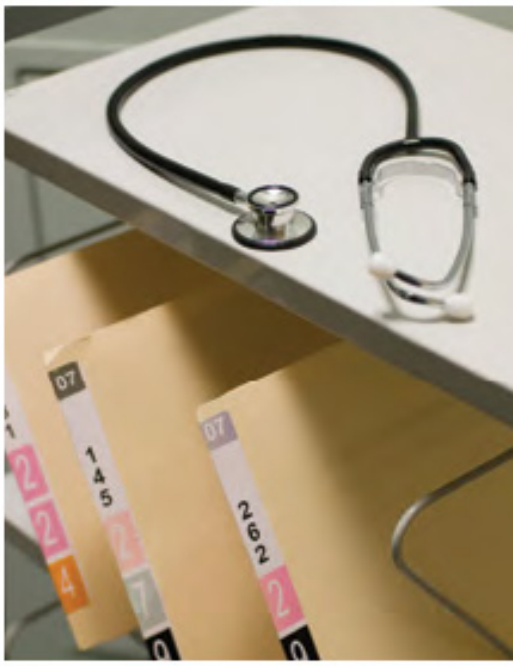


- CDC's Screen for Life program has a variety of patient materials in English and Spanish including fact sheets, brochures, posters, and print ads (**http://www.cdc.gov/cancer/colorectal/sfl/print_materials.htm**) that are free of charge.
- These publications and related materials can be ordered directly from the online ordering form of CDCs Division of Cancer Prevention and Control: **http://wwwn.cdc.gov/pubs/dcpc1.aspx**
- See Appendix C for additional patient materials and resources.


# Essential Element #3:
## Use An Office Reminder System

### CREATE ACTION CUES

- Integrated summaries and chart flags serve as visual reminders or "cues to action." All clinicians can have their clinic charts prepared with these elements, whether they are electronic or paper.
- For integrated summaries, a problem list and screening schedule on each chart should include "preventive services" or an equivalent phrase as a separate item as an ongoing cue to action. Patients who are at increased risk for colorectal cancer should have this fact listed as an item on the problem list. Age and gender-appropriate screening schedules should be easy to find on the chart.
- Electronic or paper chart flags that are HIPAA-compliant can alert office staff when screening is indicated or overdue. Since charts are usually pulled prior to the patient visit, the provider will know ahead of time if colorectal cancer screening is warranted. The same procedures will ensure follow-through for patients with a positive screening who require a complete diagnostic exam with colonoscopy.



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## TOOL I: INTEGRATED SUMMARY

**ADULT HEALTH PROBLEM LIST AND PREVENTIVE CARE FLOW SHEET: XYZ MEDICAL CENTER**

Patient Name: _____

Date of Birth: _____ Medical Record Number: _____

Primary Care Provider: _____ Height: _____

Immunizations and Date

Tdap: _____ Flu: _____ Pneumonia: _____ Shingles: _____ Hep. B: _____

Problem List

Family Medical History

Allergies and Reactions

**Prevention Discussion Topics**

Advance Directives · Oral Health · Physical Activity · Tobacco Use Cessation
Depression · Substance Abuse · Domestic Violence/Abuse

**Cancer Screening**

| Procedure / Test | Guideline | Date(s) / Result(s) |
|---|---|---|
| Mammography | (q 2 yr if 50+) | |
| Pap Smear | (q 3 yr if 21+) | |
| FOBT/FIT, flex. sig. or colonsocopy | (age 50-75)* | |

* Recommendation varies depending on family and patient history.

## TOOL J: SAMPLE CHART STICKER

**Is colon cancer screening needed?**
____Yes ____No
*Recommendation*: age ≥ 50 years or family history
Type: Colonoscopy FOBT/FIT
Other _____
Referral date: _____/_____/_____
Results: _____


http://www.nyc.gov/html/doh/downloads/pdf/csi/coloncancerkit-clin-sticker.pdf

### IMPLEMENT TICKLERS AND LOGS

- Other systems to ensure compliance include ticklers and logs. A tickler system is created when a copy of a lab order, referral, reminder, or tracking sheet is placed in a file box. When results or reports arrive, the copy is pulled from the tickler file, the patient is notified by phone or mail, the results are placed in the chart, and a visit is scheduled if appropriate. Orders with no accompanying results within 30 days require follow-up.
- The patient self-addresses a fold-over reminder that is sent if the stool cards are not returned within a specific time period.
- Another approach to improve patient adherence is to create a single log or tracking sheet of all patients who take home a FOBT/FIT kit. The log can be used to contact patients with test results, send reminders to patients who have not returned their kits, and document follow-up colonoscopies for positive stool blood tests.

## TOOL K: SAMPLE LOG

**FOBT/FIT Card Return Log: XYZ MEDICAL CENTER**

Record reminder notification in follow-up if no card returned.

| Patient Name / MR# | Date Card Given | Date Card Returned | Result + or - | Notification Date: Provider | Notification Date: Patient | Follow-Up |
|---|---|---|---|---|---|---|
| Jane Doe | 1/2/11 | 1/10/11 | - | 1/10/11 | 1/11/11 | n/a |
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## INSTITUTE PATIENT REMINDERS (LETTERS, POSTCARDS, AND TELEPHONE SCRIPTS)

- HIPAA-compliant letters and telephone messages can be modified for your specific clinic's needs. There should be three scripts:
  1. A reminder to come in for testing;
  2. A reminder to send in FOBT/FIT cards;
  3. A notification of negative CRC screening results

## TOOL L: SAMPLE HIPAA-COMPLIANT POSTCARDS

Outside of Card

Fold Line

Return Address
Practice Name
Address
Address
City, State, Zip

Postage

Patient Name
Address
Address
City, State, Zip

## TIME FOR TEST

Inside of Card

Fold Line

Dear _____ ,

It's time for your annual colorectal cancer screening test.

For people over age 50, this simple test saves lives.

Colorectal cancer is a 100% curable cancer when found in the early stages. Having a stool test every year can help find colorectal cancer early.

Remember to have this test every year. Follow up with your doctor any time you have bleeding from your bottom more than once, bloody stools, or a change in bowel habits.

Please call _____ to see your provider and pick up your stool test kit.

Sincerely,

Your healthcare provider
Address
City, State, Zip
Office Main Phone Number

## REMINDER TO RETURN TEST

Inside of Card

Fold Line

Dear _____ ,

On your last visit to your healthcare provider, _____ , you were given a test to screen for colorectal cancer.

At this time, we have not received your test back in the mail.

Colorectal cancer is a 100% curable cancer when found in the early stages. Simple tests like having a stool test every year can help find cancer early.

Please return your completed test kit to us as soon as possible.

If you have any questions about your test, please call _____ at _____ .

Sincerely,

Your healthcare provider
Address
City, State, Zip
Office Main Phone Number

## NEGATIVE RESULT

Inside of Card

Fold Line

Dear _____ ,

We are pleased to tell you that your stool test came back normal.

Colorectal cancer is a 100% curable cancer when found in the early stages. Simple tests like having a stool test every year can help find early, curable colorectal cancer.

Remember to have this test every year. Follow up with your doctor any time you have bleeding from your bottom more than once, bloody stools or a change in bowel habits.

If you have any questions about your test, please call _____ at _____ .

Sincerely,

Your healthcare provider
Address
City, State, Zip
Office Main Phone Number

## POPULATION MANAGEMENT

- For Community Health Centers that have fully implemented opportunistic screening, the next step is to proactively identify all eligible patients who are in need of screening. This can be accomplished in several ways:

  1. Generate a list from the EMR system of all patients between 50 and 75 who are not up-to-date on their screening tests, and send a reminder postcard (see Tool L).
  2. Send a birthday card to every patient who turns 50 to remind them about getting screened.
  3. Include colorectal cancer screening in recalls that are already sent out for mammograms, prostate cancer screening, and other services for patients over 50.

**THE BEST COLORECTAL CANCER SCREENING TEST IS THE ONE THAT GETS DONE!**

photo © NC Community Health Center Association

# APPENDIX A: Screening for Colorectal Cancer

## CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

This document is a summary of the 2008 recommendation of the U.S. Preventive Services Task Force (USPSTF) on screening for colorectal cancer. This summary is intended for use by primary care clinicians. Grade definitions are available on page 27.

| Population | Adults Age 50 to 75* | Adults Age 76 to 85 years* | Adults Older than 85* |
|---|---|---|---|
| Recommendation | Screen with high sensitivity fecal occult blood testing (FOBT), sigmoidoscopy, o colonoscopy. Grade: A | Do not screen routinely. Grade: C | Do not screen. Grade: D |
| | For all populations, evidence is insufficient to assess the benefits and harms of screening with computerized tomographycolonography (CTC) and fecal DNA testing.<br>**Grade: I (insufficient evidence)** | | |
| Screening Tests | High-sensitivity FOBT, sigmoidoscopy with FOBT, and colonoscopy are effective in decreasing colorectal cancer mortality.<br><br>The risks and benefits of these screening methods vary.<br><br>Colonoscopy and flexible sigmoidoscopy (to a lesser degree) entail possible serious complications. | | |
| Screening Test Intervals | **Intervals for recommended screening strategies:**<br>• Annual screening with high-sensitivity fecal occult blood testing<br>• Sigmoidoscopy every five years, with high-sensitivity fecal occult blood testing every three years<br>• Screening colonoscopy every ten years | | |

| | | |
|---|---|---|
| Balance of Harms and Benefits | The benefits of screening outweigh the potential harms for 50- to 75-year-olds. | The likelihood that detection and early intervention will yield a mortality benefit declines after age 75 because of the long average time between adenoma development and cancer diagnosis. |
| Implementation | Focus on strategies that maximize the number of individuals who get screened.<br><br>Practice shared decision making; discussions with patients should incorporate information on test quality and availability.<br><br>Individuals with a personal history of cancer or adenomatous polyps are followed by a surveillance regimen, and screening guidelines are not applicable. | |
| Relevant USPSTF Recommendations | The USPSTF recommends against the use of aspirin or nonsteroidal anti-inflammatory drugs for the primary prevention of colorectal cancer. This recommendation is available at: **http://www.preventiveservices.ahrq.gov** | |

*These recommendations do not apply to individuals with specific inherited syndromes (Lynch Syndrome or Familial Adenomatous Polyposis) or those with inflammatory bowel disease.

**Internet Citation:**
Screening for Colorectal Cancer, Topic Page. March 2009. U.S. Preventive Services Task Force. **http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm. Accessed April 2010.**

## GRADE DEFINITIONS AFTER MAY 2007

The U.S. Preventive Services Task Force (USPSTF) has updated its definitions of the grades it assigns to recommendations and now includes "suggestions for practice" associated with each grade. The USPSTF has also defined levels of certainty regarding net benefit. These definitions apply to USPSTF recommendations voted on after May 2007.

## WHAT THE GRADES MEAN AND SUGGESTIONS FOR PRACTICE

| Grade | Definition | Suggestions for Practice |
|---|---|---|
| A | The USPSTF recommends the service. There is high certainty that the net benefit is substantial. | Offer or provide this service. |
| B | The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. | Offer or provide this service. |
| C | The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. | Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. |
| D | The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. | Discourage the use of this service. |
| I Statement | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. | Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms. |

# APPENDIX B: American Cancer Society Guidelines

## AMERICAN CANCER SOCIETY RECOMMENDATIONS FOR COLORECTAL CANCER EARLY DETECTION

### PEOPLE AT AVERAGE RISK

The American Cancer Society believes that preventing colorectal cancer (and not just finding it early) should be a major reason for getting tested. Finding and removing polyps keeps some people from getting colorectal cancer. Tests that have the best chance of finding both polyps and cancer are preferred if these tests are available to you and you are willing to have them. Beginning at age 50, both men and women at average risk for developing colorectal cancer should use one of the screening tests below:

#### Tests that find polyps and cancer

- Flexible sigmoidoscopy every 5 years*
- Colonoscopy every 10 years
- Double-contrast barium enema every 5 years*
- CT colonography (virtual colonoscopy) every 5 years*

#### Tests that mainly find cancer

- Fecal occult blood test (FOBT) every year*,**
- Fecal immunochemical test (FIT) every year*,**
- Stool DNA test (sDNA), interval uncertain*

* Colonoscopy should be done if test results are positive.

** For FOBT or FIT used as a screening test, the take-home multiple sample method should be used. An FOBT or FIT done during a digital rectal exam in the doctor's office is not adequate for screening.

In a digital rectal examination (DRE), a doctor examines your rectum with a lubricated, gloved finger. Although a DRE is often included as part of a routine physical exam, it is not recommended as a stand-alone test for colorectal cancer. This simple test, which is not usually painful, can detect masses in the anal canal or lower rectum. By itself, however, it is not a good test for detecting colorectal cancer due to its limited reach.

Doctors often find a small amount of stool in the rectum when doing a DRE. However, simply checking stool obtained in this fashion for bleeding with an FOBT or FIT is not an acceptable method of screening for colorectal cancer. Research has shown that this type of stool exam will miss more than 90% of colon abnormalities, including most cancers.

## PEOPLE AT HIGH RISK

If you are at an increased or high risk of colorectal cancer, you should begin colorectal cancer screening before age 50 and/or be screened more often. The following conditions place you at higher than average risk:

- A personal history of colorectal cancer or adenomatous polyps
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- A strong family history of colorectal cancer or polyps
- A known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or hereditary non-polyposis colon cancer (HNPCC)

For the full set of risk factors and guidelines, please refer to: **http://www.cancer.org/Cancer/ColonandRectumCancer/MoreInformation/ColonandRectumCancerEarlyDetection/colorectal-cancer-early-detection-a-c-s-recommendations**

# APPENDIX C: Patient and Provider Materials

## CENTERS FOR DISEASE CONTROL AND PREVENTION

**http://www.cdc.gov/cancer/dcpc/publications/colorectal.htm**
(Materials available in Spanish)
Screen For Life Campaign Materials
- Fact Sheets, Brochures, Brochure Inserts, Posters, Print Ads

## NATIONAL CANCER INSTITUTE

**http://www.cancer.gov/cancertopics/wyntk/colon-and-rectal/page1**
(Materials available in Spanish)
- Booklet: What You Need to Know About Cancer of the Colon and Rectum

## FOUNDATION FOR DIGESTIVE HEALTH AND NUTRITION

**http://www.fdhn.org/wmspage.cfm?parm1=210**
- Fact Sheet: Colorectal Cancer Fact Sheet

## PREVENT CANCER FOUNDATION

**http://preventcancer.org/colorectal3c.aspx?id=1036** (Materials available in Spanish)
- Fact Sheet: Colorectal Cancer 2009 Fact Sheet

## AMERICAN CANCER SOCIETY

**http://www.cancer.org/colonmd**
(Materials available in Spanish and Asian languages)
ColonMD: Clinicians' Information Source
- Videos, Wall Charts, Brochures, Booklets
- Guidelines, Scientific Articles, Presentations
- Sample Reminders, Toolbox, CME Course, Medicare Coverage, Facts and Figures, Journals
- Interactive Web-based Toolkit: "How to Increase Colorectal Cancer Screening Rates in Practice" **http://www5.cancer.org/aspx/pcmanual/default.aspx**

## AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

**http://www.ahrq.gov/ppip/healthymen.htm** and **http://www.ahrq.gov/ppip/healthywom.htm**
(Materials available in Spanish)
- Health Checklists for Men and Women

## OFFICE FOR DISEASE PREVENTION AND HEALTH PROMOTION

**http://www.healthfinder.gov/prevention/ViewTopic.aspx?topicID=15&cnt=1&arealD=5**
- Quick Guide to Healthy Living: Get Tested for Colorectal Cancer

# APPENDIX D: References


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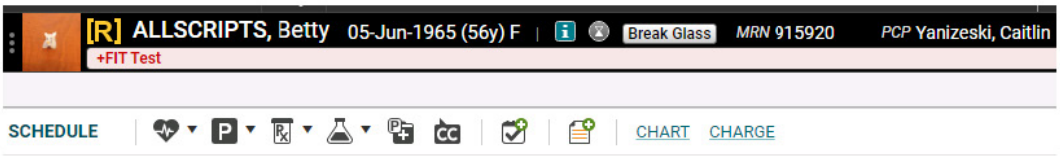
# APPENDIX C-12

## EHR Support / Chart Prompt Examples from Case Studies

**Allegheny Health Network**
Positive FIT Alert in EHR and Positive FIT Registry Screenshots

**1) Positive FIT Alert in EHR (shown on Test Patient, Betty)**



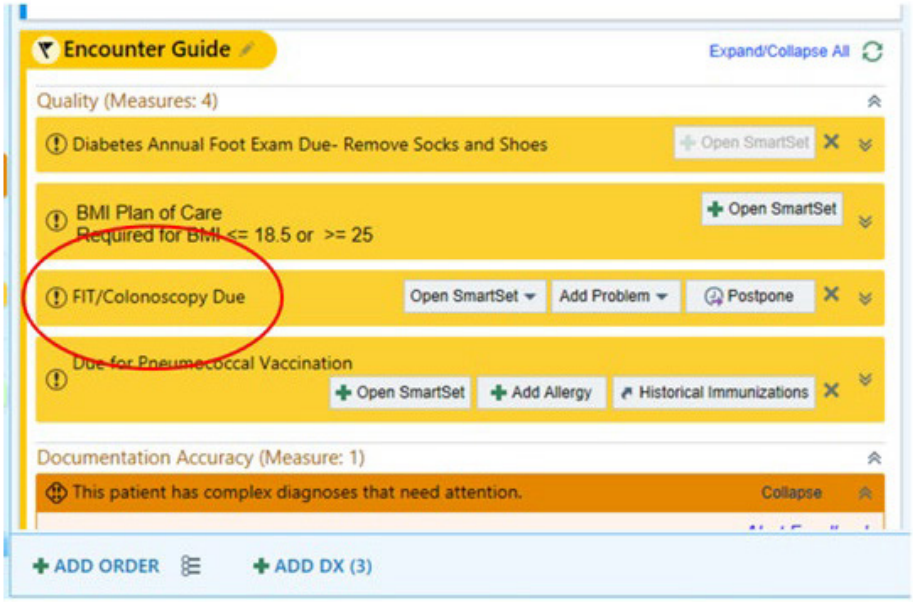

**2) Positive FIT Registry**

**This report is sent out weekly to providers for their patients who had a positive FIT Test**

| Patient name | DOB | MRUN | Date of + FIT | Home office | Provider | Action taken | Patient mailing address |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

**Point of Care Prompt Example used by Mercy Health System to alert provider that patient is due for Colonoscopy**

**Encounter Guide Screenshot from Epic**



# APPENDIX C-13

## Sample Memorandum of Understanding with GI and Other Specialty Providers (Operation Access)

This MEMORANDUM OF UNDERSTANDING ("MOU"), dated 6/16/14, is between XYZ Health Center, and the _____ Endoscopy Center, and the _____ Medical Center.

1. The agreement is effective _____ and expires on _____.
2. Eligible Patients are uninsured, unable to qualify for Medicaid, Medicare, and earn a maximum of 250% of the Federal Poverty Level. Patients return to the referring provider for ongoing care.
3. Specialty procedures provided to Patients are elective and ambulatory. Physician services are to be provided by physicians with current privileges at the _____ Endoscopy Center.
4. The _____ Endoscopy Center agrees to provide health care services ("Services") at no charge to Patients in connection with gastroenterology procedures, in coordination with volunteer physicians.
5. All _____ Endoscopy Center's policies and procedures of quality assurance, medical records, etc. will apply to Patients. The _____ Endoscopy Center ensures that Patients are protected by all state and federal laws, regulations, _____ Endoscopy Center bylaws, rules and regulations, policies and procedures applicable to all _____ Endoscopy Center patients.
6. The _____ Endoscopy Center shall retain professional and administrative responsibility for Services and warrants that it shall perform such Services in a professional manner consistent with applicable industry and accreditation standards.
7. In the event that a patient suffers a complication from their procedure that is recognized prior to their discharge from the _____ Endoscopy Center, that patient will be transferred to the emergency room at the _____ Medical Center for further evaluation and treatment. In the event of such a complication, the _____ Medical Center will admit the patient, if necessary, and will not charge the patient or XYZ Health Center for its hospital services.
8. The _____ Endoscopy Center shall obtain and continuously maintain comprehensive general liability insurance and medical liability insurance in the amounts and upon reasonable terms and conditions consistent with industry practice for acts and omissions of the _____ Endoscopy Center and its personnel pursuant to this MOU.
9. Both parties agree that to the extent required by the provisions of HIPAA and regulations promulgated thereunder, each party assure the other that it will appropriately safeguard protected health information of Patients made available to or obtained by either party pursuant to this Agreement.

10. The _____ Endoscopy Center shall defend, indemnify, and hold harmless XYZ Health Center from and against liability for any and all costs (including court costs), expenses, fees (including attorneys' fees) and payments by, and losses and damages to XYZ Health Center which arise out or are in any way connected with the negligence or willful misconduct of the _____ Endoscopy Center or its employees or agents in the performance of its duties under this MOU, unless such loss is proximately caused by the negligence or willful misconduct of the XYZ Health Center or one of its employees or agents.
11. XYZ Health Center shall defend, indemnify, and hold harmless the _____ Endoscopy Center from and against liability for any and all costs (including court costs), expenses, fees (including attorneys' fees) and payments by, and losses and damages to _____ Endoscopy Center which arise out or are in any way connected with the negligence or willful misconduct of XYZ Health Center or its employees or agents in the performance of its duties under this MOU, unless such loss is proximately caused by the negligence or willful misconduct of the _____ Endoscopy Center or one of its employees or agents.
12. If any law or governmental regulation is interpreted in a manner of newly adopted or any court decision is promulgated after the date of this MOU, and such law, regulation or court decision makes this MOU or a provision hereof illegal, the parties agree to use their best efforts to restructure this MOU in such a manner that will avoid such illegality and, to the extent practicable, will preserve the existing relationship among them.
13. Either Party may terminate this MOU without cause or penalty upon thirty days (30) days' prior written notice.

The parties hereby enter into this MOU as of the Effective Date above.

| XYZ Health Center | _____ Endoscopy Center | _____ Medical Center |
|---|---|---|
| By: _____ | By: _____ | By: _____ |
| Date: _____ | Date: _____ | Date: _____ |
| Contact information: | Contact information: | Contact information: |

# APPENDIX C-14

## Quality Measures for Colonoscopy Reports

| Measures to Assess the Quality of Colonoscopy Services | |
|---|---|
| **Quality Measure** | **Description** |
| **Elements of the colonoscopy report** | |
| ■ Depth of insertion | ■ Related to proportion of colon examined, requires clear description of anatomic landmarks to ensure cecum was reached |
| ■ Quality of bowel prep | ■ Poor bowel prep can lead to missed lesions |
| ■ Patient tolerance of the procedure | ■ Complications during the procedure may suggest patient risk factors (i.e. bleeding - anemia), which need to be evaluated and treated |
| ■ Description of polyps | ■ Documentation should include the number, size, location, morphology (pedunculated, sessile, or flat) and completeness of polyp removal |
| ■ Pathology results for any biopsies | ■ Histology of adenomas related to recurrence rate, forms the basis for determining surveillance intervals |
| ■ Recommendations for follow up and or surveillance | ■ Endoscopists AND primary care physicians need to be familiar with screening guidelines so both can actively ensure patient follow-up |
| **Cecal intubation rate** | ■ Extent to which the entire colon is examined<br>■ Several expert groups set a quality target of 90% or higher for cecal intubation rate<br>■ If the cecum cannot be reached, other imaging procedures (i.e. computed tomographic colonography or double contrast barium enema) should be used |
| **Adenoma detection rate (ADR)** | ■ Metric for the proportion of adenomas found at colonoscopy for the entire unit and individual endoscopists<br>■ ADR inversely associated with both the interval cancer rate and with colorectal cancer death |
| **Safe setting** | ■ Characteristics of the setting in which procedures are done (i.e. adequate cleaning and disinfection of equipment, well- maintained equipment, and well-trained endoscopist and staff) |

Adapted from: Fletcher RH et al. The quality of colonoscopy services--responsibilities of referring clinicians: A consensus statement of the Quality Assurance Task Group, National Colorectal Cancer Roundtable. J Gen Intern Med. 2010;25(11):1230-1234.

# APPENDIX D
# ANNOTATED BIBLIOGRAPHY

This Annotated Bibliography contains an expanded listing of references, with more references than those cited in the text of the 2022 edition. The references are arranged in descending date order and alphabetically by last name of first author by the following user topics of interest:

- **Colorectal Cancer Screening interventions and Systematic Reviews**
- **Colorectal Cancer Screening in Rural Populations**
- **FIT or High-Sensitivity FOBT Tests**
- **Mailed FIT and Colorectal Cancer Screening Outreach**
- **Follow-Up of Abnormal FIT or FOBT Results**
- **Multitarget Stool DNA (mt-sDNA)**
- **Colorectal Cancer Screening Guidelines & Statistics**
- **Social Risk Factors in Colorectal Health**
- **Patient Navigation Role in CRC Screening**
- **Electronic Health Records**
- **Practice Management**
- **Cancer Prevention**
- **Costs & Cost Effectiveness**

The references highlighted in pale yellow are references that are footnoted in the 2022 edition. References highlighted in pale blue are references footnoted in the Steps Guide Follow-Up of Abnormal Stool Results Brief.

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3. **https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification** (Brief Reference #24)
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# APPENDIX D-2.1

## US Multi-Society Task Force Guidelines for Colonoscopy Surveillance After Screening

## AGA

### Guidelines for Colonoscopy Surveillance After Screening and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer

DAVID A. LIEBERMAN,* DOUGLAS K. REX,‡ SIDNEY J. WINAWER,§ FRANCIS M. GIARDIELLO,‖ DAVID A. JOHNSON,¶ and THEODORE R. LEVIN#

*Oregon Health and Science University, Portland, Oregon; ‡Indiana University School of Medicine, Indianapolis, Indiana; §Memorial Sloan-Kettering Cancer Center, New York, New York; ‖Johns Hopkins University School of Medicine, Baltimore, Maryland; ¶Eastern Virginia Medical School, Norfolk, Virginia; and #Kaiser Permanente Medical Center, Walnut Creek, California

**Podcast interview: www.gastro.org/gastropodcast. Also available on iTunes.**

Screening for colorectal cancer (CRC) in asymptomatic patients can reduce the incidence and mortality of CRC. In the United States, colonoscopy has become the most commonly used screening test. Adenomatous polyps are the most common neoplasm found during CRC screening. There is evidence that detection and removal of these cancer precursor lesions may prevent many cancers and reduce mortality.[1] However, patients who have adenomas are at increased risk for developing metachronous adenomas or cancer compared with patients without adenomas. There is new evidence that some patients may develop cancer within 3–5 years of colonoscopy and polypectomy—so-called interval cancers.

Ideally, screening and surveillance intervals should be based on evidence showing that interval examinations prevent interval cancers and cancer-related mortality. We have focused on the interval diagnosis of advanced adenomas as a surrogate marker for the more serious end point of cancer incidence or mortality. In 2006, the United States Multi-Society Task Force (MSTF) on CRC issued a guideline on postpolypectomy surveillance,[2] which updated a prior 1997 guideline. A key principle of the 2006 guideline was risk stratification of patients based on the findings at the baseline colonoscopy. The surveillance schema identified 2 major risk groups based on the likelihood of developing advanced neoplasia during surveillance: (1) low-risk adenomas (LRAs), defined as 1–2 tubular adenomas <10 mm, and (2) high-risk adenomas (HRAs), defined as adenoma with villous histology, high-grade dysplasia (HGD), ≥10 mm, or 3 or more adenomas. The task force also published recommendations for follow-up after resection of CRC.[3]

More recently, the British Society of Gastroenterology updated their 2002 surveillance guideline in 2010.[4] Their risk stratification differs from the US guideline, dividing patients into 3 groups: low risk (1–2 adenomas <10 mm), intermediate risk (3–4 small adenomas or one ≥10 mm), and high risk (>5 small adenomas or ≥3 with at least one ≥10 mm). They recommend that the high-risk group undergo surveillance at 1 year because of concerns about missed lesions at baseline. US guidelines place emphasis on performing a high-quality baseline examination. In 2008, the MSTF published screening guidelines for CRC, which included recommendations for the interval for repeat colonoscopy after negative findings on baseline examination.[5]

New issues have emerged since the 2006 guideline, including risk of interval CRC, proximal CRC, and the role of serrated polyps in colon carcinogenesis. New evidence suggests that adherence to prior guidelines is poor. The task force now issues an updated set of surveillance recommendations. During the past 6 years, new evidence has emerged that endorses and strengthens the 2006 recommendations. We believe that a stronger evidence base will improve adherence to the guidelines. The 2012 guidelines are summarized in Table 1 and are based on risk stratification principles used in the 2006 guideline. The ensuing discussion reviews the new evidence that supports these guidelines. This guideline does not address surveillance after colonoscopic or surgical resection of a malignant polyp.

#### Methodology

##### *Literature Review*

We performed a MEDLINE search of the postpolypectomy literature under the subject headings of colonoscopy, adenoma, polypectomy surveillance, and adenoma surveillance, limited to English language articles from 2005 to 2011. Subsequently, additional articles were gleaned from references of the reviewed articles. Relevant studies include those in which outcomes addressed the relationship between baseline examination

*Abbreviations used in this paper:* CI, confidence interval; CIMP, CpG island methylator phenotype; CRC, colorectal cancer; CT, computed tomography; FDR, first-degree relative; FOBT, fecal occult blood test; HGD, high-grade dysplasia; HP, hyperplastic polyp; HR, hazard ratio; HRA, high-risk adenoma; LRA, low-risk adenoma; MSTF, Multi-Society Task Force; NCI, National Cancer Institute; OR, odds ratio; PPT, Polyp Prevention Trial; RR, relative risk; TVA, tubulovillous adenoma; USPSTF, United States Preventive Services Task Force.


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**Table 1.** 2012 Recommendations for Surveillance and Screening Intervals in Individuals With Baseline Average Risk

| Baseline colonoscopy: most advanced finding(s) | Recommended surveillance interval (*y*) | Quality of evidence supporting the recommendation | New evidence stronger than 2006 |
|---|---|---|---|
| No polyps | 10 | Moderate | Yes |
| Small (<10 mm) hyperplastic polyps in rectum or sigmoid | 10 | Moderate | No |
| 1–2 small (<10 mm) tubular adenomas | 5–10 | Moderate | Yes |
| 3–10 tubular adenomas | 3 | Moderate | Yes |
| >10 adenomas | <3 | Moderate | No |
| One or more tubular adenomas ≥10 mm | 3 | High | Yes |
| One or more villous adenomas | 3 | Moderate | Yes |
| Adenoma with HGD | 3 | Moderate | No |
| Serrated lesions | | | |
| Sessile serrated polyp(s) <10 mm with no dysplasia | 5 | Low | NA |
| Sessile serrated polyp(s) ≥10 mm | 3 | Low | NA |
| OR | | | |
| Sessile serrated polyp with dysplasia | | | |
| OR | | | |
| Traditional serrated adenoma | | | |
| Serrated polyposis syndrome[a] | 1 | Moderate | NA |

NOTE. The recommendations assume that the baseline colonoscopy was complete and adequate and that all visible polyps were completely removed.
NA, not applicable.
[a]Based on the World Health Organization definition of serrated polyposis syndrome, with one of the following criteria: (1) at least 5 serrated polyps proximal to sigmoid, with 2 or more ≥10 mm; (2) any serrated polyps proximal to sigmoid with family history of serrated polyposis syndrome; and (3) >20 serrated polyps of any size throughout the colon.

findings and the detection of CRC, advanced adenoma, or any adenoma during the follow-up period. Studies used in the final analysis are summarized in Table 2 by specific category. We also reviewed studies with results of more than one surveillance examination to determine the downstream risk that may be associated with the baseline findings. A key goal was to determine if the risk of subsequent neoplasia was reduced once a patient had negative findings on colonoscopy or had low-risk adenomas. We excluded studies that included patients with inflammatory bowel disease or prior history of CRC. This review applies to average-risk individuals and excluded patients with hereditary syndromes associated with CRC.

**Table 2.** New Papers Since 2005 With Surveillance Outcomes After Baseline Colonoscopy

| Category: baseline colonoscopy finding | No. of papers meeting criteria (reference no.) |
|---|---|
| Exposure to colonoscopy: | 6 (18–22, 52) |
| 1. Risk of CRC | |
| 2. Risk of proximal vs distal CRC | |
| Exposure to colonoscopy: rate of CRC within 10 y | 4 (18, 20, 21, 52) |
| No polyps at baseline: rates of advanced neoplasia | 6 (14, 47–51) |
| HPs | 1 (61) |
| Small adenomas <10 mm | 7 (7, 14, 51, 64–67) |
| Advanced adenomas | 3 (7, 14, 66) |
| Adenoma with HGD | 3 (7, 14, 71) |
| Serrated polyps | 2 (72, 73) |
| Family history of CRC or polyps | 1 (59) |
| Multiple rounds of surveillance | 3 (67, 77, 78) |
| Poor bowel preparation | 2 (68, 82) |
| Surveillance after FOBT | 2 (84, 85) |
| Miscellaneous risk factors | |
| Smoking | 1 (58) |
| Aspirin/nonsteroidal anti-inflammatory drugs | 4 (54–57) |

### *Levels of Evidence*

There are no high-quality randomized controlled trials of polyp surveillance performed in the past 6 years. All studies are either retrospective or prospective observational, cohort, population-based, or case-control studies. We have adopted a well-accepted rating of evidence[6] that relies on expert consensus about whether new research is likely to change the confidence level of the recommendation (Table 3).

### *Process*

The task force is composed of gastroenterology specialists with a special interest in CRC, representing the 3 major gastroenterology professional organizations: American College of Gastroenterology, American Gastroenterological Association Institute, and American Society for Gastrointestinal Endoscopy. We recognize that inherent bias can be introduced when a group of experts in the field review evidence and provide recommendations. In addition to the task force, the practice committees of the American Gastroenterological Association Institute and the

**Table 3.** Rating Evidence

| Rating of evidence | Impact of potential further research |
|---|---|
| High quality | Very unlikely to change confidence in the estimate of effect |
| Moderate quality | Likely to have an important impact on confidence and may change estimate of effect |
| Low quality | Very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate |
| Very low quality | Any estimate of effect is very uncertain |

American College of Gastroenterology and the governing board of the American Society for Gastrointestinal Endoscopy reviewed and approved this document.

### *Format of the Report*

The report includes statements that summarize new, relevant literature since 2005. This is followed by recommendations for surveillance based on the most advanced finding of the baseline colonoscopy examination. For each baseline finding (or lack of finding), there is a recommendation, background section, summary of new evidence since 2006, and discussion of unresolved issues and areas for further research.

### *Terms and Definitions*

Low-risk adenoma (LRA) refers to patients with 1–2 tubular adenomas <10 mm in diameter. High-risk adenoma (HRA) refers to patients with tubular adenoma ≥10 mm, 3 or more adenomas, adenoma with villous histology, or HGD. Advanced neoplasia is defined as adenoma with size ≥10 mm, villous histology, or HGD.

Throughout the document, statistical terms are used. The odds ratio (OR) is the ratio of the odds of an event occurring in one group to the odds of it occurring in another group. Generally there is a referent group (OR = 1.0) that is compared with another group. Relative risk (RR) is used frequently in the statistical analysis of binary outcomes where the outcome of interest has relatively low probability. The RR is different from the OR, although it asymptotically approaches it for small probabilities. The OR has much wider use in statistics, because logistic regression, often associated with clinical trials, works with the log of the OR, not RR. In survival analysis, the hazard ratio (HR) is the ratio of the hazard rates corresponding to the conditions described by 2 sets of explanatory variables in a defined period. For example, in a drug study, the treated population may die at twice the rate per unit time as the control population. The HR would be 2, indicating higher hazard of death from the treatment.

## Results of Literature Review

### *New Evidence on Limitations of Colonoscopic Surveillance*

**New evidence documents the risk of developing interval CRC after polypectomy or negative findings on baseline colonoscopy.** New data have emerged on the risk of interval cancer after colonoscopy. Data from studies in which patients had adenomas detected and removed were analyzed in a pooling project funded by the National Cancer Institute (NCI) (hereafter referred to as the NCI Pooling Project).[7] These include randomized controlled trials to evaluate chemoprevention[8–13] and cohort studies.[1,14,15] The overall rate of interval cancer was 1.1–2.7 per 1000 person-years of follow-up.

Interval cancers have also been reported in patients with baseline examinations negative for neoplasia. Studies from Ontario[16] and Manitoba[17] used cancer registries to identify patients with cancer and then linked these patients to claims data to determine if there had been a prior colonoscopy. These studies suggest that up to 9% of cancers in the registry were interval cancers, with the patients having had a colonoscopy in the 6 to 36 months before diagnosis of CRC. These studies did not include data on completion rates and quality of prior colonoscopy.

Several studies[18–22] have suggested that patients who develop cancer after colonoscopy are more likely to have proximal compared than distal cancers (Table 4). One hypothesis is that some endoscopists may be more likely to miss lesions in the proximal colon compared with the distal colon. This could be due to quality of bowel preparation, failure to fully examine the proximal colon, differences in proximal polyp/cancer morphology, the skill of the endoscopist, and variable quality of colonoscopy. Serrated polyps and some classic adenomatous polyps in the proximal colon may be challenging to detect if they are flat, covered with mucus, or behind folds. Most prior studies of colonoscopy have failed to report on the quality of the colonoscopy examinations. A second hypothesis is that neoplastic lesions of the proximal colon may biologically differ from distal lesions and progress to malignancy with a short dwell time. The serrated pathway has a predilection for the proximal colon. These lesions may be associated with BRAF or k-ras mutations, and CPG island methylation, which can lead to silencing of mismatch repair genes (MLH1), which could result in more rapid progression to malignancy in some individuals.[23]

Concerns about interval cancer may impact physician behavior with regard to surveillance intervals and may contribute to early repeat examinations in some cases.

**Important lesions are missed at baseline colonoscopy.** Considerable evidence suggests that important lesions may be missed at colonoscopy. Studies that have compared computed tomography (CT) colonography and optical colonoscopy use a method of segmental unblinding to assess the sensitivity of colonoscopy. As each segment is examined, the endoscopist is informed of findings at CT. If the CT revealed a polyp and colonoscopy did not, the region is reexamined; if a polyp(s) is found on the second look, it is considered a missed lesion by colonoscopy. These studies suggest that up to 17% of lesions ≥10 mm are missed with optical colonoscopy.[24–29] Recent studies suggest that most interval cancers are due to missed lesions at baseline colonoscopy.[30,31] Missed lesions are directly related to the quality of the examination.

**Adenomas may be incompletely removed at the time of baseline colonoscopy.** If adenoma removal is not complete, residual neoplastic tissue could progress to malignancy. New studies have found that 19%–27% of interval cancers occur in the same portion of the colon as the site of prior polypectomy. In a study of patients with large sessile polyps (>2 cm), 17.6% had residual adenomatous tissue when reexamined.[30,32–35]

**Interval CRC may biologically differ from prevalent CRC.** When interval CRCs are compared with prevalent CRC, interval lesions are more likely located in the proximal colon, be microsatellite unstable, and have CpG island methylator phenotype (CIMP). It has been proposed that the mismatch repair defects associated with microsatellite unstable tumors can lead to a rapid accumulation of mutations and accelerated tumor growth.[36,37]

**Table 4.** Risk of CRC After Colonoscopy: Case-Control or Observational Studies

| Study | Location and type of study | n | Follow-up (*y*) | CRC risk | Risk over 10 y[a] | Notes: proximal vs distal[b] |
|---|---|---|---|---|---|---|
| Singh et al, 2006[18] | Manitoba<br>Cohort/claims data | 35,975 with colonoscopy compared with expected rates of CRC in population | 10 | Incidence:<br>SIR, 0.55 (0.41–0.73) | SIR:<br>1 y, 0.66<br>2 y, 0.59<br>5 y, 0.55<br>10 y, 0.28 | Proximal CRC more common in patients with interval CRC (47%) vs those with prevalent CRC (28%) |
| Lakoff et al, 2008[20] | Ontario<br>Cohort/claims data | 110,402 with negative colonoscopy compared with rates in population | Up to 14 | | Incidence RR:<br>2 y, 0.80<br>5 y, 0.56<br>10 y, 0.45<br>14 y, 0.25 | No reduction in proximal CRC risk until year 8 of follow-up |
| Baxter et al, 2009[21] | Ontario<br>Case-control claims data | 10,292 CRC cases vs 51,460 cancer-free controls; measured exposure to colonoscopy | Median, 7.8 | Mortality:<br>OR, 0.69 (0.63–0.74) | | Proximal CRC:<br>OR, 0.99<br>Distal CRC:<br>OR, 0.33 (0.28–0.39) |
| Brenner et al, 2011[22] | Germany<br>Case-control | 1688 CRC cases vs cancer-free controls; exposure to colonoscopy | 10 | Incidence:<br>OR, 0.23 (0.19–0.27) | | Proximal CRC:<br>OR, 0.44 (0.35–0.55)<br>Distal CRC<br>OR, 0.16 (0.12–0.20) |
| Brenner et al, 2011[52] | Germany<br>Case-control | 1945 CRC cases vs 2399 controls | Up to 20 | | Incidence OR:<br>1–2, 0.14<br>3–4, 0.12<br>5–9, 0.26[c]<br>10–19, 0.28 | |

SIR, standardized incidence ratio.
[a]Based on interval since prior colonoscopy.
[b]Prevalent CRC, diagnosis of CRC at time of initial colonoscopy; interval CRC, diagnosis of CRC at time of follow-up colonoscopy, at some interval after baseline examination.
[c]At 5–9 years: OR of 0.61 in smoker, OR of 0.66 with positive family history.

**Quality of baseline colonoscopy is associated with risk of interval cancer.** An underlying premise of recommendations for surveillance is that the baseline colonoscopy was performed with high quality, which minimizes the risk of missed lesions. Since 2002, quality indicators for reporting and performance have been published.[38–40] There is now evidence of a clear relationship between specific quality indicators and the risk of interval cancer after colonoscopy. Variation in adenoma detection rate among endoscopists has been reported.[16,41] A large Polish study found that if the adenoma detection rate in screening examinations was <20%, a significantly higher risk of interval cancer occurred in the next 5 years.[42] In Ontario, investigators compared endoscopists with high and low polyp detection rates, finding that interval cancers were less likely when the colonoscopy was performed by an endoscopist with high polyp detection rates.[16] The same investigators compared endoscopists with high (>95%) and low (<80%) cecal intubation rates and similarly found that interval cancers were less common among the patients who had colonoscopy performed by higher-performance endoscopists. These new data reinforce the importance of colonoscopy quality and its impact on surveillance.

There is growing interest in using adherence to polyp surveillance recommendations as an indicator of endoscopy quality.[40] There is evidence that guideline adherence is variable and overall far from consistent with national guideline recommendations. Surveys of primary care and specialty physicians revealed that many recommend frequent surveillance colonoscopy for low-risk patients, despite recommendations for lengthened surveillance intervals.[43,44] A recent study reported on actual surveillance performance after colonoscopy.[45] Approximately 25% of patients with no adenomas at baseline had a repeat colonoscopy within 5 years, and more than 40% of patients with small adenomas had one or more examinations within 5 years. The study also revealed evidence for underutilization of surveillance in some higher-risk patients with advanced neoplasia at baseline. Roughly 40% of such patients did not have surveillance within 5 years. Overutilization exposes patients to the cost and risk of unnecessary procedures. Underutilization could result in higher-risk patients developing cancer.

### *Recommendations for Surveillance*

**Baseline examination: no adenomas or polyps.**

| | |
|---|---|
| 2008 recommendation for next examination | 10 years |
| 2012 recommendation for next examination | No change |
| Quality of evidence | Moderate – stronger than 2008 |

*Background.* The foundation of the 10-year interval is based on indirect, observational data discussed in prior guidelines.[5]

*New information since 2008.* The United Kingdom sigmoidoscopy randomized controlled trial demonstrated a reduction in CRC incidence and mortality at 10 years in patients who received one-time sigmoidoscopy compared with controls—a benefit limited to the distal colon.[46] This is the first randomized study to show the effectiveness of endoscopic screening, an effect that appears to have at least a 10-year duration.

**Table 5.** Prevalence of Advanced Neoplasia After Negative Findings on Colonoscopy

| Study | N (type of cohort) | Interval after baseline (*y*) | Advanced neoplasia (%) |
|---|---|---|---|
| Lieberman et al, 2007[14] | 291 (veterans, male) | 5 | 2.4 |
| Imperiale et al, 2008[47] | 1256 (US, men and women) | 5 | 1.3 |
| Leung et al, 2009[48] | 370 (Chinese men and women) | 5 | 1.4 |
| Brenner et al, 2010[49] | 115 (men and women) | 5 | 4.4 |
| Miller et al, 2010[50] | US veterans (99% male) | 5–10 | |
| | 5-y follow-up: n = 86 | | 7.0 |
| | 6- to 10-y follow-up: n = 111 | | 3.6 |
| Chung et al, 2011[51] | 1242 Korean men and women) | 5 | 2.0 |

**Risk of advanced adenomas at follow-up colonoscopy.** Several prospective observational studies[14,47–51] in different populations have shown that the risk of advanced adenomas within 5 years after negative findings on colonoscopy is low (1.3%–2.4%) relative to the rate on initial screening examination (4%–10%). In these studies, interval cancers within 5 years were rare (Table 5).

**Risk of cancer during surveillance.** Case-control and observational studies[18,20,21,52] have suggested that patients with prior colonoscopy have either reduced CRC incidence or mortality, with a duration of effect of 10 years or more (Table 4). A large case-control study from Germany compared patients undergoing true screening colonoscopy with unscreened controls, finding a durable risk reduction with colonoscopy for at least 10 years.[53] Other studies that have included higher-risk patients (lower gastrointestinal symptoms or positive fecal occult blood test [FOBT] result) have reported higher rates of interval cancers,[18,53] which may be due to a higher likelihood of cancer at baseline compared with asymptomatic screening cohorts.

**Other risk factors.** There are new data about the possible impact of nonsteroidal anti-inflammatory drugs (reduced risk) and smoking (no effect) on risk of adenomas during surveillance.[54–58] There is insufficient evidence to tailor recommendations based on these risk factors.

*Recommendation.* There is now stronger evidence to support the 10-year interval after negative findings on baseline colonoscopy for average-risk individuals, assuming that the baseline colon examination is complete with a good bowel preparation.

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Individuals with a first-degree relative (FDR) with CRC or HRA have an increased lifetime risk of developing CRC, particularly if the FDR was younger than 60 years at the time of diagnosis.[59] If colonoscopy is performed and the finding is normal, the recommended interval for repeat screening should be 5 years if the FDR was younger than 60 years and 10 years if the FDR was 60 years or older.

*Unresolved issues and areas for further research.* The reports of interval cancer after negative findings on colonoscopy have raised concerns about the 10-year interval recommendation. The new prospective studies are reassuring and show that the risk of advanced neoplasia is very low at 5 years. However, one Canadian population-based study suggests that the highest risk of interval CRC is within 1–5 years of the baseline examination, when it is most likely that missed lesions will progress and lead to diagnosis of CRC.[18] These data emphasize the importance of performing high-quality examinations to reduce the likelihood of missed lesions. Future studies should make every effort to document quality indicators.

**Baseline examination: no adenomas; distal small (<10 mm) hyperplastic polyps.**

| | |
|---|---|
| 2006 recommendation for next examination | 10 years |
| 2012 recommendation for next examination | No change |
| Quality of evidence | Moderate |

*Background.* There is considerable evidence that patients with only rectal or sigmoid hyperplastic polyps (HPs) appear to represent a low-risk cohort. Earlier literature focused on whether the finding in the distal colon was a marker of risk for advanced neoplasia elsewhere. Most studies show no such relationship.[2] Most evidence suggests that small lesions (<10 mm) limited to the rectum and sigmoid are benign.

*New information since 2006.* Distal HPs are a common finding at screening colonoscopy.[60] HPs accounted for 50% of polyps 1–5 mm, 27.9% of polyps 6–9 mm, and 13.7% of polyps >10 mm.

Laiyemo et al[61] followed up 437 participants of the Polyp Prevention Trial (PPT) who had baseline HPs coexisting with adenomas. Neither proximal nor distal HPs were associated with an increased risk of recurrent adenomas at 3 years after the baseline examination. There are no other new studies of follow-up colonoscopy in patients with baseline distal HPs.

*Recommendation.* Prior and current evidence suggests that distal HPs <10 mm are benign and nonneoplastic. If the most advanced lesions at baseline colonoscopy are distal HPs <10 mm, the interval for colonoscopic follow-up should be 10 years.

*Unresolved issues and areas for further research.* Future research should include patients with distal HPs in analyses of surveillance outcomes.

**Baseline examination: 1–2 tubular adenomas <10 mm.**

| | |
|---|---|
| 2006 recommendation for next examination | 5- to 10-year interval |
| 2012 recommendation for next examination | No change |
| Quality of evidence | Moderate – evidence stronger than 2006 |

*Background.* Prior evidence suggested that patients with LRAs had a lower risk of developing advanced adenomas during follow-up compared with patients with HRAs. An independent meta-analysis and systematic review in 2006 confirmed the findings of the MSTF.[63] At that time, the consensus on the task force was that "observations of cohort studies supports an interval of at least 5 years in this low-risk group; however we reasoned that based on the data from Atkin et al[62]. . .that a 10 year interval, similar to that used in the average-risk population, also would be acceptable."

*New information since 2006.* There are new studies[7,14,50,51,63–66] confirming that individuals with LRAs represent a low-risk group (Table 6). Laiyemo et al[64] used the 2006 guideline to predict risk for advanced neoplasia during surveillance in the PPT, comparing high-risk with low-risk patients. The probability of recurrence of advanced adenoma was 0.09 among patients with HRAs at baseline and 0.05 among those with LRAs at baseline (RR, 1.68; 95% confidence interval [CI], 1.19–2.38).

The NCI Pooling Project analyzed data from 8 prospective studies in which patients with baseline adenomas were followed up over 3–5 years and had repeat colonoscopy.[7] Compared with patients with LRAs, ORs were increased in patients with 3 or more adenomas, size ≥10 mm, and villous histology. The VA Cooperative Study 380[14] compared risk of advanced neoplasia at 5 years in 298 patients with no baseline neoplasia (2.4%) and 496 patients with 1–2 tubular adenomas <10 mm (4.6%), with an adjusted RR of 1.92 (0.83–4.42) not reaching statistical significance.

Korean investigators followed up patients for 5 years after baseline colonoscopy.[51] HRAs were found in 2.0% of 1242 patients with no baseline neoplasia compared with 2.4% in 671 patients with LRAs (adjusted HR, 1.14 [0.61–2.17]). The Prostate Lung Colorectal Ovarian Cancer study[67] compared rates of advanced neoplasia during 6–7 years of follow-up after baseline colonoscopy. Among 318 patients with no adenoma at baseline, the risk of advanced neoplasia during surveillance was similar to those with LRAs (5.3%).

*Recommendation.* Data published since 2006 endorse the assessment that patients with 1–2 tubular adenomas with low-grade dysplasia <10 mm represent a low-risk group. Three new studies suggest that this group may have only a small, nonsignificant increase in risk of advanced neoplasia within 5 years compared with individuals with no baseline neoplasia.

The evidence supports a surveillance interval of longer than 5 years for most patients. We recognize that quality of the bowel preparation may result in a less than optimal

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**Table 6.** Follow-up of Patients With Adenomas at Baseline Colonoscopy

| Reference | Type of study | Rate or risk of advanced adenoma during surveillance |
|---|---|---|
| Saini et al, 2006[63] | Meta-analysis:<br>5 studies stratified by index findings | Baseline RR:<br>≥3 vs 1–2 adenomas, 2.52<br>Villous vs TA, 1.26<br>Adenoma >10 mm vs ≤10 mm, 1.39<br>HGD vs low-grade dysplasia, 1.84 |
| Laiyemo et al, 2008[64] | PPT<br>N = 1905 | Baseline RR:<br>LRA, 1.00 (ref)<br>HRA, 1.68 (1.19–2.38) |
| Lieberman et al, 2007[14] | N = 895 with baseline neoplasia | Baseline rate of AA at 5 y:<br>1–2 TA <10 mm, 6.1%<br>TA >10 mm, 15.5%<br>≥3 adenomas, 15.9%<br>Villous adenoma/TVA, 16.1% |
| Martinez et al, 2009[7] | Pooling 8 studies | Baseline OR:<br>Size >10 mm, 1.56<br>≥3 adenomas, 1.32<br>Proximal adenoma, 1.68<br>Villous adenoma/TVA, 1.40 |
| Miller H et al, 2010[50] | VA cohort | Baseline rate of AA at follow-up:<br>LRA 5 y (n = 77), 5.2%<br>LRA 6–10 y (n = 81), 6.2%<br>HRA 5 y (n = 23), 26.1% |
| Miller J et al, 2010[65] | Cohort<br>N = 88 | Baseline rate of AA at follow-up:<br>1–2 small tubular adenomas, 4.5% |
| Chung et al, 2011[51] | Cohort | Baseline rate of AA at follow-up:<br>LRA (n = 671), 2.4%<br>HRA (n = 539), 12.2% |
| Cottet et al, 2011[66] | Cohort, population-based registry, France; 7.7-y follow-up | Baseline rate of CRC at follow-up:<br>LRA (n = 3236), 0.8%; SIR, 0.68<br>HRA (n = 1899), 2.8%; SIR, 2.23 |

AA, advanced adenoma; TA, tubular adenoma; SIR, standardized incidence ratio.

examination in some portions of the colon. In a recent report, when the bowel preparation was inadequate,[68] the miss rates for adenoma and advanced adenoma at 1 year were 35% and 36%, respectively. Factors associated with finding an adenoma on subsequent examination included lack of cecal intubation (OR, 3.62; 95% CI, 2.50–5.24) and finding a polyp at the baseline examination (OR, 1.55; 95% CI, 1.17–2.07). In these circumstances, a 5-year interval might still be prudent.

*Unresolved issues and areas for further research.* Most studies have not subclassified patients whose largest polyp is diminutive (1–5 mm) versus small (6–9 mm) on screening examinations. Improvements in colonoscopy have resulted in higher detection rates for diminutive polyps. Future study is needed to stratify risk for individuals with LRAs <6 mm and LRAs 6–9 mm in diameter.

**Baseline examination: 3–10 adenomas.**

| | |
|---|---|
| 2006 recommendation for next examination | 3-year interval |
| 2012 recommendation for next examination | No change |
| Quality of evidence | Moderate: if any polyp ≥6 mm<br>Low: if all polyps <6 mm<br>Evidence stronger than 2006 |

*Background.* Two independent meta-analyses in 2006 found that patients with 3 or more adenomas at baseline had an increased RR for adenomas during surveillance, ranging from 1.7 to 4.8.[3,63] Other studies show that patients with multiple adenomas are more likely to have adenomas detected at 1 year, suggesting that lesions may be more likely to be missed on the baseline examination when multiple polyps are present. These data form the basis of the recommendation for a 3-year interval, similar to the recommendation for large polyps and those with advanced histology. The earlier studies did not stratify multiplicity based on size. Many of the studies of multiplicity include patients with larger polyps. It was not possible to determine if the risk level was different if all polyps were <6 mm versus >6 mm.

*New information since 2006.* Two new studies reported outcomes in patients with multiple adenomas. The NCI Pooling Project[7] analysis found that with each additional adenoma, there is a linear increase in risk for both advanced and nonadvanced neoplasia (Table 7).

The VA study (which contributed data to the pooling project) also provided a second referent group: patients with no baseline neoplasia.[14] The risk of advanced neoplasia at 5 years was 2.4% in the nonneoplasia referent group, 4.6% if patients had 1–2 tubular adenomas <10

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**Table 7.** NCI Pooling Project (8 Studies): Risk of Advanced Adenoma at 3–5 Years Based on Number of Polyps at Baseline Colonoscopy[7]

| Baseline adenoma no. | % with advanced adenoma at follow-up (95% CI) | Adjusted OR (95% CI) |
|---|---|---|
| 1 | 8.6 (7.8–9.3) | 1.00 (referent) |
| 2 | 12.7 (11.3–14.1) | 1.39 (1.17–1.66) |
| 3 | 15.3 (12.9–17.6) | 1.85 (1.46–2.34) |
| 4 | 19.6 (15.3–19.3) | 2.23 (1.71–3.40) |
| 5+ | 24.1 (19.8–28.5) | 3.87 (2.76–5.42) |
| *P* trend | | <.0001 |

From Martinez et al.[7]

mm (RR, 1.92; 95% CI, 0.83–4.42), and 11.9% if they had 3 or more tubular adenomas <10 mm (RR, 5.01; 95% CI, 2.10–11.96). The VA study shows that even if all of the adenomas are <10 mm, there is increased risk of advanced neoplasia with multiplicity of adenomas.

*Recommendation.* The new information from the VA study and the NCI Pooling Project support the previous recommendation that patients with 3 or more adenomas have a level of risk for advanced neoplasia similar to other patients with advanced neoplasia (adenoma >10 mm, adenoma with HGD). There are insufficient new data to support a change in the prior recommendation.

*Unresolved issues and areas for further research.* Historically, some older studies had lower rates of adenoma detection compared with modern studies. In a recent review[69] of screening studies (n = 18), the prevalence of adenomas in average-risk cohorts was 30.2% (range, 22.2%–58.2%). In more recent screening studies using modern technology (such as high-definition white light), adenoma detection rates of 40% or more have been reported.[70] Therefore, it is very likely that there was misclassification of some patients in earlier studies; patients reported to have 1–2 adenomas may have had additional adenomas that were not detected.

There remains some doubt about whether patients who have 3–5 diminutive adenomas (all <6 mm) really have an increased risk of interval advanced neoplasia during surveillance. However, there is little doubt that if patients have 3 or more adenomas, and at least one is advanced, the risk of having advanced neoplasia during surveillance is high. In the VA study, these patients had a nearly 10-fold increased RR compared with patients with no neoplasia and a 5-fold increased RR compared with those with 1–2 small tubular adenomas.[14]

Further research is needed to determine the level of risk of advanced neoplasia if a patient has 3–5 adenomas all <6 mm at the baseline examination. These new studies should use modern colonoscopic technology to determine an accurate number of adenomas at baseline.

**Baseline examination: >10 adenomas.**

| | |
|---|---|
| 2006 recommendation for next examination | <3-year interval |
| 2012 recommendation for next examination | No change |
| Quality of evidence | Moderate-high |

*Background.* These patients represent a small proportion of patients undergoing screening examinations. The 2006 guideline noted that such patients should be considered for hereditary syndromes. The recommendation for early follow-up is based on clinical judgment because there is little evidence.

*New evidence since 2006.* There are no new studies that single out this small group of patients for analysis. The NCI Pooling Project notes a marked increased risk of advanced neoplasia among patients with 5 or more adenomas at baseline.

*Recommendation.* There is no basis for changing the recommendation to consider follow-up in less than 3 years after a baseline colonoscopy.

**Baseline examination: one or more tubular adenomas ≥10 mm.**

| | |
|---|---|
| 2006 recommendation for next examination | 3-year interval |
| 2012 recommendation for next examination | No change |
| Quality of evidence | High – evidence stronger than 2006 |

*Background.* The 2006 guideline reviewed data related to adenoma size, demonstrating that most studies showed a 2- to 5-fold increased risk of advanced neoplasia during follow-up if the baseline examination had one or more adenomas ≥10 mm.

*New information since 2006.* The NCI Pooling Project analyzed polyp size as a risk factor for development of interval advanced neoplasia (Table 6).[7] Compared with patients with adenomas <5 mm, those with baseline polyp(s) 10–19 mm had an increased risk of advanced neoplasia (15.9% vs 7.7%; OR, 2.27; 95% CI, 1.84–2.78). If the baseline polyp was 20 mm or more, the risk of advanced neoplasia at follow-up was 19.3% (OR, 2.99; 95% CI, 2.24–4.00). In the VA Cooperative Study 380, the referent group was patients with no neoplasia.[14] The risk of advanced neoplasia within 5.5 years was 2.4% in the no neoplasia group and 15.5% in patients with baseline adenomas >10 mm (RR, 5.01; 95% CI, 2.10–11.96).

*Recommendation.* The new information provides additional data showing that patients with one or more adenomas ≥10 mm have an increased risk of advanced neoplasia during surveillance compared with those with no neoplasia or small (<10 mm) adenomas. There is no basis for changing the recommended 3-year surveillance interval. This recommendation assumes that the examination was of high quality and complete removal of neoplastic tissue occurred at baseline. This group represents a small proportion of all patients with adenomas. If there is question about complete removal (ie, piecemeal resection), early follow-up colonoscopy is warranted.

**Table 8.** Clinical Features of Serrated Lesions of the Colorectum

| World Health Organization classification | Prevalence | Shape | Distribution | Malignant potential |
|---|---|---|---|---|
| Hyperplastic polyp | Very common | Sessile/flat | Mostly distal | Very low |
| Sessile serrated adenoma/polyp | Common | Sessile/flat | 80% proximal | |
| No dysplasia | | | | Low |
| Dysplastic | | | | Significant |
| Traditional serrated adenoma | Uncommon | Sessile or pedunculated | Mostly distal | Significant |

**Baseline examination: one or more adenomas with villous features of any size.**

| | |
|---|---|
| 2006 recommendation for next examination | 3-year interval |
| 2012 recommendation for next examination | No change |
| Quality of evidence | Moderate |

*Background.* The 2006 guideline regarded adenomas with villous histology to be HRA.

*New information since 2006.* The NCI Pooling Project analyzed polyp histology as a risk factor for development of interval advanced neoplasia (Table 6).[7] Compared with patients with tubular adenomas, those with baseline polyp(s) showing adenomas with villous or tubulovillous histology (TVA) had increased risk of advanced neoplasia during follow-up (16.8% vs 9.7%; adjusted OR, 1.28; 95% CI, 1.07–1.52). The level of risk was lower than that associated with size or multiplicity. In the VA Cooperative Study 380, the referent group was patients with no neoplasia.[14] The risk of advanced neoplasia within 5.5 years was 2.4% in the no neoplasia group and 16.1% in patients with baseline adenomas >10 mm (RR, 6.05; 95% CI, 2.48–14.71).

*Recommendation.* The new information provides additional data showing that patients with one or more adenomas with villous histology have an increased risk of advanced neoplasia during surveillance compared with those with no neoplasia or small (<10 mm) tubular adenomas. There is no basis for changing the recommended 3-year surveillance interval.

*Unresolved issues and areas for further research.* The available studies do not separately identify patients whose most advanced polyp is a TVA or villous adenoma <10 mm in size. Future studies should stratify risk based on both pathology and polyp size.

**Baseline examination: one or more adenomas with HGD.**

| | |
|---|---|
| 2006 recommendation for next examination | 3-year interval |
| 2012 recommendation for next examination | No change |
| Quality of evidence | Moderate |

*Background.* The 2006 guideline concluded that the presence of HGD in an adenoma was associated with both villous histology and larger size, which are both risk factors for advanced neoplasia during surveillance.

*New information since 2006.* In a univariate analysis from the NCI Pooling Project,[7] HGD was strongly associated with risk of advanced neoplasia during surveillance (OR, 1.77; 95% CI, 1.41–2.22). The NCI Pooling Project did not find that HGD was independently associated with an increased risk of metachronous advanced neoplasia (OR, 1.05; 95% CI, 0.81–1.35) after adjustments for size and histology, which are known confounders. Toll et al[71] followed up 83 patients with HGD over a median of 4 years, during which 7% developed new HGD or CRC.

*Recommendation.* The presence of an adenoma with HGD is an important risk factor for development of advanced neoplasia and CRC during surveillance. There is no basis for changing the recommended 3-year surveillance interval.

**Baseline examination: serrated polyps.**

| | |
|---|---|
| 2006 recommendation for next examination | None |
| 2012 recommendation for next examination | See Table 1 |
| Quality of evidence | Low |

*Background.* A total of 20%–30% of CRCs arise through a molecular pathway characterized by hypermethylation of genes, known as CIMP.[23] Precursors are believed to be serrated polyps (Table 8). Tumors in this pathway have a high frequency of BRAF mutation, and up to 50% are microsatellite unstable. CIMP-positive tumors are overrepresented in interval cancers, particularly in the proximal colon. The principal precursor of hypermethylated cancers is probably the sessile serrate polyp (synonymous with sessile serrated adenoma; Table 8). Sessile serrated polyps sometimes have foci of cytological dysplasia, which indicates a more advanced lesion in the polyp-cancer sequence.

These polyps are difficult to detect at endoscopy. They may be the same color as surrounding colonic mucosa, have indiscrete edges, are nearly always flat or sessile, and may have a layer of adherent mucus and obscure the vascular pattern.

*New information since 2006.* The clinical implications of serrated polyps are uncertain. Recent studies show that proximal colon location or size >10 mm may be markers of risk for synchronous advanced adenomas elsewhere in the colon.[72,73] Surveillance after colonoscopy was evaluated in one study, which found that coexisting serrated polyps and HRA is associated with a higher risk of advanced neoplasia at surveillance.[72] This study also found that if small proximal serrated polyps are the only finding at baseline, the risk of adenomas during surveillance is similar to that of patients with LRA.

**Table 9.** Multiple Rounds of Colonoscopy Surveillance

| | | Advanced neoplasia at second surveillance (%) | | |
|---|---|---|---|---|
| Baseline colonoscopy | First surveillance | Pinsky et al, 2009, Prostate Lung Colorectal Ovarian Cancer study[67] | Laiyemo et al, 2009, PPT[77] | Robertson et al, 2009[78] |
| HRA | HRA | 19.3 | 30.6 | 18.2 |
| | LRA | 6.7 | 8.9 | 13.6 |
| | No adenoma | 5.9 | 4.8 | 12.3 |
| LRA | HRA | 15.6 | 6.9 | 20.0 |
| | LRA | 5.7 | 4.7 | 9.5 |
| | No adenoma | 3.9 | 2.8 | 4.9 |
| No adenoma | HRA | 11.5 | | |
| | LRA | 4.7 | | |
| | No adenoma | 3.1 | | |

NOTE. HRA is defined as 3 or more adenomas, tubular adenoma ≥10 mm, adenoma with villous histology, or HGD. LRA is defined as 1–2 tubular adenomas <10 mm.

*Recommendation.* Prior surveillance guidelines did not comment on surveillance intervals if proximal serrated polyps are found at baseline colonoscopy. There are no longitudinal studies available on which to base surveillance intervals after resection. Our recommendation is based on low-quality evidence and will require updating when new data are available. The current evidence suggests that size (>10 mm), histology (a sessile serrated polyp is a more significant lesion than an HP; a sessile serrated polyp with cytological dysplasia is more advanced than a sessile serrated polyp without dysplasia), and location (proximal to the sigmoid colon) are risk factors that might be associated with higher risk of CRC. A sessile serrated polyp ≥10 mm and a sessile serrated polyp with cytological dysplasia should be managed like HRA (Table 1). Serrated polyps that are <10 mm and do not have cytological dysplasia may have lower risk and can be managed like LRA.

*Unresolved issues and areas for further study.* There is considerable variation in detection rate by different endoscopists[74,75] and histologic interpretation by pathologists[76] that makes it challenging to evaluate the natural history of serrated polyps. It is likely that many patients are misclassified because of one or both of these factors. Because of this interobserver variation in pathologic interpretation, some experts endorse a position that all proximal colon serrated lesions ≥10 mm should be considered sessile serrated polyps, even if the pathologic interpretation is HP. Further study is needed to reduce interobserver variability in diagnosis and determine natural history.

### *Other Issues Related to Colon Surveillance*

**Surveillance after the first follow-up colonoscopy.** The follow-up of patients after they undergo surveillance has been uncertain. It is not clear if risk continues to be increased if surveillance colonoscopy reveals an LRA or no neoplasia. There are 3 new cohort studies that have followed up patients over several surveillance cycles to determine the risk of advanced neoplasia over time.[67,77,78] These studies all have important limitations, because many patients did not receive a second surveillance, which could lead to selection bias, and intervals were irregular. Data from these studies are summarized in Table 9. These data suggest that the detection of an advanced adenoma is an important risk factor for finding advanced adenoma at the next examination. Once patients have a low-risk lesion or no adenoma, the risk of advanced neoplasia at the next examination is lower. Patients with LRA at baseline and no adenomas at first surveillance have a very low risk (2.8%–4.9%) of having advanced adenomas at the second surveillance examination 3–5 years later. Although the evidence is weak due to incomplete follow-up of the cohorts, it is consistent across 3 longitudinal studies.

*Recommendation.* We believe that patients with LRA at baseline and negative findings at first surveillance can have their next surveillance examination at 10 years. Patients who have HRA at any examination appear to remain at high risk and should have shorter follow-up intervals for surveillance. A summary of these recommendations is outlined in Table 10.

**When should surveillance stop?** There is considerable new evidence that the risk of colonoscopy increases with advancing age.[79,80] Both surveillance and screening should not be continued when risk may outweigh benefit. The United States Preventive Services Task Force (USPSTF) determined that screening should not be continued

**Table 10.** Recommendations for Polyp Surveillance After First Surveillance Colonoscopy

| Baseline colonoscopy | First surveillance | Interval for second surveillance (*y*) |
|---|---|---|
| LRA | HRA | 3 |
| | LRA | 5 |
| | No adenoma | 10 |
| HRA | HRA | 3 |
| | LRA | 5 |
| | No adenoma | 5[a] |

[a]If the findings on the second surveillance are negative, there is insufficient evidence to make a recommendation.

AGA

after age 85 years[81] because risk could exceed potential benefit. Patients with HRA are at higher risk for developing advanced neoplasia compared with average-risk screenees. Therefore, the potential benefit of surveillance could be higher than for screening in these individuals. For patients aged 75–85 years, the USPSTF recommends against continued routine screening but argues for individualization based on comorbidities and findings of any prior colonoscopy. This age group may be more likely to benefit from surveillance, depending on life expectancy.

It is the opinion of the MSTF that the decision to continue surveillance should be individualized, based on an assessment of benefit, risk, and comorbidities.

**When should colonoscopy be repeated if there is a poor bowel preparation at baseline colonoscopy?** Poor-quality bowel preparations that obscure visualization of the colon may be associated with missed lesions at the baseline colonoscopy.[68,82] Current quality indicators for colonoscopy call for monitoring the quality of bowel preparation,[39] with the goal of achieving preparations adequate for detection of lesions >5 mm. There is now substantial evidence[83] that splitting the dose of bowel preparation results in better quality, and this practice is strongly encouraged by the MSTF.

If the bowel preparation is poor, the MSTF recommends that in most cases the examination should be repeated within 1 year. Alternative methods of imaging, such as CT colonography, also require excellent bowel preparation for an adequate examination. If the bowel preparation is fair but adequate (to detect lesions >5 mm) and if small (<10 mm) tubular adenomas are detected, follow-up at 5 years should be considered.

**Positive FOBT (guaiac FOBT or fecal immunochemical test) result before scheduled surveillance.** If patients have an adequate baseline colonoscopy, surveillance colonoscopy should be based on the current guidelines. Patients should not have interval fecal blood testing if colonoscopy is planned. The role of interval fecal testing is uncertain.[84] A recent study from Australia found that interval fecal immunochemical test led to diagnosis of cancers before the scheduled surveillance.[85] However, this study included patients with baseline cancer and did not provide information about the findings or quality of the baseline examination, which may have been important risk factors for interval pathology.

In clinical practice, patients may have had an interval FOBT performed. A decision to perform an early colonoscopy due to positive fecal test result could be based on careful review of the baseline examination. If this examination was not complete or somewhat compromised by fair bowel preparation, it may be quite reasonable to perform an early examination. There are no data to support the practice of a routine early examination and no evidence that these patients have a higher than expected risk of cancer or advanced adenoma.

Interval fecal testing should not be a substitute for high-quality performance of colonoscopy. The task force recommends that interval fecal testing not be performed within the first 5 years after colonoscopy. There is currently insufficient evidence to support this practice. The likelihood of false-positive test results is high, which would result in unnecessary early colonoscopies.

If fecal blood test is performed in the first 5 years after colonoscopy, there is insufficient evidence to make a recommendation. If the patient does have an interval-positive FOBT result, the clinician's judgment to repeat colonoscopy could consider the prior colonoscopy findings, completeness of examination and bowel preparation, and family history. Despite the low likelihood of significant pathology if the baseline examination was high quality, we recognize that there may be concerns about missed lesions at the baseline examination. Potential medical-legal issues often lead to repeat examination. Future studies of this subject should carefully document the quality of the baseline examination and determine rates of significant pathology.

**Development of new symptoms during the surveillance interval (minor rectal bleeding, diarrhea, constipation).** Patients may develop new problems within 3–5 years after colonoscopy that might otherwise be indications for colonoscopy. If patients develop significant lower gastrointestinal bleeding as defined by clinical judgment, they may need further evaluation.

Change in bowel habits, abdominal pain, or minor rectal bleeding are common symptoms that may occur after completion of a colonoscopy. This creates a clinical dilemma: should colonoscopy be repeated before the scheduled surveillance examination? The likelihood of finding significant pathology after a prior complete and adequate colonoscopy is uncertain but likely to be low. However, if the colonoscopy will answer an important clinical question, it may be valuable to repeat.

The consensus of the task force is that there is insufficient evidence to make a recommendation.

**Should surveillance be modified based on lifestyle risk factors for CRC?** There is considerable new evidence that risk of recurrent adenomas may be reduced by taking aspirin or nonsteroidal anti-inflammatory drugs.[11,54–57] We believe there is insufficient evidence to recommend any change in surveillance intervals in patients who are taking these medications.

**Should surveillance be modified based on patient race, ethnicity, or sex?** CRC age-adjusted risk varies based on patient demographic characteristics. However, there is no new evidence that that the surveillance interval should be altered once patients have had colonoscopy and polypectomy based on these factors.

## Discussion

The 2006 MSTF guideline provided a valuable framework for polyp surveillance based on the histology and number of polyps detected at the baseline examination. We find that new data since 2006 support these recommendations.

The current guideline recommendations apply only to high-quality baseline examinations.

Quality indicators[37–39] for reporting and performance have been well documented and should become part of routine endoscopic practice. Several key performance indicators, such as cecal intubation rate and adenoma detection rate, are associated with rates of interval cancer.[16,42] The task force believes that quality indicators must be measured as an essential part of a colonoscopy screening and surveillance program.

The 2006 guideline posed several important questions, some of which are now addressed:

*What are the reasons that guidelines are not followed more closely?* The utilization of colonoscopy for surveillance has an important impact on resource utilization and health care costs. New evidence suggests that surveillance is often overutilized, which increases cost and risk to patients and the health care system. Reasons for poor adherence to guidelines are unclear. We speculate that concerns about interval cancer after colonoscopy may result in some overutilization during surveillance. Incorporation of the guidelines as quality indicators of colonoscopy may improve adherence.

*Will emerging studies with longer colonoscopy follow-up times support the safety of lengthening surveillance intervals?* New evidence from 3 longitudinal studies in which patients have undergone multiple surveillance examinations has identified a low-risk group that may require little or no surveillance after 2 examinations.[65,77,78]

*What is the role of family history in predicting advanced adenomas and CRC?* There is some new evidence that individuals with an FDR with CRC or HRA have an increased risk of developing HRA or CRC.[59]

*What roles will chromoendoscopy, magnification endoscopy, narrow band imaging, and CT colonography play in postpolypectomy surveillance?* The role of new endoscopic technologies has not been studied in surveillance cohorts, although there are ongoing studies of CT colonography. The technical endoscopic enhancements may increase the likelihood of detecting small polyps. Chromoendoscopy and narrow band imaging may enable endoscopists to accurately determine if lesions are neoplastic, and if there is a need to remove them and send material to pathology. At this point, these technologies do not have an impact on surveillance intervals.

*What is the usefulness of FOBT in postpolypectomy surveillance?* A new study[85] found that a positive fecal immunochemical test performed at some interval before scheduled surveillance colonoscopy, may help identify patients who may benefit from early surveillance. This study did not evaluate baseline findings or examination quality to determine their relationship to development of interval CRC. The question of interval testing to detect interval CRC is important and merits further study.

*What is the importance of the serrated polyp pathway and detection of serrated adenomas and proximal HPs?* The current guideline reviews new information about serrated polyps and makes recommendations for follow-up.

*What is the appropriate surveillance of patients who had an adenoma removed in piecemeal resection?* Flat and sessile adenomatous and serrated polyps >15 mm are increasingly removed using injection-assisted polypectomy and piecemeal resection technique. There are insufficient data upon which to base a recommendation. However, the MSTF recommends consideration of a short interval for repeat colonoscopy (<1 year) if there is any question about completeness of resection of neoplastic tissue.

The MSTF believes that the evidence supporting these recommendations for screening and surveillance intervals has become stronger in the past 6 years. We have highlighted areas of uncertainty that require further research. The guidelines are dynamic and will be revised in the future based on new evidence. This new evidence should include information about the quality of the baseline examinations. The task force recommends that all endoscopists monitor key quality indicators as part of a colonoscopy screening and surveillance program.

## Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Gastroenterology* at www.gastrojournal.org, and at http://dx.doi.org/10.1053/j.gastro.2012.06.001.

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*Reprint requests*

Address requests for reprints to: David A. Lieberman, MD, Division of Gastroenterology, Oregon Health and Science University, L-461, 3181 SW Sam Jackson Park Road, Portland, Oregon 97239. e-mail: lieberma@ohsu.edu; fax: (503) 220-3426.


*Conflicts of interest*

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# APPENDIX D-2.2

## Risk Assessment And Screening Toolkit To Detect Familial, Hereditary And Early Onset Colorectal Cancer

# RISK ASSESSMENT AND SCREENING TOOLKIT

## TO DETECT FAMILIAL, HEREDITARY, AND EARLY ONSET COLORECTAL CANCER

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We gratefully acknowledge the contributions of the following individuals and organizations:

### Authors

The Jackson Laboratory Clinical Education Staff:

Emily Edelman, MS, CGC

Therese Ingram, MA

Kate Reed, MPH, ScM, CGC

Linda Steinmark, MS, LCG

### Advisors

Dennis Ahnen, MD, co-chair

Paul Schroy, MD, MPH, co-chair

Thomas Weber, MD, FACS, co-chair

Cindy Borassi

Anjee Davis, MPPA

Robin Dubin, MBA

W. Gregory Feero, MD, PhD

Stephanie Guiffre, MPA

Heather Hampel, MS, LGC

Djenaba Joseph, MD, MPH

Xavier Llor, MD, PhD

Susan Miesfeldt, MD

Martha Raymond, MA, CPN

Michelle Tropper, MPH

Jennifer Weiss, MD

### Reviewers & Contributors

Siobhan Dolan, MD, MPH

Caitlin Gutheil, MS

Paul Han, MD, PhD

Kenneth Lin, MD, MPH, FAAFP

Leigh LoPresti, MD

Natalie Mikat-Stevens, MPH

Trudie Milner, PhD

Randa Sifri, MD

Alissa Terry, ScM, CGC

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Caleb Levell

Mary Doroshenk, MA

Rebecca Siegel, MPH

Durado Brooks, MD, MPH

Robert Smith, PhD

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# CHAPTER 1

# Introduction

# THE VALUE OF FAMILY HISTORY IN CANCER RISK ASSESSMENT

*Family history is a powerful screening tool.*

In conjunction with the patient's medical history, family history can inform diagnosis, promote risk assessment, and prevent, detect and manage disease. This is especially true for cancer.

### When it works

Family history is most useful when it is available in a structured format in the medical record and of course, when it is accurate and complete to support risk assessment. Not all family history information is equal. Seeing that a patient has a "family history of cancer" in the medical record is not specific enough to allow for immediate analysis; seeing documentation that the patient's mother had colon cancer at age 53 allows for personalized risk assessment and possibly, a change in screening regimen.

### How it works

The goal of family history risk assessment is to identify individuals with strong and moderate genetic predispositions to disease so that they can adopt prevention or screening activities to reduce risk and detect disease early. The risk assessment process starts by identifying red flags and patterns in the patient's family history, and then uses that information to stratify individuals into average, increased, or high risk.

### Necessary for guidelines-based screening

National guidelines recommend earlier and more frequent screening for individuals at increased risk for CRC. For individuals at high (hereditary) risk, additional evaluations and health services may be indicated, such as genetic testing or prophylactic surgery. In order to accurately identify the best cancer management plan for each patient, clinicians must assess the family history.

### Extra benefits

In addition to its critical role in risk assessment, the act of family history collection can be a benefit to the patient, as can the discussion about the family history between patient and provider. The process of eliciting a family history provides an excellent opportunity to build a relationship with the patient and to become aware of the patient's motivations and concerns. Such information can be beneficial as the provider helps the patient make health-related decisions. The emphasis on disease prevention and management based on the family history may motivate changes in behavior that forestall disease or reduce its adverse effects.

Eliciting and summarizing family history information can:

- help the patient understand the condition in question,
- clarify patient misconceptions,
- demonstrate variation in disease expression (such as different ages at onset),
- provide a reminder of who in the family is at risk for the condition, and
- emphasize the need to obtain medical documentation on affected relatives.

See best practices in family history collection and risk assessment for primary care in the Appendix.

# THE IMPORTANCE OF IDENTIFYING COLORECTAL CANCER FAMILY HISTORY

*Colorectal cancer can be prevented when we know who is at increased risk.*

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the United States. In 2018, there are predicted to be 140,250 new cases of CRC in the United States.[2] Individuals who have a first-degree relative with CRC are at least two times more likely to develop CRC themselves, with the risk increasing with earlier ages of diagnosis and the number of relatives diagnosed with CRC.[3,4] Therefore, knowledge of and adherence to screening guidelines is important to improve morbidity and mortality from CRC in these families at increased risk.

Routine screening has been shown to be effective in prevention and early detection of CRC. Early detection of CRC saves lives. The survival rate for patients with stage 1 (local) CRC is 90% but drops to 14% for patients with stage 4 (metastatic) disease.[2] Approximately 4,600 lives could be saved per year if individuals with CRC under age 50 are diagnosed at a localized stage.

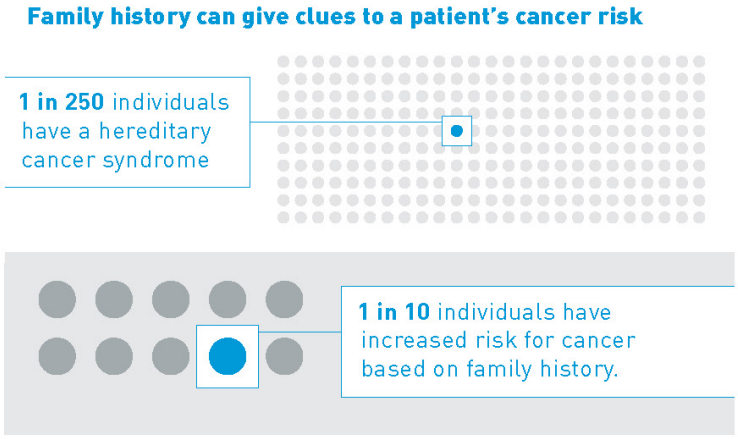



Figure 1. Incidence of familial and hereditary cancer risks for colon and breast cancers.

National screening guidelines exist for the general population at average risk, for individuals at moderately increased risk due to a positive family history and/or personal history, and for those at high risk due to a hereditary cancer syndrome. However, fewer than half of individuals with a family history of CRC or advanced adenoma (> 1 cm) receive personalized counseling and follow risk-based screening guidelines.[4,5]

This concerning state is due in part to a lack of family history collection among a significant number of patients. Less than 40% of individuals with a family history of CRC have talked with a healthcare provider about their family history.[5] Even in symptomatic patients with rectal bleeding, family history is not always adequately collected, with 38% of cases lacking necessary information for risk evaluation.[6] Expanding beyond CRC to include additional common conditions in primary care, one study showed that less than 4% of patients' medical records had sufficient family history information to assess risk.[7]

Limited or inaccurate family history collection and risk assessment is a major barrier to successful cancer screening. In order to focus screening and prevention efforts on those with familial or hereditary risk, these individuals must first be identified as having an increased risk, which requires collecting the necessary family history information for risk assessment. Primary care clinicians play a pivotal role in identifying people at increased CRC risk and facilitating recommended screening. This toolkit aims to help the clinician implement best practices in CRC family history collection, risk assessment, and management to prevent cancer or detect it at the earliest possible stage.

# EARLY ONSET COLORECTAL CANCER

*The incidence of CRC is increasing in individuals under age 50.*

Recent data show a rising rate of CRC under the age of 50, despite an overall decrease in the rate of CRC diagnoses across older age groups. One in ten colorectal cancers are now diagnosed in patients younger than 50.[8] CRC is often under- and misdiagnosed in younger patients. Younger individuals are significantly more likely to be diagnosed with late stage disease compared to older individuals, due in part to delayed work-up of symptoms by the patient and/or provider.[9]

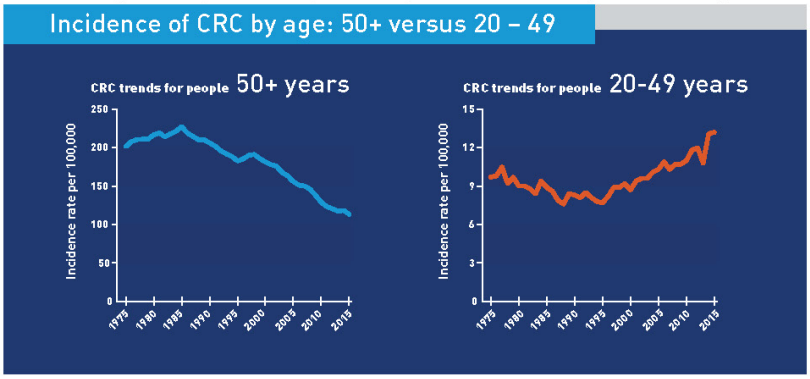



Figure 2. Incidence of CRC by age.[5]

A substantial proportion of early onset CRC may be preventable by taking a family history and screening individuals with an increased risk earlier and more frequently. Approximately 16% of cases occur in individuals with a hereditary condition, such as Lynch syndrome, and 14% have a family history of CRC.[10] Additionally, a currently undefined portion of this group has a family history of advanced adenomas that would warrant earlier screening. Early onset CRC may also develop due to personal risk factors such as chronic inflammatory bowel disease (e.g., ulcerative colitis), lifestyle factors such as limited exercise, a diet low in fruits and vegetables and high in fat, overweight and obesity, tobacco use and alcohol consumption, and other as of yet unknown causes.

In addition to routinely using family history to identify people at increased risk, primary care clinicians can help reduce CRC mortality by promoting primary prevention and early detection as well as considering CRC in the evaluation of a patient with possible alarm signs and symptoms, regardless of age.

# UPDATE ON COLORECTAL CANCER SCREENING

*in the general population from the American Cancer Society*

The American Cancer Society (ACS) now recommends that CRC screening begin at age 45, while the US Preventative Services Task Force (USPSTF) recommended in 2016 that CRC screening should begin at age 50.[11, 12] The difference in these two recommendations is due to new data about rising incidence in younger birth cohorts that was published in 2017. See Table 1 for a comparison of the two recommendations and view an FAQ about the new guideline at NCCRT.

The ACS firmly believes that the evidence, including a concerning trend in CRC incidence in younger adults discussed in this toolkit, now points to CRC initiation starting at age 45. Having said that, ACS does anticipate that implementation will be a multi-year process, as measurement and coverage issues are worked out. ACS recognizes that many organizations will continue to follow the USPSTF recommendations for the time being. For practices that do start screening at age 45, those individuals should still be assessed for risk, as it may determine screening frequency or test selection.

Table 1. CRC screening guidelines for average risk adults: Comparison of American Cancer Society (ACS, 2018) and US Preventative Services Task Force (USPSTF, 2016) recommendations. Q = Qualified Recommendation, S = Strong Recommendation, A = A Evidence Grade, C = C Evidence Grade.

| Recommendations | ACS[11] | USPSTF[12] |
|---|---|---|
| Age to start screening (Level of evidence) | 45y<br>Starting at 45y (Q)<br>Screening at 50y and older (S) | 50y (A) |
| Choice of test | High-sensitivity stool-based test or structural exam | Different methods can accurately detect early stage CRC and adenomatous polyps |
| Acceptable test options | FIT annually<br>HSgFOBT annually<br>mt-sDNA every 3y<br>Colonoscopy every 10y<br>CTC every 5y<br>FS every 5y<br><br>All positive non-colonoscopy tests should be followed up with colonoscopy. | HSgFOBT annually<br>FIT annually<br>sDNA every 1 or 3 y<br>Colonoscopy every 10y<br>CTC every 5y<br>FS every 5y<br>FS every 10y plus FIT every year |
| Age to stop screening (Level of evidence) | Continue to 75y as long as health is good and life expectancy 10+y (Q)<br>76-85y individual decision-making (Q)<br>>85y discouraged from screening (Q) | 76-85y individual decision making (C) |

# HOW TO USE THIS TOOLKIT

### Purpose of the toolkit

The primary goal of this toolkit is to enable primary care clinicians to implement a structured family history collection system to identify individuals at increased or high risk of CRC and develop a management strategy for those individuals. A secondary goal is to facilitate timely diagnostic evaluation of patients with signs or symptoms of early onset CRC.

### Learning objectives

1. Create a system to integrate family history collection and screening into practice flow
2. Identify patients at increased or high risk of CRC based on personal and/or family history
3. Apply screening guidelines to patients at increased and high risk
4. Refer high risk patients to genetic services for further evaluation, counseling, and testing
5. Include CRC in the differential diagnosis of adults under age 50 with alarm signs and symptoms

### Who should use the toolkit

The toolkit is intended for primary care clinicians and administrators, including physicians, nurse practitioners, and physician assistants who specialize in internal medicine, family practice, and obstetrics/gynecology, and office managers or administrators working in these settings. Components of the toolkit may also be used by other primary care staff, such as nurses and medical assistants, who may be involved in family history collection and other associated activities.

This toolkit is designed to be used by a clinical champion or administrator to identify and implement a CRC risk assessment solution that works for the practice. The toolkit also contains guidance and education for clinicians and staff who are interested to learn more about family history collection, CRC risk assessment and risk management, and the detection of early onset CRC.

### Approach towards practice change

There are different philosophies about how to introduce a new program in practice. This toolkit recommends a systemic approach with buy-in of practice or health system leadership. Other approaches could include encouraging providers and patients to engage with the program based on their interest, rather than directing a practice-wide implementation. In these cases, elements of this toolkit can still be helpful to help clinicians implement activities of interest.

Implementation and practice change are complex processes. Clinicians and staff may be able to leverage quality improvement experts from their practice or health system to assist in implementation. They may also consider additional training on evidence-based approaches that can augment the information in this toolkit. See the Appendix for select training opportunities.

### Personalize the toolkit for your needs

The toolkit is designed so that you can customize your experience. Each page provides the information you need to complete a task so you can create a customized toolkit by assembling only the pages that are relevant to your practice needs.

The toolkit can be used by practices that are considering a systematic family history collection process for the first time, as well as those that may have already begun implementation who are looking for guidance on a specific issue. New and experienced users may use the toolkit in different ways. For example, practices that are new to systematic family history collection may want to read the entire toolkit prior to implementing processes, while those who have already embarked on implementation may wish to use only the tools and pages to build clinical skills around family history collection and identification of early onset colorectal cancer.

### Opportunities to build on the toolkit instruction

**Risk assessment beyond colorectal cancer.** Recognizing that family history collection and interpretation is ideally an integrative and comprehensive process that considers risk for multiple conditions, this toolkit provides suggestions for how to implement a system for general family history collection that would allow the provider to assess a broad range of conditions. Beyond family history collection, the information about risk assessment and cancer management is specific to CRC. Practices may wish to expand their activities to include other cancers and health conditions when developing a risk assessment process.

**Cancer genetic testing**. Most primary care clinicians refer high risk individuals to a genetic specialist for genetic counseling and genetic testing. However, some clinicians and practices perform these processes in the primary care office, due to provider interest, patient demand, and/or limited access to genetic services. This toolkit does not provide instruction on how to integrate genetic testing into the primary care practice. Page 42 summarizes important considerations for practices considering ordering genetic testing in-house.

### Navigating the toolkit in Adobe Acrobat

The toolkit contains links to external web sites and links to pages within the document. If you use internal links you may want to return to the page you were previously viewing.

You can find PDF pages that you viewed earlier by retracing your viewing path. It's helpful to understand the difference between previous and next pages and previous and next views. In the case of pages, previous and next refer to the two adjacent pages, before and after the currently active page. In the case of views, previous and next refer to your viewing history. For example, if you jump forward and backward in a document, your viewing history retraces those steps, showing you the pages you viewed in the reverse order that you viewed them.

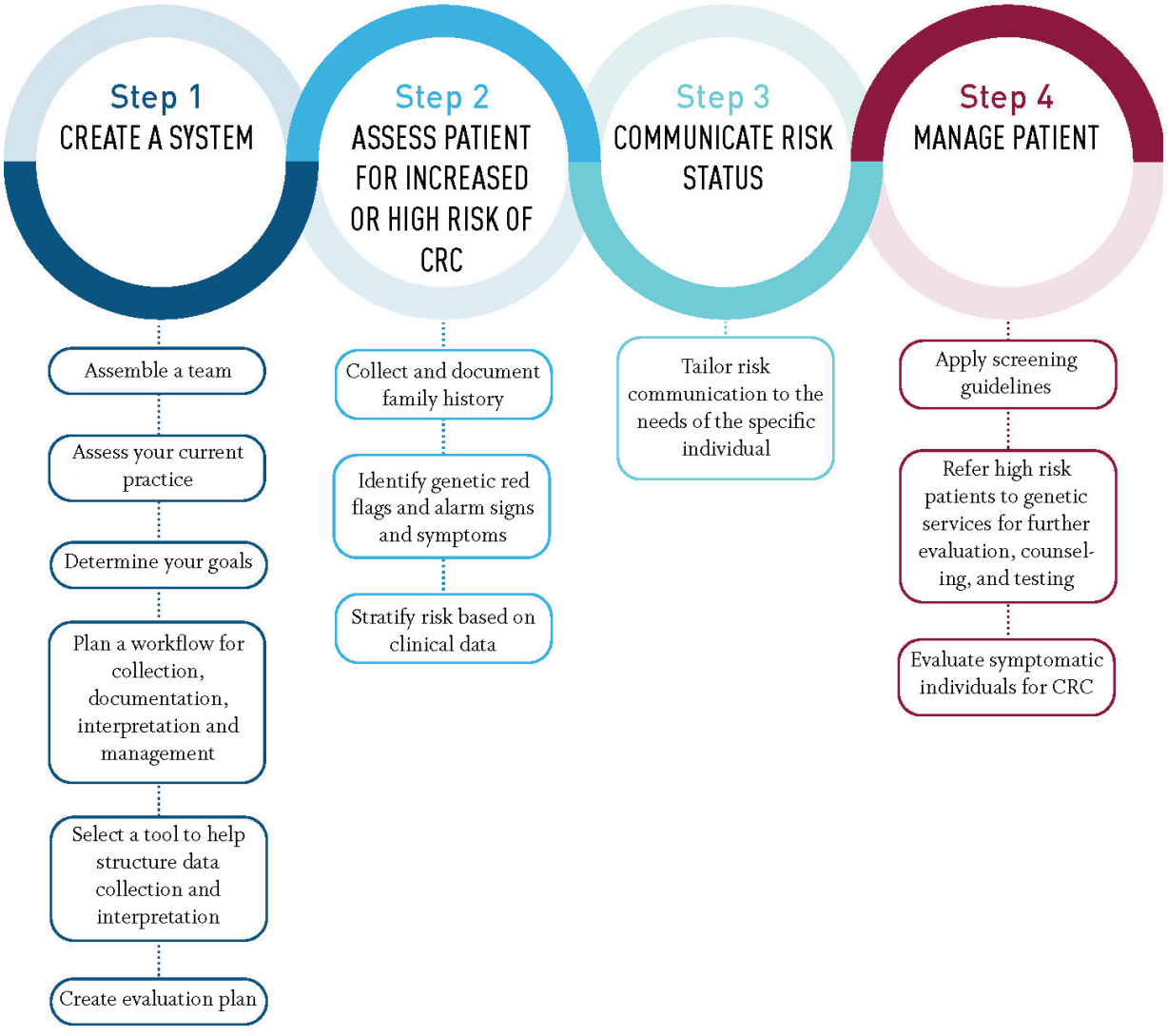
**Steps**

1. Choose View > Page Navigation > Previous View.
2. To continue seeing another part of your path, do either of the following:
   - Repeat step 1.
   - Choose View > Page Navigation > Next View.

**Note:**
You can make the Previous View button and Next View button available in the toolbar area by right-clicking the Page Navigation toolbar and choosing them on the context menu, or choosing Show All Tools.

You can also use the keyboard shortcut. "Alt+Left Arrow" on a PC or "Command+Left Arrow" on a Mac.

# OVERVIEW OF THE FAMILY HISTORY COLLECTION AND CRC RISK ASSESSMENT PROCESS

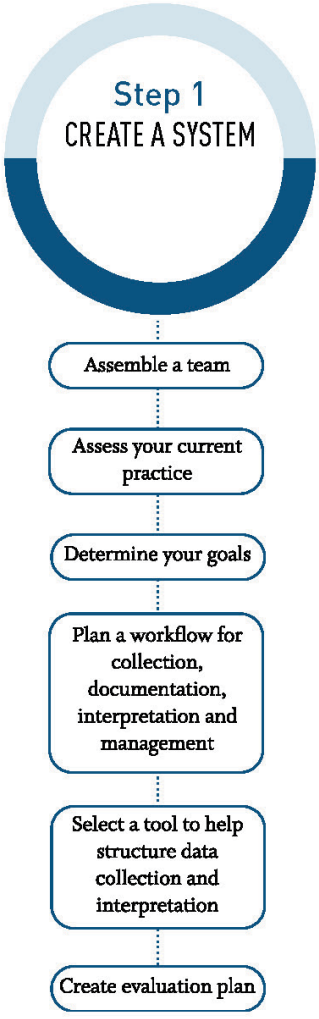


# CHAPTER 2

# Establish a System for Structured Assessment Across the Practice

# ESTABLISH A SYSTEM FOR STRUCTURED ASSESSMENT

*A cancer risk assessment system includes a standardized process for family history collection and interpretation as well as guidance for developing a personalized management plan for patients.*




To improve identification of individuals at increased risk of colorectal cancer, primary care clinicians need to recognize those patients who have a personal and family history that increases their cancer risk and identify the appropriate cancer screening and genetic services indicated for a given patient. The most successful programs are those that engage the entire practice in developing and implementing a systematic, team-based approach to family history collection and interpretation.

Chapter 2 is intended to help practices establish a system for cancer family history collection and risk assessment. This process can and should be customized to the needs of your practice. It can also be adapted to coordinate with other initiatives, such as assessing risk for a more comprehensive list of conditions, promoting cancer screening among eligible patients, or rapid diagnosis of individuals presenting with alarm signs and symptoms of cancer.

This chapter will guide practices through setting goals for family history collection, assessing current processes, and working through best practices and different methods for family history collection and risk assessment to identify opportunities for improvements to the clinic workflow, if needed. Generally, a family history process identifies when to collect and where to document family history data, the team members who are involved in collection and interpretation, and any tools used to aid the patient or provider in collecting or assessing family history. Practices should also consider CRC screening protocols based on professional society guidelines for increased risk individuals and collaboration with genetic and other cancer specialists for referral and consultation for individuals at high risk.

Adopting a new process in clinical practice is a major endeavor. Before embarking on the planning activities outlined in Chapter 2, you should take stock of your organization and its resources to determine whether you are ready to make this change. A precursor activity may be to conduct a needs assessment within the practice or health system, which could include formal or informal surveying of staff as well as calculating baseline risk assessment and screening rates for the increased risk population. Even with compelling needs assessment data, you still may find that your organization is not yet fully ready to adopt a new system and thus needs to take intermediate steps to prepare.

The following sections were adapted with permission from AHRQ[1]:

- Assembling a team
- Assessing your existing workflow
- Setting goals and the Goals Worksheet
- Identifying opportunities for improvement and defining new workflow
- Training
- Planning for launch
- Monitoring and evaluation

# ASSEMBLING A TEAM

*Identify core members of the implementation team and engage them in planning sessions.*

Successful programs utilize the team in creating, supporting, and following the plan for family history risk assessment. Your team should have a provider champion and an implementation manager. The provider champion will act as the lead change agent within the practice. At a minimum, the champion will lead decision making during the planning stages, negotiating consensus among stakeholders. During implementation, he or she will maintain communication and enthusiasm among the other providers. The champion should be a respected and recognized leader within the practice as well as a practitioner who will ultimately use the system alongside his or her colleagues.

The implementation project manager will drive the implementation process by tracking and supervising the activities that need to take place. In the planning stages, the project manager will ensure that the necessary information is gathered and provided to the key decision makers and that decisions are made in a timely and appropriate manner. During the later implementation phases, this person will, at a minimum, create and oversee the timeline for setup, training, and launch. In some practices, the office manager may step into the project manager role. In some instances, the same person may act both as champion and as implementation project manager.

**PARTICIPANTS**
Clinical champion, implementation lead, stakeholders

**WHAT YOU'LL NEED**
Goals Worksheet

**BARRIERS**
Competing priorities, time, staff, infrastructure

## STEPS

1. Identify the clinical champion and implementation project manager.
2. Identify the additional stakeholders that should be included in team meetings and project planning. Which clinicians and staff should be involved in discussions about goals for cancer family history collection and assessment? Determining which stakeholders to engage should be based, in part, on who has relevant expertise (i.e., anyone whose job is affected by current processes), whose job will be affected by the new process, or who will be involved in the implementation process (e.g., the office manager). Consider including patients as stakeholders.
3. Engage stakeholders throughout the planning process to set shared goals, identify the pain points in the current process, brainstorm potential solutions, and define desired outcomes.

# ASSESSING YOUR EXISTING WORKFLOW

*Review and describe your existing workflow to identify potential improvements.*

Understanding your current workflow will enable you to examine what is happening in your office, diagnose any workflow problems from the perspectives of those involved or impacted, and develop an updated process that will work successfully with available staff, space, and resources. In general, there are three main processes involved in assessing a family history: (a) collection and updating over time, (b) documentation, and (c) risk assessment. Practices are likely to have different workflows for family history processes, with specific people carrying out tasks, such as eliciting the family history, transcribing the data in the medical record, and analyzing the data for risk assessment. Regardless of the specific system established at your clinic, your workflow should address the three processes above.

As you assess your workflow, consider possible improvements to processes, needs for staff training and streamlining of tasks, and points where using a family history tool may help.

**PARTICIPANTS**
Implementation lead, staff involved in family history processes

**BARRIERS**
Competing priorities, time, infrastructure

**LEARN MORE**
AHRQ Workflow Assessment for Health IT Toolkit

## STEPS

1. Gather information on the current workflow. Observe providers and staff involved in collecting, documenting, and assessing family history information. During the observation process, ask the following questions:
   - Where are potential problems or delays likely to occur in the current process?
   - Where in the process are opportunities to achieve more benefits from family history collection?
   - Where could patient handouts or resources help the process?
2. Organize the information into the basic processes of: (a) collection, (b) documentation, and (c) risk assessment.
3. Summarize the sequence of tasks in a workflow diagram. A workflow is the set of sequenced tasks used to reach a specific goal, such as identifying patients at increased risk of disease based on family history. The workflow may include factors that affect the completion of the task, such as the staff involved, materials and equipment needed, methods used, and physical environment (e.g., the layout of the site where the process occurs). See the example workflows Patient Collection (Figure 3) and Nurse Collection (Figure 4) as a starting point for how you might develop your practice's family history workflow, with more or less detail as needed.
4. You may learn you have multiple workflows depending on the visit type, such as annual preventative health vs. sick visit, or other variables, new patient vs. established patient. Sketch out workflows for each of the different ways family history is collected in your practice.

# SETTING GOALS

*Establishing your goals and desired outcomes for risk assessment will help you identify the best process and tools for your practice.*

After you have assessed your current workflow, you should identify your desired goals and outcomes for cancer risk assessment and CRC screening. This toolkit is designed to help you reach these goals:

- Identify patients at increased or high risk based on personal and/or family history
- Apply screening guidelines to patients at increased and high risk
- Refer high risk patients to genetic services for further evaluation, counseling, and testing

Your practice may have additional goals, which can be defined during planning. The implementation process will take time, especially for users to become comfortable with new tools and work processes. Having clear goals and realistic expectations helps to ensure that the team will persist in achieving these changes because they know why the changes are occurring. Further, discussion of goals and expectations can ensure that stakeholders are "on board" with the changes, have reasonable expectations regarding the disruption of existing routines, and are ready to recognize the changes when they occur.

**PARTICIPANTS**
Clinical champion, implementation lead, stakeholders

**WHAT YOU'LL NEED**
Goals Worksheet

**BARRIERS**
Competing priorities, time, staff, infrastructure

## STEPS

1. Read about goals that are commonly considered achievable. See the next page for suggestions.
2. Working with the previously identified stakeholders, choose the three or four goals that are most important and achievable for your practice. These should be goals that would help you improve patient care, perform as a practice, or streamline the daily work of the practice. Write these goals down in the Step 2 section of the Goals Worksheet (available in the Appendix).
3. For each goal, set a specific, measurable "target" for what level of performance can be achieved to improve the existing conditions. Write these targets down in Step 4 of the Goals Worksheet.
4. Next, you will develop your "measurement plan." This means you will determine how you will measure the progress in reaching the explicit targets of your goals, and who will be responsible for collecting these measurements.
5. Consider feasibility. Feasibility is usually determined by having sufficient staff and opportunities to collect the data. Be sure to discuss feasibility with the stakeholders in your office who will be assigned responsibility for monitoring. Are the expectations for measuring progress towards the goal realistic? Rate the feasibility from 1 (not very feasible), 2 (somewhat feasible) or 3 (very feasible) and record under Step 4 of the Goals Worksheet.
6. Set a target date by which the measurable goal will be met. You may find you need to adjust this date further into planning, but it can be helpful to set an agreed-up date with stakeholders. Write this down under step 4 of the Goals Worksheet.
7. Communicate the final goals, expected outcomes, and timeframe to stakeholders and team members.

# GOALS FOR FAMILY HISTORY CANCER RISK ASSESSMENT

*Review these with an eye towards choosing goals that are important to your practice. The list of goals provided below is intended to provide examples, but is not exhaustive.*

- Increase identification of patients who qualify for earlier or more frequent cancer screening
- Increase identification of patients for referral to genetic counseling and genetic testing
- Increase identification of patients for genetic testing (if in-house genetic counseling is available)
- Standardize cancer screening and surveillance practices
- Improve care coordination for patients at high risk of cancer
- Improve patient compliance with cancer screening and/or genetic referrals
- Reduce time spent on family history collection and/or risk assessment
- Systematize cancer risk assessment
- Improve the quality of patient-provided family history information
- Improve access to patient educational and decision support resources

For goals related to risk assessment, consider the additional questions to target your efforts:

- Will your risk assessment integrate personal and family history risk factors, or create separate processes?
- What conditions will be included in the risk assessment process? A specific cancer such as colorectal or breast cancer, all cancers, and/or a broader panel including non-cancer conditions (e.g., cardiovascular disease)?

Worked example of the Goals Worksheet

# GOALS WORKSHEET

**Step 1. Review goals. Consider how these goals align with practice and stakeholder priorities.**

Review what goals can be achieved with cancer family history collection and risk assessment.

**Step 2. Pick the most relevant goals for your practice.**

- Goal: Reduce time spent on family history collection and/or risk assessment
- Goal: Collect sufficient family history data to inform cancer risk assessment
- Goal: Automate cancer risk assessment
- Goal: Increase identification of patients who qualify for earlier or more frequent cancer screening
- Goal: Increase identification of patients for referral for genetic counseling and genetic testing

**Step 3. Choose priorities.**

Meet with stakeholders to frame the three highest-priority goals. Rewrite the goals in language that resonates with them. Record the top three goals here:

- Goal 1. Collect sufficient family history data to inform cancer risk assessment
- Goal 2. Increase identification of patients who qualify for earlier or more frequent cancer screening
- Goal 3. Increase identification of patients for referral for genetic counseling and genetic testing

**Step 4. Plan. Set a target date for when you want to achieve the goal.**

Determine an explicit target for each goal, plan to measure how well you achieve each target, and rate the feasibility of measuring each (1 = not feasible, 3 = very feasible).

| Goal | Target | Measurement Plan | Measurement Responsibility | Measurement Feasibility (1, 2, 3) | Goal Completion Date |
|---|---|---|---|---|---|
| Goal 1 | 75% of patients seen since implementation will have cancer family history included in the medical record | Review of patient records using spreadsheet | Population Health | 2 | May 1, 2019 |
| Goal 2 | 100% of patients with a first-degree relative with CRC will receive a recommendation for increased screening | Review of patient records using spreadsheet | Population Health | 2 | May 1, 2019 |
| Goal 3 | 75% of patients with a family history of CRC will have documented cancer risk assessment<br><br>100% of patients who are identified to be at high risk will receive a recommendation for genetic referral | Review of patient records using spreadsheet | Population Health | 2 | May 1, 2019 |

**Step 5. Communicate the final goals to stakeholders and team members.**

# WHEN TO COLLECT

*Figure out when family history should initially be collected and assessed, and how often it should be updated.*

Family history information by nature changes over time. Once collected, it is only valuable so long as it is an accurate representation of health and disease states among the patient's family members. Your practice should establish a plan for how to collect an initial family history on existing patients and how to update the family history over time. To the degree possible, work with your practice to automate the steps so they are part of standard workflows and templates.

**PARTICIPANTS**
Implementation lead, staff involved in family history processes

**WHAT YOU'LL NEED**
Family history collection tool, knowledge of the type of information to collect

**BARRIERS**
Time, staff, infrastructure, IT

**LEARN MORE**
Collecting Sufficient Family History

## STEPS

*For initial collection*

1. Include family history collection as a standard activity for all new patients entering the practice.
2. Determine how to best roll out your family history collection system to active patients in the practice, such as:
   - Incorporate it into preventive visits.
   - For patients that do not complete annual check-ups, run a report in the EHR to identify who has not participated and take action to include them (either through a separate appointment or adding family history collection into their next sick visit).
   - If your family history collection system does not center around an appointment with a provider, send a letter to patients and post flyers in the office advertising this new service for interested patients.

*For updating*

1. Encourage the patient to share changes to the family history over time, providing concrete examples, such as a new cancer diagnosis in a relative.
2. Update family history regularly. For adults aged 30-60 years, the family history should be updated annually in order to identify individuals that may benefit from increased cancer screening. It may be helpful to incorporate a standard question about updates to the family history as part of annual preventive visits, or setting a flag in the EHR to prompt updating the family history at the designated interval.
3. Ask about any new cancer diagnoses in the family when the patient presents with symptoms or concerns that may suggest cancer. For colorectal cancer, concerning signs or symptoms include blood in stool, anemia, and a change in bowel habits, among others.

# WHERE TO DOCUMENT

*Choose a documentation method that allows for easy retrieval, assessment and updating, as family history changes over time.*

There are different approaches to documenting family history information, including in narrative or list form, a structured table, and visual representations such as a pedigree. Recording information in a pedigree can help you see patterns of disease more easily, but pedigrees are not typically supported in most EHRs. If you prefer to have the option of viewing family history information in a pedigree or genogram format, consider evaluating different family history tools as well as the capability of your EHR system.

Family history data can be entered into the EHR in numerous ways, and methods may be different even among providers in the same office. Standardizing how and where family history data is recorded in the EHR will increase the usability of this information. It is generally considered best practice to record family history data in preset structured fields rather than as free text, when structured data collection is an option.

**PARTICIPANTS**
Implementation lead, staff involved in family history processes, IT vendor or EHR superuser

**WHAT YOU'LL NEED**
Family history collection tool, clinic workflow, EHR

**BARRIERS**
Time, varying preferences among providers, EHR functionality

**LEARN MORE**
Collecting Sufficient Family History

Documenting Family History Information

## STEPS

1. Work with your EHR and/or family history tool vendor to learn about available reports and what kinds of fields can be included in reports, that will help your practice monitor family history activities. The outcome of this discussion may impact decisions you make about where and how to document family history data.
2. Determine where practice staff will enter family history data in the EHR: the family history section, problem list, visit summary, and/or progress report. There may be different rules for the comprehensive information collected and information deemed relevant for the patient's risk assessment.
3. For practices that use a paper questionnaire or stand-alone electronic family history tool, establish a process for how these forms or reports get scanned or uploaded in the EHR for reference over time.

# TIPS FOR DOCUMENTING FAMILY HISTORY IN THE ELECTRONIC HEALTH RECORD

*These tips can help streamline documentation to result in family history data that can be utilized for risk assessment over time.*

Record family history data in structured fields rather than as free text to enable the use of clinical decision support and accurate reporting, when possible. This usually means recording the family history in the family history section, rather than in the narrative progress note.

Add family history through ICD10 diagnoses to the patient's medical history or problem list. This will support the use of alerts and clinical decision support.

Work with your EHR vendor to determine whether red flags or alerts can be generated based on known risk factors.

Explore ways to adapt existing EHR functionality and workflows with your vendor, in order to maximize the benefits of collecting family history.

**Note:**
The Electronic Health Record has the potential to be a powerful tool for family history collection, documentation, and risk assessment as well as to facilitate the use of family history information in medical decision making through clinical decision support systems. While significant advances are being made by some vendors and researchers, many EHRs currently lack the functionality necessary to support the clinician in recording the necessary family history data in structured fields to perform accurate risk assessment or to use the collected family history information for medical decision making. For this reason, some clinicians look to external vendors for a family history tool solution that can collect family history in structured and usable way, and also perform varying degrees of automated risk assessment. Such external tools may or may not be designed to interface with the EHR and even when they are, the level of integration is often limited to importing a PDF report into the EHR as a static document.

Efforts are ongoing to improve standards and EHRs capabilities in this area. In 2012, the Stage 2 Meaningful Use rules addressed collecting a structured family history for the first time. NCCRT and other national organizations are currently working towards a set of best practice recommendations for both the process and content of cancer family history collection that should be included in high quality EHRs.

# METHOD IN ACTION

*Using an electronic patient questionnaire to collect cancer family history.*

University Women's Care is an obstetric and women's health practice affiliated with an academic teaching hospital in an urban setting. Staff include attending physicians, nurse practitioners, and nurses. OBGYN residents and medical and nursing students participate in rotations. After an initial pilot project with the medical genetics department, the practice adopted a family history collection approach that is based on an electronic collection and risk assessment tool.

New patients are asked to arrive 15 minutes early to their appointment to check in and fill out paperwork. This includes completing a short electronic questionnaire on a tablet computer in the waiting room. The questionnaire collects information about the family history of cancer. When the patient is done, the questionnaire data is automatically run through the tool database to perform cancer risk assessment and a report is generated and imported into the EHR.

During the clinical encounter, the provider reviews the risk assessment results and clarifies family history information with the patient as needed. Using the risk assessment results, the provider and patient discuss red flags in the family history and next steps, which can include a recommendation for cancer screening and/or a referral for genetic counseling and further evaluation. The provider documents the encounter and any referrals in the EHR.

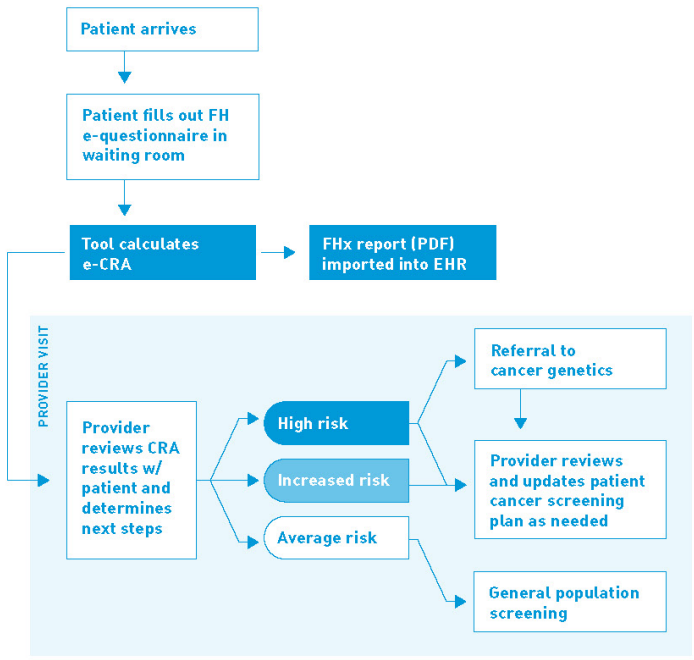



Figure 3. Workflow with patient-entered family history collection in the waiting room and provider risk assessment using an electronic tool. CRA = cancer risk assessment. FH = family history. EHR = Electronic Health Record.

*This example was adapted from published reports[13,14,15] and commercial tools, such as CRA Health, Family Healthware, MyLegacy, and Progeny. See the Family History Features Worksheet for additional family history tools.*

# WHO WILL COLLECT

*Work with your team to determine who will collect the family history: the patient him- or herself, allied health professional, the primary provider, or some combination of the three.*

Consider how to best execute the initial family history collection for patients in your practice. Selecting tools to assist you should be closely tied to determining who will actually be involved in collecting the family history. Could your average patient complete a questionnaire to document his or her family history for you? Do you have Medical Assistants or Nurses on staff who can be trained to interview the patient to collect the necessary information? The answers to these questions can help determine a time efficient solution for your practice.

**PARTICIPANTS**
Implementation lead, staff involved in family history processes

**WHAT YOU'LL NEED**
Family history collection tool, clinic workflow

**BARRIERS**
Competing priorities, patient and provider knowledge, time, institutional role restrictions

## APPROACHES

1 *Patient collection*

To save time in the face-to-face clinical encounter, many practices prefer for patients to collect family history information prior to their appointment, either through a mailed questionnaire (or emailed electronic questionnaire), or in the waiting room. Collecting this information prior to the visit allows patients to research their family histories more completely.

2 *Allied health professional collection*

Some practices have developed innovative models for family history collection, with or without a triaging component, in which a nurse or medical assistant interviews the patient to collect standard family history information. This may include the allied health professional administering a screening tool to the collected information to triage whether the patient should be seen by a provider for further risk assessment and management. In these models, the health professional conducting the family history interview receives training on what information to collect and how to document it.

3 *Provider collection*

Family history collection as part of the visit intake by the primary care provider is the most common method used in practice. This process can be streamlined by using a tool or template in the clinic note and educating the provider on the essential elements to collect and red flags to recognize for individuals with increased cancer risk.

# METHOD IN ACTION

*Utilizing nurse wellness visits for cancer family history risk assessment.*

Family Care USA is a large family medicine residency program in a rural setting. Staff include attending physicians, physician assistants, family medicine residents, and nurses. The practice recognized a need to improve the identification of at-risk individuals for hereditary cancer syndromes, including hereditary breast and ovarian cancer syndrome and Lynch syndrome. A new telegenetics satellite office recently opened in the community, reducing access barriers for patients to be seen in cancer genetic clinic.

Family Care developed a cancer risk assessment model that utilized an existing clinic infrastructure for nurse wellness visits. The RN received specialized training on collecting and assessing family health history information for cancer. To systematize the risk assessment criteria, the practice, in collaboration with the genetic clinic, developed a Red Flags Checklist for the nurse and a Genetic Referral Checklist for the provider.

There are two points of entry into the Cancer Family History Nurse Wellness visit: (1) the provider recognizes a potential concern and refers the patient for more thorough family history collection and risk assessment or (2) the patient initiates the appointment request after receiving education through materials in the waiting room.

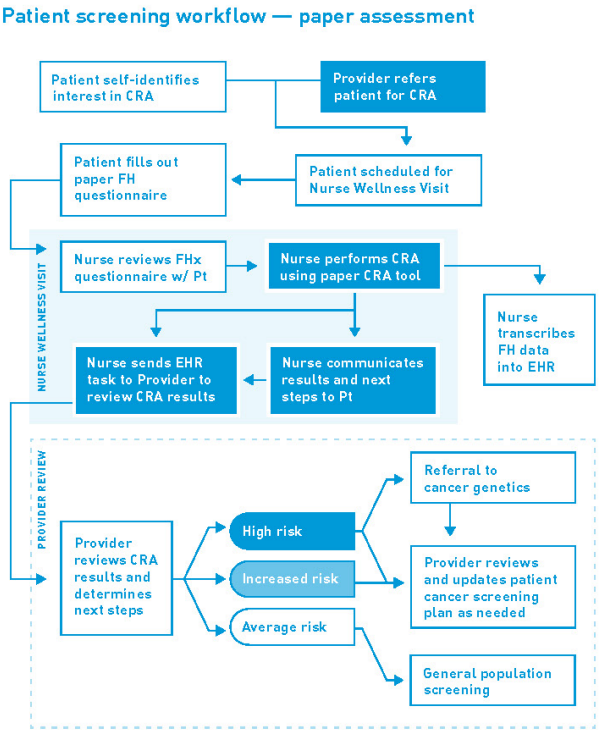



Figure 4. Workflow with 2-tiered risk assessment utilizing nurse appointment and secondary provider review of family history and paper family history collection and risk assessment tools. CRA = cancer risk assessment. FH = family history. EHR = Electronic Health Record.

In the Wellness Visit, patients complete a paper family history questionnaire that elicits structured family history information. The nurse reviews the family history, asking for additional information as needed, and completes a Red Flags Checklist to determine if the patient should be considered for changes in screening and/or a referral to genetic clinic.

The nurse submits a task in the EHR for the provider to review the patient's family history and nurse recommendation. The provider can use a Genetics Referral Checklist to determine if the patient should be referred to cancer genetic clinic. The patient is scheduled for a follow-up appointment after the Nurse Wellness Visit and genetic appointment to review any recommendations for changes in management.

*This example was based on Maine Dartmouth Family Medicine Residency's model for cancer risk assessment in family practice. For more information, contact Dr. Greg Feero at W.Gregory.Feero@MaineGeneral.org.*

# WHO WILL INTERPRET

*Family history interpretation and risk assessment may be performed by the primary care provider, but can also be aided by other team members and specialists.*

After the family history is collected, determine who in the practice will be involved in interpretation of the data and performing risk assessment. This decision, too, may be made in coordination with selecting a family history tool. An electronic risk assessment tool can perform initial assessment of the family history based on algorithms, but a clinician should also review the results before changing patient management.

**PARTICIPANTS**
Implementation lead, staff involved in family history processes

**WHAT YOU'LL NEED**
Risk assessment tool

**BARRIERS**
Competing priorities, knowledge, infrastructure

**LEARN MORE**
Assessing Risk and Identifying Red Flags

Categorizing Cancer Risk

Provider Education Resources

## APPROACHES

1 *Provider interpretation*

The primary care provider will always have an important role in reviewing and interpreting collected family history and performing risk assessment. These activities may fall solely on the provider, or may be shared with one (or more) of the methods described below.

2 *Two-tiered: Allied health provider and provider*

As previously described, some practices may utilize another team member to perform family history collection, which can also include initial or preliminary risk assessment. This information is shared with the provider through the EHR or another channel, and the provider reviews the initial interpretation to make a final risk assessment and recommendation to the patient.

3 *Genetic expert review*

Some practices have established relationships with local genetic clinics or commercial genetic services to assist in risk assessment. A genetic specialist reviews charts at regular intervals to identify candidates for further genetic evaluation, and communicates the recommendations back to the practice for review and follow-up.

Figure 3. Workflow with patient-entered family history collection in the waiting room and provider risk assessment using an electronic tool. CRA = cancer risk assessment. FH = family history. EHR = Electronic Health Record.

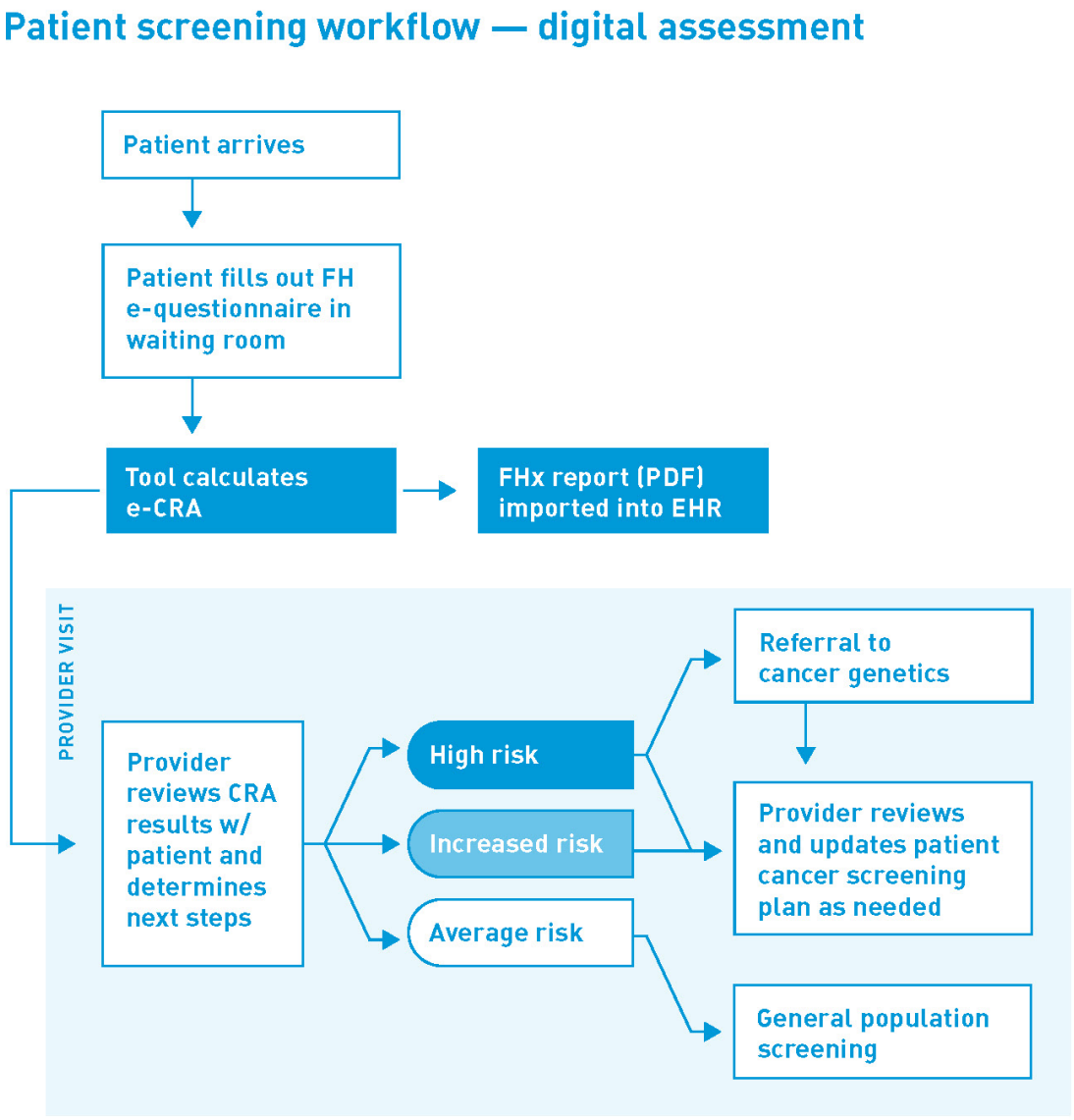
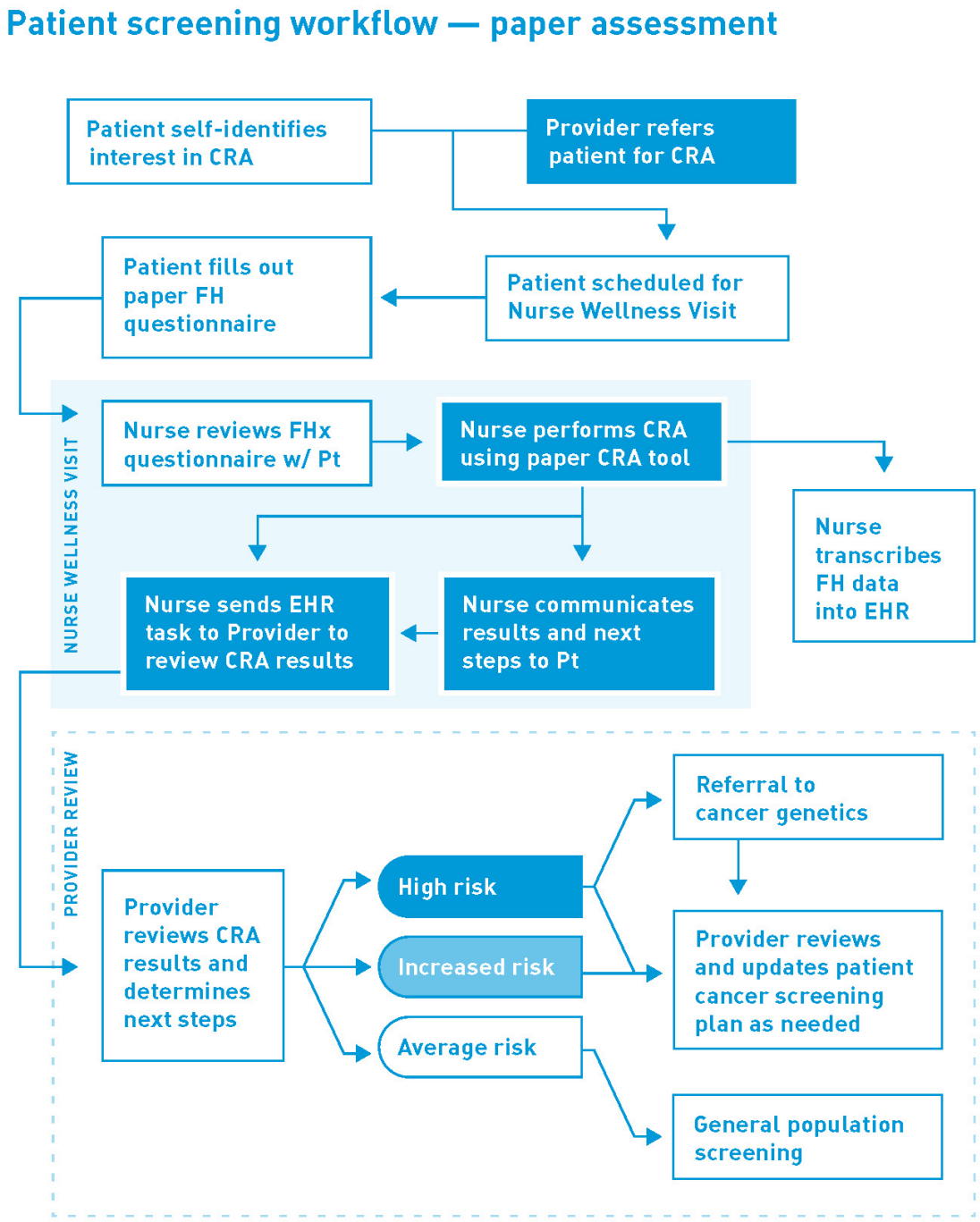


Figure 4. Workflow with 2-tiered risk assessment utilizing nurse appointment and secondary provider review. In this scenario a paper family history and risk collection tools are used. CRA = cancer risk assessment. FH = family history. EHR = Electronic Health Record.



# IDENTIFYING OPPORTUNITIES FOR IMPROVEMENT AND DEFINING NEW WORKFLOW

*Identify opportunities to improve your current workflow through incorporation of best practices and integration of a family history tool.*

While thinking through your current and future workflows as well as best practices and examples from other clinics, you should be able to identify potential improvements to your process. Develop a new or updated workflow that will help achieve your practice's goals for using family history.

**PARTICIPANTS**
Implementation lead, staff involved in family history processes

**WHAT YOU'LL NEED**
Understanding of existing workflow

**BARRIERS**
Competing priorities, staff, time, infrastructure

**PATIENT MATERIALS**
Patient Education Materials

## STEPS

1. Identify the points where delays and waste occur. Perhaps some current steps can be eliminated, such as gathering data that is never used, duplicating forms, repeating questions for patients, and storing paperwork unnecessarily.
2. Identify all the steps that you want to change with a new family history system.
3. Define a new family history workflow and summarize it in a new workflow diagram. Note the differences between your current and future workflows. You will refer to the proposed workflow as you select and implement your new system.
4. Depending on the scope of your planned changes, you may need to identify additional resources for the initial infrastructure development and/or supporting the process over time. Some practices have been successful in applying for small grants or tying cancer family history collection to institution-wide financial metrics to obtain funding.
5. Plan the change from the current system to the new one. Identify where the workflow changes occur and whether there are any intermediate transitional changes, as well as the time sequence of changes.
6. Review the proposed new system, particularly changes and new assignments, with management and all concerned parties to ensure that all issues have been resolved, to gain consensus on key decisions, and to ensure readiness to implement.

# IDEAS FOR IMPROVING YOUR WORKFLOW

*Consider the following steps that have been helpful for other practices.*

- Have the patient collect family history information before the provider visit, and/or identify another team member such as a nurse or medical assistant who can help collect this information. Collecting this information prior to the visit allows the patients to research their family history more completely and provide more accurate information.
- Identify time for a team member to review the patient's provided family history and clarify any information, as needed.
- Provide patient education before and/or during family history collection, at the appropriate literacy level and in the patient's preferred language, to help the patient understand why it is important to share family health history with the provider and how to learn more about the family history. See page 39 and the Appendix for suggested patient materials.
- Use a tool to aid in standardized family history collection and/or risk assessment.
- Document family history in the medical record consistently across the practice.

# SELECTING AND EVALUATING TOOLS FOR COLLECTION AND RISK ASSESSMENT

*There are a number of tools available to aid in family history collection and family history risk assessment, with different strengths and limitations. You should pick the tool that best fits the needs of your practice.*

Once you have established your goals for family history collection and risk assessment and considered your ideal workflow, it is time to determine what systems or tools you will need to aid in collection and/or risk assessment. Some EHRs provide robust family history collection systems, including pedigree generation, while the family history documentation capacity in others will be limited. In these cases, practices may consider identifying an external tool to collect the necessary information for risk assessment, or to run risk algorithms automatically. Selecting an external tool may be complex, especially if you are seeking to integrate with or adapt features of your EHR. It may involve searching out vendors who offer a solution that will do what you need to fulfill your goals at a price that fits your budget.

Start by taking inventory of what you want the tool to do. This is the point at which you review your goals for family history collection and risk assessment (page 17), as well as the workflows that you expect to have after the new process is implemented (page 29). If you want a risk assessment tool that ties to screening guidelines, you may want to review page 35, Identifying Screening Protocols, before you begin evaluating tools. Planning your workflow before you select family history tools may help you choose a tool or system that can support the workflows you need, but these activities can also be planned in parallel.

**PARTICIPANTS**
Implementation lead, stakeholders

**WHAT YOU'LL NEED**
Goals for family history; Family History Tool Features Worksheet

**BARRIERS**
Time, cost, competing priorities, lack of validated tools for the practice environment

**LEARN MORE**
Global Alliance Family History Tool Inventory

Review and Comparison of Electronic Patient-Facing Family Health History Tools

## STEPS

1. Begin to find out what your options are by examining some example tools and reviewing the features shown in the Family History Tool Features Worksheet. Once you have a sense of the features available, select those that are required to enable your desired workflows. This would constitute your "must-have" list of features.
2. Generate a list of tools you will initially evaluate based on key features important to the practice, for example, an electronic collection questionnaire, or a freely available tool. You can start with tools identified in the Family History Tool Features Worksheet and add additional ones through your own search. Include your EHR on your list of tools to evaluate if appropriate.
3. Test your short list tools to evaluate what will work best for your practice.
4. Select a tool, or a set of tools, to use in your practice.

# ADDITIONAL CONSIDERATIONS

*Additional considerations when evaluating a family history tool*

Your patient population's health literacy and language may impact required features for a family history tool. Additionally, baseline risk factors in your population may influence their needs for a tool. A tool that considers patient race and ethnicity as part of risk assessment may be important in some populations, such as those with a high proportion of African Americans.

Consider evaluating tools separately for collection and risk assessment needs. You may find that combining two tools is a better solution for your practice than just using one of the currently available tools.

If you can't find a tool that addresses all of your "must have" features, you may also need to widen your search or reevaluate your desired features, and rank them in order of importance to your patients, your office, and your goals.

If you have decided to pursue a tool that integrates with your EHR system, rather than stand-alone, evaluating and selecting a tool can be more complicated, and you may need to work with a Health IT expert to determine how to customize a solution for your practice, which is beyond the scope of this toolkit.

Worked example of the Family History tool Features Worksheet

# FAMHX TOOL FEATURES WORKSHEET

To download the spreadsheet and navigate to the tools: https://tinyurl.com/ycqeko6h

| Tool Name | Collection Features | | | | Risk Assessment | | | | | Scope | | | Other | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Collection of all 1st- and 2nd-degree relatives | Patient entered collection | Electronic questionnaire | Paper questionnaire | Includes risk assessment (vs. just a collection tool) | Electronic risk assessment | Stratification to 3 categories: average, increased, high | Stratification to 2 categories: average, increased/high | Links to provider management recommendations | Includes personal as well as family history risks | Assessment of multiple cancers beyond CRC | Assessment of non-cancer conditions | Free | Spanish/other language versions available | Validated for primary care | Maintained technology and clinical content | EHR integration |
| Check the "must have" features for your practice: | X | X | X | | X | | | | | | | | X | | | | |
| Does It Run in the Family? | YES | YES | NO | YES | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | YES | YES | YES | NO |
| Family Health History Workbook | YES | YES | NO | YES | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | NO | NO | YES | NO |
| AMA Adult Family History Form | YES | YES | NO | YES | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | NO | NO | YES | NO |
| Family History Questionnaire | YES | YES | NO | YES | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | NO | NO | YES | NO |
| My Family Health Portrait | YES | YES | YES | YES | PARTIAL | YES | NO | YES | NO | NO | PARTIAL | PARTIAL | YES | YES | YES | YES | NO |
| It Runs in My Family | YES | YES | YES | NO | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | NO | NO | YES | NO |
| MyLegacy | YES | YES | YES | NO | YES | YES | NO | NO | YES | YES | YES | YES | NO | NO | YES | YES | YES |
| Family Healthware | YES | YES | YES | NO | YES | YES | YES | NO | YES | YES | YES | YES | NO | NO | YES | YES | NO |
| MeTree | YES | YES | YES | NO | YES | YES | YES | NO | YES | YES | YES | YES | NO | NO | YES | YES | YES |
| Myriad Family History Tool | YES | YES | YES | NO | YES | YES | NO | YES | NO | NO | YES | NO | YES | NO | NO | YES | NO |
| Progeny/Ambry | YES | YES | YES | NO | YES | YES | NO | NO | NO | YES | YES | YES | PARTIAL | NO | NO | YES | YES |
| CancerGene Connect/Invitae | YES | YES | YES | NO | YES | YES | NO | NO | NO | YES | YES | NO | YES | YES | NO | YES | NO |
| CancerIQ | YES | YES | YES | NO | YES | YES | NO | NO | YES | YES | YES | NO | NO | NO | NO | YES | NO |
| CRA Health | YES | YES | YES | NO | YES | YES | NO | NO | NO | YES | YES | NO | PARTIAL | YES | NO | YES | YES |
| NCI CRC Risk Assessment Tool | NO | YES | YES | NO | YES | YES | NO | YES | NO | YES | NO | NO | YES | NO | NO | YES | NO |
| MMRPRo | NO | NO | NO | NO | YES | YES | NO | NO | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| PREMM5 | NO | YES | YES | NO | YES | YES | NO | NO | NO | NO | YES | NO | YES | NO | NO | YES | NO |
| MMRPredict | NO | NO | YES | NO | YES | YES | NO | NO | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| MyRisk Hereditary Cancer Questionnaire | NO | YES | NO | YES | YES | NO | NO | NO | NO | NO | YES | NO | YES | NO | NO | YES | NO |
| Columbia University 3-question survey | NO | YES | NO | YES | YES | NO | NO | YES | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| Families Sharing Health Assessment and Risk Evaluation (SHARE) workbook | NO | YES | NO | YES | YES | NO | NO | YES | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| User-friendly Lynch syndrome risk assessment tool | NO | YES | NO | YES | YES | NO | NO | YES | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| University of Michigan 5-question survey | NO | YES | YES | YES | YES | NO | NO | YES | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| Simple Family History Screening Tool for CRC (See Appendix) | NO | YES | NO | YES | YES | NO | YES | NO | YES | NO | NO | NO | YES | NO | NO | YES | NO |
| CRC Risk Assessment Checklist (See Appendix) | NO | NO | NO | n/a | YES | NO | YES | NO | NO | YES | NO | NO | YES | NO | NO | YES | NO |

**Instructions**

1. Identify the "must have" features for your practice, from the table above and others important to you.

   Collection of 1st and 2nd degree relatives, patient-entered collection, electronic questionnaire option, includes risk assessment, free

2. Use the Family History Tool Table to identify available tools that meet your criteria. Write down the names of your top tools below.

3. Test your list of tools to evaluate what will work best for your practice.

Tool 1: My Family Health Portrait

Tool 2: Myriad Family History Tool

Tool 3: Progeny/Ambry

Tool 4: CancerGene Connect/Invitae

Tool 5: CRA Health

# IDENTIFYING GENETIC & CANCER SPECIALISTS FOR CONSULTATION

*Collaborate with specialists to deliver cancer services to your patients.*

One of the outcomes of risk assessment should be to identify individuals with a high cancer risk based on their personal and family histories, who should undergo further genetic evaluation for hereditary cancer syndromes. Cancer care providers and genetic experts can be a source for answers about risk assessment, genetic testing, risk communication, surveillance and risk reduction. You may develop a relationship in which you can call on these team members directly for consultation, as well as referring patients for specialty care.

**PARTICIPANTS**
Implementation lead

**WHAT YOU'LL NEED**
Accessing Genetic Services Tool

**BARRIERS**
Limited access to genetic services, lack of knowledge of local specialists

**LEARN MORE**
Referring to a Genetic Expert

## STEPS

1. Identify a team of specialists who can collaborate in your patient's diagnosis, treatment, and management. Collect this information in one place to make referrals and care transitions more efficient.

2. Find your local genetic providers. Genetic counselors, clinical geneticists, and physicians, nurses, and physician assistants with specialty genetic training/expertise may be available in your institution or you may need to contact someone elsewhere. You can find a genetic specialist through:

   - National Society of Genetic Counselors (www.nsgc.org)
   - American Board of Medical Genetics (www.abmgg.org)
   - International Society of Nurses in Genetics (www.isong.org)

   It can sometimes be challenging to find a genetic expert locally. There are some opportunities available for telecounseling through academic institutions and businesses. The National Society of Genetic Counselors search function includes information about telegenetics options.

   If your practice has a relationship with a genetic testing laboratory, the lab may provide access to genetic experts to support the provider and/or provide direct patient counseling.

3. Consider contacting your local genetic and/or cancer specialists prior to making a referral to learn more about their services.

4. Inform genetic specialists about your practice's risk assessment program and referral protocols. Ideally this should be a collaborative process, with bidirectional patient and information flow over time.

# IDENTIFYING SCREENING PROTOCOLS FOR INCREASED AND HIGH RISK PATIENTS

*Pick the set of guidelines your practice will use to determine screening recommendations for patients with a positive family history of cancer or polyps.*

There are at least eight organizations that provide guidelines for CRC screening for individuals with a family history of cancer or polyps. There is a consensus across guidelines regarding recommended screening in certain scenarios. Individuals with a first-degree relative with CRC at any age should start CRC screening at age 40. Guidelines also recommend colonoscopy at age 40, or 10 years younger than the earliest diagnosis in the immediate family, when the first-degree relative had CRC under 60 years, or when two or more first-degree relatives have CRC at any age. However, the guidelines vary in their recommendations for individuals with other patterns of family history, such as a first degree relative with history of large or advanced adenomatous colon polyps.

To develop a standardized system for CRC risk assessment and screening, providers should decide how they will consistently recommend cancer screening for patients with certain family and personal history patterns across the practice population. The evaluation of guidelines and selection of a single set of recommendations for the practice may depend on the organization(s) publishing the guidelines (e.g., single vs. multi-society, primary care vs. specialty organizations), publication year, the organizations' guideline development process, availability of evidence to support recommendations, and other factors.

**PARTICIPANTS**
Implementation lead, providers, specialists who may be receiving referrals or performing screening

**WHAT YOU'LL NEED**
Professional Society Guideliness

**BARRIERS**
Conflicting guidelines

**LEARN MORE**
NCCRT Steps for Increasing CRC Screening Rates

ACS CRC Screening Algorithm

## STEPS

1. Review professional society guidelines of interest (see Table 2).
2. Select a guideline to apply to patients with a family or personal history of cancer and polyps.
3. Be aware that patients with a genetic diagnosis that significantly increases cancer risk, such as Lynch syndrome, should undergo high risk screening and surveillance per specialty guidelines (see Table 2). Management plans for such patients are often developed in coordination with cancer genetic and gastroenterology experts.

# METHOD IN ACTION

## *Identify Screening Protocols for Increased Risk Patients*

Greenville Family Medicine is a private family medicine practice in a suburban community outside of a large city. Greenville recently went through a process to establish a standardized system for CRC screening across its three locations. In addition to targeting the general population for screening, Greenville also wanted to include specific screening schedules for individuals with a positive family history of CRC or polyps according to guidelines.

The clinical champion physician and office manager started by looking for guidelines from primary care societies, and reviewed the American College of Physicians (ACP) 2012 Guidance Statement on Screening for Colorectal Cancer and American Academy of Family Physicians (AAFP) 2018 guidelines on Colorectal Cancer Screening and Surveillance in Individuals at Increased Risk.[17,19] They evaluated the guidelines focusing on the recommendations for those with a family history. ACP recommends screening with colonoscopy at 40 or 10 years prior to the youngest cancer diagnosis in the family for "high risk" patients, but does not define what family history scenarios meet criteria for high risk. AAFP also recommends colonoscopy at 40 or 10 years prior to the youngest cancer diagnosis in the family, specifying this should be for individuals with a first-degree relative* with CRC or advanced adenoma prior to 60 years of age, with repeat every 5 years. AAFP also recommends specific screening plans for additional family history scenarios, including a single first-degree relative over age 60 (colonoscopy starting at 40), multiple first-degree relatives at any age, and two second degree relatives at any age.

To confirm the population of patients who should be offered earlier screening, the practice team then expanded their review to include additional organizations. They reviewed guidelines from the National Comprehensive Cancer Network (NCCN), updated in 2018, and the Colorectal Cancer Screening Multi-Society Task Force (MSTF; includes the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy), published in 2017.[22,23] These guidelines were consistent with AAFP in recommending CRC screening at 40 for individuals with a first-degree relative with CRC or advanced adenoma at any age, although the recommended screening modalities vary when CRC occurs > 60 years. For those with a first-degree relative with CRC < 60, all guidelines agree that colonoscopy should begin at 40 or 10 years prior to the youngest cancer diagnosis in the family, whichever is earlier. However, while AAFP and NCCN recommend colonoscopy as the screening test for all patients with a first-degree relative with CRC regardless of age of onset, the MSTF states that individuals with a first-degree relative > 60 could be offered any of CRC screening tests used for average risk patients. The repeat screening intervals were also somewhat discordant between AAFP, NCCN and MSTF for the different risk categories (5-10 years).

After reviewing ACP, AAFP, NCCN, and MSTF, the practice ultimately adopted the AAFP guidelines, which are aligned with the others but with more detailed criteria for at-risk individuals.

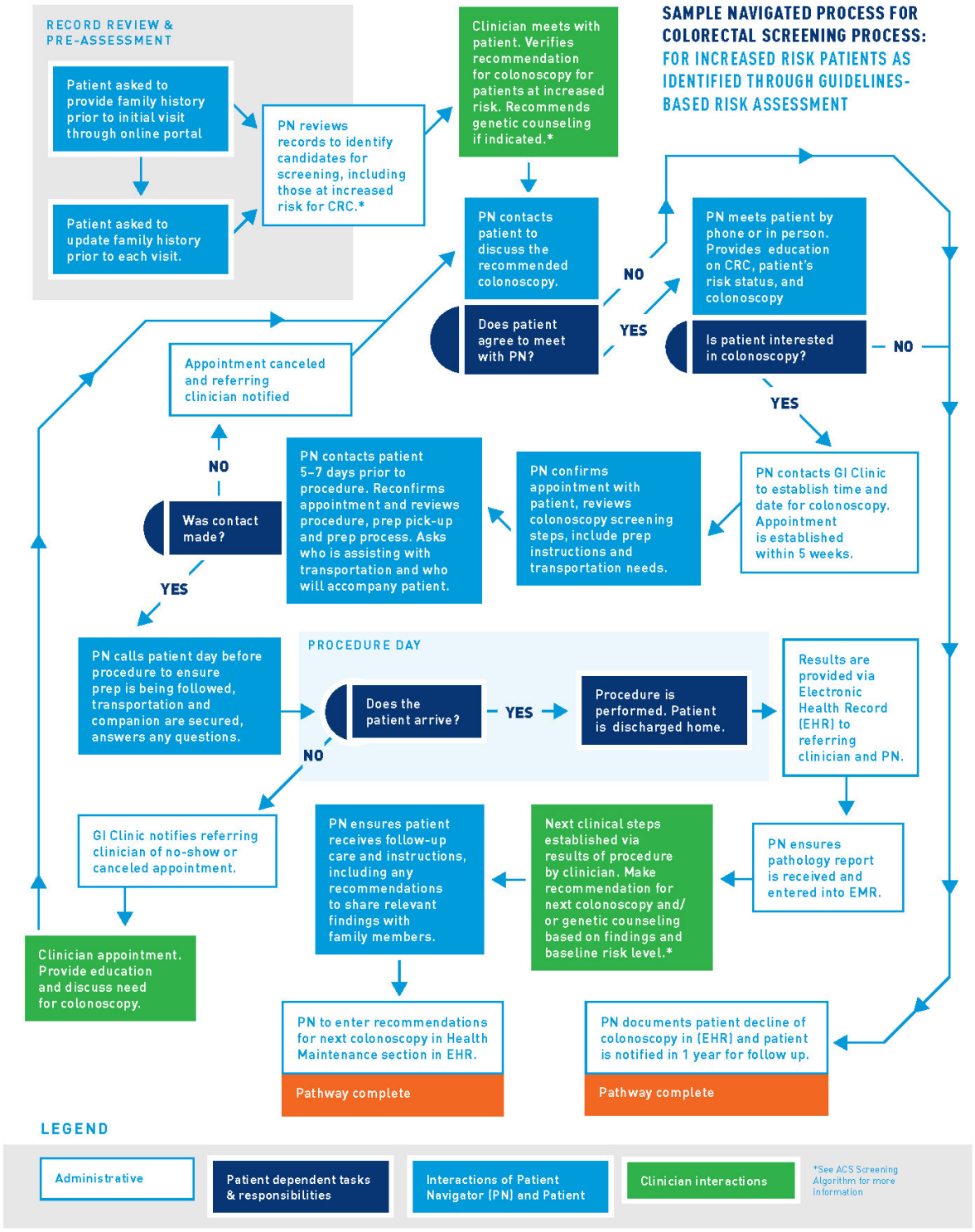
*First-degree relatives (FDR): Parents, siblings, children. Second-degree relatives (SDR): Grandparents, aunts, uncles, nieces, nephews, half-siblings, grandchildren.

# PROFESSIONAL SOCIETY SCREENING GUIDELINES

Table 2. Select professional society guidelines that address screening for individuals with a family history of CRC or polyps or a high-risk cancer predisposition syndrome. See the Appendix for more detail. LS = Lynch syndrome, BMMRD = biallelic mismatch repair deficiency syndrome.

| ORGANIZATION | YEAR OF PUBLICATION | |
|---|---|---|
| | Family history of CRC or polyps (Increased risk) | Cancer predisposition syndrome (High risk) |
| American Academy of Family Physicians | 2018[17] | 2018[17] |
| American College of Gastroenterology | 2009[18] | 2015[24] |
| American College of Obstetricians and Gynecologists | | 2014[25] |
| American College of Physicians | 2012[19] | |
| American Gastroenterological Association | | 2015[26] |
| American Society for Gastrointestinal Endoscopy | 2006[20] | |
| American Society of Clinical Oncology | | 2015[27] |
| Institute for Clinical Systems Improvement | 2014[21] | |
| Multi-Society Task Force (American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy) | 2017[22] | LS 2014[28]<br>BMMRD 2017[29] |
| National Comprehensive Cancer Network | 2018[23] | 2018[23] |

Figure 5. Sample navigated process for colorectal screening: For increased risk patients as identified through guidelines-based risk assessment



# IDENTIFYING PATIENT MATERIALS

*Engage the patient with patient-friendly education and information.*

Patient brochures and websites can be helpful to provide more information and reinforce your discussions about family history risk assessment, genetic evaluation, cancer screening, and healthy lifestyle.

**PARTICIPANTS**
Implementation lead

**WHAT YOU'LL NEED**
Workflow

**BARRIERS**
Patients with low literacy levels and non-English language, limited patient-focused educational and decision support resources

**PATIENT MATERIALS**
Patient Education Materials

## STEPS

1. Review your clinical workflows to identify the points of the process at which patient materials are indicated. This may include education about:
   - Family health history. Resources to help the patient collect family history information. This may be part of or independent from your selected family history collection tool.
   - Cancer risk factors and prevention. Resources that address cancer risk factors and strategies for disease prevention.
   - Genetic counseling referral. Resources to help prepare the patient for a genetic counseling appointment.
   - Colorectal cancer screening. Resources to educate the patient about CRC screening and to support shared medical decision making.
2. Review and select materials that address the needs of your patient population. See the curated list of resources in the Appendix as a starting point and identify additional materials as needed. Consider your patients' general health literacy, preferred languages, and culture when selecting resources.

# IDENTIFYING EVIDENCE-BASED INTERVENTIONS TO FACILITATE SCREENING ADHERENCE IN INCREASED RISK PATIENTS

*Increase CRC screening through interventions tailored to the patient's health beliefs and barriers.*

In addition to establishing a system for family history collection and risk assessment, primary care practices can consider interventions to promote cancer screening in the increased and high risk populations. Like other areas of medicine, a proportion of patients will not follow through with appropriate screening despite a clinician's recommendation. Studies have shown that more intensive, personalized interventions, which are built on an awareness of patient barriers and motivators, are most likely to have a positive impact on CRC screening adherence in individuals with a family history of cancer.

**PARTICIPANTS**
Implementation lead, staff involved in family history processes

**BARRIERS**
Time, infrastructure, funding, limited patient-focused educational and decision support resources

**LEARN MORE**
NCCRT How to Increase Preventive CRC Screening Rates in Practice

NCCRT Messages to Reach the Unscreened

## STEPS

1. Review recommended interventions for individuals with a family history of CRC. Select programs that have been shown to increase screening rates are listed on the next page.
2. Review recommended interventions for general population screening. See the How to Increase Preventative CRC Screening Rates in Practice Clinician's Guide from NCCRT for recommendations.
3. Work through the implementation process to integrate interventions into practice: Set goals, select interventions, develop or adapt workflows, launch, and evaluate.

# RECOMMENDED INTERVENTIONS

*Recommended interventions for individuals with a family history of CRC. Select programs that have been shown to increase screening rates are listed below.*

Combination of a culturally sensitive face-to-face health counseling intervention, print materials, and follow-up phone calls.[30]

Print and telephone interventions tailored to patient response on a baseline survey and also to demographics of marital status, gender, and ethnicity.[31]

Telephone and in-person consults for noncompliant individuals.[32]

Combination of letters, face-to-face counseling and phone calls.[33]

Telephone interventions tailored to patient response on a baseline survey.[34,35]

A remote, tailored-risk communication and motivational interviewing intervention delivered by a genetic counselor. The program also included an arm with free or low-cost colonoscopy to individuals who were noncompliant and had previously reported that cost was a barrier (Tele-Cancer Risk Assessment and Evaluation; TeleCARE).[36,37,38]

A printed booklet with personalized risk assessment, ethnically targeted to African American, Latino, White and Asian patients and tailored to patient response on a baseline survey, followed by a tailored telephone intervention to unscreened individuals.[39]

A tailored intervention in which patients fill out a health behaviors self-questionnaire and then received personalized printed materials to share with their primary care clinicians.[40]

# CONSIDERATIONS FOR PROVIDING DIRECT GENETIC COUNSELING AND TESTING

*Cancer genetic testing can be complex, and should be done in conjunction with genetic counseling by qualified providers.*

Patients at risk of a hereditary cancer syndrome should undergo further cancer risk assessment, genetic counseling, and genetic testing. The genetic counseling process helps people understand and adapt to the medical, psychological, and familial implications of genetic contributions to disease. This process integrates risk assessment, education, and counseling. In some cases, it includes the offer of genetic testing, decision-making support and interpretation of results. Genetic counseling is best provided by specialists with knowledge and experience in clinical genetics, such as board certified genetic counselors, physician geneticists, and physicians, advanced-practice nurses, and physician assistants with dedicated training and expertise in cancer genetics.

This toolkit does not provide instruction on how to integrate genetic testing into the primary care practice, but interested practices may consider the following issues when deciding to offer counseling and testing in-house.

**PARTICIPANTS**
Implementation lead, providers

**BARRIERS**
Provider and staff training, time

**LEARN MORE**
Provider Education Resources

## CONSIDERATIONS

**Education.** Primary care clinicians that offer genetic counseling and genetic testing do so after advanced training, which may include participation in specialized training programs, seeking out relevant education courses, finding a mentor, and education and support through a genetic testing laboratory. Clinicians should continually keep abreast of rapidly changing information and guidelines in cancer genetic testing. See the Appendix for a select list of education and training.

**Genetic testing labs.** Many laboratories offer cancer genetic testing. Select a reputable, CLIA-certified lab that can work with your institution and the patient's insurance company. In addition, consider the level of guidance you and your patient will need and investigate the support services the lab offers throughout the testing process. Labs may offer provider training, genetic counseling, a family history tool, and assistance with test ordering.

**Implementation.** Just as you would for other clinical processes, incorporating genetic counseling and genetic testing into practice requires an implementation plan that includes administrative and workflow planning. This may include defining certain scenarios in which the office would offer testing (for example, for hereditary colon and breast cancers) with a policy to refer other and more complex cases to a specialist. It should also include protocols for providing pre- and post-test genetic counseling. Systems must be in place to track insurance issues, advancements in genetic testing technology, and evolving clinical science.

**Management.** Practices that order genetic testing should be well versed on management protocols for high risk patients.

# TRAINING

*Prepare the whole team for success by providing adequate training.*

Now that you have selected your system, planned the transition and any work process changes that will be needed, and started the system setup, you are ready to train the members of your practice for transition to the new system.

**PARTICIPANTS**
All team members

**WHAT YOU'LL NEED**
Workflow, family history tool

**BARRIERS**
Time, infrastructure, funding

## STEPS

1. Identify training goals and what is needed for different members of the team. Depending on their roles and existing skills, the following training might be needed:
   - How to use the family history tool
   - Orientation to new workflows
   - Orientation to the value of the new system
   - Education about how to collect family history information, cancer genetic red flags, and criteria for increased and high risk.
2. Perform a needs assessment to inform what level of education is needed for staff and how to best deliver training.
3. Provide opportunities for hands-on practice with the family history tool and interpretation of family history risks. Use example patient histories to move through risk assessment and management workflows to ensure team members are comfortable with the steps of the process.
4. Consider when to provide training refreshers for the team and how you will train any new staff joining the practice after implementation.

# PLANNING FOR LAUNCH

*Prepare staff and patients for launch.*

Make plans for launching the new system in practice. Consider other practice, health system, and community events when deciding when to deliver training and launch the new system. Try to avoid initial implementation at the same time as major initiatives are launching, such as significant EHR updates or other quality improvement projects.

**PARTICIPANTS**
Implementation lead

## STEPS

1. Establish a launch date and create a transition plan leading up to launch.
2. Plan for forms, hardware and internet needs. If your workflow requires a new form or the use of tablet computers for patients to fill out their family history, create a plan for obtaining and setting up these components.
3. Schedule and deliver training.
4. Communicate to patients and clinical partners. You may find it helpful to announce the initiative to patients through a poster in the waiting room or message through your portal. If you anticipate increased referrals to genetic or other specialists, let them know what to expect.

# MONITORING AND EVALUATION

*Evaluation and iteration will promote improvement.*

Monitoring and iterative program improvement are arguably the most important implementation steps, yet are frequently overlooked. The areas that you decide to measure and monitor should be directly related to the goals that you originally set. Now you or someone in your practice will need to compile data on these measures, review the results, and decide whether or not action is needed to achieve (or better achieve) your original goals.

**PARTICIPANTS**
Implementation lead

**WHAT YOU'LL NEED**
Measurement plan

**BARRIERS**
Time, competing priorities

**LEARN MORE**
NCCRT Evaluation Toolkit

## STEPS

1. Review and update the measurement plan you first identified when goal-setting. As needed, further define the metrics and outcomes you will assess to monitor progress towards your goals.
2. A simple tracking system will help you follow up as needed. Track actions taken over time, such as referrals to genetic and cancer specialists and screening and surveillance procedures for those individuals at increased risk. Maximize the capacity of your EHR to assist with tracking.
3. Keep up with clinical knowledge. Some guidelines are updated multiple times a year. Ensure that updates are made to the clinic process when risk assessment or management guidelines are changed, and that staff are kept abreast of relevant changes in clinical knowledge.
4. Evaluate patient and provider satisfaction and suggestions for change. Consider modifying your workflow or providing focused training on areas identified for improvement.

# Chapter 3

# Clinical Skills and Tools for Patient Care

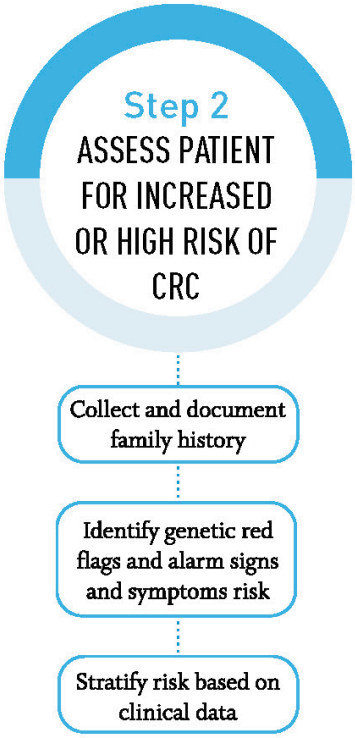
# ASSESS PATIENT FOR INCREASED OR HIGH RISK OF CRC

Approximately 1 in 10 individuals has a family history of cancer that would warrant earlier screening. In order for these patients to benefit from the preventative and risk reducing benefits of cancer screening, primary care clinicians need to collect and interpret family health history, identify next steps in management based on risk, and evaluate for CRC. The steps in Chapter 3 can help clinicians build essential knowledge and skills related to the collection, assessment, and management of cancer risk, regardless of the specific workflow in place in the office.

In order to identify patients with an increased or high risk of CRC, the clinician needs to collect family history information with enough detail to inform accurate risk assessment. It is also important that this family history data is documented in the medical record in a way that can be easily accessed and updated over time.

Family history risk assessment involves interpreting the patient's family history as well as personal history to identify red flags and patterns that may suggest predisposition to CRC and then using that information to stratify risk into average, increased, and high risk categories to inform personalized management. Risk assessment for CRC may also include looking for alarm signs and symptoms of a possible presenting cancer.

As you work through the following sections on risk assessment, visit the links to online education on the left side-bar for opportunities to practice these skills.



# COLLECTING SUFFICIENT FAMILY HISTORY

*Collect history that indicates family structure and manifestations of disease.*

Most patient family history forms and EHR templates are not specific enough to allow you to assess for cancer risk appropriately. It is important to ask additional questions about any relatives who have been diagnosed with cancer to assess the potential for underlying genetic risk. A good tool can help structure your questioning.

**PARTICIPANTS**
Provider, patient

**WHAT YOU'LL NEED**
Family history collection tool

**BARRIERS**
Lack of complete family history knowledge, misattributed family relationships (e.g., paternity), time

**PRACTICE THIS SKILL**
Web module on Collecting Family History

**LEARN MORE**
Selecting and Evaluating Tools for Collection and Risk Assessment

ACS Understanding Your Pathology Report: Polyps

## STEPS

1. Determine who is in the family. Include at least parents, children, siblings, grandparents, aunts/uncles and nieces/nephews on both the maternal and paternal side. Expand to more distant relatives, such as first cousins, when it will help clarify your risk assessment. Asking about additional relatives can be helpful in situations in which there is an unusual cancer history, such as a rare or single early-onset cancer, or where there is limited family history information on closer relatives. Asking about each individual is more effective than just asking if anyone in the family has had cancer.
2. Ask about all types of cancer history, not just CRC. Cancer syndromes can include risk for multiple types of cancers. CRC is not always a presenting cancer. Ask about age of onset, history of more than one cancer, whether cancer is multifocal (multiple primary foci of cancer in the same organ at the same time) or bilateral. Ask about detailed polyp history, including the total number of polyps removed, ages at removal, and polyp type.
3. Ask if any relatives have had genetic counseling and/or genetic testing.
4. Ask about ancestry and ethnicity. African American ethnicity may be considered a risk factor for CRC.

# DOCUMENTING FAMILY HISTORY INFORMATION

*Record the collected family history in a way that is easy to read and update by anyone on the team.*

In addition to the family structure and details about cancer history in the family, include documentation about when the information was collected or updated and who provided it. See the sidebar link for guidance on standardizing where to document family history in the medical record.

**PARTICIPANTS**
Provider, patient

**WHAT YOU'LL NEED**
Family history collection tool, EHR

**BARRIERS**
EHR limitations, time

**PRACTICE THIS SKILL**
Web based module on Collecting Family History

**LEARN MORE**
Where to Document

## STEPS

1. Include date of collection (or date of update), and the name of collector (or updater).
2. Identify the patient, the historian (person providing the information). The historian may be the patient or someone else, such as a parent.
3. Include the detailed information you collected about family and cancer history.
4. Include a legend or key, if symbols are used to designate disease.

# ASSESSING RISK AND IDENTIFYING RED FLAGS

*Accurate risk assessment involves a synthesis of multiple data points, including family and medical history, patient race or ethnicity and lifestyle, behaviors, and exposures.*

Risk assessment begins with identifying genetic red flags and looking for patterns in the family history, as well as considering any alarm signs and symptoms for a present cancer. The next step will be to stratify risk. The next page includes the risk factors that may change risk from one level to another, for example, from average to increased risk. See the resources on the left side-bar to learn more about cancer risk factors.

**PARTICIPANTS**
Provider, patient

**WHAT YOU'LL NEED**
Risk assessment tool

**BARRIERS**
Incomplete or missing family history information, misattributed family relationships (e.g., paternity), complex family relationships and structure, small families, adoption, early deaths due to other causes, prophylactic surgeries that may prevent cancers, and lack of medical record documentation

**PRACTICE THIS SKILL**
Web based module on Identifying Red Flags and Patterns that Increase Cancer Risk

Web based module on Identifying and Managing Lynch Syndrome

**LEARN MORE**
NCI CRC Prevention PDQ

## STEPS

1. Identify personal risk factors that may change risk level.
2. Identify genetic red flags in the family history.
3. Identify patterns in the family history that can point to inheritance patterns, familial clustering of cancer, or specific high-risk syndromes.
4. Identify alarm signs and symptoms in the patient's current clinical presentation that may be indicative of underlying CRC. Don't ignore these signs because the patient is young; though less common, young adults can develop CRC.

# RISK FACTORS THAT INFLUENCE RISK STRATIFICATION

### PERSONAL RISK FACTORS THAT MAY CHANGE RISK LEVEL

- past cancer, especially colorectal or endometrial
- past advanced adenomas or serrated colon or rectal polyps (confirmed by pathology reports)
- inflammatory bowel disease
- African American ethnicity may change risk level, but guidelines are conflicting on this point

### GENETIC RED FLAGS IN THE FAMILY HISTORY

- early onset (< 50 years) cancer or advanced adenomatous colorectal polyp (> 1 cm, confirmed by pathology)
- multiple relatives with the same or associated cancers* on the same side of the family
- multifocal (multiple primaries) or bilateral cancer
- individual with greater than 10 adenomatous colorectal polyps (confirmed), or polyps with unusual histology (e.g., juvenile polyps, Peutz-Jeghers polyps, or ganglioneuromas)
- known genetic syndrome in family

### PATTERNS IN THE FAMILY HISTORY

- several colon, rectal, endometrial, gastric, small bowel, ovarian, urinary system, renal pelvis, pancreatic, brain (usually glioblastoma) and/or sebaceous cancers on the same side of the family
- associated cancers* in multiple generations (dominant inheritance)
- predominately siblings affected (recessive inheritance)

### ALARM SIGNS AND SYMPTOMS IN THE PATIENT'S CURRENT CLINICAL PRESENTATION THAT MAY BE ASSOCIATED WITH CRC REGARDLESS OF AGE OR FAMILY HISTORY

- blood in stool
- recent onset, persistent or progressive diarrhea and/or constipation
- persistent or progressive abdominal pain
- unexplained iron deficiency anemia
- abdominal mass
- unexplained weight loss

**colon, rectal, endometrial, gastric, small bowel, ovarian, urinary system, renal pelvis, pancreatic, brain (usually glioblastoma) and/or sebaceous skin lesions and keratocanthomas*

# CATEGORIZING CANCER RISK

*Stratify patient cancer risk into average, increased (moderate) or high risk to determine management and next steps.*

The risk assessment process starts by identifying red flags and patterns in the patient's family history, and then uses that information to stratify individuals into average, increased, or high risk. The goal of this simplified 3-tiered stratification is to identify individuals who should 1) consider more frequent and/or earlier screening (increased risk) or 2) be referred to genetics for further evaluation and undergo high risk cancer screening (high risk). Remember that anyone presenting with alarm signs and symptoms of CRC should move straight to further evaluation (see page 61), but still might need to see genetics in the future for cancer genetic risk assessment. See guidelines for specific increased and high risk criteria.

The steps below are educational in nature and address general patterns seen in hereditary and familial cancers. As discussed in Chapter 2, you can customize your process and select tools to help you assess and stratify risk that align with the goals of your practice.

**PARTICIPANTS**
Provider, patient, IT

**WHAT YOU'LL NEED**
Risk assessment tool

**BARRIERS**
Incomplete or missing family history information, misattributed family relationships (e.g., paternity), complex family relationships and structure, small families, adoption, early deaths due to other causes, prophylactic surgeries that may prevent cancers, and lack of medical record documentation

**PRACTICE THIS SKILL**
Web based module on Categorizing Cancer Risk

**LEARN MORE**
Establish a System for Structured Assessment

Professional Society Guidelines

## STEPS

1 Based on the red flags identified in the patient history, assign a risk category.

**High risk: individuals at risk for a hereditary cancer syndrome.**
Individuals at high risk for a hereditary cancer syndrome typically have one or more of these general family history features:

- 3 or more relatives with similar or related cancers
- 2 generations of cancer cases, and
- 1 or more individuals diagnosed at a younger than usual age (< 50 years) or with a rare presentation, such as > 10 adenomas or a known hereditary cancer syndrome

**Moderate/increased risk: those with personal or familial risk factors.**

A patient may be at increased risk for cancer because of a family history contribution, or personal and lifestyle risk factors, or a combination of the two.

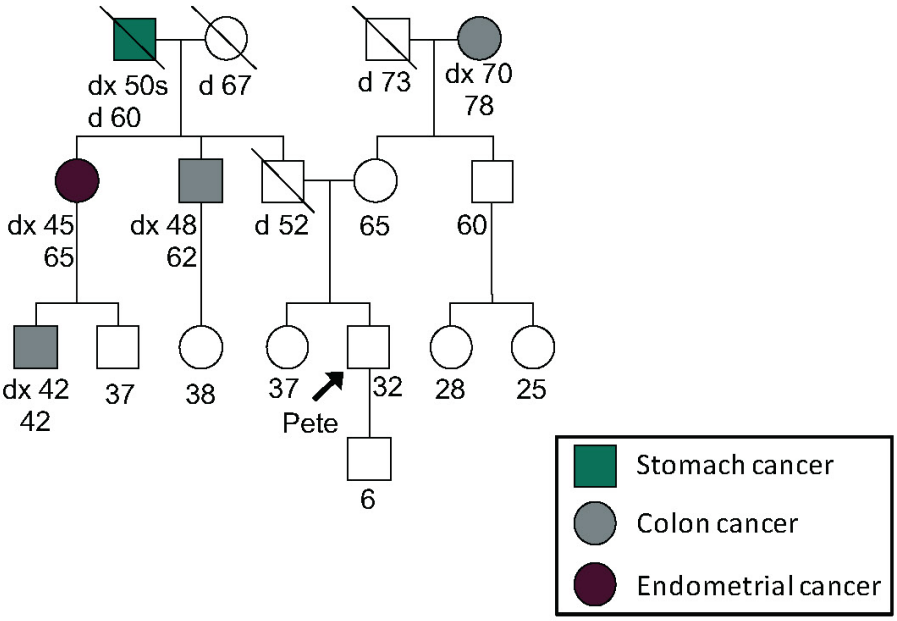
- Family histories suggestive of increased risk may show familial clustering of cancer but do not meet the criteria for high risk.
  - One first-degree relative with CRC at average age (> 60 years), or
  - Two second-degree relatives with CRC at any age
- Consider risk factors in personal history, such as inflammatory bowel disease and ethnicity.

**Average risk: those with few or no risk factors.**

# WORKED EXAMPLE OF RISK ASSESSMENT TOOLS

Patient presents with the following collected family history:

Paternal uncle with CRC dx at 48, living at 62
Paternal aunt with endometrial cancer dx at 45, living at 65
Paternal cousin with CRC dx at 42, living at 42
Paternal grandfather with stomach cancer in 50s, died at 60
Maternal grandmother with CRC dx at 70, living at 78



Worked example of the Colorectal Cancer Risk Assessment Checklist

# COLORECTAL CANCER RISK ASSESSMENT CHECKLIST

## POSSIBLY HIGH RISK

- ☐ Patient or first-degree relative[1] with colon or rectal cancer before age 50
- ☐ Patient or first-degree relative with uterine cancer before age 50
- ☐ Patient or relative with more than one of the Lynch-associated[2] cancers (in the same person) (Lynch-associated cancers include: Colon, rectal, uterus, stomach, small intestine, ovary, urinary system, renal pelvis, pancreas, brain (usually glioblastoma), and sebaceous skin lesions and keratoacanthomas)
- ☐ Patient with cancer and an abnormal tumor screening test for Lynch syndrome
- ☐ Patient with 10 or more precancerous polyps (adenomas), 2 or more hamartomatous polyps, or 5 or more serrated polyps
- ☒ One member of the family (may include the patient) with colon cancer at or after age 50 and a first- or second-degree relative on the same side of the family with any of the Lynch-associated cancers[2] before age 50
- ☒ Three members on the same side of the family (may include the patient) with any of the Lynch-associated cancers[2] at any age
- ☐ Patient or a relative with any of the Lynch-associated cancers[2] at any age with a limited family history due to early death, a small family or adoption
- ☐ A known mutation in a colon cancer gene (*MLH1*, *MSH2*, *MSH6*, *PMS2*, *APC*, others) in the family

## POSSIBLY INCREASED RISK

- ☐ Personal history of CRC
- ☐ Personal history of adenomas or sessile serrated polyps
- ☐ Personal history of inflammatory bowel disease (Ulcerative colitis or Crohn's colitis)
- ☐ African American ancestry
- ☐ One or more first-degree relatives with CRC or confirmed advanced adenoma at any age
- ☒ One or more second degree relatives with CRC <50

## AVERAGE RISK

- ☐ Absence of the above risk factors

1 First-degree relatives (FDR): Parents, siblings, children. Second-degree relatives (SDR): Grandparents, aunts, uncles, nieces, nephews, half-siblings, grandchildren.

2 Colon, rectal, uterus, stomach, ovary, small intestine, pancreas, ureter and renal pelvis, brain (usually glioblastoma), as well as sebaceous skin lesions and keratoacanthomas.

Adapted with permission from work by Gregory Feero, MD, PhD and Susan Miesfeldt, MD. Disclaimer: This checklist was developed by primary care and genetic experts based on NCCN guidelines but has not been validated. These risk criteria are designed to assist in the clinic-based evaluation of patients and families. They do not reflect all increased and high risk criteria, and may not reflect guidelines that have been updated past the date of this publication. For questions regarding individual patients and families, contact your local cancer genetic provider.

Worked example of the Simple Family History Screening Tool for CRC

## SIMPLE FAMILY HISTORY SCREENING TOOL FOR CRC

| | YES | NO |
|---|---|---|
| 1. Have you had either of the following conditions diagnosed before age 50? | | |
| **Colon or rectal cancer** | | |
| **Colon or rectal polyps** | | |
| 2. Do you have a first-degree relative (mother, father, brother, sister, or child) with any of the following conditions diagnosed before the age of 50? | | |
| **Colon or rectal cancer** | | |
| **Cancer of the uterus, ovary, stomach, small intestine, urinary tract (kidney, ureter, bladder), bile ducts, pancreas, or brain** | | |
| 3. Do you have three or more relatives with a history of colon or rectal cancer? (This includes parents, brothers, sisters, children, grandparents, aunts, uncles, and cousins) | X | |
| **If YES to any question → Refer for additional assessment or genetic evaluation.** | | |
| **If NO to all → proceed with the following questions:** | | |
| 4. Do you have any first-degree relatives (mother, father, brother, sister, or child) with cancer of the colon or rectum? | | |
| **If NO → Average risk family. Provide average risk screening guidelines to patient and their family members (start screening with any acceptable test at age 50)*** | | |
| **If YES to #4, proceed with the following questions:** | | |
| 5. Was the first-degree relative under age 60 when CRC was diagnosed? | | |
| 6. Do you have more than one first-degree relative with CRC? | | |
| **If both NO → Intermediate risk family. Provide risk-based screening guidelines to patient and their family members.** | | |
| **If either YES → High risk family. Provide high risk screening guides for patient and their family members.** | | |

**The 2018 ACS guidelines for CRC screening now recommend that CRC screening start at age 45 for average risk individuals, while the USPSTF recommends starting at age 50. Please adjust the chart as needed, per your practice's protocol.*

*Published by:*
*Kastrinos et al. Am J Gastroenterol. 2009;104:1508.*
*Giardiello et al. Am J Gastroenterol. 2014;109:1159.*
*Patel et al. Dig Dis Sci. 2015;60:748.*

# COMMUNICATING RISK

*Tailor conversations about levels of risk to patient learning styles and needs.*

Talk with your patient about their level of cancer risk (average, increased, high) based on your assessment. People understand risk differently, and it can be helpful to communicate risk in multiple ways to facilitate patient understanding.

**PARTICIPANTS**
Provider, patient, possibly family members

**BARRIERS**
Provider ability to tailor risk communication, patients with limited health literacy, patients with limited numeracy, patients may not be in contact with at-risk relatives, limited existing resources to aid in family communication

**PRACTICE THIS SKILL**
Web based module on Categorizing Cancer Risk

**LEARN MORE**
Communicating Risk Factsheet

Understanding Cancer Risk

## STEPS

1. Tailor risk communication to the specific individual. People interpret and react to risk numbers differently based on many factors. Try to frame risk in multiple ways to facilitate understanding: quantitative or qualitative, which may include absolute and relative risks (see examples below). It can be helpful to compare the patient's risk to the general population to promote understanding of the increase in risk based on your assessment.

2. Consider using visuals and teaching tools. Illustrations and factsheets may be helpful to reinforce important information. Visual representations of risk such as pictographs and bar graphs can help the patient understand his or her personal risk.

3. Recommend that your patient share risk information with relatives. When your patient's history affects his or her relatives' risk, clinicians have a duty to warn their patients about the risk of the condition among relatives and encourage the patient to communicate about their risk. This is especially important if there is a positive genetic test result.

Table 3: Risk Communication Examples

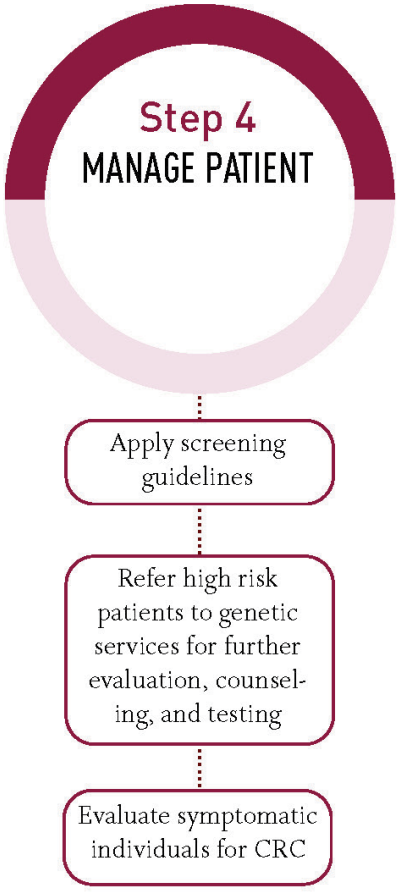
| *For an individual with about a 10% lifetime risk of colorectal cancer when the general population risk is about 5%.* | | |
|---|---|---|
| **Quantitative:** | Risk given in fractions or percentages | |
| | **Absolute** | "You have about a **10% chance** to develop colon cancer in your lifetime, compared to the average person with a 5% chance." |
| | | "You have about a **1 in 10 risk** of colon cancer." |
| | **Relative** | "Your chance to develop colon cancer is **doubled**." |
| | | "You are **twice as likely** to develop colon cancer than an individual without your risk factors." |
| **Qualitative** | Risk given in descriptive terms | |
| | | "Your risk is **increased** compared to the general population." |

# MANAGE PATIENT BASED ON RISK LEVEL AND CLINICAL SIGNS AND SYMPTOMS

Management of patients with increased risk can include a range of tests, services, and clinical actions. Generally speaking, individuals at increased risk of CRC should undergo earlier and/or more frequent CRC screening and individuals at high risk should be referred for genetic counseling and possible genetic testing and may be candidates for high-risk cancer screening, surveillance, and prevention practices. In the following sections, you will read more about cancer screening, surveillance, and prevention practices for individuals at different risk levels.

Patient communication is also a key element of effective management. In addition to communicating about CRC risk and prevention in a patient-friendly way, the patient should have a clear understanding of the management plan outlined by his or her clinician. A clinician's recommendation is the main factor influencing whether or not a patient undergoes CRC screening.

The management activities discussed in this toolkit are for the most part focused on mitigating risk for a future cancer. However, the section on evaluating symptomatic patients for CRC has an additional context: the presenting patient may actually have cancer at the time of the clinical encounter. When the presenting patient exhibits alarm signs or symptoms of a possible cancer, clinicians should follow guidelines about evaluation and diagnosis of cancer, regardless of the patient's age and other risk factors. Screening guidelines that identify when and how at-risk individuals should undergo screening do not apply to the symptomatic individual.



# USING FAMILY HISTORY TO INFORM MANAGEMENT

*Family history information can help guide management decisions for increased and high risk patients.*

In general, increased risk patients are candidates for earlier or more frequent CRC screening and high risk patients should be referred to genetics for further evaluation and care coordination. The steps below are educational in nature and summarize general components of a management plan as outlined in national guidelines. Always consult the most recent guidelines for patient management. As discussed in Chapter 2, your practice may wish to identify a set of cancer screening guidelines that will be used consistently across the practice.

In some cases, professional guidelines about management for different risk levels are inconsistent. Especially in these cases, providers should use family history information to help facilitate informed decision-making by the patient about screening, and may contact an expert if in doubt.

**PARTICIPANTS**
Provider, patient

**WHAT YOU'LL NEED**
CRC screening algorithm

**BARRIERS**
Conflicting guidelines, changing recommendations

**PRACTICE THIS SKILL**
Web based module on Using Family History to Inform Management

Web based module on Identifying and Managing Lynch Syndrome

**LEARN MORE**
Cancer Screening Factsheet

Identifying Screening Protocols for Increased and High Risk Patients

Professional Society Guidelines

NCCRT Steps for Increasing CRC Screening Rates

**PATIENT MATERIALS**
Patient Education Materials

## STEPS

1. Develop an appropriate risk reduction plan based on personal and family history assessment. See next page for ideas.
2. Communicate your recommendations to the patient and engage the patient in shared-decision making about screening and management options. **A provider's recommendation is the #1 factor influencing the patient's decision to undergo screening. See the example script that follows.**
3. Colonoscopy, rather than other CRC screening tests, is generally recommended for patients at increased or high risk based on personal and/or family history. As always, a screening test should be selected through shared-decision making with the patient to discuss the benefits, risks, limitations, and alternatives.
4. Encourage individuals at increased or high risk to communicate with their family members about the cancer risk in the family, so that relatives can also talk with their providers about cancer screening and genetic testing as appropriate.
5. Provide patient education materials about the next steps, such as a colonoscopy or referral to genetics.
6. Identify a plan to follow-up and discuss additional patient questions and medical management issues as needed. Document plan in medical record and provide patient with a written copy of the plan.

# RISK REDUCTION PLAN

*Always consult the most recent guidelines for patient management.*

### AVERAGE RISK

- Regular CRC screening at age 45 or 50 according to recognized guidelines and the practice's desired protocol.*
- Other screening as recommended by recognized guidelines
- Advise that specific lifestyle changes may modify the risk for cancer

### INCREASED (MODERATE) RISK

- CRC screening at earlier ages/more frequent intervals than average risk individuals, such as screening at 40 or 10 years earlier than the youngest diagnosis in the immediate family (dependent on family/medical history and polyp burden)
- Consider chemoprevention, such as aspirin
- Regular updates of family history are important (diagnosis of colon or a Lynch-associated cancer** in one or more family members may change risk category)
- Advise that specific lifestyle changes may modify the risk for cancer

### HIGH (STRONG) RISK

- More intensive and frequent colonoscopy and screening for other related cancers (often annually) beginning in the twenties or earlier
- Consider chemoprevention, such as aspirin for CRC risk and oral contraceptives for ovarian cancer risk
- Prophylactic surgery as an option for risk reduction
- Participation in clinical trials
- Examinations to detect other manifestations of the hereditary syndrome
- Cancer genetic counseling (if not already done)
- Advise that specific lifestyle changes may modify the risk for cancer

** The 2018 ACS guidelines for CRC screening now recommend that CRC screening start at age 45 for average risk individuals, while the USPSTF recommends starting at age 50.*

***colon, rectal, endometrial, gastric, small bowel, ovarian, urinary system, renal pelvis, pancreatic, brain (usually glioblastoma) and/or sebaceous skin lesions and keratocanthomas*

## SAMPLE INCREASED-RISK COUNSELING SCRIPT[42]

"Because you are at increased risk for colorectal cancer [state the reasons], I recommend that you have a colonoscopy. A colonoscopy is an exam in which the doctor inserts a thin, flexible tube to look at the inside of the intestine. This procedure is usually painless and allows us to find and remove growths (polyps) in the colon. If you have a polyp, it can be removed right there during the time of the colonoscopy, and taking it out may help prevent cancer. The main risks are perforation (making a small hole), complications from anesthesia, or bleeding following removal of a polyp. These risks are very uncommon. If we do find cancer, then treating it early may help save your life."

# REFERRING TO A GENETIC EXPERT

*A genetic expert can provide comprehensive cancer risk assessment, facilitate genetic testing, and interpret and communicate results to the patient.*

Genetic experts are medical geneticists, genetic counselors, and physicians, advanced practice nurses, and physician assistants with specialized genetic expertise and training. Through patient education and shared-decision making, the genetic expert will facilitate genetic testing when indicated, and interpret results in context of the patient's personal and family history. Genetic experts are also a resource for you for guidance on cancer genetic risk assessment as well as management.

**PARTICIPANTS**
Provider, patient, genetic expert

**WHAT YOU'LL NEED**
Accessing Genetic Services Tool

**BARRIERS**
Lack of knowledge of where to refer, lack of patient follow-up

**PRACTICE THIS SKILL**
Web based module on Pre-test Decisions and Counseling

**LEARN MORE**
Components of a GC Session Factsheet

Identifying Genetic & Cancer Specialists for Consultation

**PATIENT MATERIALS**
Patient Education Materials

## STEPS

1. Communicate the reason for the referral. Patients are more likely to adhere to the recommendation to undergo genetic counseling if they understand the potential benefits of the process.

2. Prepare your patient for what to expect during a genetic visit. A genetic counseling appointment may seem very different compared to other medical encounters, due to the length, detailed discussions, and involvement of family members. Review the main components and logistics of a genetic counseling visit to help prepare the patient and set expectations.

   Tip | For all patients and especially those that are uncertain about genetic testing, reassure them that genetic counseling is the process to help them decide if genetic testing is right for them. Genetic testing is optional, and the appointment is an opportunity to learn more.

3. Provide contact information for genetic services and identify next steps in the referral process. If you don't already know your local genetic providers, you can identify them on these websites, which include information about telegenetics:

   - National Society of Genetic Counselors (www.nsgc.org)
   - American Board of Medical Genetics (www.abmgg.org)
   - International Society of Nurses in Genetics (www.isong.org)

4. Facilitate the flow of necessary information to the specialist. A genetic consultation is most effective and efficient when you can share the collected family history and reason for referral. This may be sent to the specialist's office in advance and/or printed for the patient to bring to the appointment.

5. Schedule a follow-up to discuss the outcomes of the genetic appointment, and to implement personalized management as indicated. Two months may be a good time to bring the patient back, although the specific time frame will depend on the genetic clinic and type of testing ordered.

# EVALUATING THE SYMPTOMATIC INDIVIDUAL FOR CRC

*CRC incidence and mortality are rising in young adults.*

While CRC is decreasing nationally, it is actually rising in individuals under the age of 50, for reasons not yet understood. Additionally, younger individuals are more likely to be diagnosed with late stage disease compared to older individuals, due in part to delayed work-up of alarm signs and symptoms. Primary care clinicians can help reduce CRC mortality by considering CRC in the evaluation of a patient with possible signs and symptoms, regardless of age or family history, in addition to preemptively identifying people with risk factors based on personal and family history risk assessment.

**PARTICIPANTS**
Provider, patient

**BARRIERS**
Patient lack of awareness, patient willingness to present to provider and/or undergo physical exam and colonoscopy; CRC is not the most likely explanation for patients with nonspecific symptoms and/or no other risk factors

## STEPS

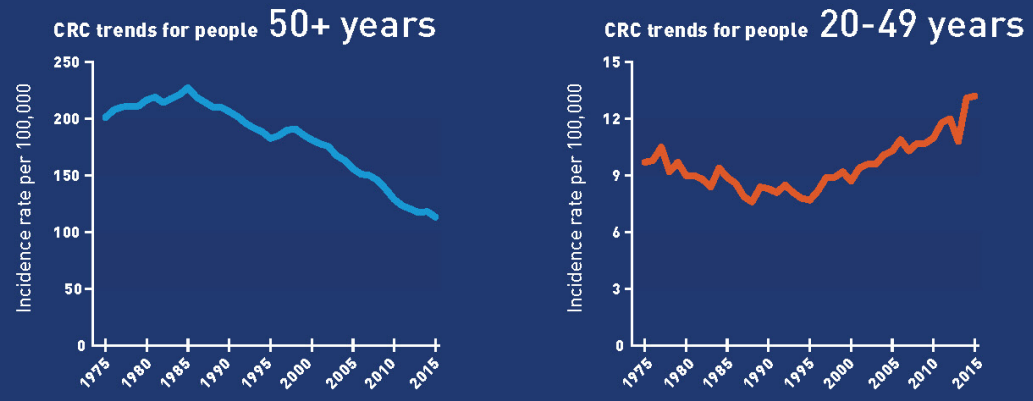
1. Consider evaluation for CRC in individuals with any of the following signs or symptoms, regardless of age, and even in the absence of other personal or family history risk factors:
   - blood in stool
   - recent-onset, persistent or progressive diarrhea and/or constipation
   - persistent or progressive abdominal pain
   - abdominal mass
   - unexplained iron deficiency anemia
   - unexplained weight loss
2. Evaluate for CRC per guidelines. This may include a physical exam, including a rectal exam, and assessing CBC and iron levels.
3. Colonoscopy is a recommended diagnostic procedure for patients presenting with the alarm signs and symptoms discussed above. Note that a fecal occult blood test (FOBT) is not indicated as a diagnostic test for symptomatic patients, and a negative FOBT does not rule out the possibility of CRC.

# Colorectal cancer (CRC) in adults under 50 is on the rise

**74%** growth in incidence since 1988

**1 in 10** CRC patients are under 50

## Incidence of CRC by age: 50+ versus 20 – 49




**AVERAGE TIME**
to diagnose is delayed for those under 50

**~1 in 3** early onset colorectal cancers **may be preventable** by taking a family history and screening those at increased risk

**Don't minimize symptoms in young patients**

SOURCES
Siegel et al. JNCI. 2017, 109:djw322.
Scott et al. AM J Surg. 2016, 211:1014.
NCI SEER, seer.cancer.gov

# EDUCATING THE PATIENT ABOUT RISK FACTORS AND CANCER PREVENTION

*Cancer risk is affected by environmental and genetic factors. Patients should know what risk factors they can control, and be aware of signs and symptoms of cancer, especially when they have an increased risk.*

Patient understanding of the factors contributing to cancer risk can increase motivation for lifestyle changes and acceptance of screening and risk-reducing measures to lower morbidity and mortality from cancer. After you communicate your CRC risk assessment and management recommendations, it is important to educate the patient about ways to mitigate cancer risk.

**PARTICIPANTS**
Provider, patient

**WHAT YOU'LL NEED**
Knowledge of cancer risk factors & prevention strategies

**BARRIERS**
Patient compliance, limited support resources

**LEARN MORE**
Colon cancer prevention (NCI)

**PATIENT MATERIALS**
Patient Education Materials

## STEPS

1 Discuss actions the patient can take to reduce cancer risk factors and increase cancer prevention practices. This may include lifestyle changes such as modifications in diet regarding consumption of processed meat, red meat, fruits, and vegetables, exercise, weight loss, alcohol consumption, and smoking cessation as well adherence to his or her recommended screening regimen.

2 Educate the patient about cancer signs and symptoms. Patients at risk of CRC should be aware that the following symptoms can be associated with a CRC: blood in stool, recent-onset, persistent or progressive diarrhea and/or constipation, persistent or progressive abdominal pain, abdominal mass, and unexplained weight loss.

# CHAPTER 4

# Key Messages and Limitations of the Toolkit

# KEY POINTS FROM THE TOOLKIT

### Early onset colorectal cancer

- Recognize that the incidence of CRC is increasing in individuals under age 50.
- Be aware that a substantial proportion of early onset CRC may be prevented or detected at an earlier stage by identifying people with a family history of cancer and adenomas.
- Regardless of age, consider CRC in the evaluation of patients with alarm signs and symptoms, including blood in the stool, recent-onset and persistent or progressive diarrhea/constipation, persistent or progressive abdominal pain, abdominal mass, unexplained iron deficiency anemia, and/or unexplained weight loss.
- Promote awareness among young patients.

### Developing a system for family history collection

- Collect history that indicates family structure and manifestations of disease.
- Develop a systematic, team-based approach to family history collection and interpretation. This should include a standardized process for family history collection and interpretation as well as guidance for developing a personalized management plan for patients.
- Use a tool (and/or EHR) to assist in family history collection and risk assessment. There are a number of tools available to aid in family history collection and family history risk assessment, with different strengths and limitations. You should pick the tool that best fits the needs of your practice.
- Standardize how and where family history data is recorded in the medical record to increase the usability of this information.

### CRC risk assessment & management of risk

- Assess patterns and red flags. Accurate risk assessment involves a synthesis of multiple data points, including family and medical history, patient race or ethnicity and lifestyle, behaviors, and exposures.
- Assign to risk category: Average, increased (moderate or familial), high (hereditary).
- Tailor risk communication to patient learning styles and needs.
- Use patient risk to adapt plan for cancer screening, surveillance, and prevention, and genetic referral. Average risk individuals should follow general population guidelines for cancer screening. Increased risk individuals typically should undergo earlier and/or more frequent screening, and individuals with a first-degree relative with CRC should begin CRC screening at age 40. Individuals at high risk should be referred for genetic counseling and genetic testing. Depending on the results of genetic evaluation, the patient may undergo high-risk cancer screening and surveillance and consider additional treatments.
- Be aware that cancer genetic testing can be complex, and should be done in conjunction with genetic counseling by qualified providers.
- Select a set of CRC screening guidelines for use in practice. There are numerous organizations that have developed guidelines for individuals with a family history of cancer or polyps. Pick the set of guidelines that aligns with your practice's and patient's needs and use this across your patient population.
- Consider implementing evidence-based interventions tailored to the patient's health beliefs and barriers in order to increase CRC screening adherence.
- Track clinical actions taken over time, including (a) referrals to genetic and cancer specialists, and (b) screening and surveillance procedures for those individuals at increased risk.
- Ensure that updates are made to the clinic process when risk assessment or management guidelines are changed.

# LIMITATIONS OF THIS TOOLKIT

**Practice variation.** While we have tried to provide steps and resources that could be applicable to diverse primary care practices, one size does not fit all. Some practices may find that their needs related to family history collection, cancer screening and/or detection are not addressed within this toolkit.

**Best practices.** Evidence-based best practices are limited in certain areas of cancer risk management in primary care practice, particularly how to implement family history collection and risk assessment, and how to detect early onset CRC. The toolkit presents recommendations and experiences based on current practices and expert opinion where evidence-based guidelines are not available. See the best practices recommendations in the appendix.

**Family history tool.** The ideal risk assessment tool will stratify risk into average, increased/moderate, and high risk categories and be validated for primary care use. At the time of developing this toolkit, such a tool was not available. Additionally, many providers prefer algorithms and tools that are electronic and integrated with the Electronic Health Record, which are not widely available. We have provided examples and a list of currently available tools that primary care practices may wish to evaluate for their needs. This is a rapidly developing area of health IT, and additional tools may become available in the near future.

**A comprehensive risk assessment process.** Ideally, CRC family history collection and risk assessment should be integrated into risk assessment for other conditions relevant to the primary care clinic. The scope of this toolkit is to support CRC best practices, recognizing that clinicians may choose to expand their efforts to include other cancers and health conditions.

**Ongoing evaluation and iteration.** Just as one educational program cannot sustain behavior change over time, implementation of a new clinical process without monitoring and iterative improvement is unlikely to be successful. Practices should continue to evaluate their family history and cancer screening workflows and processes to identify areas for update and improvement.

# CHAPTER 5

# Appendix

# GOALS WORKSHEET

**Step 1. Review goals. Consider how these goals align with practice and stakeholder priorities.**

Review what goals can be achieved with cancer family history collection and risk assessment.

**Step 2. Pick the most relevant goals for your practice.**

**Step 3. Choose priorities.**

Meet with stakeholders to frame the three highest-priority goals. Rewrite the goals in language that resonates with them. Record the top three goals here:

**Step 4. Plan. Set a target date for when you want to achieve the goal.**

Determine an explicit target for each goal, plan to measure how well you achieve each target, and rate the feasibility of measuring each (1 = not feasible, 3 = very feasible).

| Goal | Target | Measurement Plan | Measurement Responsibility | Measurement Feasibility (1, 2, 3) | Goal Completion Date |
|---|---|---|---|---|---|
| Goal 1 | | | | | |
| Goal 2 | | | | | |
| Goal 3 | | | | | |

**Step 5. Communicate the final goals to stakeholders and team members.**

# FAMHX TOOL FEATURES WORKSHEET

To download the spreadsheet and navigate to the tools: https://tinyurl.com/ycqeko6h

| Tool Name | Collection Features | | | | Risk Assessment | | | | | Scope | | | Other | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Collection of all 1st- and 2nd-degree relatives | Patient entered collection | Electronic questionnaire | Paper questionnaire | Includes risk assessment (vs. just a collection tool) | Electronic risk assessment | Stratification to 3 categories: average, increased, high | Stratification to 2 categories: average, increased/high | Links to provider management recommendations | Includes personal as well as family history risks | Assessment of multiple cancers beyond CRC | Assessment of non-cancer conditions | Free | Spanish/ other language versions available | Validated for primary care | Maintained technology and clinical content | EHR integration |
| Check the "must have" features for your practice: | | | | | | | | | | | | | | | | | |
| Does It Run in the Family? | YES | YES | NO | YES | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | YES | YES | YES | NO |
| Family Health History Workbook | YES | YES | NO | YES | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | NO | NO | YES | NO |
| AMA Adult Family History Form | YES | YES | NO | YES | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | NO | NO | YES | NO |
| Family History Questionnaire | YES | YES | NO | YES | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | NO | NO | YES | NO |
| My Family Health Portrait | YES | YES | YES | YES | PARTIAL | YES | NO | YES | NO | NO | PARTIAL | PARTIAL | YES | YES | YES | YES | NO |
| It Runs in My Family | YES | YES | YES | NO | NO | n/a | NO | n/a | NO | NO | n/a | n/a | YES | NO | NO | YES | NO |
| MyLegacy | YES | YES | YES | NO | YES | YES | NO | NO | YES | YES | YES | YES | NO | NO | YES | YES | YES |
| Family Healthware | YES | YES | YES | NO | YES | YES | YES | NO | YES | YES | YES | YES | NO | NO | YES | YES | NO |
| MeTree | YES | YES | YES | NO | YES | YES | YES | NO | YES | YES | YES | YES | NO | NO | YES | YES | YES |
| Myriad Family History Tool | YES | YES | YES | NO | YES | YES | NO | YES | NO | NO | YES | NO | YES | NO | NO | YES | NO |
| Progeny/Ambry | YES | YES | YES | NO | YES | YES | NO | NO | NO | YES | YES | YES | PARTIAL | NO | NO | YES | YES |
| CancerGene Connect/Invitae | YES | YES | YES | NO | YES | YES | NO | NO | NO | YES | YES | NO | YES | YES | NO | YES | NO |
| CancerIQ | YES | YES | YES | NO | YES | YES | NO | NO | YES | YES | YES | NO | NO | NO | NO | YES | NO |
| CRA Health | YES | YES | YES | NO | YES | YES | NO | NO | NO | YES | YES | NO | PARTIAL | YES | NO | YES | YES |
| NCI CRC Risk Assessment Tool | NO | YES | YES | NO | YES | YES | NO | YES | NO | YES | NO | NO | YES | NO | NO | YES | NO |
| MMRPRo | NO | NO | NO | NO | YES | YES | NO | NO | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| PREMM5 | NO | YES | YES | NO | YES | YES | NO | NO | NO | NO | YES | NO | YES | NO | NO | YES | NO |
| MMRPredict | NO | NO | YES | NO | YES | YES | NO | NO | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| MyRisk Hereditary Cancer Questionnaire | NO | YES | NO | YES | YES | NO | NO | NO | NO | NO | YES | NO | YES | NO | NO | YES | NO |
| Columbia University 3-question survey | NO | YES | NO | YES | YES | NO | NO | YES | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| Families Sharing Health Assessment and Risk Evaluation (SHARE) workbook | NO | YES | NO | YES | YES | NO | NO | YES | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| User-friendly Lynch syndrome risk assessment tool | NO | YES | NO | YES | YES | NO | NO | YES | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| University of Michigan 5-question survey | NO | YES | YES | YES | YES | NO | NO | YES | NO | NO | NO | NO | YES | NO | NO | YES | NO |
| Simple Family History Screening Tool for CRC (See Appendix) | NO | YES | NO | YES | YES | NO | YES | NO | YES | NO | NO | NO | YES | NO | NO | YES | NO |
| CRC Risk Assessment Checklist (See Appendix) | NO | NO | NO | n/a | YES | NO | YES | NO | NO | YES | NO | NO | YES | NO | NO | YES | NO |

**Instructions**

1. Identify the "must have" features for your practice, from the table above and others important to you.

2. Use the Family History Tool Table to identify available tools that meet your criteria. Write down the names of your top tools below.

3. Test your list of tools to evaluate what will work best for your practice.

Tool 1:

Tool 2:

Tool 3:

# COLORECTAL CANCER RISK ASSESSMENT CHECKLIST

## POSSIBLY HIGH RISK

- ☐ Patient or first-degree relative[1] with colon or rectal cancer before age 50
- ☐ Patient or first-degree relative with uterine cancer before age 50
- ☐ Patient or relative with more than one of the Lynch-associated[2] cancers (in the same person) (Lynch-associated cancers include: Colon, rectal, uterus, stomach, small intestine, ovary, urinary system, renal pelvis, pancreas, brain (usually glioblastoma), and sebaceous skin lesions and keratoacanthomas)
- ☐ Patient with cancer and an abnormal tumor screening test for Lynch syndrome
- ☐ Patient with 10 or more precancerous polyps (adenomas), 2 or more hamartomatous polyps, or 5 or more serrated polyps
- ☐ One member of the family (may include the patient) with colon cancer at or after age 50 and a first- or second-degree relative on the same side of the family with any of the Lynch-associated cancers[2] before age 50
- ☐ Three members on the same side of the family (may include the patient) with any of the Lynch-associated cancers[2] at any age
- ☐ Patient or a relative with any of the Lynch-associated cancers[2] at any age with a limited family history due to early death, a small family or adoption
- ☐ A known mutation in a colon cancer gene (*MLH1*, *MSH2*, *MSH6*, *PMS2*, *APC*, others) in the family

## POSSIBLY INCREASED RISK

- ☐ Personal history of CRC
- ☐ Personal history of adenomas or sessile serrated polyps
- ☐ Personal history of inflammatory bowel disease (Ulcerative colitis or Crohn's colitis)
- ☐ African American ancestry
- ☐ One or more first-degree relatives with CRC or confirmed advanced adenoma at any age
- ☐ One or more second degree relatives with CRC <50

## AVERAGE RISK

- ☐ Absence of the above risk factors

1 First-degree relatives (FDR): Parents, siblings, children. Second-degree relatives (SDR): Grandparents, aunts, uncles, nieces, nephews, half-siblings, grandchildren.

2 Colon, rectal, uterus, stomach, ovary, small intestine, pancreas, ureter and renal pelvis, brain (usually glioblastoma), as well as sebaceous skin lesions and keratoacanthomas.

*Adapted with permission from work by Gregory Feero, MD, PhD and Susan Miesfeldt, MD. Disclaimer: This checklist was developed by primary care and genetic experts based on NCCN guidelines but has not been validated. These risk criteria are designed to assist in the clinic-based evaluation of patients and families. They do not reflect all increased and high risk criteria, and may not reflect guidelines that have been updated past the date of this publication. For questions regarding individual patients and families, contact your local cancer genetic provider.*

# SIMPLE FAMILY HISTORY SCREENING TOOL FOR CRC

| | YES | NO |
|---|---|---|
| **1.** Have you had either of the following conditions diagnosed before age 50? | | |
| **Colon or rectal cancer** | | |
| **Colon or rectal polyps** | | |
| **2.** Do you have a first-degree relative (mother, father, brother, sister, or child) with any of the following conditions diagnosed before the age of 50? | | |
| **Colon or rectal cancer** | | |
| **Cancer of the uterus, ovary, stomach, small intestine, urinary tract (kidney, ureter, bladder), bile ducts, pancreas, or brain** | | |
| **3.** Do you have three or more relatives with a history of colon or rectal cancer? (This includes parents, brothers, sisters, children, grandparents, aunts, uncles, and cousins) | | |
| **If YES to any question → Refer for additional assessment or genetic evaluation.** | | |
| **If NO to all → proceed with the following questions:** | | |
| **4.** Do you have any first-degree relatives (mother, father, brother, sister, or child) with cancer of the colon or rectum? | | |
| **If NO → Average risk family. Provide average risk screening guidelines to patient and their family members (start screening with any acceptable test at age 50)*** | | |
| **If YES to #4, proceed with the following questions:** | | |
| **5.** Was the first-degree relative under age 60 when CRC was diagnosed? | | |
| **6.** Do you have more than one first-degree relative with CRC? | | |
| **If both NO → Intermediate risk family. Provide risk-based screening guidelines to patient and their family members.** | | |
| **If either YES → High risk family. Provide high risk screening guides for patient and their family members.** | | |

**The 2018 ACS guidelines for CRC screening now recommend that CRC screening start at age 45 for average risk individuals, while the USPSTF recommends starting at age 50. Please adjust the chart as needed, per your practice's protocol.*

*Published by:*
*Kastrinos et al. Am J Gastroenterol. 2009;104:1508.*
*Giardiello et al. Am J Gastroenterol. 2014;109:1159.*
*Patel et al. Dig Dis Sci. 2015;60:748.*

# ACCESSING GENETIC SERVICES TOOL

## Patient talking points about referral

The following points are important for you to convey to the patient in order for him or her to fully benefit from a genetic counseling appointment.

**Reason for referral**

Explain the reason you are referring the patient to help to set expectations and increase the likelihood of follow-through.

- Reason for referral. Some common reasons include: follow-up on family history information, discussion of risk and preventative/screening measures, assessment of appropriateness for genetic testing, or discussion of benefits and risks of genetic testing.
- Possible benefits of seeing a genetic counselor. Some benefits include: determining if you are at increased risk, determining whether genetic testing is appropriate.
- Possible harms of not pursuing the referral. Some possible harms include: not knowing about certain cancer screening or prevention services you might qualify for, continued anxiety or uncertainty of not knowing if you or others in the family (such as your children) are truly at risk or not.
- The expected outcome. Some outcomes include diagnosis, information, testing, risk assessment.

**What to expect**

Review what will be covered during an appointment, and how the patient can prepare.

- Components of a cancer genetic counseling session. This may be a long appointment (30-60 minutes), and can include:
  - Detailed medical and family history
  - Risk assessment and risk counseling
  - Addressing psychosocial issues and emotional concerns
  - Directing an in-depth consent process for genetic testing, when applicable
  - Discussing insurance coverage and cost for genetic testing, if indicated
  - Disclosing results of genetic testing, when applicable
  - Determining and communicating screening and manage ment plans
  - Summarizing and planning for follow up
- Know that genetic testing is always optional. The appointment may or may not include genetic testing, and if it is offered, the genetic expert will discuss the benefits and risks of testing for supported decision-making.
- Be aware testing may be recommended for affected relatives first.
- How to prepare for the appointment. It can be helpful for patients to learn more about their family health history and to talk to affected family members about their interest and willingness to undergo genetic evaluation, in case that is recommended.

## Logistics of referral

- Provide names, roles and credentials of genetic professional(s) involved
- Discuss insurance coverage of genetic appointment
- Give directions and contact information
- Make a plan for how the patient will follow-up with you after the consult

## Finding a genetic professional

**General resources**

Genetic counselors, clinical geneticists, and nurse specialists in genetics may be available in your institution or you may need to contact someone elsewhere. You can find a genetic specialist through:

- National Society of Genetic Counselors Directory (www.nsgc.org)
- American Board of Medical Genetics Directory (www.abmgg.org)
- International Society of Nurses in Genetics (www.isong.org)

It can sometimes be challenging to find a genetic expert locally. There are some opportunities available for telecounseling through academic institutions and private businesses. In some cases, insurance companies will pay for these services.

# PROFESSIONAL SOCIETY GUIDELINES

*that Address Screening for Individuals with a Cancer Predisposition Syndrome or a Family History of CRC or Polyps*

American Academy of Family Physicians. Wilkins T, McMechan D, Talukder A et al. Colorectal cancer screening and surveillance for individuals at Increased risk. Am Fam Physician. 2018;97(2):111-116. PMID: 29365221.

American College of Gastroenterology. Rex DK, Johnson DA, Anderson JC, et al. American College of Gastroenterology guidelines for colorectal cancer screening 2009 [corrected]. Am J Gastroenterol. 2009;104:739-750. PMID: 19240699.

Syngal S, Brand RE, Church JM. ACG Clinical Guideline: Genetic Testing and Management of Hereditary Gastrointestinal Cancer Syndromes. Am J Gastroenterol. 2015; 110:223–262. PMID: 25645574.

American College of Obstetricians and Gynecologists. Committee on Practice Bulletins-Gynecology; Society of Gynecologic Oncology. American College of Obstetricians and Gynecologists Practice Bulletin No. 147: Lynch syndrome. Obstet Gynecol. 2014;124(5):1042-54. PMID: 25437740.

American College of Physicians. Qaseem A, Denberg TD, Hopkins RH, et al. Screening for Colorectal Cancer: A Guidance Statement From the American College of Physicians. Ann Intern Med. 2012;156:378–386. PMID: 22393133.

American Gastroenterological Association. Rubenstein JH, Enns R, Heidelbaugh J, et al. American Gastroenterological Association Institute Guideline on the Diagnosis and Management of Lynch Syndrome. Gastroenterology. 2015;149(3):777-82. PMID: 26226577.

American Society of Clinical Oncology. Stoffel EM, Mangu PB, Limburg PJ, et al. Hereditary colorectal cancer syndromes: American Society of Clinical Oncology clinical practice guideline endorsement of the familial risk-colorectal cancer: European Society for Medical Oncology clinical practice guidelines. J Oncol Pract. 2015; 33(2):209-17. PMID: 25829526.

American Society for Gastrointestinal Endoscopy. Davila RE, Rajan E, Baron TH, et al. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc. 2006;63:546-557. PMID: 16564851.

Institute for Clinical Systems Improvement. Preventive Services for Adults guideline: Colorectal Cancer Screening (Revised October 2014). https://www.icsi.org/guideline_sub-pages/preventive_services_adults/level_i__colorectal_cancer_screening/.

# PROFESSIONAL SOCIETY GUIDELINES

*that Address Screening for Individuals with a Cancer Predisposition Syndrome or a Family History of CRC or Polyps*

Multi-Society Task Force (American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy). Rex DK, Boland CR, Dominitz JA, et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol. 2017 Jul;112(7):1016-1030. Epub 2017 Jun 6. Review. PMID: 28555630.

Giardiello FM, Allen JI , Axilbund JE et al. Guidelines on genetic evaluation and management of Lynch syndrome: a consensus statement by the U.S. Multi-Society Task Force on Colorectal Cancer. Gastrointest Endosc. 2014; 80: 197 – 220. PMID: 25043945.

Durno C, Boland CR, Cohen S, et al. Recommendations on Surveillance and Management of Biallelic Mismatch Repair Deficiency (BMMRD) Syndrome: A Consensus Statement by the US Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol. 2017;112(5):682-690. PMID: 28349994.

National Comprehensive Cancer Network. Colorectal Cancer Screening (v1.2018). www.nccn.org.

For additional guidance for screening individuals at average risk, see the U.S. Preventative Services Task Force recommendations, ACS guidelines, and NCCRT Steps for Increasing CRC Screening Rates manual.

For additional guidance for managing individuals with high risk cancer syndromes, see GeneReviews.

# PROVIDER EDUCATION RESOURCES

### Assessing Your Existing Family History Workflow

AHRQ Workflow Assessment for Health IT Toolkit, by the Agency for Healthcare Research and Quality. Learn how to plan, design, implement, and use health IT in ambulatory care.

### Selecting and Evaluating Tools for Collection and Risk Assessment

Global Alliance Family History Tool Inventory, by the Global Alliance for Genomics and Health. View a catalogue of family history tools currently available for documenting family health history information.

Review and Comparison of Electronic Patient-Facing Family Health History Tools, by Welch BM, Wiley K, Plieger L, et al. A paper that evaluates and discusses 17 electronic family history tools.

### Identifying Screening Protocols for Increased Risk Patients

Steps For Increasing CRC Screening Rates: A Manual for Community Health Centers, by the National Colorectal Cancer Roundtable. A step-by-step manual to help implement processes that will and increase CRC screening in the general population.

### Identifying Evidence-based Interventions to Facilitate Screening Adherence in Increased Risk Patients

How to Increase Preventative CRC Screening Rates in Practice, by the National Colorectal Cancer Roundtable. A practical guide containing evidenced-based tools, sample templates and strategies that help practices improve their screening performance.

Messages to Reach the Unscreened, by the National Colorectal Cancer Roundtable. A guidebook designed to help educate, empower and mobilize key audiences who are not getting screened for colorectal cancer.

### Monitoring & Evaluation

How To Evaluate Activities To Increase CRC Screening And Awareness: Evaluation Toolkit, by the National Colorectal Cancer Roundtable. Apply the seven basics of evaluation to CRC screening programs and other implementation projects.

### Collecting Sufficient Family History Information

Collecting Family History with Sufficient Detail Online CME, by The Jackson Laboratory. Practice asking the right questions to elicit enough information to assess family history disease risk and get tools to implement your skills.

Understanding Your Pathology Report: Colon Polyps (Sessile or Traditional Serrated Adenomas), by the American Cancer Society. Review explanations of common polyp pathologies.

### Documenting Family History Information

Collecting Family History with Sufficient Detail Online CME, by The Jackson Laboratory. Practice asking the right questions to elicit enough information to assess family history disease risk and get tools to implement your skills.

### Assessing the Personal and Family History to Identify Red Flags and Patterns

Identifying Red Flags and Patterns that Increase Cancer Risk Online CME, by The Jackson Laboratory. Practice identifying risk factors in case scenarios and receive tools to help make this task easy to implement in your practice.

Identifying and Managing Lynch Syndrome Online CME, by The Jackson Laboratory.
Practice recognizing Lynch syndrome red flags, communicating about the Lynch syndrome testing process, and incorporating increased screening into patient care.

Colorectal Cancer Prevention (PDQ®), by National Cancer Institute (NCI). Provides comprehensive, peer-reviewed, evidence-based information about colorectal cancer prevention.

# PROVIDER EDUCATION RESOURCES

### Categorizing Cancer Risk

Categorizing Cancer Risk Online CME, by The Jackson Laboratory. Analyze family histories and classify patients' risk into average, increased (moderate), or high risk for cancer.

### Communicate Risk

Categorizing Cancer Risk Online CME, by The Jackson Laboratory. Analyze family histories and classify patients' risk into average, increased (moderate), or high risk for cancer.

Communicating Risk Factsheet, by The Jackson Laboratory. A factsheet with information about types of risk and key communication points.

Understanding Cancer Risk Tutorial, by Research Advocacy Network. A publication that explores aspects of cancer risk, including risks associated with developing cancer, risks related to cancer treatment, and the risk of cancer recurrence .

### Using Family History to Inform Management

Using Cancer Family History to Inform Management Online CME, by The Jackson Laboratory. Practice determining appropriate management based on family history risk stratification.

Cancer Screening Factsheet, by The Jackson Laboratory. Summarizes professional society guidance about screening for individuals at average, increased, and high risk for breast, prostate, and colorectal cancer.

Steps For Increasing CRC Screening Rates: A Manual for Community Health Centers, by the National Colorectal Cancer Roundtable. A step-by-step manual to help implement processes that will and increase CRC screening in the general population.

### Referring to a Genetic Expert

Cancer Pre-test Decisions & Counseling Online CME, by The Jackson Laboratory. Practice deciding when and if genetic testing is appropriate given a patient's clinical and personal context.

Components of a Genetic Counseling Session Factsheet, by The Jackson Laboratory. Discusses the core components of a cancer genetic counseling session.

### Educate the Patient about Risk Factors and Cancer Prevention

Colorectal Cancer Prevention (PDQ®), by National Cancer Institute (NCI). Provides comprehensive, peer-reviewed, evidence-based information about colorectal cancer prevention.

### Additional Educational Resources for Providers

Cancer Risk Assessment, Testing and Management, by The Jackson Laboratory. Free, self-directed online program for continuing education credit.

Intensive Course in Cancer Risk Assessment, by the City of Hope. Advanced training in cancer risk assessment, management, and prevention.

Webinars for Medical Professionals, by Hereditary Colon Cancer Foundation. Learn about best practices for screening and treating individuals with Lynch syndrome and familial adenomatous polyposis syndrome through multiple webinar presentations.

Adenomatous Polyposis Case Study (Gabe), by the Global Genetics and Genomics Community (G3C). Practice evaluating a virtual patient with adenomatous polyps for a hereditary cancer syndrome in an interactive case study.

Genetics and Gynecologic Cancers Toolkit, by the Society of Gynecologic Oncology. Learn about cancer risks and management for hereditary cancer syndromes through case studies.

PDQ Cancer Information Summaries: Genetics, by the National Cancer Institute. Learn about topics in cancer genetics, including genetic risk assessment and counseling and the genetics of colorectal cancer.

IHI Open School Online Courses, by the Institute for Healthcare Improvement. Learn about topics in Quality Improvement.

# PATIENT EDUCATION MATERIALS

### Family History

Have You or a Family Member Had Colorectal Cancer?, by the Centers for Disease Control. An overview of the importance of family history collection for colorectal cancer risk assessment and Lynch syndrome.
www.cdc.gov/features/lynchsyndrome
Spanish-language version: www.cdc.gov/spanish/especialesCDC/SindromeLynch/

Knowing is Not Enough—Act on Your Family Health History, by the Centers for Disease Control. Education and resources about family health history.
www.cdc.gov/features/familyhealthhistory/index.html
Spanish-language version: www.cdc.gov/spanish/especialesCDC/AntecedentesMedicos/index.html

Does It Run in the Family? Toolkits, by Genetic Alliance. Two customizable booklets about family history and genetics and health for a patient or community: 1) A Guide to Family Health History and 2) A Guide to Genetics and Health. Available in English, Spanish, and Tagalog. www.geneticalliance.org/publications/fhhtoolkit

Family Health History Toolkit, by the Utah Department of Public Health. A booklet explaining why it is important to know family health history, and tips on how to gather this information. Includes a list of ten helpful questions to ask relatives. http://health.utah.gov/genomics/familyhistory/documents/Toolkit/new%20entire%20toolkit.pdf
Spanish-language version: http://health.utah.gov/genomics/familyhistory/documents/Toolkit/Final%20Spanish%20Toolkit.pdf

### Cancer Risk Factors

Six Ways to Lower Your Risk for Colon Cancer, by the American Cancer Society. A list of ways to reduce the risks you can change, and the familial risk factors that you cannot change.
www.cancer.org/latest-news/six-ways-to-lower-your-risk-for-colon-cancer.html

What Are the Risk Factors for Colon Cancer?, by the Centers for Disease Control. A resource that lists medical, familial and lifestyle risk factors for colorectal cancer.
www.cdc.gov/cancer/colorectal/basic_info/risk_factors.htm
Spanish-language version: www.cdc.gov/spanish/cancer/colorectal/basic_info/risk_factors.htm

Colorectal Cancer Factsheet, by the Prevent Cancer Foundation. A short but comprehensive resource that outlines information about colorectal cancer, risk facts and how to reduce risk, screening, symptoms, and treatment.
preventcancer.org/wp-content/uploads/2015/06/Colorectal-Cancer-Fact-Sheet-2013.pdf
Spanish-language version: preventcancer.org/wp-content/uploads/2015/06/Colorectal-Cancer-Fact-Sheet_Spanish_Prevent-Cancer-Foundation.pdf

### Genetic Counseling & Genetic Testing

Genetic Counselors: Personalized Care for Your Genetic Health, by the National Society of Genetic Counselors. Describes the training and skills of genetic counselors, and includes information on what to expect during an appointment and how to locate a genetic counselor.
www.aboutgeneticcounselors.com

The Genetics of Cancer, by the National Cancer Institute. An overview of cancer genetics and genetic testing, designed for the general public and patients.
www.cancer.gov/about-cancer/causes-prevention/genetics

Genes in Life, by Genetic Alliance. A website where patients can learn about how genetics impacts their lives and their families.
genesinlife.org/

Genetic Counselors for Hereditary Colon Cancer Syndromes, by the Hereditary Colon Cancer Foundation. Describes the genetic counselor role on the care team, including how a genetic counselor can help individuals make personalized decisions regarding genetics and their

health.
www.hcctakesguts.org/about-genetic-counselors

### Colorectal Cancer Screening

Screen for Life, by the Centers for Disease Control and National Colorectal Cancer Roundtable. A web-based quiz to test knowledge on who should be screened, how often, types of screening, insurance coverage, and symptoms of CRC.
www.cdc.gov/cancer/colorectal/sfl/quiz/index.htm
Spanish-language version: www.cdc.gov/spanish/cancer/colorectal/sfl/quiz/index.htm

Colorectal Cancer Screening Brochure, by the Centers for Disease Control (English). A guide to CRC screening, including how to identify low-cost or free screening programs.
www.cdc.gov/cancer/colorectal/pdf/no_pocket_brochure.pdf
Spanish-language version: www.cdc.gov/spanish/cancer/colorectal/pdf/no_pocket_brochure.pdf

CRC Early Detection, Diagnosis, and Staging, by the American Cancer Society (English). Provides information about screening, early detection, staging, and questions to ask the provider.
www.cancer.org/content/cancer/en/cancer/colon-rectal-cancer/detection-diagnosis-staging.html
Spanish-language version: https://www.cancer.org/es/cancer/cancer-de-colon-o-recto/deteccion-diagnostico-clasificacion-por-etapas.html

ACS Recommendations for Colorectal Cancer Early Detection, by the American Cancer Society. A resource that outlines screening recommendations based on details of an individual's personal and family history.
www.cancer.org/content/cancer/en/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html
Spanish-language version: https://www.cancer.org/es/cancer/cancer-de-colon-o-recto/deteccion-diagnostico-clasificacion-por-etapas/recomendaciones-de-la-sociedad-americana-contra-el-cancer.html

### Hereditary Colon Cancer Support and Advocacy Groups

Hereditary Colon Cancer Foundation. A nonprofit organization serving patients with hereditary colon cancer and healthcare providers with provision of educational, social, and financial resources, including booklets about Lynch syndrome and familial adenomatous polyposis syndrome for patients.
www.hcctakesguts.org/

AliveAndKickn. A patient organization that aims to improve the lives of individuals and families affected by Lynch syndrome and associated cancers through research, education, and screening.
https://aliveandkickn.org/

Lynch Syndrome International. A patient organization that aims to provide support for individuals with Lynch syndrome, raise awareness of the condition, educate the public and healthcare providers, and provide support for Lynch syndrome research.
https://lynchcancers.com/

Stupid Cancer A patient organization that seeks to empower, support, and improve health outcomes for the young adult cancer community.
www.stupidcancer.org/

# BEST PRACTICES

*in family history collection and risk assessment for primary care*

This toolkit was developed based on a set of best practices in family history collection and risk assessment in the primary care setting. This effort focused on cancer, specifically colorectal cancer risk assessment, but the same principles apply to other diseases. These best practices were derived from national guidelines and expert consensus, which included primary care clinicians. The upcoming chapters of the toolkit provide more detail on how to achieve the best practices below.

## *Clinical Skills Best Practices (Chapter 3)*

### Family history collection

- Collect sufficient family history information to assess underlying cancer risk. This includes clarifying family structure for at least the patient's and parents' generations and grandparents at a minimum. Depending on the patient's age, collect information about additional relatives (e.g., cousins). Identify cancer history in affected individuals, and identify if anyone in the family has had genetic testing.
- Ask about cancer (all types) and polyps and ages of onset on both sides of the family. An individual does not have to be affected with a condition to pass on genetic risk factors to the next generation.
- Remember to ask about any types of cancer in the family, not just CRC. Cancer syndromes can include risk for multiple types of cancers. CRC is not always a presenting cancer.
- Be aware of factors that can complicate family history collection and interpretation (e.g., patients with incomplete or missing family history information such as early deaths, complex family relationships and structure, small families, adoption, surgeries that may prevent cancers).

### Personal history risk assessment

- Identify personal and lifestyle risk factors, including: past cancer, especially colorectal or endometrial; past adenomatous or serrated colon polyps (confirmed by pathology reports); inflammatory bowel disease.
- Identify red flags in the patient's current clinical presentation that may be signs or symptoms of CRC: blood in the stool, recent-onset and persistent or progressive diarrhea/constipation, persistent or progressive abdominal pain, abdominal mass, unexplained iron deficiency anemia, and/or unexplained weight loss.

### Family history risk assessment

- Identify red flags in the personal and family history that indicate increased cancer risk: early onset cancer or (confirmed) adenomatous or serrated colon polyps; multiple relatives with the same or associated cancers on the same side of the family; bilateral or multifocal disease; individual with greater than 10 (confirmed) adenomatous colon polyps; disease in the absence of known risk factors; ethnic predisposition to certain disorders.
- Identify patterns in the family history that can point to inheritance patterns, familial clustering of cancer, or specific high-risk syndromes , such as Lynch syndrome.
- Stratify patient cancer risk into average, increased (moderate) or or high risk according to guidelines-based criteria to determine management and next steps.
- Consult with a genetic expert when you have questions about risk assessment.

### Management based on risk assessment

- Develop an appropriate evaluation plan based on personal and family history assessment. Patients

with increased risk of cancer should be considered for earlier and/or more frequent screening. Patients at high risk of having a hereditary cancer syndrome in the family should be referred for genetic evaluation. Patients with a diagnosis of a hereditary cancer syndrome should undergo disease prevention and be managed based on syndrome-specific guidelines.
- Educate the patient about risk factors, prevention strategies, and CRC signs and symptoms.
- Incorporate specialist consultant input and recommendations from guidelines into the patient's personalized management plan as needed.

**Patient-centered communication**

- Communicate risk assessment and management guidelines tailored to the patient's comprehension and needs.

## *Clinical Processes Best Practices (Chapter 2)*

- Develop a systematic, team-based approach to family history collection and interpretation.
- Use a tool (and/or EHR) to assist in family history collection and risk assessment.
- Consider using or developing a standardized tool for risk assessment that can be used by members of the care team to streamline the work of physician, nurse practitioner, and/or physician assistant team members.
- Maximize your EHR's capacity to support family history collection and risk assessment.
- Incorporate CRC risk assessment into standard data collection and risk assessment processes for other conditions (e.g., breast cancer, diabetes).
- Develop a professional relationship with local genetic professionals, and oncologists and gastroenterologists with interest and/or expertise in hereditary cancer, and seek consultation around management issues as needed.
- Develop systems and workflows that connect risk assessment outcomes to clinical actions.
- Develop systems and workflows to track actions taken over time, including (a) referrals to genetic and cancer specialists, and (b) screening, surveillance, and prevention procedures for those individuals at increased risk.
- Develop systems to ensure that updates are made to the clinic process when risk assessment or management guidelines are changed.
- Update the family history over time. Relatives' health and disease status may change, which may affect your patient's risk assessment.

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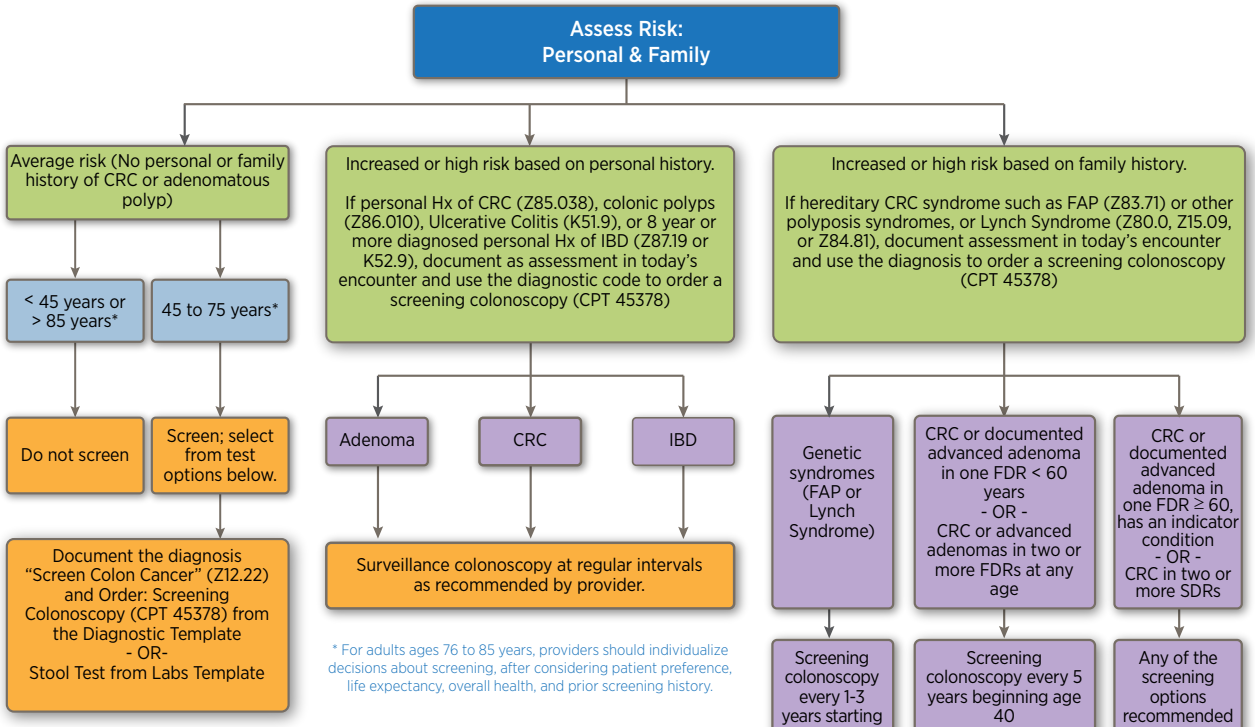
# APPENDIX D-2.3

## Sample Colorectal Cancer Screening Algorithm

Per 2018 American Cancer Society Guideline




## SCREENING OPTIONS

### *Stool Tests*

- Yearly fecal immunochemical test (FIT)*, or
- Multi-target stool DNA (FIT-DNA), or
- Yearly high-sensitivity guaiac test (HS-gFOBT)*

### *Direct Visualization*

- Colonoscopy every 10 years, or
- CT colonography (virtual colonoscopy) every 5 years, or
- Flexible sigmoidoscopy every 5 years

* Stool samples obtained by digital rectal exam (DRE) have low sensitivity for cancer (missing 19 of 21 cancers in one study) and should *never be used for CRC screening*.

All patients who undergo a test other than colonoscopy as a first-line screening exam and receive a positive test result must follow up with a colonoscopy to complete the screening process.

***For Medicare patients, use G codes:***

**G0105** – Colonoscopy (high risk)

**G0121** – Colonoscopy (not high risk)

**G0328** – Fecal Occult Blood Test (FOBT), immunoassay, 1–3 simultaneous

**G0464** – Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3)

## DEFINITIONS

- **IBD:** inflammatory bowel disease
- **CRC:** colorectal cancer
- **FDR:** first-degree relative
- **SDR:** second-degree relative
- **CTC:** computed tomographic colonography
- **FAP:** familial adenomatous polyposis
- **FIT:** fecal immunochemical test

- **Screening colonoscopy** is performed on asymptomatic patients due for colorectal cancer screening because of age or familial risk indicators such as a family history of CRC or adenomatous polyps.
- **Surveillance colonoscopy** is performed when a patient has an indicator condition or has had a personal malignancy or premalignancy that needs follow up and requires colonoscopy at more frequent intervals. Examples are Personal history of CRC (Z85.038) or Personal History of Colonic Adenomatous Polyps (Z86.010).
- **Diagnostic colonoscopy** is performed when a patient has indicator condition requiring diagnostic workup that includes consideration of colon cancer as a potential diagnosis (i.e. persons with a history of rectal bleeding, anemia, or unexplained weight loss).
- An "**advanced adenoma**" is a lesion ≥1 cm in size or having high-grade dysplasia or villous elements.

*Current as of July 2018*