Steps for Increasing Colorectal Cancer Screening Rates:

A Manual for Community Health Centers

American Cancer Society®

NATIONAL Colorectal Cancer ROUNDTABLE

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Introduction

Why Screen for Colorectal Cancer?

> "Screening for colorectal cancer is effective and can save your life."
> – CDC Director Tom Frieden, MD, MPH

Colorectal cancer – the third most commonly diagnosed cancer in the United States – kills more men and women than nearly any other cancer, second only to lung cancer.

Americans have a 5% lifetime risk of developing colorectal cancer. In 2014, an estimated 136,830 people will be diagnosed with colorectal cancer in the United States, and 50,310 people are expected to die from colorectal cancer.[1]

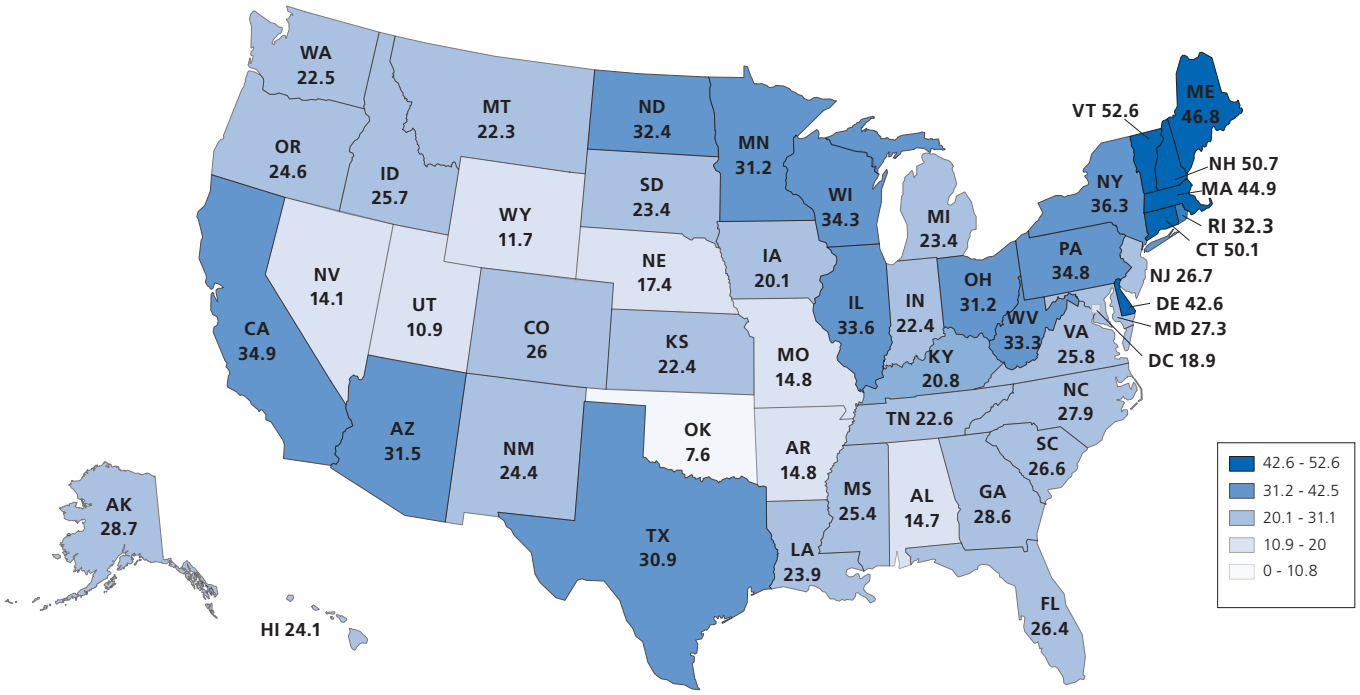
Early detection of colorectal cancer can save lives.

Because colorectal cancer usually begins as a small growth known as a polyp, some of which can develop slowly into cancer over a period of 10 to 15 years, screening is an important opportunity for both prevention (removing the polyps) and early detection (finding the cancer early if there is one).[2] Out of the 50,310 people who died from colorectal cancer in 2013, many thousands could have potentially been saved if they had received screening.[1,3] Based on a national study of colonoscopies performed on 2,602 patients who had polyp removal, these patients had a 53% lower risk of death from colorectal cancer.[4] An annual stool-based screening program in multiple randomized controlled trials has shown to decrease colorectal cancer mortality by about 25%.[5]

Screening for colorectal cancer costs less than cancer treatment.

Preventing cancer costs the least, treating cancer costs more, and treating advanced cancer costs the most. In a Pennsylvania study, the cost per patient with a primary diagnosis of colorectal cancer increased according to disease stage – from early diagnosis in Stage 1 ($36,395) nearly doubled to Stage 2 ($54,938), and peaked at the terminal stages ($62,845), with a total treatment admission-related cost of $540,533,844 in 2005.[6] In 2010, the cost of cancer care nationally was approximately $124.57 billion, with colorectal cancer accounting for the second highest medical costs at $14.14 billion.[7]

Figure 1. Colorectal Cancer Screening Rates in Community Health Centers by State



Data Source: UDS data 2012.
Adults 50-75 years of age who have received any of the following: colonoscopy during reporting year or previous 9 years, flexible sigmoidoscopy conducted during reporting year or previous 4 years, or FOBT or FIT during reporting year.

Community health centers can do better with colorectal cancer screening rates.

About one in three adults 50 to 75 years of age (23 million people) has never been screened for colorectal cancer.[8] Screening rates are especially low among Hispanics, recent immigrants, and those with lower socioeconomic status, minimal education, and limited or no access to care.[9] Follow-up of screening abnormalities is also lower among racial and ethnic minorities.[10] In community health centers (CHCs), which largely serve these populations, the national screening rate for colorectal cancer in 2012 was 30.2%,[11] ranging from 7.6% (Oklahoma) to 52.6% (Vermont).[12] The existence of these disparities suggests that CHCs have tremendous potential to improve colorectal cancer screening rates and to reduce colorectal cancer morbidity and mortality in racially and ethnically diverse, socioeconomically challenged communities across the country. A map of colorectal cancer screening rates in CHCs by state follows.

New Colorectal Cancer Screening Mandate from HRSA

The Federal Health Resources and Services Administration (HRSA) has recognized the important role of CHCs in reducing disparities in colorectal cancer screening and outcomes in the United States. Since 2012, HRSA has required CHCs to report colorectal cancer screening rates as a standard performance measure as part of the Uniform Data System (UDS). The timing is right to work together to increase colorectal cancer screening rates in CHCs across the country.

How Can This Manual Help CHCs Improve Screening Rates?

The goal of this manual is to offer evidence-based, expert-endorsed recommendations for planning and implementing strategies in CHCs to improve colorectal cancer screening rates. This manual serves as a supplement to the existing *How to Increase Colorectal Cancer Screening Rates in Practice: A Primary Care Clinician's Evidenced-based Toolbox and Guide*, by providing succinct step-by- step instructions for CHC teams to improve CRC screening and outcomes in practice. These easy steps will assist in the process to effectively:

- Develop and come to agreement (get "buy-in") on an office screening strategy.
- Provide education on appropriate and high-quality screening.
- Screen patients.
- Track follow-up of screening and results.
- Build networks between providers and health systems.

The national goal is to increase the colorectal screening rate to 80% by the year 2018, and we believe that CHCs can also work toward that goal!

Instructions for Using This Manual

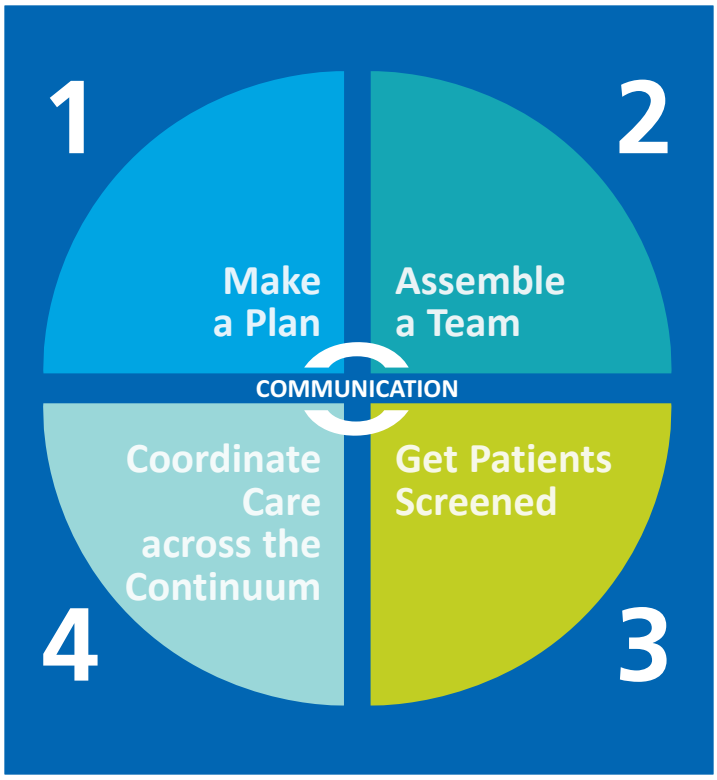
The goal of this manual is to offer practical advice for implementing expert-endorsed processes for improving colorectal cancer screening and follow-up care – one step at a time. The manual, which provides step-by-step instructions for CHC teams to improve CRC screening and outcomes in practice, serves as a supplement to the existing *How to Increase Colorectal Cancer Screening Rates in Practice: A Primary Care Clinician's Evidenced-based Toolbox and Guide*.

It is organized into three primary sections: 1) An **Introduction** that provides information on the importance of colorectal cancer screening; 2) **Steps to Increase Cancer Screening Rates**, which maps out a plan for improving your screening rates and gives step by step instructions for doing so; and 3) The **Appendices**, which provides field-tested tools, templates, and resources to get you started.

We suggest that you use the manual in segments, focusing on the three or four pages of information you need at a time, and make good use of the appendices, which have several templates, tools, and resources to save you time.

If you use the live links throughout the manual, you can get back to where you were by pressing "Alt+Left Arrow" on a PC or "Command+Left Arrow" on a Mac.

Steps to Increase Cancer Screening



The Manual Includes Four Important Steps:

Step #1 Make a Plan

Step #2 Assemble a Team

Step #3 Get Patients Screened

Step #4 Coordinate Care across the Continuum

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.
- Calculate the baseline screening rate.
- Improve the accuracy of the baseline screening rate.

Design Your Practice's Screening Strategy.

- Choose a screening method.
- Use a high-sensitivity stool-based test.
- Understand insurance complexities.
- Calculate the clinic's need for colonoscopy.
- Consider a direct endoscopy referral system.

Step #2 Assemble a Team

Form an Internal Leadership Team within the CHC.

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

Partner with Colonoscopists.

- Identify a physician champion.

Step #3 Get Patients Screened

Prepare the Clinic.

- Conduct a risk assessment.

Prepare the Patient.

- Provide patient education materials.

Make a Recommendation.

- Convince reluctant patients to get screened.

Ensure Quality Screening for a Stool-based Screening Program.

Track Return Rates and Follow-up.

Measure and Improve Performance.

Step #4 Coordinate Care across the Continuum

Coordinate Follow-up after a Colonoscopy.

- Establish a medical neighborhood.

Step #1: Make a Plan

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

– Sidney J. Winawer, MD

Determine Baseline Screening Rates.

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

1. Identify the patients.
2. Identify patients who have received screening.
3. Calculate the screening rate.

Identify your patients due for screening.

An important step involves identifying the active, current patients of your CHC who are eligible for screening. For example, some patients may have enrolled with one visit but have never been seen again in the clinic. Others may have had two or three visits but have not yet designated a clinician as their primary care provider.

As screening rate reports of individual CHCs are created, clinicians will generally want to know their own personal success rate. This will require assigning each patient to a specific provider. CHCs should clarify each provider's patient panel on an ongoing basis to bring better organizational structure to this screening effort. Sites with electronic health records (EHR) typically have the capacity to designate the primary care provider (PCP) for each patient electronically during patient registration or between visits, making the process of creating PCP panel reports easier. For patients who do not currently identify a provider, a helpful four-step method for patient panel designation is below.[14]

According to HRSA, patients who have had at least one visit within the calendar year should be counted as active patients.[13]

Table 1. Four-step Method of Patient Panel Designation

Type	Report Description	PCP Assignment
1	Patients who have seen only one provider in the past year	Assign to that sole provider.
2	Patients who have seen multiple providers, but one provider the majority of the time in the past year	Assign to majority provider.
3	Patients who have seen two or more providers equally in the past year (no majority provider can be determined)	Assign to the provider who performed the last physical exam.
4	Patients who have seen multiple providers	Assign to last provider seen.

Identify patients who have received screening.

CHCs have the option of reporting on screening for their entire patient population (referred to as the "universe") or selecting a scientifically drawn random sample to review. If the CHC cannot report on the universe (or chooses not to), then they must report with a random sample. One useful tool to help collect and identify sources of data is the **Collect Health System Data Work Sheet**[15] in **Appendix A-1**.

Active patients who have received appropriate screening as defined by the UDS[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)
- Guaiac-based fecal occult blood test (gFOBT) or fecal immunochemical test (FIT) during the reporting year

A **Chart Audit Sample Template**[16] is available in **Appendix A-2**. Data for this section may be obtained from a chart audit selected by EITHER:

A) Report 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 51 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) A process of scientific random sampling – This will be a scientifically drawn sample of 70 patients selected from all patients who fit the above criteria. The sample must include 70 patients and must be drawn from the entire patient population identified as the universe. See **Appendix A-3** for a detailed description of how to perform this measure.[13]

An EHR may be used in lieu of a review of a sample of charts if and only if:

- The EHR includes every single clinic patient who meets the criteria for inclusion in the universe (i.e., the number of patients who were 51 through 74 years of age at some point during the measurement year, who had at least one medical visit during the reporting year).
- The EHR excludes every single clinic patient who meets one or more exclusion criteria described below for exclusion from the universe (i.e., patients who have or who have had colorectal cancer).
- Every item in both the inclusion and the exclusion criteria is regularly recorded for all patients.
- The EHR has been in place long enough to be able to find the data required in the prior year's activities. For colorectal cancer screening, this means the EHR has been in operation for at least two full calendar years.[13]

The process to calculate the screening rate for CHC 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 **Appendix D-4**.

The following codes can be useful in identifying the patients who have received colorectal cancer screening criteria: CPT/ICD-9 (CPT-II codes):

- ICD-9 = 45.22 - 45.25, 45.42 - 45.43, V76.51
- CPT = 45330 - 45345, 44388 - 44397, 45355 - 45392, 82270, 82274, G0104, G0105, G0121, G0328

Calculate the baseline screening rate.

The HRSA formula for calculating the screening rate is:

- **Denominator:** Total number of patients who were 51 through 74 years of age at some point during the measurement year, who had at least one medical visit during the reporting year
- **Exclusions:** Patients who have or who have had colorectal cancer
- **Numerator:** Number of active patients 51 through 74 years of age who have received appropriate colorectal cancer screening. The UDS definition of screening includes patients who have received any of the following[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
  - Guaiac-based fecal occult blood test (gFOBT) or fecal immunochemical test (FIT) during the reporting year

*Tip: CHCs are often surprised to learn that their CRC screening rate is very low. It is recommended that CHCs utilize the first baseline rather than re-evaluate the baseline in hopes of getting a higher rate. Oftentimes, the second rate is even lower than the first one!

Improve the accuracy of the baseline screening rate.

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

- Establish a protocol in which the staff asks patients about prior screening during the patient visit.
- Use a written self-administered preventive care checklist for patients with adequate literacy and appropriate language skills.
- Establish a protocol for staff to contact all patients prior to a scheduled appointment to inquire about prior screening.
- The staff can "flag" the patients' charts on the schedule who are not up to date with screening so that recommendations and orders can be integrated into the upcoming appointment. For CHCs with EHRs, an electronic **alert** or **flag** can be placed in the patient's chart to prompt the clinical team to recommend screening during the patient visit.

* Note: Documentation of screening should include the date, test, and result.

Design Your Practice's Screening Strategy.

Choose a screening method.

The two most commonly used screening strategies for average-risk patients are either colonoscopy every 10 years or annual stool blood testing. Screening with either colonoscopy every 10 years or an annual high-sensitivity guaiac-based fecal occult blood test (FOBT) or fecal immunochemical test (FIT) has been shown to decrease incidence and mortality of colorectal cancer.[17]

There is no evidence from randomized controlled trials that one screening method is the "best." Based on modeling studies that assume 100% patient adherence for stool testing and colonoscopy , years of life saved through an annual high-quality stool-blood screening program are COMPARABLE to a high-quality colonoscopy-based screening program when positive stool tests are followed by colonoscopy.[17-19]

Although trials establish that flexible sigmoidoscopy is also an effective screening method for average-risk patients, flexible sigmoidoscopy is not in frequent use for screening in the United States. In locales where high-quality flexible sigmoidoscopy is available, it can continue to be used by CHC providers as long as positive screening results are followed up with colonoscopy.[17]

A high-sensitivity guaiac-based FOBT (HSgFOBT) refers to modern highly sensitive forms of the guaiac-based test, such as Hemoccult 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 Sensa) or FIT should be used for colorectal cancer screening.

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 and digital rectal exams are not appropriate methods of screening for colorectal cancer**. A single digital FOBT is a poor screening test for colorectal cancer; an in-office stool test missed 90% of cancers found at subsequent colonoscopy in one study.[20] A high-quality stool screening program requires that specimens be collected at home, the stool-based test be repeated annually, and all positive stool tests results must be followed by colonoscopy.

Awareness on the benefits of FIT and HSgFOBT in CHCs 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 guaiac-based FOBT this favorably. In addition, colonoscopy was preferred despite the fact that 51% of providers reported colonoscopy was not readily available for their patients, and 82% felt that many of their patients had financial barriers to screening

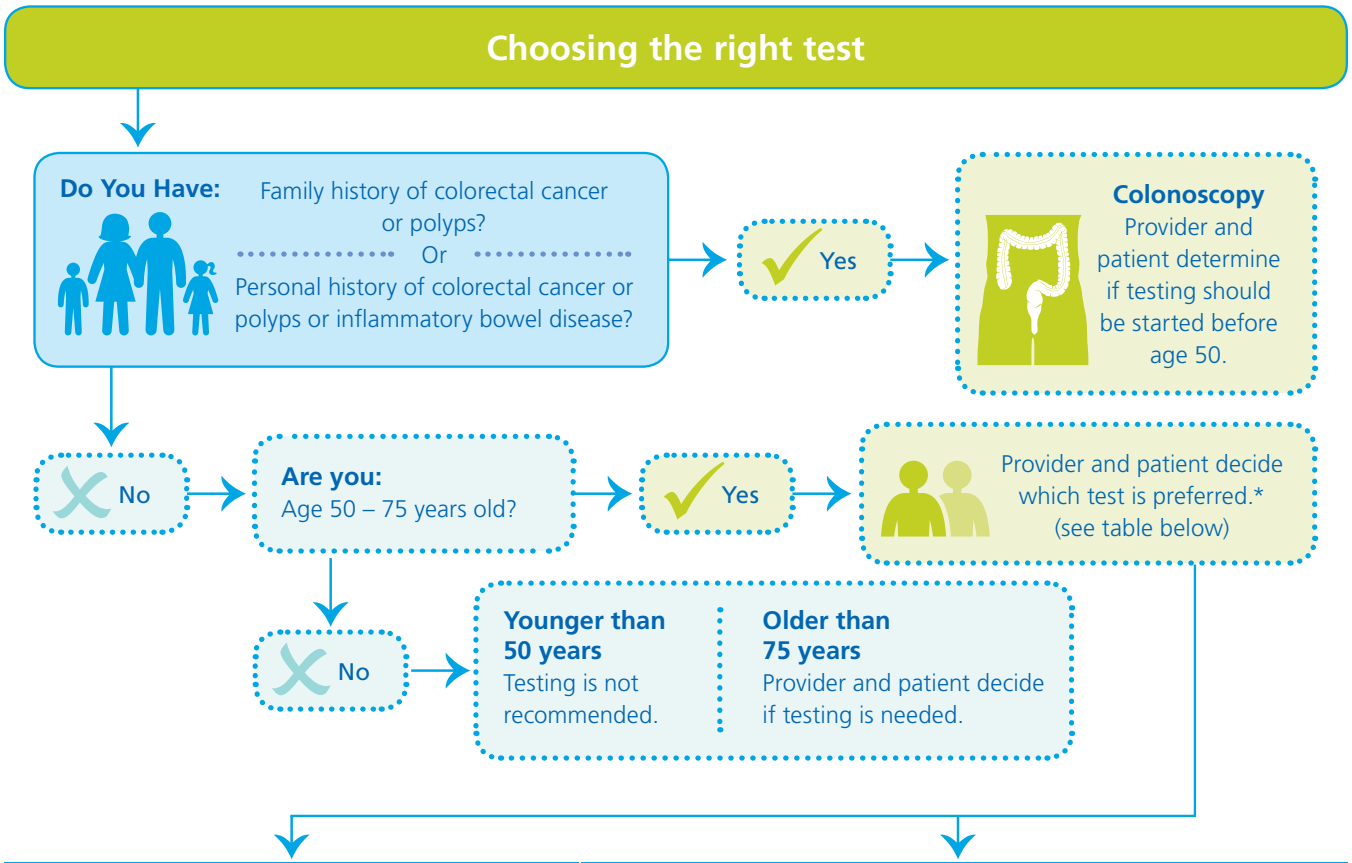
colonoscopy.[21] Because of these barriers to colonoscopy, screening rates could significantly rise with use of stool-based testing with either FIT or HSgFOBT.

As highlighted in this manual, achieving target screening rates will require use of both colonoscopy screening and a stool-based strategy. Many patients will not be able to afford or access colonoscopy or will prefer a less invasive test; using FIT or HSgFOBT offers an evidence-based alternative. On the other hand, reaching high screening rates with a stool strategy alone is challenging, demanding a very organized approach to recalling patients every year. 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, allowing a focus on other patients. However, offering only colonoscopy may be problematic. In one study of a CHC population, they found screening adherence was lower in patients offered screening colonoscopy alone, compared to those who were offered a stool-based method alone or a choice between the two options.[22]

If possible, programs should offer patients both options: screening colonoscopy or high- sensitivity stool testing. The screening strategy of each individual CHC should also consider the characteristics of the patient population, including patient history and risk level, patient preferences (culture, language), insurance status, and local medical resources.

Some CHCs will find it is difficult to get access to colonoscopy for their patients. These centers may opt to choose FIT or HSgFOBT 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 stool blood tests.** In fact, patients who test positive on an HSgFOBT or FIT 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**.

Figure 2. Choosing the Right Test



FOBT/FIT†	Colonoscopy
Key facts • Reduces death from colorectal cancer • Safe, available, and easy to complete • Done on your own at home and returned • Finds cancer early by finding blood in the stool • Finds most cancers early when done every year	**Key facts** • Reduces death from colorectal cancer • Can prevent cancer by removing polyps (or abnormal growths in the colon) during test • Examines entire colon • Finds most cancers or polyps that are present at the time of the test • Done every 10 years if no polyps are found
Things to consider • May produce positive test results, even when no polyps or cancer are in the colon • When the test is positive colonoscopy is required • Person testing themselves comes into brief close contact with stool samples on a test kit † Guaiac Fecal Occult Blood Test (FOBT) or Fecal Immunochemical Test (FIT)	**Things to consider** • Stomach pain, gas or bloating is possible before, during or after test • 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 • A clear liquid diet is required before test • Must take medication that will cause loose bowel movements to clean out the colon prior to test • Likely needs to take a day off work/activities • Small risk of serious complications (for example, bleeding or perforated colon)

*Flexible sigmoidoscopy may not be readily available and has largely been replaced by colonoscopy in the US.
SOURCE: Vital Signs 2013 and USPSTF http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm

+ FOBT should be high-sensitivity gFOBT, such as Hemoccult Sensa

Use a high-sensitivity stool-based test.

Traditional stool guaiac-based tests such as the **Hemoccult II™ and its generic equivalent Seroccult, are no longer recommended** for colorectal cancer screening and should be replaced with high-sensitivity guaiac-based tests such as the Hemoccult SENSA or an evidence-based FIT.

As mentioned above, all programs should be sure to offer a stool blood test option. For some programs, a stool blood test option may be the primary screening method. For others, a stool blood test option will be important to offer to patients who refuse a colonoscopy. Either way, it is very important for programs to select a high-quality stool blood test.

Performance characteristics of different types of stool-based tests are summarized in the table below, which shows that HSgFOBT and FIT are both more sensitive and specific than traditional guaiac-based FOBT (Hemoccult II or Seroccult).[23]

FIT has several advantages when compared with traditional stool-based tests, and therefore FIT should replace these tests whenever possible. FIT had higher patient participation, higher diagnostic yield, and improved sensitivity with preserved specificity compared to guaiac-based testing in one study.[24] Other advantages include:

1. FIT is more specific for human blood compared to guaiac-based tests, and therefore less affected by dietary factors such as rare meat.
2. Unlike gFOBT, FIT is not subject to false-negative or false-positive results in the presence of many foods or medicines.
3. FIT is also more specific for lower gastrointestinal bleeding, thus improving colorectal cancer detection.

Figure 3. Performance Characteristics of Guiaic-based FOBT and FIT

Two main types of FOBT are available – guaiac-based FOBT and FIT

Guaiac-based FOBTs have been the most common form of stool tests used in the United States. 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 United States, 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-based FOBT; this may be a result of preparation needed by patients (e.g., no dietary or 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.

4. The sample collection for some types of FIT are less cumbersome for patients compared to gFOBT, requiring fewer samples or less direct handling of stool.[25]

Although FITs are paid for by virtually all insurers, FIT does cost slightly more than traditional low-sensitivity gFOBT. At this time, the approximate cost of traditional gFOBT is $2-3 US compared to FIT cost of $10-20 US.[26] However, the overall cost of FIT can be comparable to traditional gFOBT in the long term. An analysis by one city's public health department found that switching to FIT from the traditional low-sensitivity guaiac-based test (Hemoccult II or Seroccult) would result in only a small overall cost difference on an individual patient basis. This is based on better return rates and Medicare reimbursement with FIT, and taking into account promotions by manufacturers. This analysis is one example of an effort to switch an entire system from an old guaiac-based test of low sensitivity to a FIT test of greater sensitivity in the context of relatively high volume, central purchasing, and competitive pricing from the supplier.

It is important to recognize that not all FITs are created equal.

FITs vary in collection methods – dry cards versus samples mixed with liquid buffer, number of samples (1, 2, 3), and how they are read (most in US are mailed to a lab and read by an automated reader, reported as positive/negative).[24] While there are several characteristics of FITs to consider (cost-effectiveness, efficacy, price, ease of use, FDA approval), a trial period of various types is recommended before making a long-term decision. A comprehensive, evidence-based list of HSgFOBTs and FITs tests is under development and will be added to the online/digital version of this manual as soon as it becomes available.

Understand insurance complexities.

Although great progress in insurance coverage for colorectal cancer screening has occurred in the past few years, the CHC needs to help patients understand and navigate through the coverage complexities. In 2001, Medicare began paying for screening colonoscopy for people age 50 and older. The Patient Protection and Affordable Care Act (ACA), passed in 2010, waives the copay and deductible for many preventive health screenings, including colonoscopy. In 2013, the federal government clarified that patients with *most private insurance plans* are no longer liable for cost sharing (i.e., no copay or deductible) when a colon polyp is removed during a screening colonoscopy. Patients may still be responsible for cost sharing for certain types of sedation, pathology, facility charges, or out-of-network costs. Still, patients should review their health insurance plan for specific details, including whether their plan falls under this guidance. Patients with Medicare coverage still pay a copay (but not a deductible) if a polyp is removed during screening colonoscopy, because the procedure is no longer categorized as a screening once polyp removal occurs. The American Cancer Society, gastroenterology societies, the National Colorectal Cancer Roundtable (NCCRT), and other advocacy organizations are working to remove the Medicare copay for this circumstance.[27,28]

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. This also remains an issue for colonoscopies done after a positive stool-based test. Currently, there is no legal protection from a copay for a follow-up colonoscopy following a positive stool blood test. There are a few insurance companies that have established the principle that no colonoscopy should require a copay, but they are exceptions, not the rule. There is ongoing work to try and ensure that colonoscopies following a positive stool blood test are free from copays, but this is not yet the case. Insured patients should be aware of this distinction when making a choice between colonoscopy and stool testing for colorectal cancer screening.

Calculate the clinic's need for colonoscopy.

Colorectal cancer screening programs in many CHCs depend on FIT or high-sensitivity gFOBT (HSgFOBT) as the primary screening method.

All programs must have colonoscopies available for increased-risk patients and for diagnostic purposes for patients with positive screens.

In some locations, limited capacity for colonoscopy results from a poor supply of colonoscopists, low rates of insurance coverage, or restricted acceptance of Medicaid 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.

Calculating the extent of the need for colonoscopy will help the CHC understand its 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 calculation producing an estimate of the finite number needed can be derived in the following way:

Patients with a positive stool test will require colonoscopy. The overall stool test positivity rate in a population is generally 5-10%, depending on patient population and test characteristics.[29]

Patients at increased risk (as determined by personal and family medical history) will require colonoscopy for screening. This number (also epidemiologically derived) is roughly about 15% of the population over age 40.[30] Not all of the 15% at increased risk is likely to get a colonoscopy in the first year of a program. It is fine to start a stool-based screening program before a robust risk assessment program is developed, and the CHC can explore ways to assess and document risk more comprehensively over time. Once these increased-risk patients have had one colonoscopy, most of them will need repeat screening only once every 5-10 years.

From these two numbers, the total number of colonoscopies needed per year can be determined. A sample calculation is as follows:

Let's say a practice has 1,000 patients 40 to 75 years of age and 750 patients between the ages of 50 and 75.

We know that 15% of the population over 40 is likely to require colonoscopy because of increased risk status.

Number of patients at increased risk requiring colonoscopy in a given year = A.

A = 0.15 x 1000 patients = 150.

For planning purposes, screening the entire increased-risk group in the first year of a program is not likely, so the 150 colonoscopies could be spread over 3 years. We can calculate that for years 1-3 the total need would be one-third of that or 150/3 = 50 per year.

In subsequent years, the demand of 150 could be expected to spread out over more years. We can use five years for this calculation, which means about 150/5 = 30 colonoscopies per year would be needed.

A (Year 1, 2, 3) = (0.15 x 1000) ÷ 3 = 50 colonoscopies needed/year

A (Years 4+) = (0.15 x 1000) ÷ 5 = 30 colonoscopies needed/year

Of the 85% of those 50 to 75 years of age (N=750) who are at average risk (0.85 x 750), 5% of those are expected to have positive stool tests.

B = 0.05 x (0.85 x 750) = 32

A + B = total number of colonoscopies needed/year

Year 1, 2, 3: **50 + 32 = 82 colonoscopies needed/year**

Years 4+: **30 + 32 = 62 total colonoscopies needed/year**

Some of these colonoscopies can be purchased easily in the local health system marketplace by the patients who have Medicare or commercial insurance. If 30% of the screening-eligible patients of the CHC are covered by Medicare or other insurance, the total of donated colonoscopies needed during the early and latter years may be reduced by 30% and becomes about 57 and 43 colonoscopies/year, respectively. The finite number allows the CHC to negotiate with each potential colonoscopy supplier for a limited number of donated colonoscopies. Over a 52-week year, this is about one colonoscopy per week. With rising rates of private insurance through the new health exchanges, the number of colonoscopies requiring special planning may be even further reduced. If there are several gastroenterologists in the area, it may be possible to get more than one donated colonoscopy per week from each office.

Despite rising rates of Medicaid coverage, the acceptance of Medicaid patients remains a problem in most medical marketplaces. Additionally, the uninsured are likely to continue to account for a large segment of the CHC population. These patients who are uninsured or inadequately insured may still need to be scheduled based on special agreements between the health center and area gastroenterologists, surgeons, or hospitals.

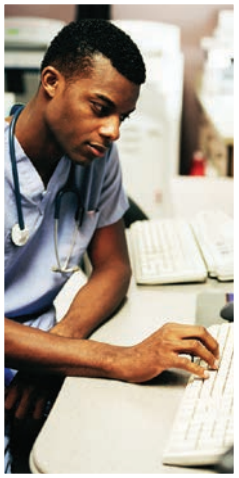
Because colonoscopy is performed in a facility and often involves an anesthesiologist and pathologist, enlisting the aid of a colonoscopy champion and/or a hospital-based physician champion will help to line up the array of providers and facilities that are needed for your patients and CHC. This medical 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 **Table 2**). 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.

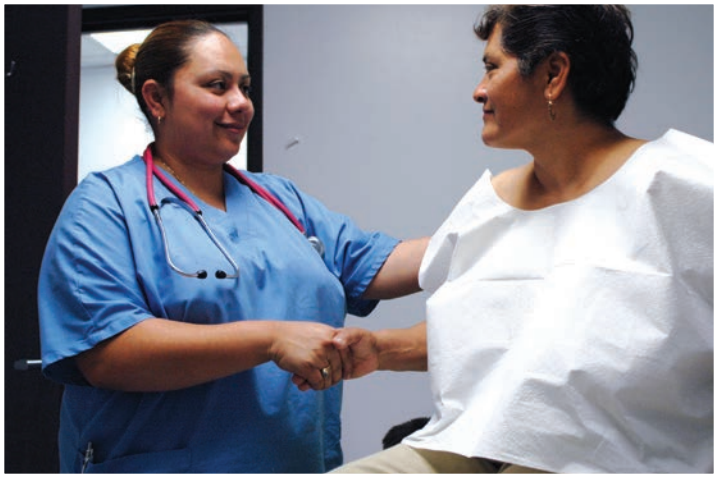
Consider a direct endoscopy referral system.

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 providers to medically clear patients and prepare patients to go directly for colonoscopy. In order to do this, the patient needs to be:

- Be well oriented and prepped before this procedure.
- Take a day off from work and have someone to drive them.
- Have a good understanding of the procedure.

In New York City's colonoscopy-based 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 is referenced in **Table 3** in the Step #3 section called Prepare the Patient and sample forms used for direct endoscopy referral are available in **Appendix C-3** and **C-4**.[31,32]





Step #2: Assemble a Team

"Coming together is a beginning.
Keeping together is progress.
Working together is success."
– Henry Ford

Form an Internal Leadership Team within the CHC.

A clear organizational structure is needed early in the process of developing an effective screening system. The internal team can include the medical director, clinic manager, providers, medical assistants, nurses, quality improvement leaders, and other staff. Once the CHC 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.

Identify an internal champion.

- Consider someone who has a personal interest in colorectal cancer or cancer screenings.
- Choose someone who is a motivated "do'er" and is respected in the organization.
- Consider having two champions – one medical and one administrative.
- Consider community health staff, marketing staff, practice administrator, informatics staff, and clinical staff – all of whom have served as champions and have been successful.

Define roles of internal champion.

- Set up an introductory meeting with health center staff to discuss how to increase screening rates and to review strategies that will be implemented.
- Become familiar with the guide *How to Increase Colorectal Cancer Screening Rates in Practice: A Primary Care Clinicians Evidence-Based Toolbox and Guide* (http://nccrt.org/about/provider-education/crc-clinician-guide).
- Work with health center staff to develop a year-long plan that may include presentations on current screening guidelines, development of a screening policy, workflow analysis, small media campaigns, and establishing goals for increasing rates.
- Act as a spokesperson when called upon by your CHC.
- Serve as the point of contact for CHC 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 screening can be addressed with the assistance of patient navigators, community health workers, and/or health educators. Patient barriers to colorectal cancer screening in CHCs include medical comorbidities, difficulty following the preparation and other screening steps, negative screening experiences of others, high-cost, low-patient awareness and knowledge about CRC and screening, or cultural and

psychosocial issues.[33,34] Other studies have identified a lack of trust in physicians, lack of symptoms, fear of pain and of discovering cancer, the shame of being seen as sick or weak, and feelings of violation, as reasons for not getting screened.[35]

> Navigators have provided a significant boost to screening programs with underserved populations, including colorectal cancer screening.[36,37]

They can assist with patient education, scheduling appointments, appointment reminders, transportation needs, addressing cultural barriers, communicating between referring providers, and coordinating follow-up after procedures. Navigators can be recruited and trained from among patients, social workers, community health workers, nurses, or case managers.[38,39] For additional information on **how to design a patient navigation intervention for colorectal cancer screening**, see the following reference in **Appendix D-3**: Degroff et al, Key considerations in designing a patient navigation program for colorectal cancer screening, *Health Promotion Practice* 2013.[40]

Successful patient navigation has been implemented in colorectal cancer screening programs in states and regions around the country, including colonoscopy-based programs.[38] In the New Hampshire Colorectal Cancer Screening Program, navigators helped reduce the no-show rate to zero, with less than 1% inadequate preps. The Cancer Coalition of South Georgia's patient navigation system has led to a 2% no-show rate and less than 5% of inadequate preps. The effective use of patient navigators by Operation Access in San Francisco has led to a 97% patient compliance rate.[41] A CHC in Boston, Massachusetts, had a higher number of navigated patients complete colonoscopy, compared to those without navigation (54% vs 13%).[42] 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.[43]

Additionally, patient navigation has proved to be valuable in stool-based screening programs. Navigators in these programs have assisted with test choice, scheduling appointments, patient support and motivation, appointment reminders, and education on stool-based blood tests and bowel prep. An East Harlem, New York, program with a largely Hispanic, low-income and publicly insured population, saw an increase to 42% of navigated patients completing stool-based tests compared to 25% of non-navigated patients.[44] At a CHC in Somerville, Massachusetts, where navigators spent an average of four hours of telephone navigation per intervention patient, navigated patients were more likely to be screened with gFOBT and colonoscopy in six months compared to those not receiving navigation (31% vs 9%).[45] 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% 20%).[36]

One CHC in Fair Haven, Connecticut, has even partnered with a local community college to create a patient navigation certification with online modules. 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.

Following is a description of the possible roles a patient navigator could provide to your CHC. Additional resources and manuals for patient navigators are available in **Appendix D-3**.

- Review of patient charts beforehand to identify and flag individuals who are not up-to-date with colorectal cancer screening
- Patient level
  - Provide patients with education on colorectal cancer 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).
  - Arrange appointments (colonoscopy and follow-up tests).
    - Use a direct line to 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 diagnosed patients to hospital patient navigation.
- Document interventions and number of people reached.

- Staff level
  - Conduct in-service educational training with staff on colorectal cancer 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 religious groups, local businesses or employers, pharmacies, schools, libraries, and community groups to increase colon health awareness (can involve the community in program planning whenever possible).
    - Promote screening at health fairs, at local festivals, announcements at local sporting events, or with local media.
  - Formulate and implement strategies and methods to reach target population.
  - Provide the community with educational classes on colon cancer prevention, early detection, and give screening guidelines.

To ensure patients are properly prepped and show up, successful CHCs have implemented protocols for following up with patients. As an example, the CHC in Fair Haven, Connecticut, has their patient 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. These checklists are included in **Appendix C-6**. CHCs can also consider partnering with local businesses to donate the prep materials to the center.

An important question for programs will include how to obtain funding for patient navigators. Several programs with patient navigation systems currently have 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. A list of resources is below regarding possible funding sources for patient navigation:

- The National Cancer Institute Health Patient Navigator Program
  crchd.cancer.gov/pnp/pnrp-index.html
- American Cancer Society Patient Navigator Program (1-800-227-2345)
  cancer.org
- Centers for Disease Control and Prevention
  cdc.gov
- Centers for Medicare and Medicaid Services
  cms.hhs.gov

Agree on team tasks.

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

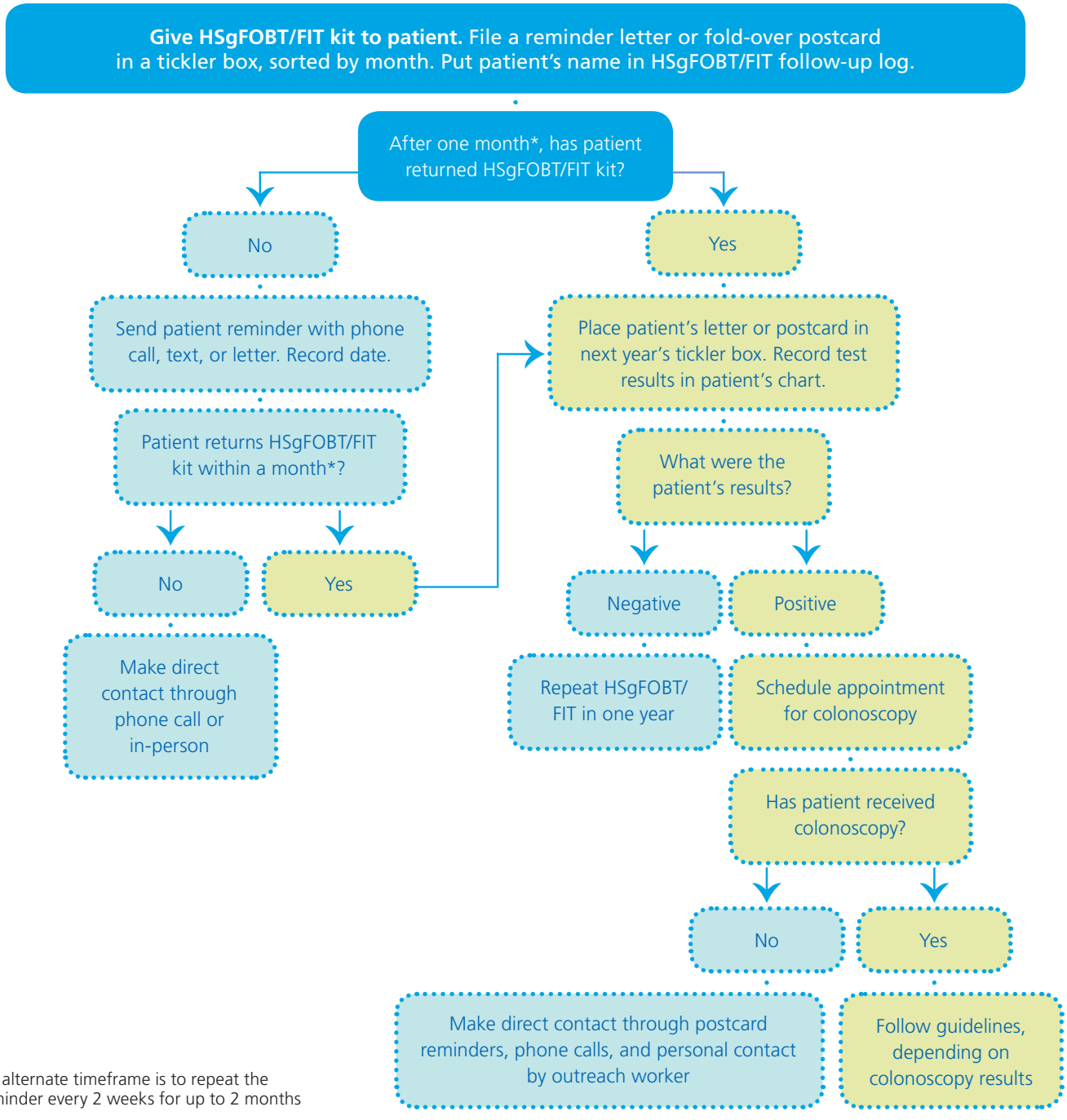
- Define program goals, objectives, and time frame.
- Formulate a patient navigator role description.
- Identify supervisor (for feedback and support) of the patient navigator role.
- Identify potential costs (patient navigator hiring, training, salary, and benefits, supplies, materials, and equipment, 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 are in **Appendix A**, including a **Health System Experience with CRC Screening Work Sheet**[15] **(A-4)**, **Health System Intervention Strategies Work Sheet**[15] **(A-5)**, **Interventions for Health Insurance Plans**[15] **(A-6)**, and **Action Plan Work Sheet**[15] **(A-7)**.
  - Choose the specific type of stool-based kit and decide about processing lab work in house or out. A list of evidence-based stool-based tests is under development and will be added to the online/digital version of this manual as soon as it becomes available.
  - Navigator/staff training – see **Appendix D-3** for examples of training manuals from several programs.
- Develop or adopt tools (standardized intake form, tracking system/follow-up log, brochures describing the program):
  - **Standard history and physical form with labs** in **Appendix C-3** (Operation Access)
  - **Standing orders for HSgFOBT/FIT**[46] – see flow chart in **Figure 4** on page 23.
  - **Direct endoscopy referral** – For a sample referral form from the New York program Citywide Colon Cancer Control Coalition (C5), see **Appendix C-4**.
  - **Sample colonoscopy appointment letters** in English and Spanish (Operation Access) in **Appendix C-5**
  - Navigator checklists – A CHC in Fair Haven, Connecticut, has colonoscopy preparation checklists to review with patients before the procedure. These **colonoscopy preparation navigator checklists** are included in **Appendix C-6**.
  - FLU-FIT and FLU-FOBT – evidence-based programs that allow clinic staff to identify eligible patients and offer home stool tests at the time of their annual flu shots. Coupling colorectal cancer screening with established annual flu shot activities can be an excellent way to introduce the importance of colorectal cancer screening to clinic teams and patients and have been shown to improve screening outreach.[47,48] **For a description of five steps for implementing a FLU-FIT or FLU-FOBT in your health center**, see **Appendix C-7**. For additional websites describing evidence-based programs that could be useful in your community, see **Appendix D-5**.
    - FluFIT website: flufit.org
    - American Cancer Society FluFOBT program website: cancer.org/flufobt
- Reminder follow-up tools are available in **Appendix C**[46], including:
  - **Sample HSgFOBT/FIT results tracking sheet (C-8)**
  - **Sample reminder cards (C-9)**
  - **Sample patient reminder letter for screening (C-10)**
  - **Sample patient reminder letter to return test (C-11)**
  - **Sample patient letter regarding a negative test (C-12)**
  - **Sample chart stickers (C-13)**
  - **Sample memorandum of understanding with GI and other specialty providers (C-14)** from Operation Access
- Determine the resources you are going to devote to follow up and adherence
  - EHR support (chart prompts, provider and staff prompts, guidelines in EHR, EHR-generated patient reminders/letters), staff involvement (calls/letters/postcards)
  - A **sample tracking template**[16] is available in **Appendix A-8**.

- 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 has an evaluation toolkit that can help those with little to no evaluation experience evaluate their programs: http://nccrt.org/about/public-education/evaluation-toolkit.
  - **Assess your progress work sheet**[15] – **Appendix A-9**.

The CHC 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 constantly reviewing the quality improvement infrastructure.

Figure 4. Standing HSgFOBT/FIT flow chart[46]



*An alternate timeframe is to repeat the reminder every 2 weeks for up to 2 months

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 screens.[49] However, from a regional 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.

Identify a physician champion.

Whether your program is based on offering all patients 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.

> **Several pilot programs have implemented colorectal cancer screening programs in community health centers with a physician champion as a key component of their success.**

These efforts to improve screening often start at the physician level, and grow by recruiting other physicians 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 by screening. This experience becomes a strong motivator. This physician 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.

Following is a table outlining programs that have been championed by a physician(s) with a description of their effective strategies.

Table 2. List of Programs with Physician Champion(s) and Strategies of Success

Program	Description	Physician Champion and Strategies for Success
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 • Strong collaboration between PCPs, specialists, hospitals, and community health centers • Coalition estimates county need and apportions to colonoscopists • Use of patient navigators has led to a 2% no-show rate and less than 5% of inadequate 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 • Utilization of internal champions • Highly effective patient navigation • Clear protocols • Secured the commitment of leadership at community health centers, hospitals, endoscopy sites
Volunteers in Medicine/Project Access	Two partnering programs that provide free medical care to low-income, uninsured residents in Chattanooga, Tennessee	• Project Access founded by surgeon champion • Volunteers in Medicine includes 400 volunteer physicians • Project Access managing the volume so that patients are equitably distributed • Availability of volunteer medical licenses for retired physicians
Operation Access	Collaboration of community clinics, hospitals, surgery centers, endoscopy centers to provide surgical and specialty care to the underserved in San Francisco, California	• Founded by surgeon champions • Clear level of commitment (one colonoscopy per week) helps with physician recruitment • Mostly follow-up colonoscopy after positive FIT; limited screening colonoscopy those at elevated risk • Highly effective care coordination and patient navigation (bilingual staff members) -> 97% patient compliance rate, which also helps recruit and sustain physician volunteers
National CRC Screening and Awareness Event	Program started by the American Gastroenterological Association (AGA) to provide donated colonoscopies to the underserved and uninsured	• AGA volunteer physicians donate colonoscopies, obtain support from their hospitals and specialists (surgeons, pathologists), and partner with the CDC's Colorectal Cancer Control Program

Step #3: Get Patients Screened

A provider recommendation is the most powerful influence on a patient's decision to get screened for cancer.

Prepare the Clinic.

All participating CHC staff should be educated about colorectal cancer and the office screening strategy, either annual high-sensitivity gFOBT/FIT or colonoscopy screening. This includes information on appropriate screening intervals, and how to stratify patients into average- and elevated-risk categories. All providers should be aware of the most recent guidelines for colorectal cancer screening for patients at average risk, increased risk, and high risk. Documentation of prior screening should include the date, test, result, and recommended follow-up.

It is always worth adding a reminder to all providers and staff that **in-office stool testing and digital rectal exams are not appropriate methods of screening for colorectal cancer.**

Colorectal cancer screening with HSgFOBT/FIT requires that stool specimens be collected at home. One study demonstrated that the in-office stool test missed 90% of cancers found at subsequent colonoscopy.[20]

It is important to keep in mind that most patients are at average risk. If your CHC has very low baseline screening rates, it is perfectly acceptable to start a robust stool-based screening program even before you have gotten this risk assessment program in place. 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 has no personal history of either adenomatous polyps or colorectal cancer, no first-degree relatives with a history of either of these problems, and no history of inflammatory bowel disease.

Increased-risk patients have a personal or family history of adenomatous polyps or colorectal cancer.

High-risk patients include those with hereditary colorectal cancer syndromes: 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. Other high-risk patients include those with Crohn's disease or ulcerative colitis, whose risk increases with the extent and duration of the disease (usually after at least eight years).[50]

For a more detailed description of the criteria and screening recommendations for increased- and high-risk patients, see the **American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in People at Average Risk, Increased Risk, or at High Risk**, which is also available in **Appendix D-2**:

cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations

Questions to Determine Risk

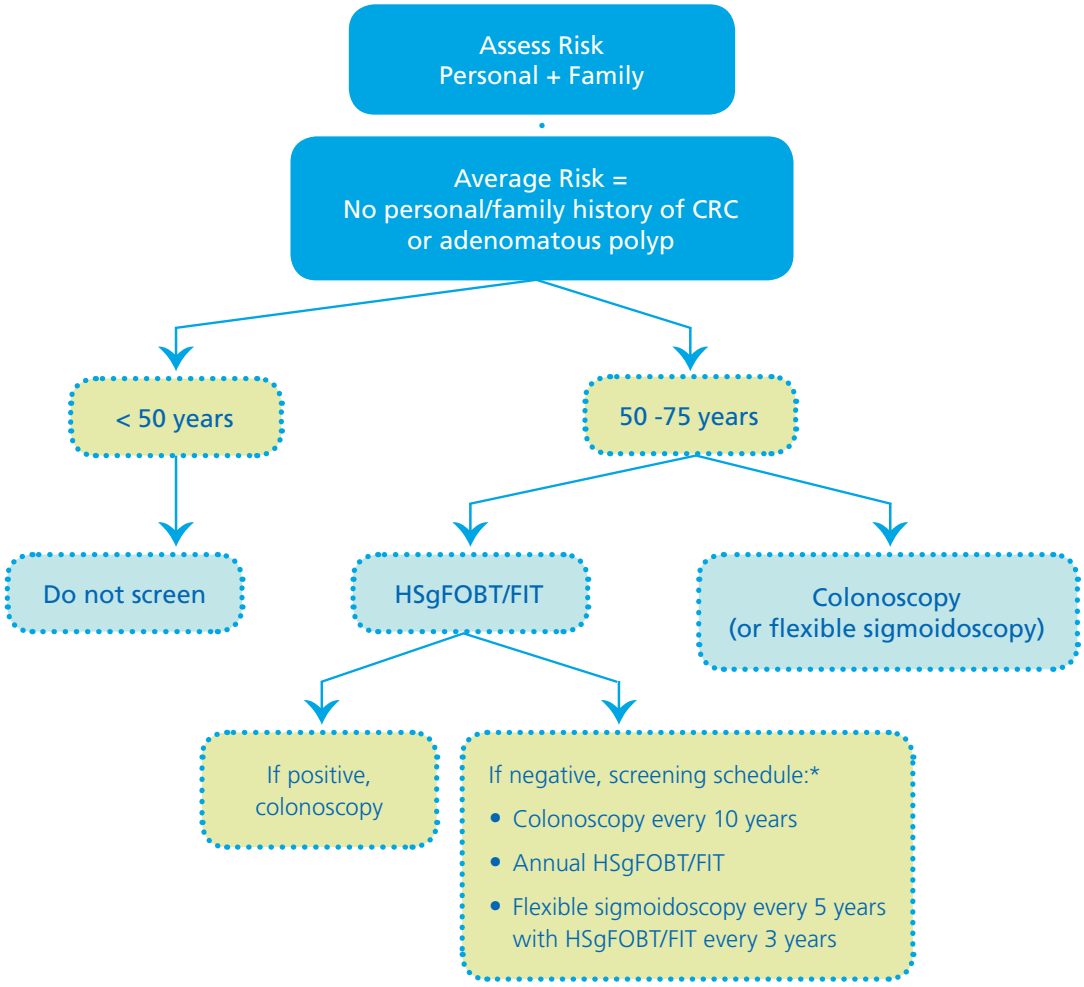
- Have you or any members of your family had colorectal cancer?
- Have you or any members of your family had an adenomatous polyp? (Request old pathology records if possible since most people will not know the type of polyp.)
- Has any member of your family had a CRC or adenomatous polyp when they were under the age of 50? (If yes, consider a hereditary syndrome.)
- Do you have a history of Crohn's disease or ulcerative colitis (more than eight years)?
- Do you or any members of your family have a history of cancer of the endometrium, small bowel, ureter, or renal pelvis? If the answer to any one of these is yes, a genogram will help assess for other cancers at young ages associated with hereditary non-polyposis colorectal cancer (HNPCC).

Genetic testing should be offered to those who have a personal or family history suggestive of one of the hereditary colorectal cancer syndromes. Genetic testing is often located in cancer centers that are interested in serving the community. However, genetic counseling and testing may not be accessible in rural communities. CHCs should do the best they can with available resources. If there is suspicion of a high-risk situation, send the patient for colonoscopy. See the list below for a list of websites with additional information.

Resources for Genetic Testing and Genetic Counseling

- American Cancer Society – Genetic Testing: What You Need to Know
  cancer.org/cancer/cancercauses/geneticsandcancer/genetictesting/genetic-testing-what-you-need-to-know-toc
- National Society of Genetic Counselors – The "Consumer Information" link on the website has 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
  nsgc.org
- American Board of Genetic Counseling – Additional information on how to find a genetic counselor
  abgc.net/ABGC/AmericanBoardofGeneticCounselors.asp
- National Cancer Institute – List of services related to cancer genetics (cancer risk assessment, genetic counseling, genetic susceptibility testing)
  cancer.gov/cancertopics/genetics/directory

Figure 5. Screening Algorithm for Average-risk Patients



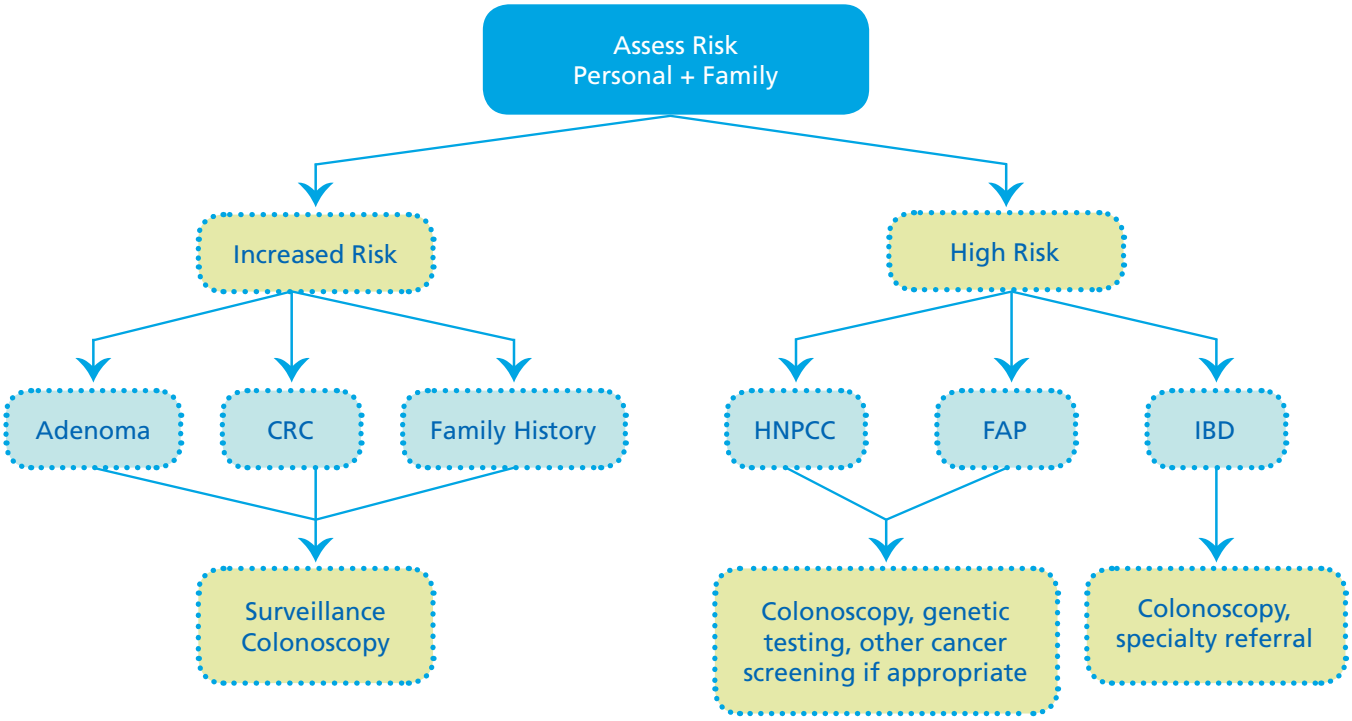
CRC = colorectal cancer

HSgFOBT = high-sensitivity fecal occult blood test

FIT = fecal immunohistochemical test

*Note: Additional recommendations for screening exist by ACS, which are available at:
www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines

Figure 6. Screening Algorithm for Increased- and High-risk Patients



CRC = colorectal cancer

HNPCC = Hereditary non-polyposis colorectal cancer

FAP = Familial adenomatous polyposis

IBD = Inflammatory bowel disease

*Note: Additional recommendations for screening exist by ACS, which are available at:
www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines

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 an educational DVD/video presenting CRC screening education to patients.
  - A UNC web-based educational tool for patients to view at home or in a waiting room: decisionsupport.unc.edu/CHOICE6/choice6.htm
  - An American Cancer Society DVD or web-based educational tool for patients (available in English and Spanish): cancer.org/healthy/toolsandcalculators/videos/get-tested-for-colon-cancer-english
  - The FluFIT and FluFOBT website has multilingual videos with instructions on conducting a stool-based test (available in 10 languages): flufit.org/programmaterials.html
- In the office and community, post and distribute multicultural and multilingual health information materials, including flyers, inserts, posters, brochures, fact sheets, letters, postcards, phone scripts, greeting cards, or birthday cards.
- Great resources for patient education – additional **patient education materials** in **Appendix D-1**
  - Resources to educate patients about the importance of CRC screening
    - MIYO (Make It Your Own – library with hundreds of templates for creating customized patient education materials in multiple languages/cultures) beta.miyoworks.org
    - CDC Screen for Life – Fact sheets, brochures, brochure inserts, posters, print ads (available in Spanish) cdc.gov/cancer/colorectal/sfl/print_materials.htm
    - Northwestern University's CRC Patient Education Materials Library: A look at Northwestern's comprehensive library of materials in English, Spanish, Chinese and Vietnamese) Please contact Shira Goldman, MPH, research project coordinator, at shira.goldman@northwestern.edu for materials.
  - Resources to educate patients about how to use gFOBT and FIT
    - The FluFIT and FluFOBT website has test instructions in various languages that can be modified based on your patient population. flufit.org/programmaterials.html
    - Instructions on how to use FIT in English and Spanish (Northwestern University) Please contact Shira Goldman, MPH, research project coordinator, at shira.goldman@northwestern.edu for materials.

- Resources about colonoscopy preparation
  - Educational video on colonoscopy after a positive stool test in English and Spanish (Northwestern University)
    Please contact Shira Goldman, MPH, research project coordinator, at shira.goldman@northwestern.edu for materials.
  - A YouTube video link to prep instructions provided by the New Hampshire program (NHCRCSP)
    youtube.com/watch?v=xd1N0WOcd5A
  - Prep instructions in more than 20 languages provided by the New Hampshire Colorectal Screening Program (NHCRCSP)
    Contact information: Janene.Robie@hitchcock.org
  - Colonoscopy MoviPrep instructions in English and Spanish (Northwestern University)
    Please contact Shira Goldman, MPH, research project coordinator, at shira.goldman@northwestern.edu for materials.
  - 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 colorectal cancer screening or explain the CHC's protocol for screening.

- Depending on state medical practice policies, you may be able to utilize standing orders for HSgFOBT/FIT[46] (**Figure 4**) so that staff may distribute these tests to those at average risk who are not initiating screening with colonoscopy. Train staff to communicate with patients and to provide appropriate test instructions. See below for sample counseling scripts for average- and increased-risk patients.
- For those going straight to colonoscopy, provide direct access to endoscopy when available. See **Tables 3** and **4** on page 33 for **eligibility criteria for direct endoscopy referral** and for a **list of colonoscopy preparatory agents**.
  - Direct endoscopy referral – see **Appendix C-4**
    nyc.gov/html/doh/downloads/pdf/cancer/cancer-colon-ders.pdf
- For those patients who are unsure about screening, flag the chart so a provider will discuss it.
- Another option for average-risk patients who are not up to date with CRC screening is to mail FIT kits.

Kaiser Permanente in Northern California has been mailing FIT kits to patients, 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%.[24,51] This type of system may seem resource intensive for many CHCs, but many aspects of their program are readily translatable to CHCs with a highly motivated quality improvement team and an EHR.

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 50 years of age and older.

Our CHC offers screening for patients who are at average risk with a take-home test (FIT/gFOBT) that looks for blood in the stool. If you are found to have blood in your stool, 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 50 years of age and older.

Our CHC 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/gFOBT) that looks for blood in the stool. If you are found to have blood in your stool, 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."

Table 3. Eligibility Criteria for Direct Endoscopy Referral[31]

Which patients are eligible for direct endoscopy referral?	
Most Patients ARE Eligible (Indications)	**Some are NOT (Contraindications)**
Patients who meet one of these criteria ARE eligible for direct referral:	**Patients who meet one or more of these criteria are NOT eligible for direct referral:**
Colorectal cancer screen in patients aged 50 to 75 years	On anticoagulation therapy*
Positive fecal occult blood test (FOBT) or rectal bleed in a patient <75 years of age with no prior GI endoscopic workup	Age 76 or older
Iron deficiency anemia in patients < 75 years of age with NO prior GI endoscopic workup	Has a prosthetic heart valve
Family history of colorectal cancer (provided patient is at least 5 years younger than the age at which relative was diagnosed)	Has a co-morbidity with a future life expectancy of less than 5 years
Personal history of adenomatous colon polyps in a patient 50 to 75 years of age whose last colonoscopy was at least 5 years prior to referral	Under treatment for any heart disease or heart failure
Colonic mass lesion seen on barium enema or CT scan	Under treatment for diabetes, emphysema, or hypertension* (if coordination with primary care provider is limited)

*Patients being treated for heart disease, heart failure, diabetes, emphysema, or hypertension should be evaluated prior to endoscopy. This may be done in the primary care setting if good coordination and information flow exists with the endoscopy unit. Patients with these conditions, in a primary care setting without good coordination with the endoscopy unit, should be referred to the GI/surgery outpatient clinic.

Table 4. Colonoscopy Preparatory Agents[31,52]

Summary of Agents for Colonoscopy Preparation			
Agent	**Volume**	**Cost**	**Comments**
PEG-based Prep – Recommended for general use			
Colyte, GoLYTELY, NuLytely, TriLyte	4 L	$15 - $30 brands*	• Relatively safe for patients with electrolyte imbalance, advanced liver disease, poorly compensated congestive heart failure, or renal failure • No solid foods at least 2 hrs before administration
HalfLytely	2 L + 2 bisacodyl 5 mg tabs	$50*	• Consume only clear liquids on the day of administration.
MoviPrep	2 L + 1 L clear liquid	$50*	• MoviPrep contains ascorbic acid (avoid in patients with G-6-PD deficiency).
Miralax, Glycolax	2 L + 2 bisacodyl 5 mg tabs	$20 - $40*	• Does not contain electrolytes; consume only clear liquids on the day of administration; mix entire bottle (238 or 255 gm) with 64 oz of Gatorade or Crystal Light (if diabetic) and shake well
PEG-based Prep – Recommended for general use			
NaP (aqueous) Fleet Phosphosoda	90 ml	$5 for 2 1.5 oz. bottles*	• May be contraindicated in patients with renal failure, acute myocardial infarction or unstable angina, congestive heart failure, hypertension, ileus, intestinal malabsorption, and significant ascites
NaP (tablet) Visicol, OsmoPrep	32 - 40 tabs + 64-80 oz clear liquid	$2-3/tab	• Improved taste of tablet NaP compared with aqueous NaP • OsmoPrep is gluten-free

*Based on average wholesale price as listed in the Amerisource Price Lookup and/or the Red Book May 2008 Update

Make a Recommendation.

Multiple studies have shown that a recommendation from the provider (or a member of the provider's team) is the most influential factor on patient screening behavior.[53-55] If the CHC is able to offer screening options to patients because they have insurance and access to colonoscopy (which is usually the case for Medicare patients), providers should explore individual patient preferences. For example, patients who place a high value on having only one test less frequently may prefer a colonoscopy, so that potential pre-cancerous or cancerous polyps can be removed and biopsied 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. Studies in CHC patients 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.[22,56] Based on the patient's risk factors (personal and family history) and individual preferences, the provider can help provide the best screening recommendation using shared decision making.

Helpful recommendations include one-on-one patient-provider 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 30-31 of this manual.

Convince reluctant patients to get screened.

There will still be patients who are reluctant to get screened despite the provider recommendation. At every visit, the provider and members of the provider team should continue to recommend screening. In a CHC focus group study, all of the providers 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 provider and patient. Several providers 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 with family before committing to a decision. It was also considered necessary to hold the patient accountable and revisit the screening decision with the patient at the next visit. One provider 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.[57] 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 providers 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.[58]

Ensure Quality Screening for a Stool-based Screening Program.

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

- CRC screening using HSgFOBT/FIT requires that stool samples be collected at home.
- Verify date of collection with the patient if not written on sample.
- Use trained, experienced personnel to develop and report the test kits.
- Send test kits to a central laboratory for processing when possible to assure good quality control
- Monitor test positivity rates (usually will be between 5-10%, depending on patient population and test characteristics).[29]

When giving normal (negative) results, it is always good to tell the patient that a repeat test will be needed in one year so that they know what to expect.

Once colorectal screening has been completed, it is critical to follow-up on positive results. Track positive test results and refer all patients with positive tests for colonoscopy. Abnormal results should be documented in the patient's medical problem list, as well as in the electronic medical record. This helps ensure that providers caring for the patient will be alerted to the result and need for follow-up if the patient fails to get a colonoscopy immediately.

For patients with a positive stool test who have not yet had diagnostic 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 resulting in detection of adenomatous polyps or cancerous lesions, clinic staff and navigators can help track down these patients to ensure appropriate treatment and follow-up.

The final important step is to sustain annual test completion. On an ongoing basis, the CHC should assess numbers and rates of the following: eligible patients, test kits provided, test kits returned and processed, test kits rejected by laboratory, abnormal test results, and colonoscopy for abnormal results.[59] These programmatic quality features are summarized in the Clinician's Reference figure on next page.

Figure 7. 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 program.

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-based tests when compared to older stool guaiac 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 inoffice 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-based 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.

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 CHC resources.

A tickler system is a longstanding method for tracking results and follow-up. A tickler file is created when a copy of a lab order, referral, reminder, or tracking sheet is placed in a file. When results or reports are available, the copy can be pulled from the tickler file, the patient notified by phone or mail, and the results placed in the chart. A follow-up appointment can be scheduled if needed. Orders with no accompanying results within 30 days can be followed up with a phone call by a staff member.[46]

The electronic health record (EHR) can also be utilized to provide prompts to the provider when patients who are due for screening seek care at the clinic. Seeing the alert, the provider can refer the patient for colonoscopy or 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 CHC can create a registry in the EHR for colorectal cancer 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 abnormal results so staff can notify patients and refer them for diagnostic colonoscopy.

Orders with no accompanying results within a specified timeframe (i.e., 30 days) can be followed up with a phone call by a staff member.[46]

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 helpful tools on 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**[15] in **Appendix A-9**)
- Ensure thorough documentation of screening tests, results, and tracking follow-up.
- Gather feedback from staff, patients, navigators, clinicians, specialty providers on process.
- Share responsibility and attain good communication between colonoscopists and PCPs.

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.

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 by disseminating their strategies.

Step #4: Coordinate Care across the Continuum

Coordinate Follow-up after a Colonoscopy.

Good communication between colonoscopists and primary care providers is essential. The colonoscopy reports must be complete, including the colonoscopist's follow-up recommendation. The National Colorectal Cancer Roundtable published a report in 2010 on assessing the quality of colonoscopy services. See **Appendix C-15** for a list of the **quality measures for colonoscopy reports**.[60] After PCPs receive and read colonoscopy reports, the result and appropriate follow-up should be documented. PCPs need to be familiar with CRC screening and surveillance guidelines so that both colonoscopists and primary care providers actively ensure patient follow-up. The table at right summarizes the appropriate surveillance follow-up guidelines.[61]

Establish a medical neighborhood.

A successful screening program requires ongoing funding and resources to continue to provide services.

> The creation of a medical neighborhood will be critical in coordinating the care of patients, and this will include the facility, pathology, anesthesia, backup surgery, radiology, hospital, and possibly oncology.

Table 5. 2012 Recommendations for Surveillance and Screening Intervals in Individuals at Average Risk

Most advanced finding(s) on baseline colonoscopy	Recommended surveillance interval (years)
No polyps	10
Small (<10 mm) hyperplastic polyps in rectum or sigmoid	10
1-2 small (<10 mm) tubular adenomas	5-10
3-10 tubular adenomas	3
> 10 adenomas	<3
One or more tubular adenomas 10 mm	3
One or more villous adenomas	3
Adenoma with high grade dysplasia*	3
Serrated lesions • Sessile serrated polyp (s) < 10 mm with no dysplasia • Sessile serrated polyp with dysplasia OR • Traditional serrated adenoma	5 3
Serrated polyposis syndrome*	1

Table adapted from Lieberman et al. Guidelines for colonoscopy surveillance after screening and polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology.* 2012 Sep;143(3):844-57, with permission from Elsevier.

*The recommendations assume that the baseline colonoscopy was complete and adequate and that all visible polyps were COMPLETELY removed. 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.

A CHC 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 CHCs can then negotiate with the hospitals and oncology centers. This is because most of the cancers found on screening are stage 1 and if not picked up until later are usually stage 3 or 4, and could be considered a greater financial liability for the hospital and oncology center. Hospitals that are accredited by the American College of Surgeon's 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. CHCs 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 providers, specialty providers, and health systems. Some states may already receive funding through the CDC 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 providers, gastroenterologists, oncologists, radiation oncologists, and surgeons in underserved communities.

On the next page is a table describing several programs' strategies for funding and partnering with other organizations, which can provide helpful models for CHCs.

Conclusion

We have an opportunity to increase colorectal cancer screening rates in health centers across the United States. For the underserved and underinsured populations that have access to these health centers, we have the ability to detect colorectal cancer early and help prevent people from dying of the disease. The steps in this manual will help your health center implement an appropriate screening strategy for your patients, successfully navigate the process with tracking of results and follow-up, and bridge the gap between primary care and other specialty providers. Our goal is to make a difference in patients' lives by increasing colorectal cancer screening rates, and ultimately decreasing colorectal cancer incidence and mortality around the country.

Table 6. List of Programs with Funding Sources and Organizational Strategies [41]

Program	Funding Sources/Organization
Collaboration between Community Health Centers and Cancer Coalition of South Georgia	• Funding shared among primary care groups, hospitals, and other providers • Secured commitment from local health care providers (hospital, specialists, labs) to provide service regardless of patient's ability to pay • Defined a finite number of colonoscopies needed to help recruit gastroenterologists to provide a limited number of donated colonoscopies • Advocated for hospital participation by presenting it as a sound business strategy (i.e., hospitals would save more money by paying for screening rather than the cost of cancer cases that would present in the ER) • Service can fulfill the hospital community benefit requirement
Project Access/Volunteers in Medicine	• Project Access funded by a combination of federal/state grants and fundraising • Volunteers in Medicine funded by private donations and foundation support to provide the medical home • Project Access Operations Council meets monthly and includes representatives from all the major hospitals, also organizes the various partners • Success also due to its full integration into the health care community – Project Access viewed just like another payer • Patients carry Project Access cards that act like insurance cards and can help with tracking • Tracking of results has provided strong credibility, forming the basis for further support from foundations and grants
Operation Access – San Francisco	• Funded by philanthropic donations – $15 in donated care for each $1 spent • Primarily stool-based screening program, with colonoscopy only for positive stool tests • Program cost is $300 per colonoscopy, which includes coordination, prep, patient translation services, etc. • Operation Access partners with 90 community clinics and 39 hospitals, surgery centers and endoscopy centers across the six-county Bay area • Successful also because it operates in counties with safety net hospitals
New Hampshire Colorectal Cancer Screening Program	• One of 29 CDC-funded programs with grantees in 25 states and 4 tribal organizations, funded through the CDC's Colorectal Cancer Control Program (CRCCP) • Program is able to pay for colonoscopies through the CDC grant funding • Hospitals agree to cover cost of care for cancers found through the program, as well as any complications
New York Citywide Colon Cancer Control Coalition	• Provided by the NYC Department of Health and Mental Hygiene (DOHMH) • The program includes 23 NYC hospitals and 11 health and hospital corporations • Uninsured colonoscopies are funded by the city
Project Access – New Haven	• Early funding from the Community Foundation for Greater New Haven and the Aetna Foundation, local New Haven County Medical Association, and the Medical Staff Funds of both the Hospital of Saint Raphael and the Yale New Haven Hospital • Their Steering Committee and executive director oversee the funding and collaboration with the hospitals, foundations, and local and state legislators

Appendix A:

Appendices: Tools, Templates, and Resources

Appendix A: 1 – Collect Health System Data Work Sheet

Collect Health System Data Work Sheet

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 colonoscopy in a specific time period.		
Percentage of eligible patients screened with sigmoidoscopy in a specific time period.		

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.

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

REVIEWS

INTRODUCTION

For each measure discussed on Table 6B and 7 (with the exception of the perinatal measures), health centers have the option of reporting on their entire patient population as a universe or to select a scientifically drawn random sample to review. To report on the universe, the data source such as an Electronic Health Record must include *all* medical patients from *all* service delivery sites and grant funded programs (e.g., CHC, HCH, MHC, PH) in the defined universe. In addition, the data source must cover the period of time to be reviewed (e.g., three years for pap tests, four years for immunizations, etc.) and include information to assess meeting the measurement standard with the clinical measure as well as to evaluate exclusions. Reporting on the universe is more accurate (i.e., it reports on 100% of patients) and can be easier (if queries are automated). If the health center cannot report on the universe (or chooses not to), a random sample must be used to report. Note that the health center can report on the universe for some measures while using a sample to report others. It is not necessary that all measures be reported using the same method.

RANDOM SAMPLE

A random sample is defined as a part of a universe where each member of the universe has the exact same chance of being selected as every other member of the universe.

Thus, a true random sample will generate outcomes which are similar to outcomes reported for the universe of patients because the sample is "representative" of the universe.

STEP BY STEP PROCESS FOR REPORTING CLINICAL MEASURES USING A RANDOM SAMPLE

For each measure, perform each of the following steps.

STEP 1: Identify the patient population to be sampled (the universe)

Define the universe for each condition.

- Including *all* active (measurement year) medical patients
- Including *all* sites in the scope of project
- Including contracted medical services

Identify the number of patients who fit, or who initially appear to fit, the criteria for that measure. Create a list and number each member of the patient population in the universe. The list may be in any sequence since randomization will remove any order bias.

STEP 2: Determine the sample size for manual chart review

BPHC has mandated that, if a sample is to be used, it must be a sample of 70.

STEP 3: Select the random sample

Using one of the two recommended sampling methodologies, identify the sample of 70 charts.

STEP 4: Review the sample of records to determine having met the measurement standard with the clinical measure

For each measure, review available data sources to identify any automated sources to simplify data collection. Since these data sources will be augmented by the paper record, they do not need to be available for all patients. Examples of data sources include:

- Electronic health records
- Disease specific (PECs, i2i-track, etc.) databases
- State immunization registries for vaccine histories
- Logs
- Practice management system

For each patient in the sample, determine whether sufficient information is available in these alternative resources to confirm meeting the measurement standard. If meeting the measurement standard cannot be confirmed from the alternative source, pull the paper record to retrieve required information.

STEP 5: Replacing patients that should be excluded from the sample

Best practices would dictate that the methodology used to select the sample (or the universe) should be able to test for each and every required criteria. Some criteria (such as the age of the patient) will almost always be easily implemented. Others, such as whether or not the patient had two medical visits during the year may be more difficult to add to a query. Others, such as whether a woman has ever had a hysterectomy, may not be available. When criteria cannot be used to screen the universe, it may be used to exclude patients from a sample. If, upon inspection, it is determined that one or more criteria used to identify the universe or sample was not met, the case (chart) would be removed. If the review is of a sample of charts, than another chart is selected to replace the chart that was originally selected.

If a patient is selected that should be excluded from the sample, the patient will be replaced with a substitute. Use the replacement methodology described for the sampling methodology selected. Any criteria which was missed in selecting a chart (e.g., not noting that the three year old was first seen after their third birthday) may be used to exclude a chart. Some specific criteria which may be used to exclude a patient/chart include:

- All measures – not a medical patient
- Childhood immunizations – none
- Pap tests – women who have had a hysterectomy
- Controlled hypertension – Pregnant patients, end stage renal disease
- Controlled diabetes – patients with a diagnosis of polycystic ovaries that do not have two face-to-face visits with the diagnosis of diabetes, in any setting, during the measurement year or year prior to the measurement year; gestational diabetes (ICD-9-CM Code 648.8); or steroid-induced diabetes (ICD-9-CM Code 962.0, 251.8) during the measurement year
- Adolescent weight – pregnancy
- Adult weight – pregnancy or imminent demise
- Asthma – allergic response to asthma medication
- Tobacco use – patient is no longer a tobacco user
- CAD – LDL < 130mg/dL; or allergic response to LDL lowering medication
- IVD – none
- Colorectal cancer screening – patients who have or had colorectal cancer

METHODOLOGY FOR OBTAINING A RANDOM SAMPLE

Two methods are approved for generating a random sample and a sample of replacements for excluded patients:

- Work with a list of random numbers generated for your total patient population.
- Select a random starting point and use a calculated interval to find each next member of the sample.

Either method can be used to create a "replacement list" used to replace patients who are excluded.

Option #1: Random Number List

The preferred method for selecting a random sample is to use a random number list. An individualized list of random numbers can be created at the Web site http://www.randomizer.org/form.htm.

The Web site requires no password or subscription to access. To obtain a list of random numbers, complete the questions as documented below.

Identifying an Initial List

Request **1** list of **70** numbers. Complete the "Number Range" by entering the **1** as the first number and the **total number of patients** in the universe for the particular measure under consideration as "n." For example, if there are 628 children who turn three in the reporting year in the universe, enter 628 as **N**. It is often helpful, *but not necessary* to sort the selected random numbers.

Then click on the button, "Randomize Now!" A list of randomly generated numbers will be created. These numbers correspond with the numbered list of patients in the universe prepared in Step 1, above.

Identifying a Replacement

To create a "sample" of patients to substitute for patients who should be excluded from the sample, follow the instructions for creating a list of random numbers for a replacement sample. Rather than selecting 70 numbers for the set, select a smaller sample of 5 to 10 charts. In this instance, the list *should not be sorted* since doing so will "bias" the replacement sample toward the lower numbers on the list.

If, upon review, it is determined that a patient should be excluded from the original random sample of 70, replace that patient with one of the patients from the replacement sample. Because of the need to replace ineligible charts, more than 70 patients may be need to be evaluated for meeting the measurement standard for a particular measure but the final sample will include 70 patients who meet all the selection criteria.

Alternatively, you can draw a sample of 80 patients (for example) and use the first 70. If one needs to be replaced, use the 71st, hen the 72nd, and so on. In this instance, do not request a sorted list since it will be biased toward lower numbers.

Input	Initial Sample	Replacements

Set of Numbers	1	1
Number per set	70	At least 5 or as many as needed
Number range = 1-"n"	Last sequence number in list	Last sequence number in list
Unique numbers	Yes	Yes
Sort numbers	Yes, least to greatest	No

Sample Interval Size (SI) = Population size (number in universe) / Sample size (70)

Option #2: Interval

A second method uses the same numbered list of patients in the universe created in Step 1, above. To generate the sample:

1. Randomly pick a patient from the first sampling interval. For example, if the sampling interval is 10, the first sampling interval includes patients no.1 through no.10. Randomly select one patient from this interval.

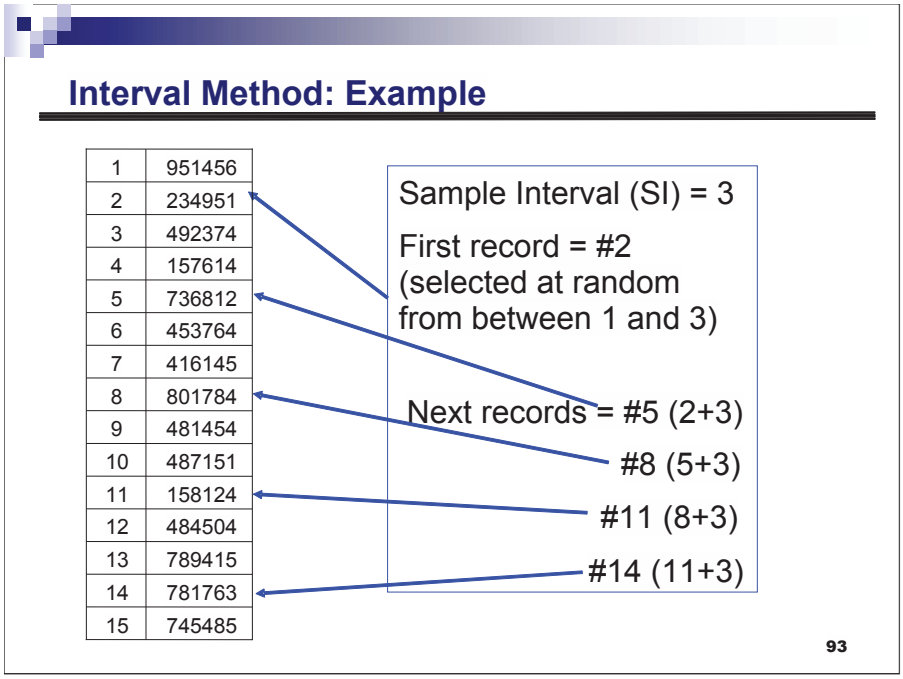
2. Calculate sampling interval (SI) by dividing number of patients in the universe by 70.

3. That will be your first record sequence number

4. Then, select every nth patient based on the sampling interval until you reach the desired sample size. In our example, if the first patient selected is number 8, and the sampling interval is 10, then the remaining patients to be selected are no.18, 28, 38, etc.

   first sequence # + SI = second #

5. Continue through list until all 70 have been identified.



Identifying a Replacement
If a selected patient should be excluded from the sample, return to the original list and substitute the next patient on the list for the excluded patient. If that patient should be excluded select the next patient on the list until an eligible patient is selected. Resume selection using the next chart you had pre-selected for the sample. (If you run out of patients, continue your count back at the beginning of the universe.) In this manner, more than 70 patients may be evaluated for meeting the measurement standard for a particular measure but the final sample will include 70 patients who meet all the selection criteria.

Obtaining a Sample of 70 Patients
Under certain situations, a larger number of charts may need to be pulled to achieve a total of 70 charts. Specifically for CY 2013, for users unable to determine a universe using existing systems, alternative instructions for determining a universe and determining meeting the performance standard are provided. This may include the two tobacco measures and the asthma measure. The steps below explain how to obtain a sample of 70 using the two tobacco measures:

<u>Tobacco Assessment</u>

1. Prepare a list of all patients born on or before 12/31/1995; with at least one medical visit in a clinic setting; who have been seen at least twice ever. This list is the universe for tobacco assessment reported on Table 6B Line 14 Column A.

2. Randomly order entire list. If using the Randomizer set the “Numbers in set” to be equal to the total number of cases. Do not sort from least to greatest.

3. Pull the first 70 charts from the randomly ordered list. These are the 70 charts that will be used to assess meeting the performance standard for tobacco assessment. Enter 70 in Table 6B Line 14 Column B.

4. Review the 70 charts for documentation that patient was queried about tobacco use any time within 24 months of their last visit. Report the number of charts found to have met the measurement standard on Line 14 Column C. NOTE: you can look for documentation of tobacco assessment at any visit, regardless of the category of service.

Tobacco Cessation Intervention

5. Continue to pull charts from the randomly ordered list until you have the charts of 70 tobacco users. Keep track of how many charts you had to review in the list to obtain 70 tobacco users.

6. Divide 70 by the total number of charts that were reviewed to achieve 70 tobacco users. This percentage will be used as the percent of the adult population who are tobacco users. Multiply this percentage by the total universe on Table 6B Line 14 Column A - this is the universe of tobacco users for the cessation measure (Table 6B Line 15 Column A).

7. Review the charts of the 70 tobacco users to get the measurement standard rate for tobacco users with documented cessation intervention. Report 70 on Table 6B Line 15 Column B and the number of compliant charts on Line 15 Column C.

Health System Experience with CRC Screening Work Sheet

Questions	Answers
What is the health system doing now to make sure eligible patients are screened for colorectal cancer (CRC)?	
Is the health system using evidence-based interventions to screen patients for CRC?	
What has worked and not worked in the past when the health system has tried to increase CRC screening?	
What has worked and not worked in the past when the health system has tried to increase screening for other diseases—such as breast cancer, cervical cancer, or diabetes? Are there lessons learned that can be applied to CRC screening?	

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.

Health System Intervention Strategies Work Sheet				
Name of Health System:				
Evidence-Based Strategies	Existing Tools or Resources	Support from CDC's Colorectal Cancer Control Program or Local Stakeholders	Can These Tools or Resources Be Used for This System? (Yes, No, or Maybe)	Next Steps
Interventions for Health Care Systems				
Use reminder and recall systems for health care providers[a] and electronic medical records to improve the delivery of colorectal (CRC) screening services.				
Promote USPSTF[b] guidelines and quality standards for CRC screening.				
Promote practice-based system changes designed to increase primary care referrals for CRC screening.				
Promote the use of assessment and feedback interventions for health care providers[a] to improve the delivery of **CRC** screening services.				
Offer and promote alternative clinic hours.[a]				
Simplify administrative procedures.[a]				

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.

Interventions for Health Insurance Plans				
Encourage coverage or expanded benefits for CRC screening.				
Encourage adequate reimbursement rates for CRC screening, diagnostic tests, and patient support services.				
Promote reimbursement strategies that reward health systems that follow USPSTF guidelines for CRC screening.				
Encourage use of HEDIS[c] measures.				
Promote reporting of deaths or serious injuries related to colonoscopies by hospitals or health insurance plans.				
Other Promising Interventions				
Set up patient navigation programs.				
Create strategies that encourage or require patients to establish a medical home.				

[a] Strategy recommended by The Guide to Community Preventive Services (www.thecommunityguide.org).

[b] U.S. Preventive Services Task Force.

[c] Healthcare Effectiveness Data and Information Set.

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: 7 – Action Plan Work Sheet

Action Plan Work Sheet

Name of Health System:

Colorectal (CRC) screening goal:

Existing methods, processes, and programs that can be used to achieve the goal:

How will progress be tracked and how often?

Evidence-Based Strategies Chosen	Major Tasks to Implement Strategy	Expected Outcomes	Challenges and Potential Solutions	Person(s) Responsible	Due Date	Information or Resources Needed

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.

Colorectal Cancer Screening – Tracking Template

Checklist	Date
A. Stool-Based Test	
1. Home HSgFOBT/FIT kit given	_____
2. HSgFOBT/FIT test completed	_____
3. Results received	_____
4. If no completion or results, reminder call/text/letter sent	_____
5. Patient notified of finding	_____
6. Referred for colonoscopy if positive	_____
7. Placed in tickler file if negative for next year	_____
B. Colonoscopy	
1. Referred for colonoscopy	_____
2. Colonoscopy scheduled	_____
3. Colonoscopy test completed	_____
4. Results received	_____
5. If no completion or results, reminder call/text/letter sent	_____
6. Patient notified of finding	_____
7. Placed in tickler file if negative	_____

Assess Your Progress Work Sheet

Instructions: Work with stakeholders and health systems to answer the following questions. Use a separate work sheet for each system.

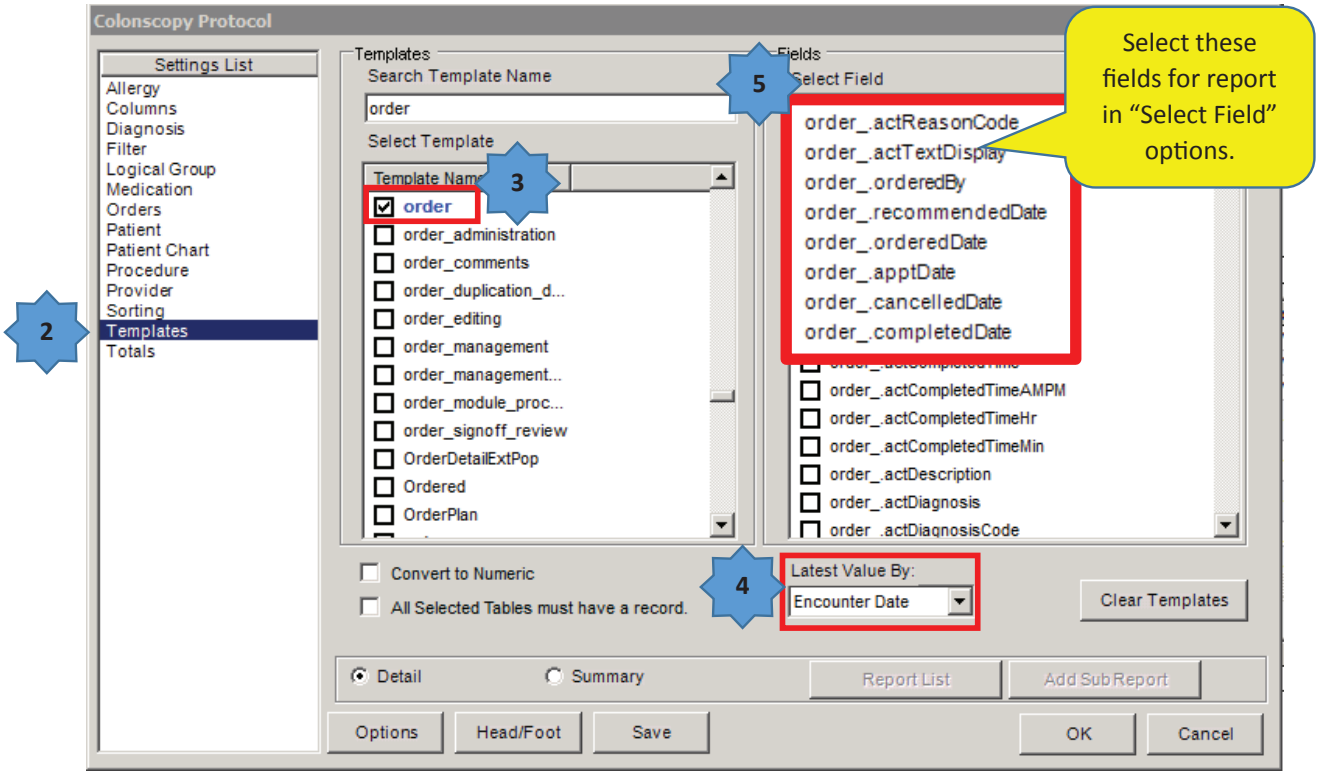
Assess Your Relationship with the Health System	Answers and Plans for Change
1. Has the action plan been completed? If not, why?	
2. Are you in contact with your health system champion regularly? How do you communicate (in person, by phone, by e-mail)? Is your contact method effective?	
3. Are problems 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.

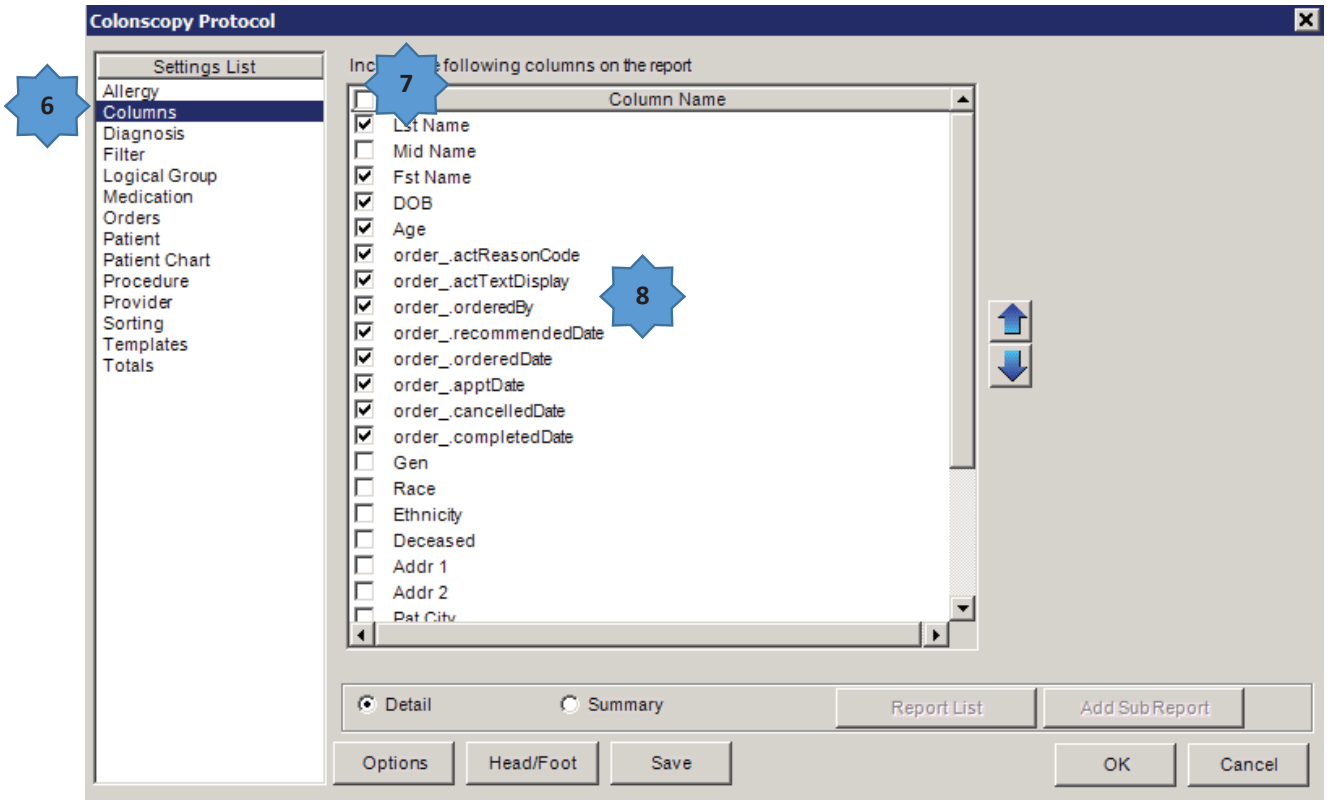
Colonoscopy Protocol Report Build Tool

Memorized report build for KBM 7.9 and 8.0 or other KBMs that utilize protocols template.

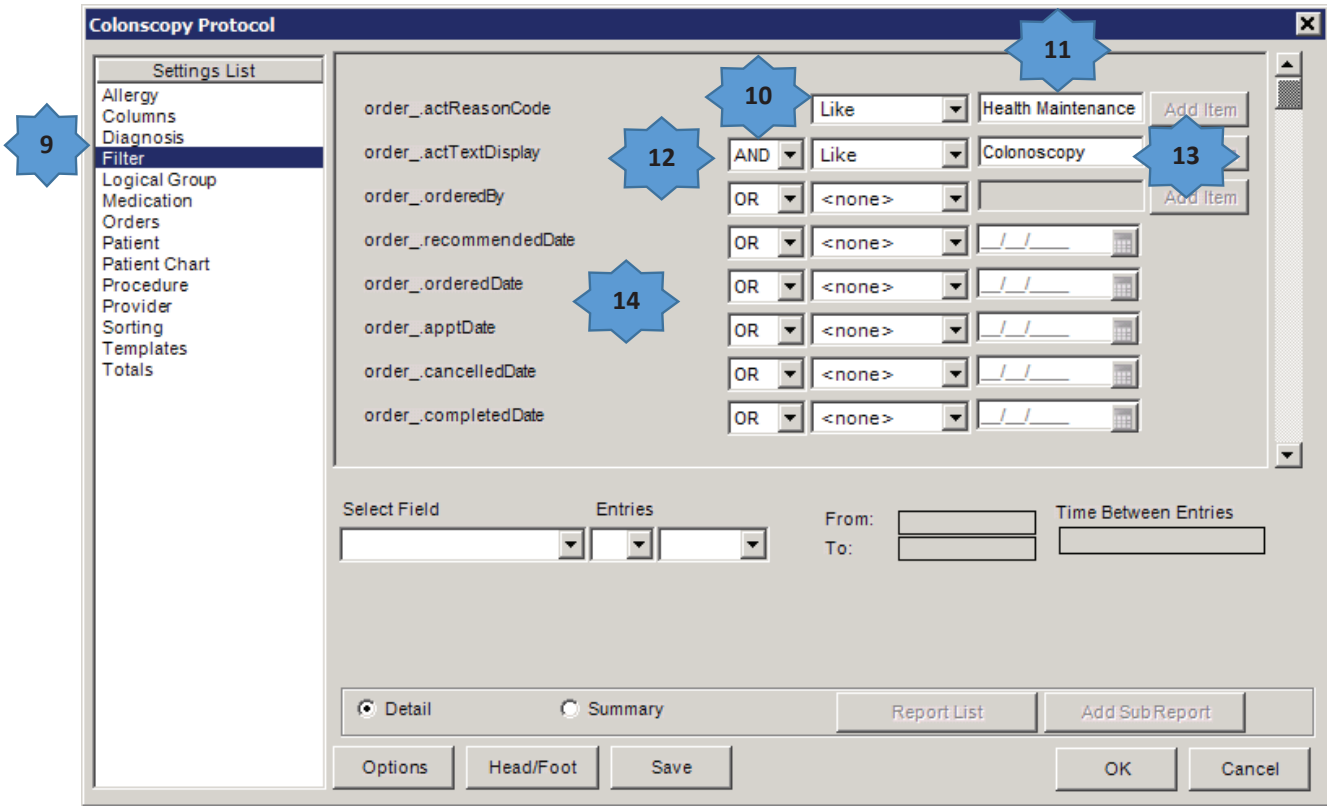
1. NextGen EHR → File → Reports → Generate Report → By Practice
2. Select "Templates" in Setting List.
3. Locate "order" and select.
4. Indicate to pull "Latest Value By" by "Encounter Date".
5. Select listed fields to pull for report.



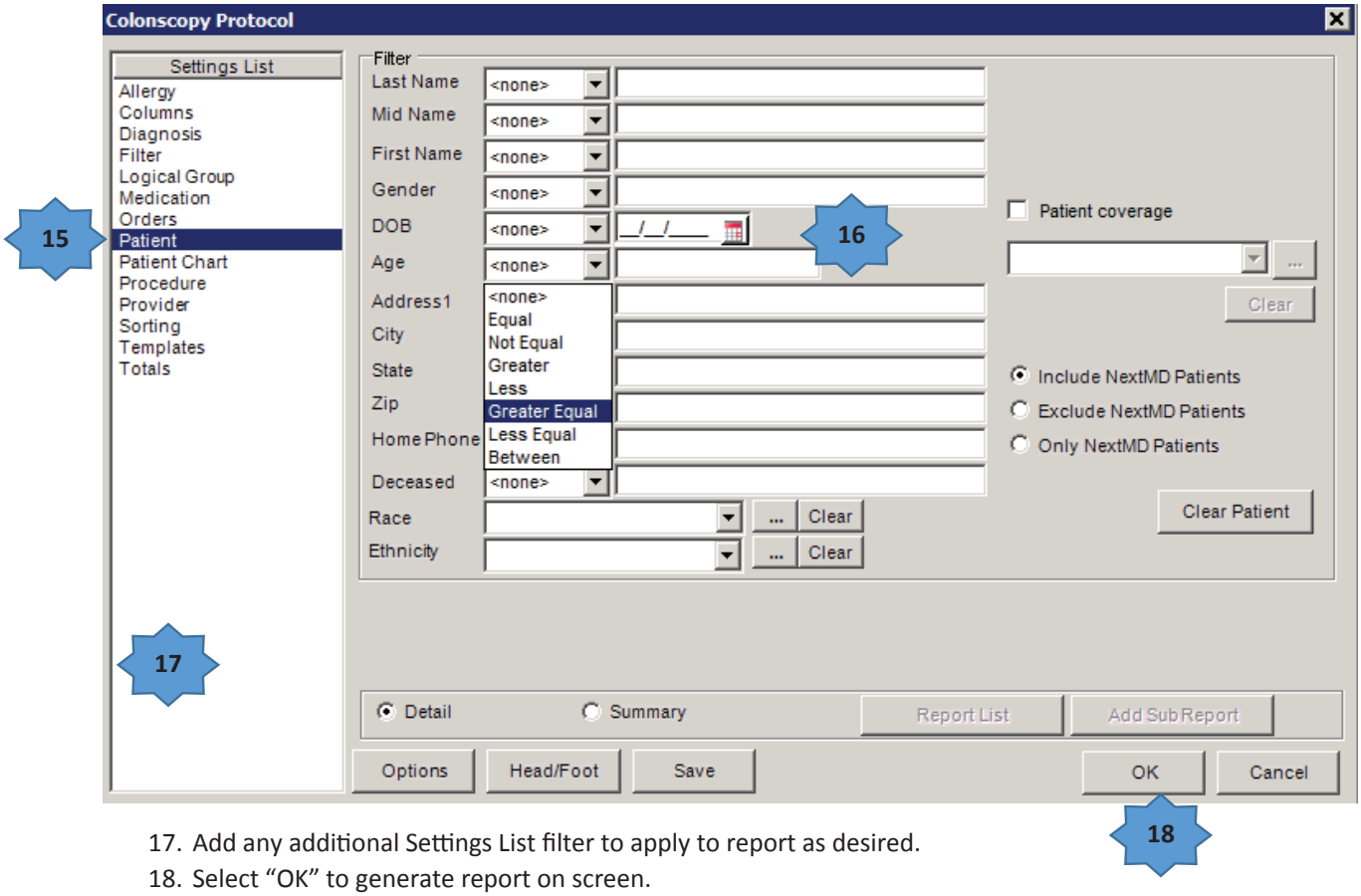
6. Select “Columns” in Settings List.
7. Select desired column names for report by placing check in boxes by description.
8. Recommend field order below for report.



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. For example, you may select a specific age group to pull.



17. Add any additional Settings List filter to apply to report as desired.
18. Select "OK" to generate report on screen.

Sample headers seen on report after renaming columns for viewing.

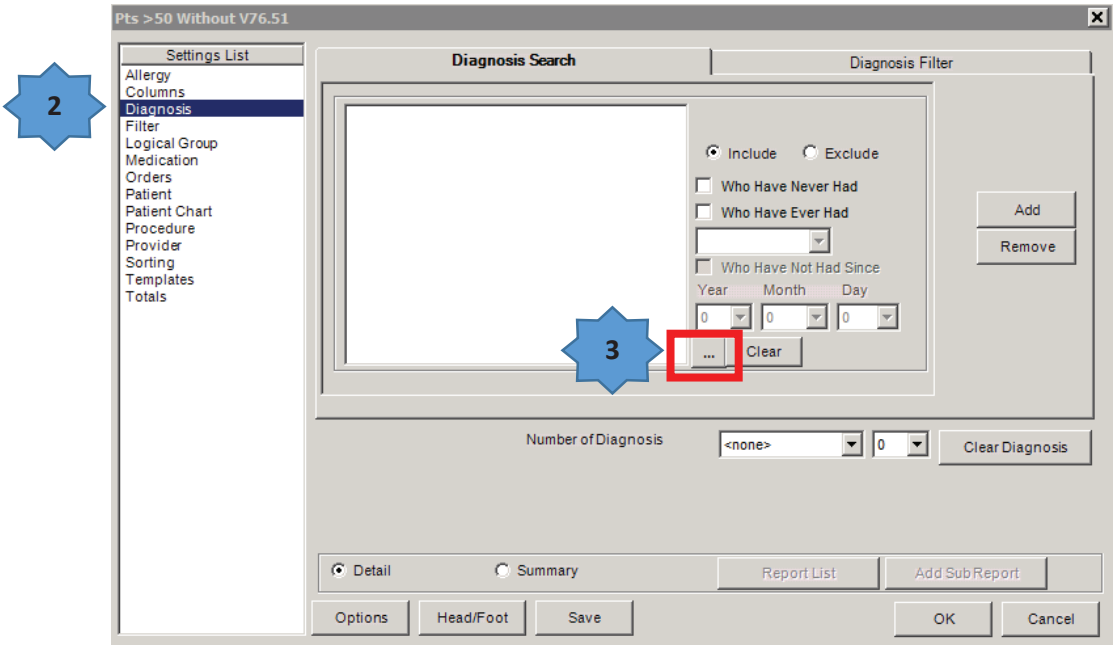
Colonscopy Tracking

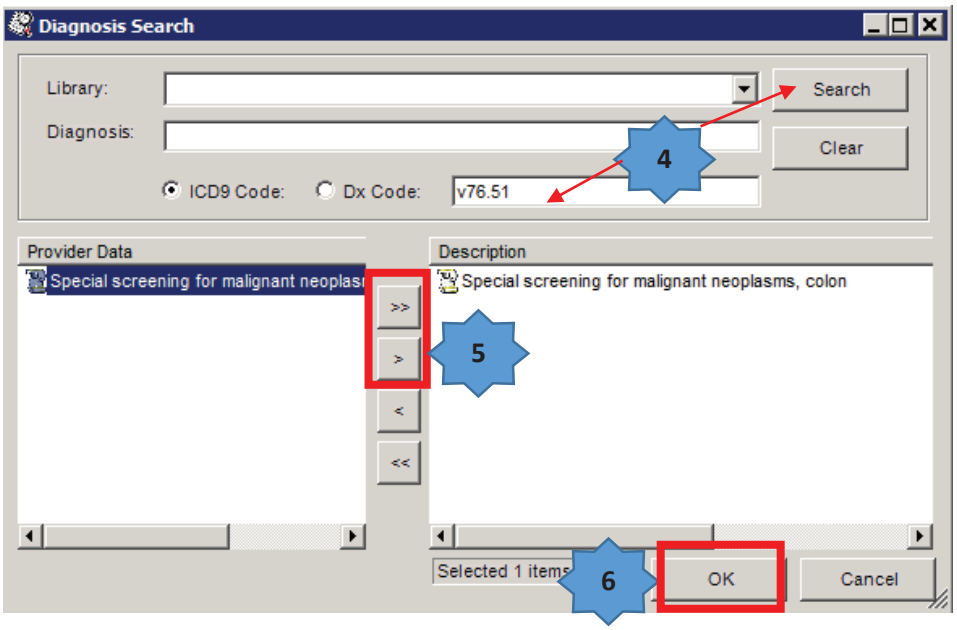
Lst Name	Fst Name	DOB	Age	Reason	Order	Recommend Date	Order Date	Appt Date	Cancel Date	Completed Date

EHR Diagnosis Report V76.51 Screening for Colon Malignancy

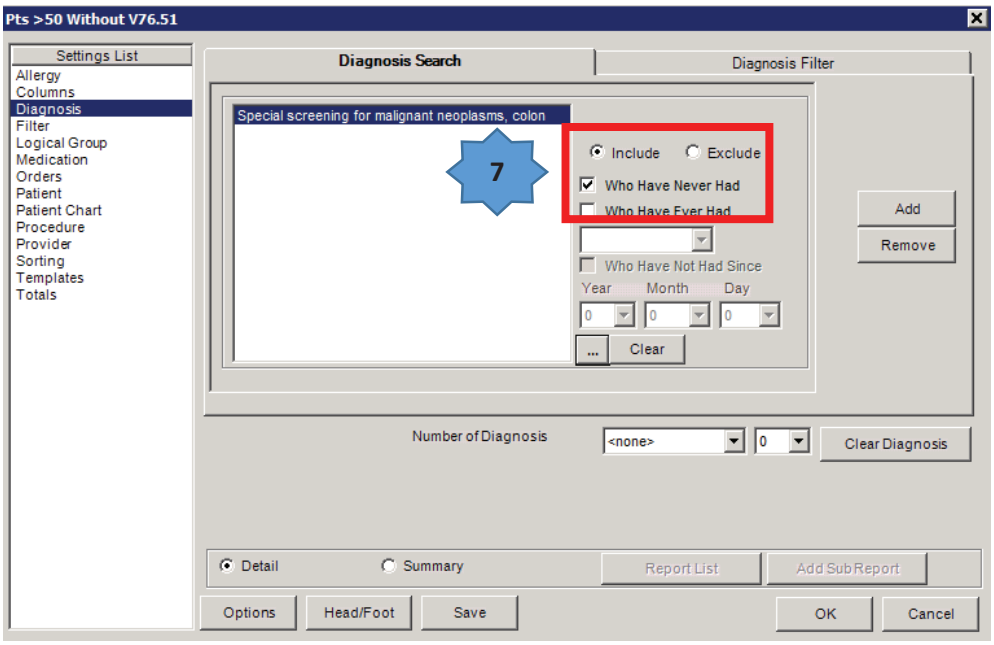
Memorized report build for KBM 7.9 and 8.0 or other KBMs that utilize diagnosis ICD-9 codes.

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 V76.51 in open box and select "Search".
5. Use arrows in center to move desired data to description box.
6. Select "OK"

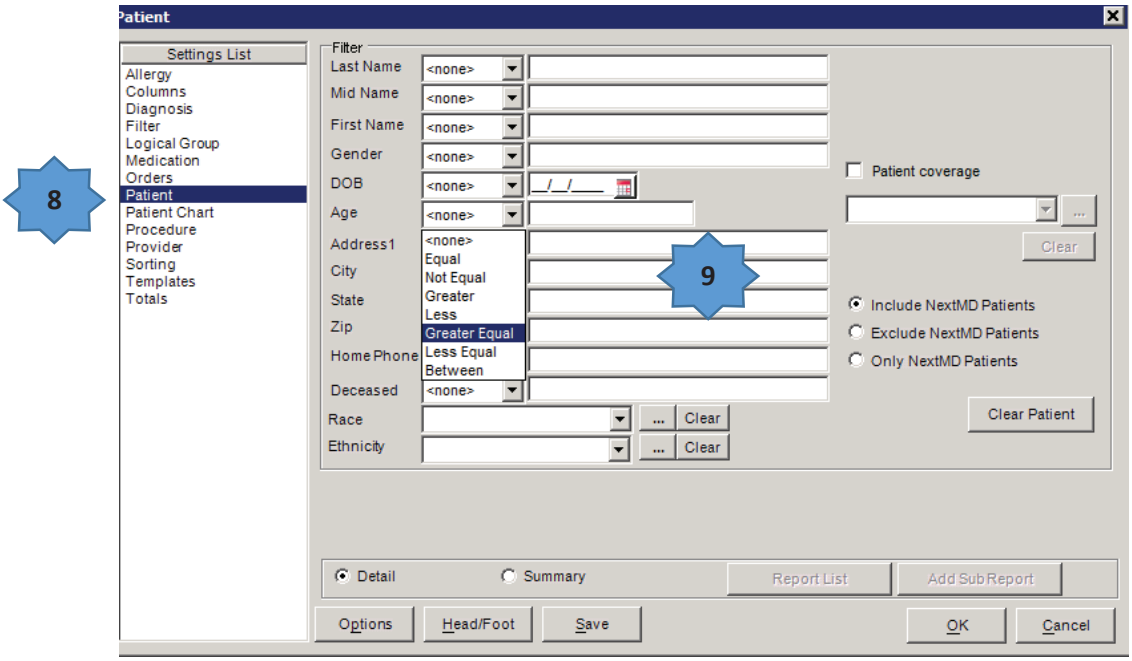


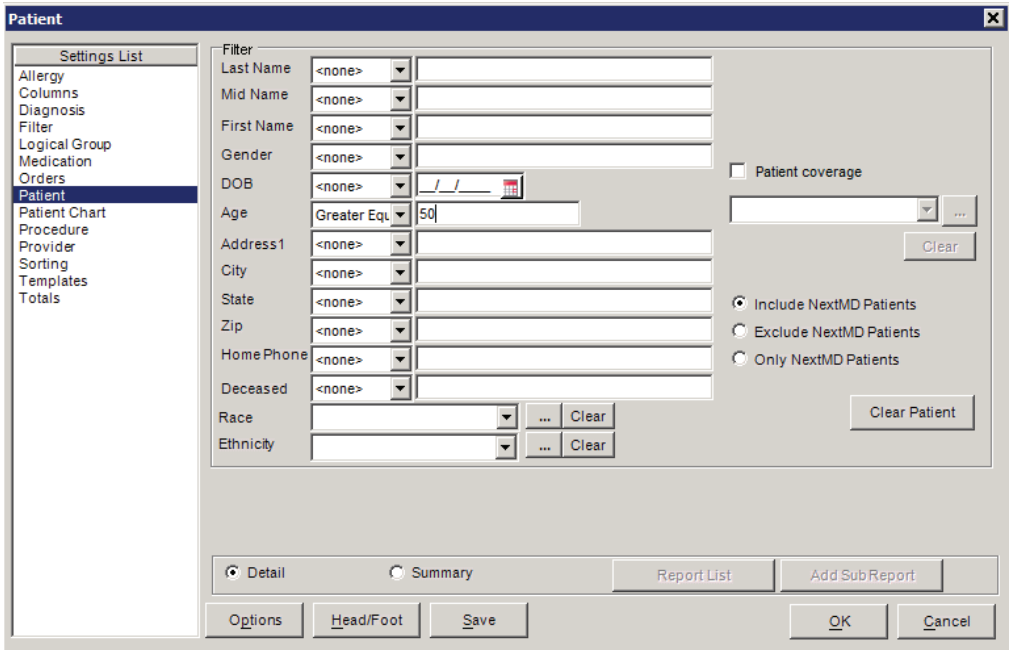


7. Check box to include patients "Who Have Never Had". Other options are available depending upon desired report.

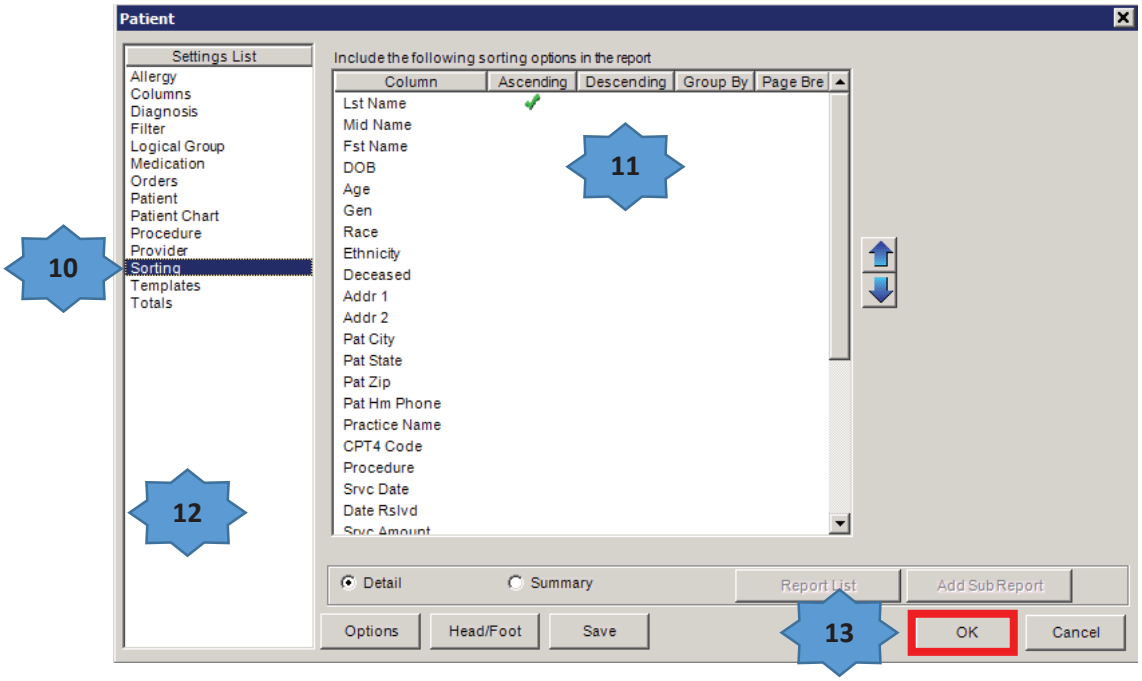


8. Select "Patient" in Settings List.
9. Select any desired Patient filters for report generation. For example, selecting to pull data for patient's age equal or greater than 50 years of age.





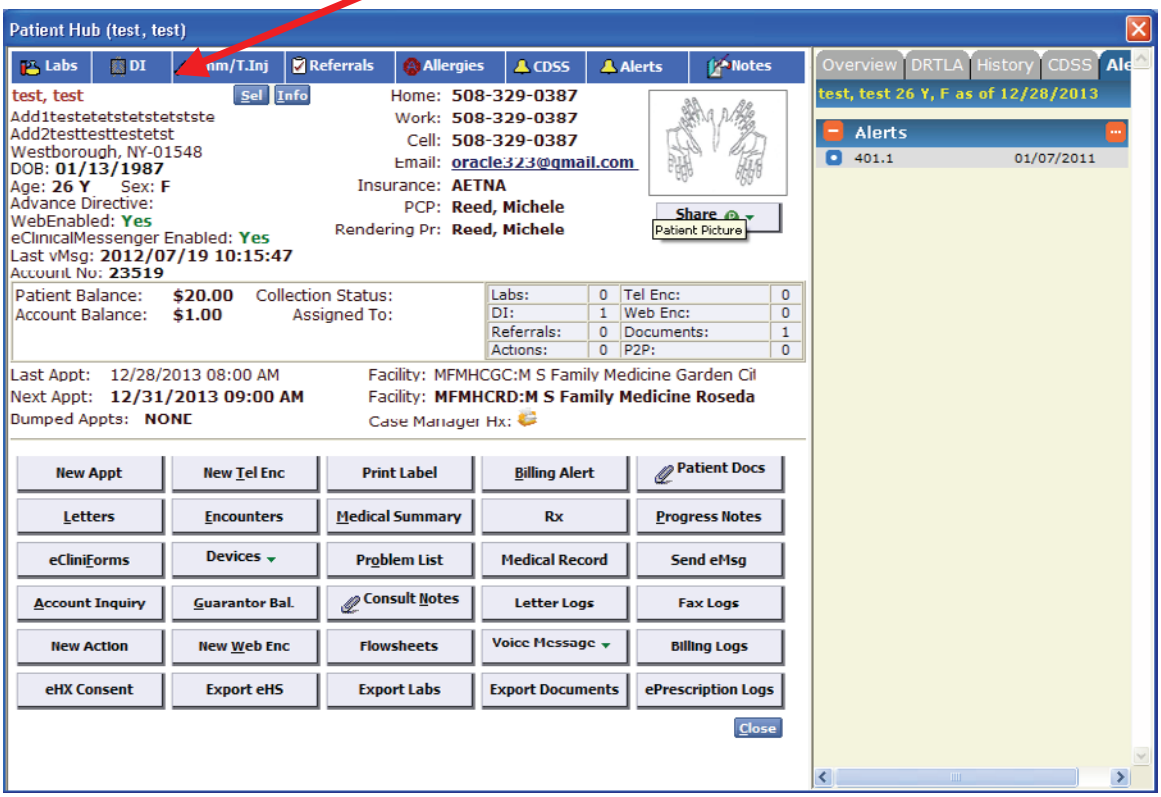
10. Select "Sorting" in Settings List.
11. Indicate desired sorting for report generation. Example below indicates report will be sorted based upon patient's last name in ascending order.



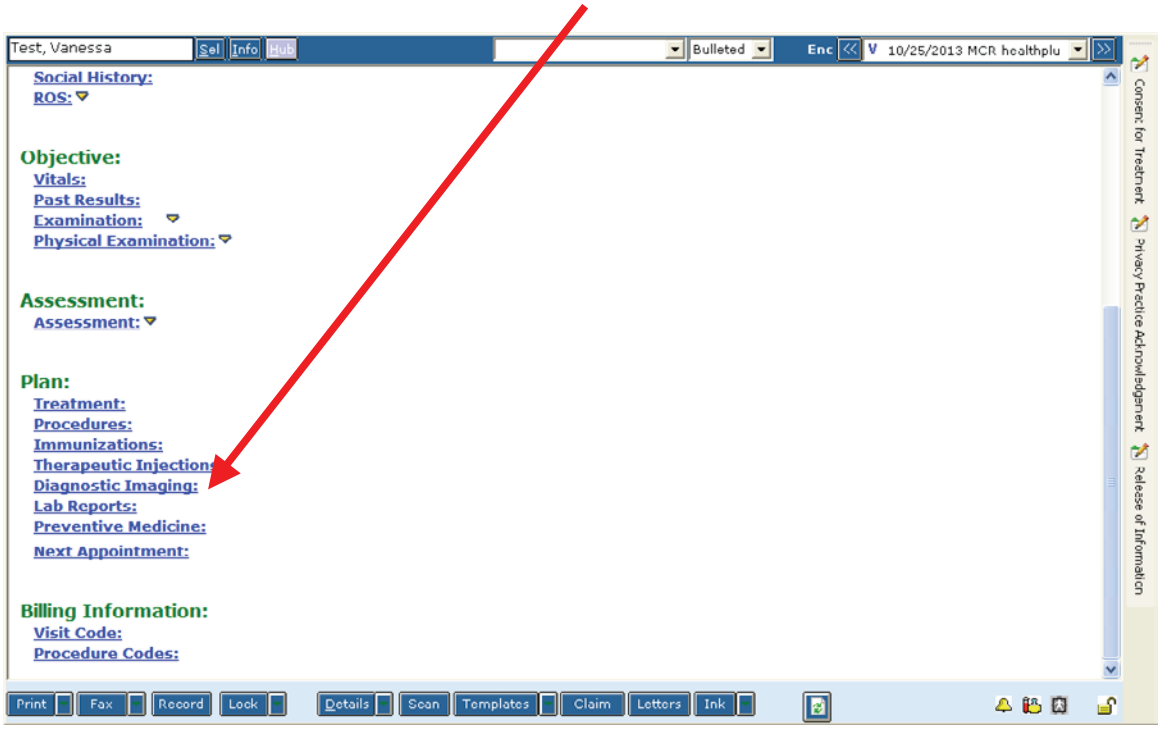
12. Add any additional filters from Settings List as desired for report generation.
13. Select "OK' to generate report on screen.

Ordering Colonoscopy through **D**iagnostic **I**maging in eClinicalworks Version 9.0

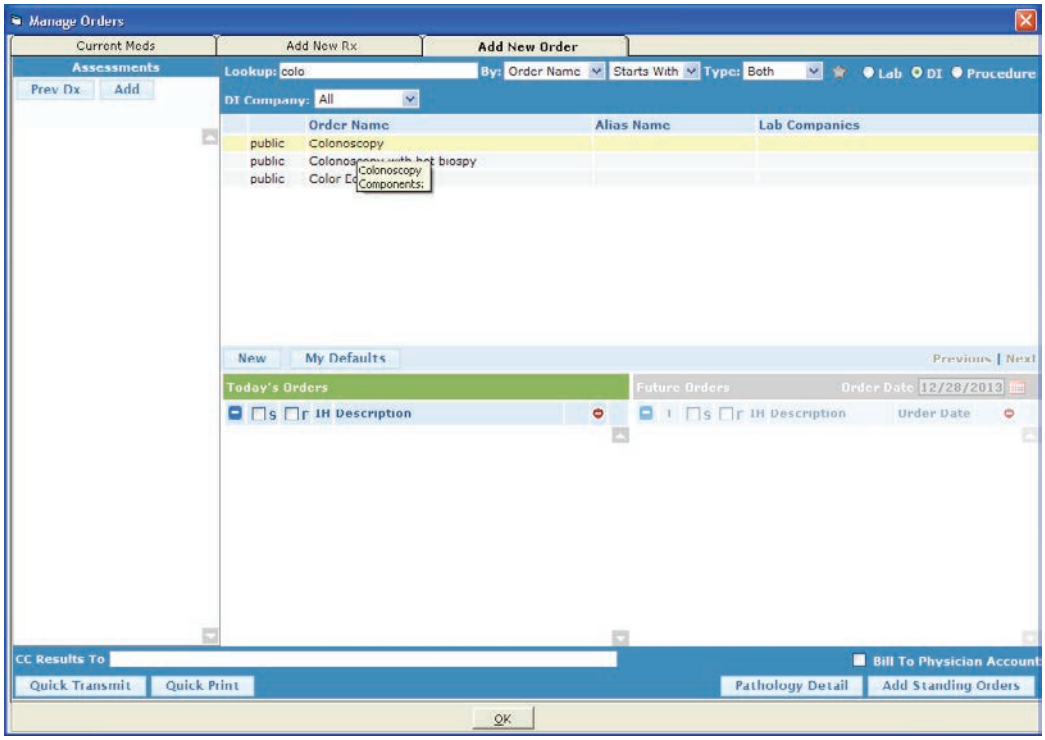
From patient hub screen - Click on DI



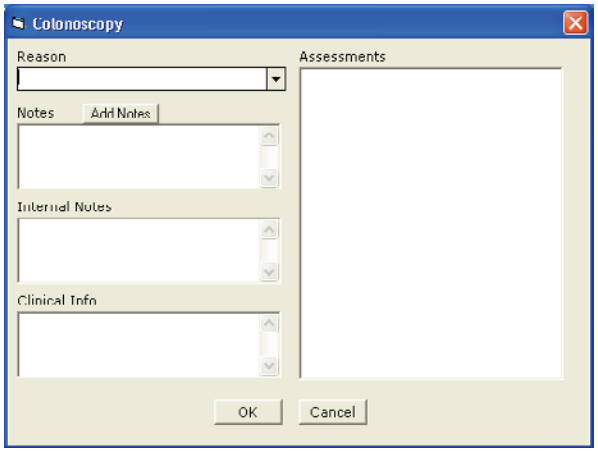
Or from encounter Plan section view - click into Diagnostic Imaging

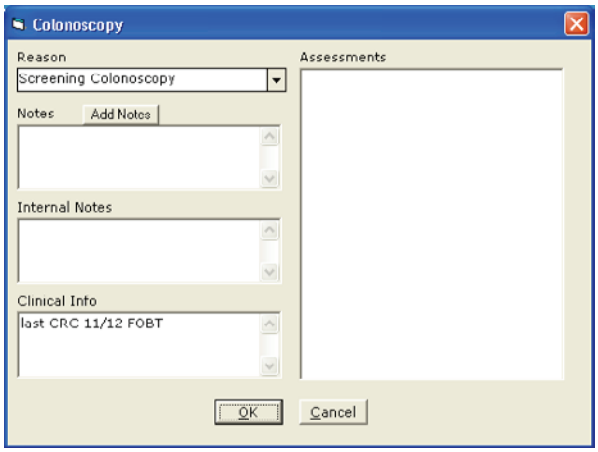


This order screen will appear

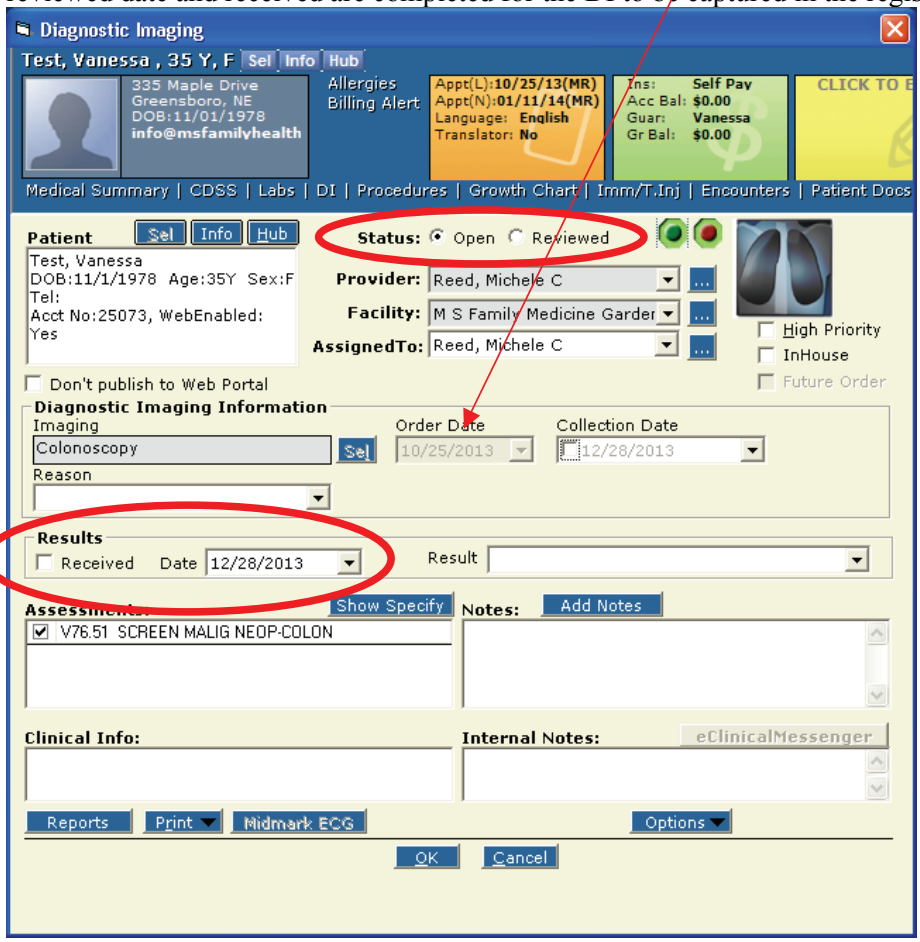


Complete the order screen making sure you enter a Dx code for the colonoscopy to be performed

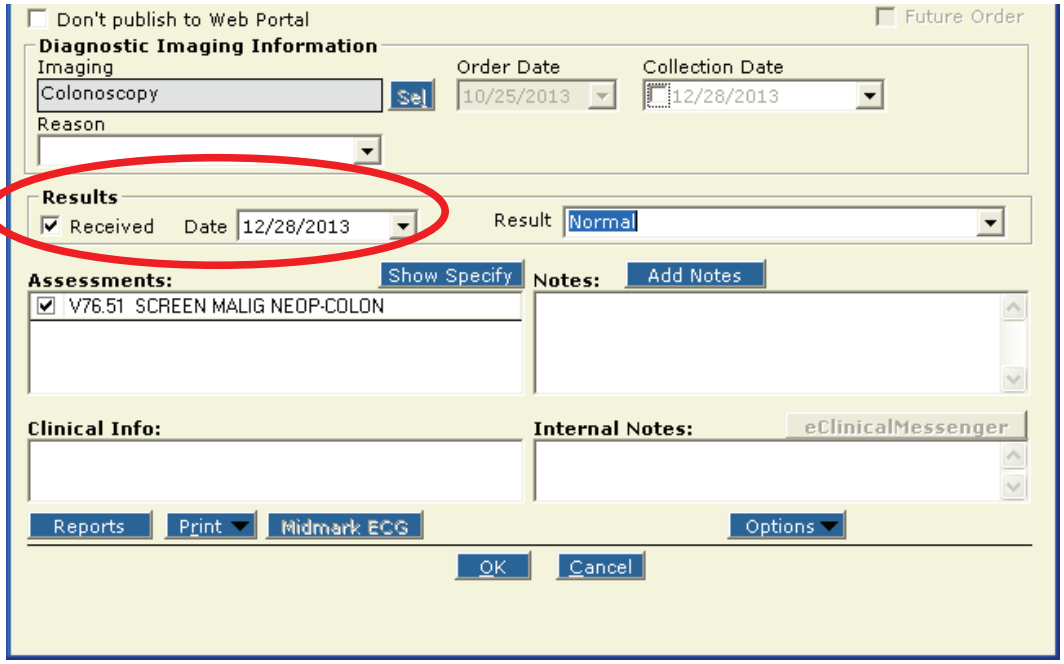




This is a completed colonoscopy order screen from 10/25/13. To address open orders you click on the appropriate order then this screen will appear. Enter the information to address the order making sure both reviewed date and received are completed for the DI to be captured in the registry.

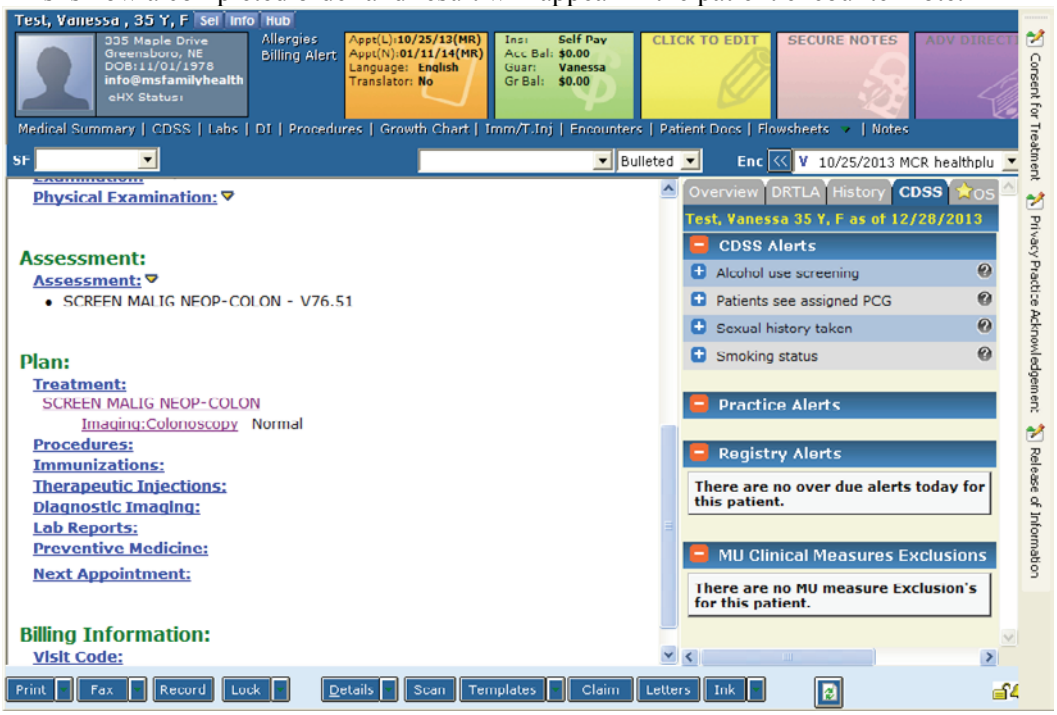


If an order is opened in DI then you must close out the order in DI. ***Scanning results into patient documents does not close orders.*** Scanned results should always be associated to an order or referral… otherwise they are not reportable in the registry section.

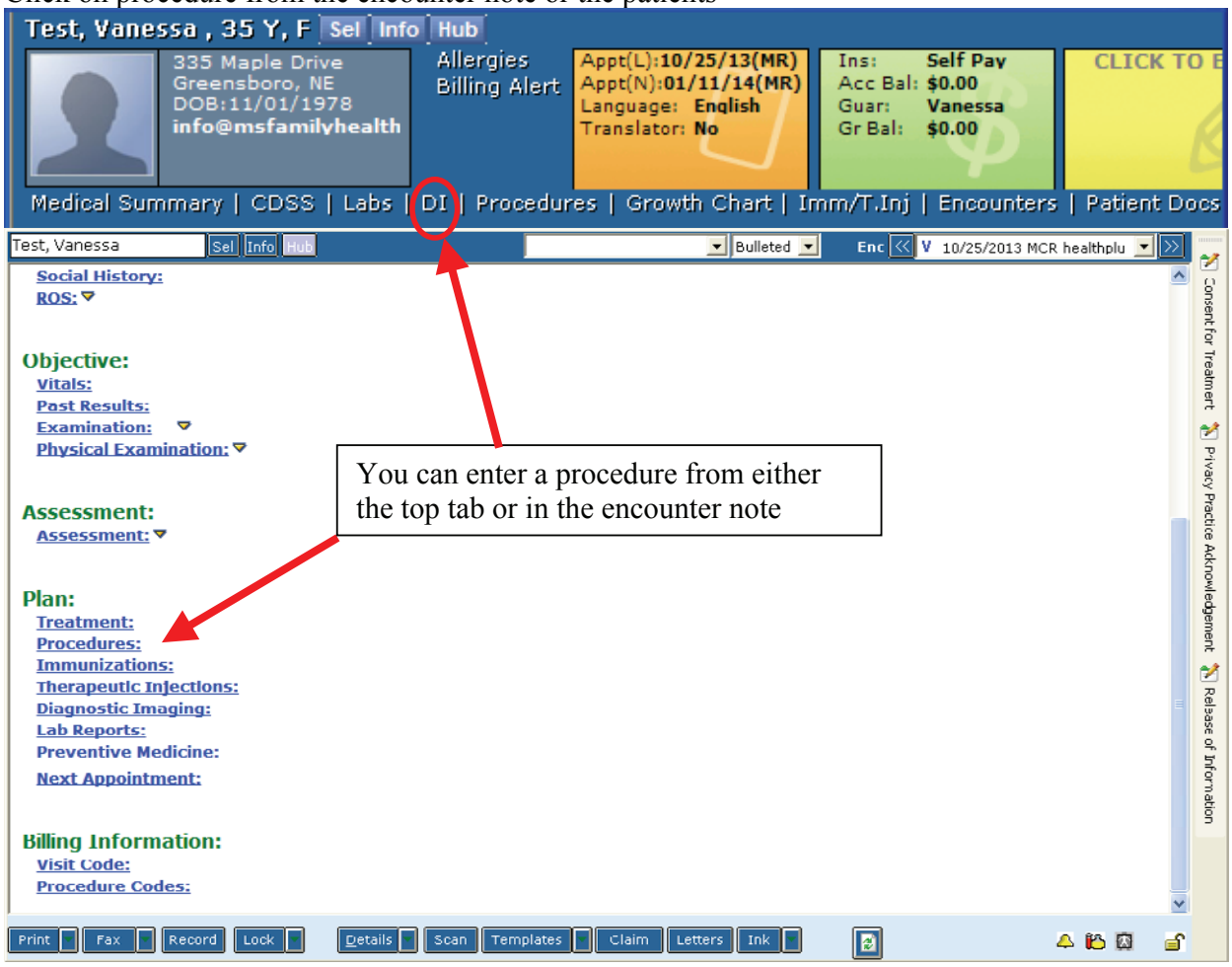


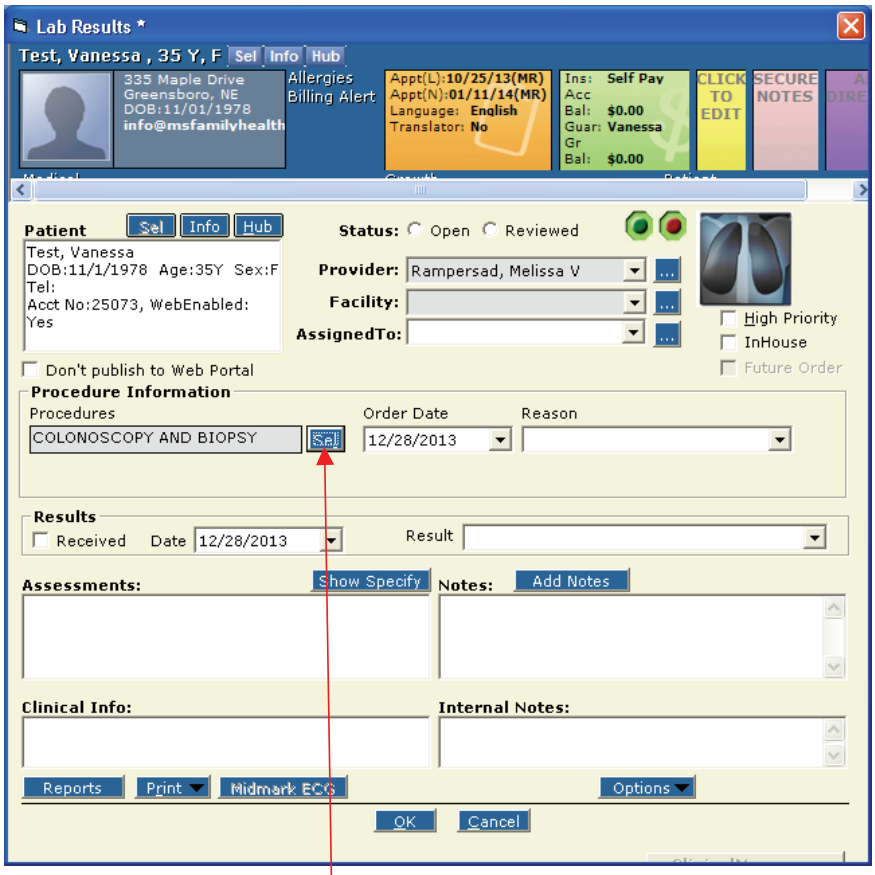
Depending on your workflow, the staff person responsible for documenting the receipt of the results may not be responsible for reviewing the results

This is how a completed order and result will appear in the patient encounter note.

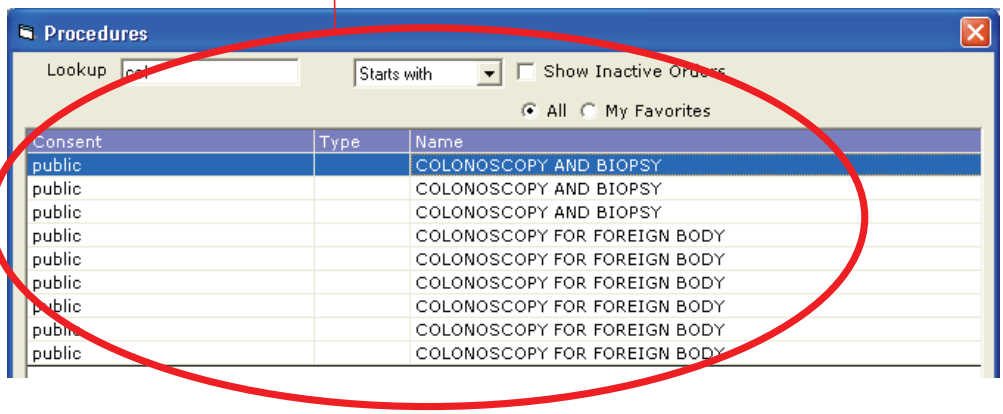


Ordering Colonoscopy as a Procedure
Click on procedure from the encounter note or the patients

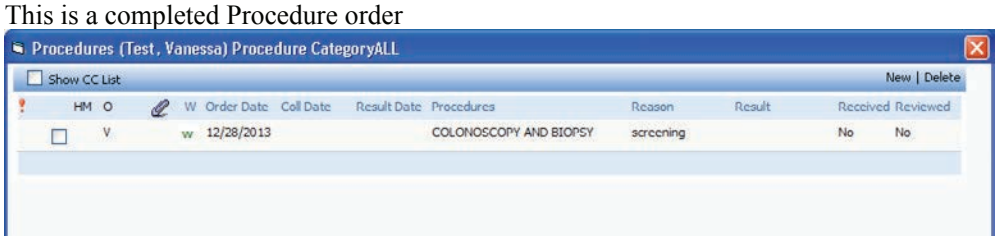




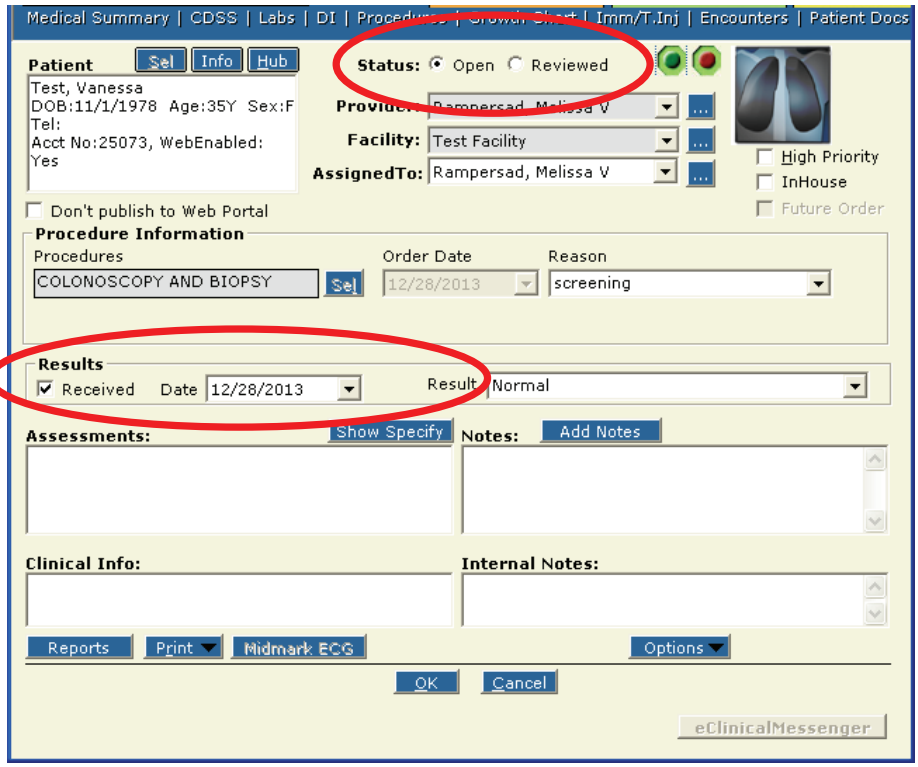
To create orders in the procedure section you must have permission/rights to access this section of the EMR.



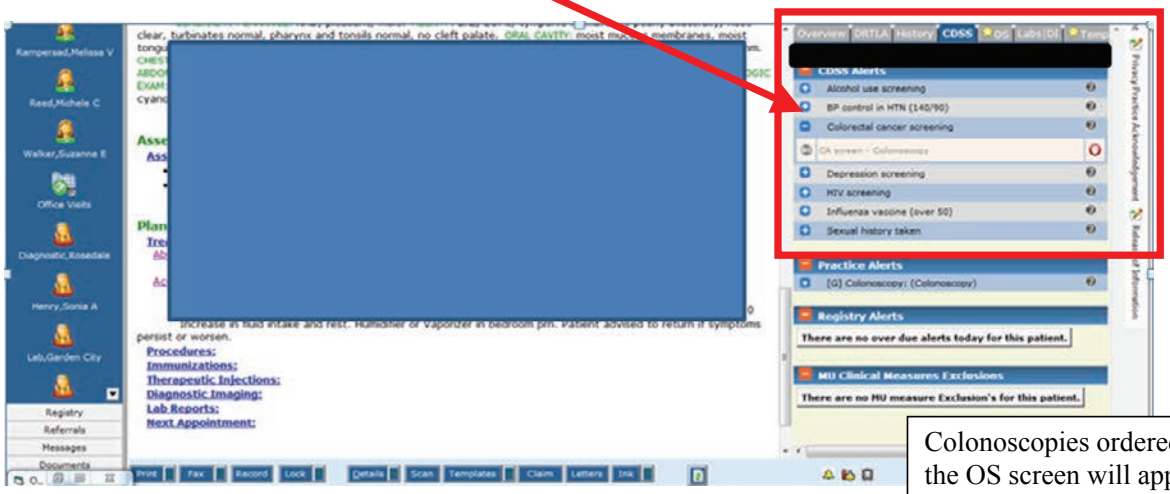
This is a completed Procedure order



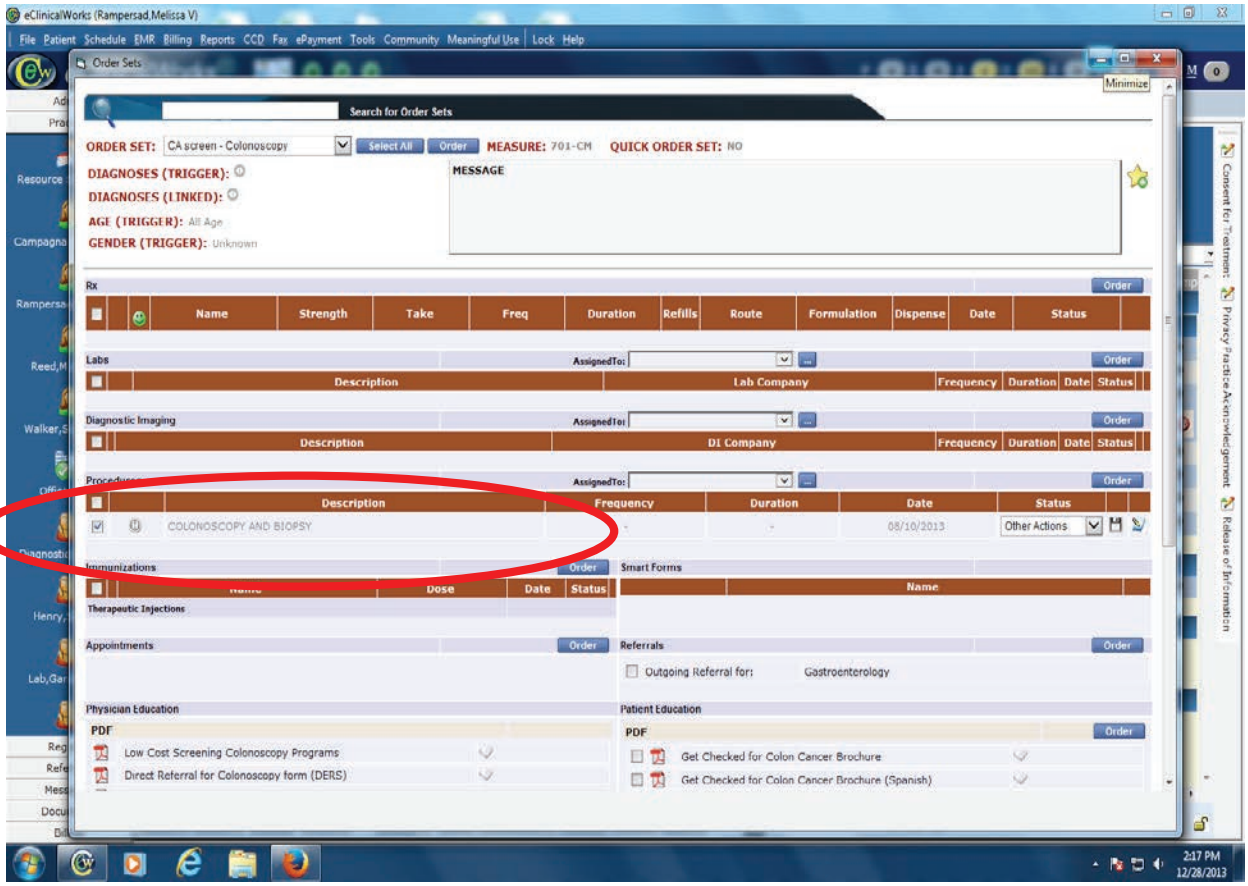
To enter the results from the order you must click back into the order under the Procedures section and complete both received and reviewed sections



Ordering Colonoscopy from the order sets section.
You must have the CDSS and or Order Sets (OS) enabled on your system, then Click on the "+" to complete the order

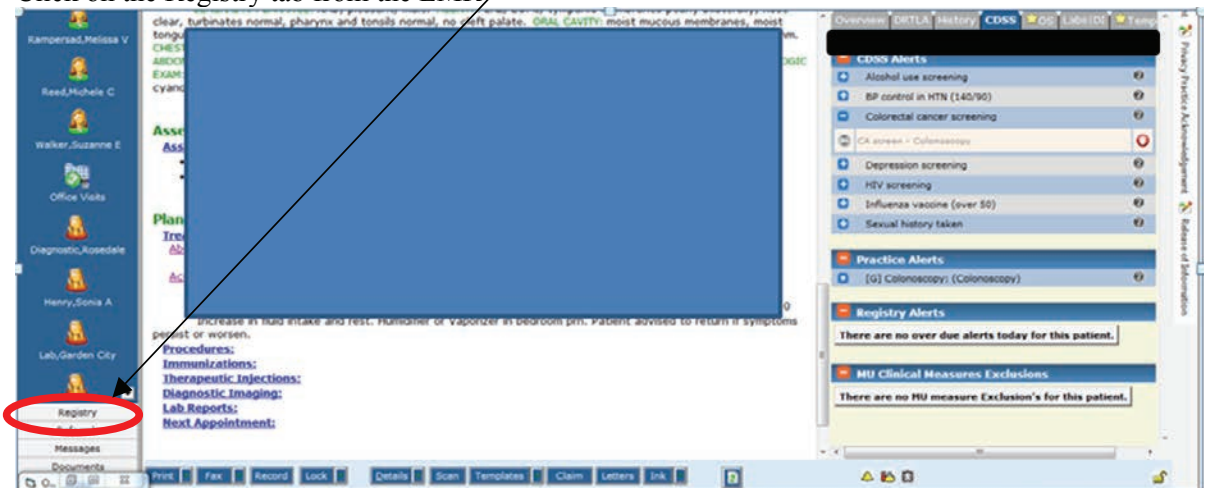


Colonoscopies ordered from the OS screen will appear in the procedures section of the encounter note. Not the DI section.

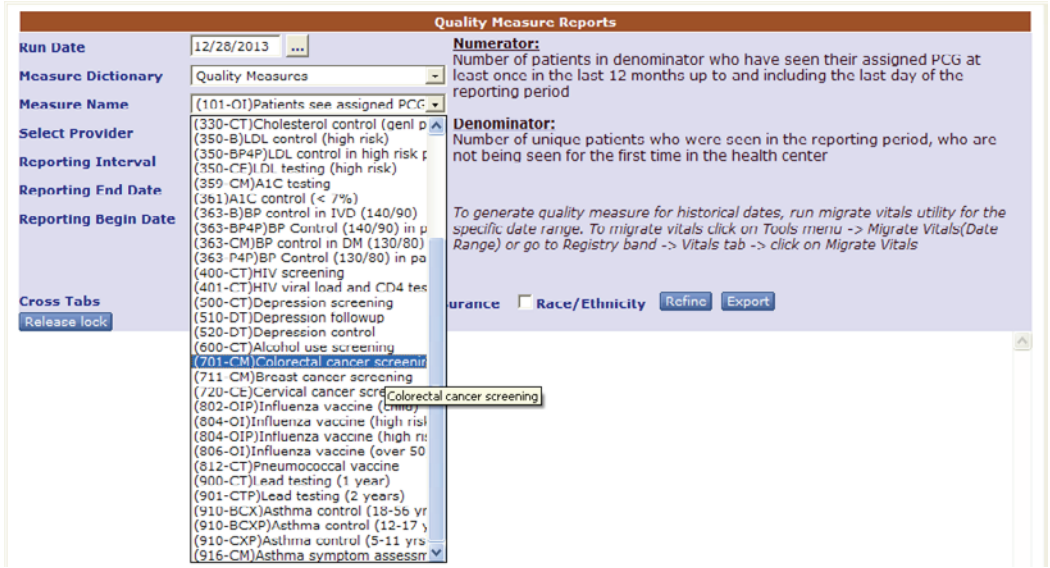

eClinicalWorks (Rampersad,Melissa V)
File Patient Schedule EMR Billing Reports CCD Fax ePayment Tools Community Meaningful Use Lock Help
Order Sets
Search for Order Sets
ORDER SET: CA screen - Colonoscopy
Select All
Order
MEASURE: 701-CM
QUICK ORDER SET: NO
DIAGNOSES (TRIGGER):
DIAGNOSES (LINKED):
AGE (TRIGGER): All Age
GENDER (TRIGGER): Unknown
MESSAGE
Rx
Name
Strength
Take
Freq
Duration
Refills
Route
Formulation
Dispense
Date
Status
Labs
Description
Lab Company
Frequency
Duration
Date
Status
Diagnostic Imaging
DI Company
Procedures
COLONOSCOPY AND BIOPSY
08/10/2013
Other Actions
Immunizations
Dose
Smart Forms
Therapeutic Injections
Appointments
Referrals
Outgoing Referral for:
Gastroenterology
Physician Education
Patient Education
PDF
Low Cost Screening Colonoscopy Programs
Direct Referral for Colonoscopy form (DERS)
Get Checked for Colon Cancer Brochure
Get Checked for Colon Cancer Brochure (Spanish)
2:17 PM
12/28/2013

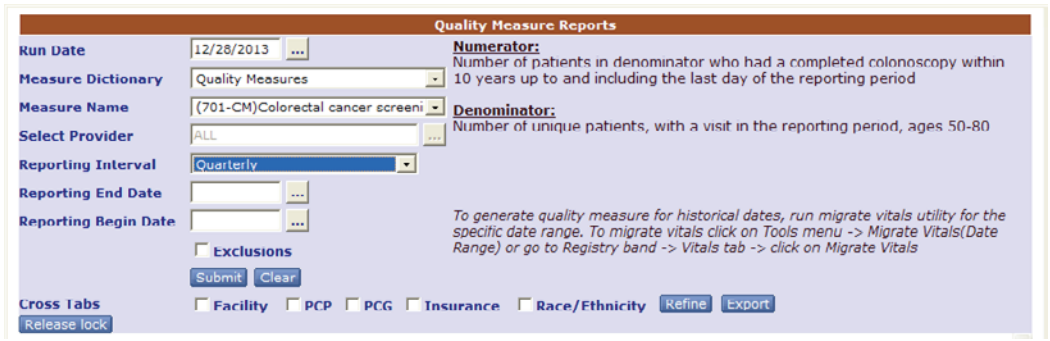
Reporting for Colonoscopy Quality measure performance using the Quality Measures canned reports

Click on the Registry tab from the EMR.

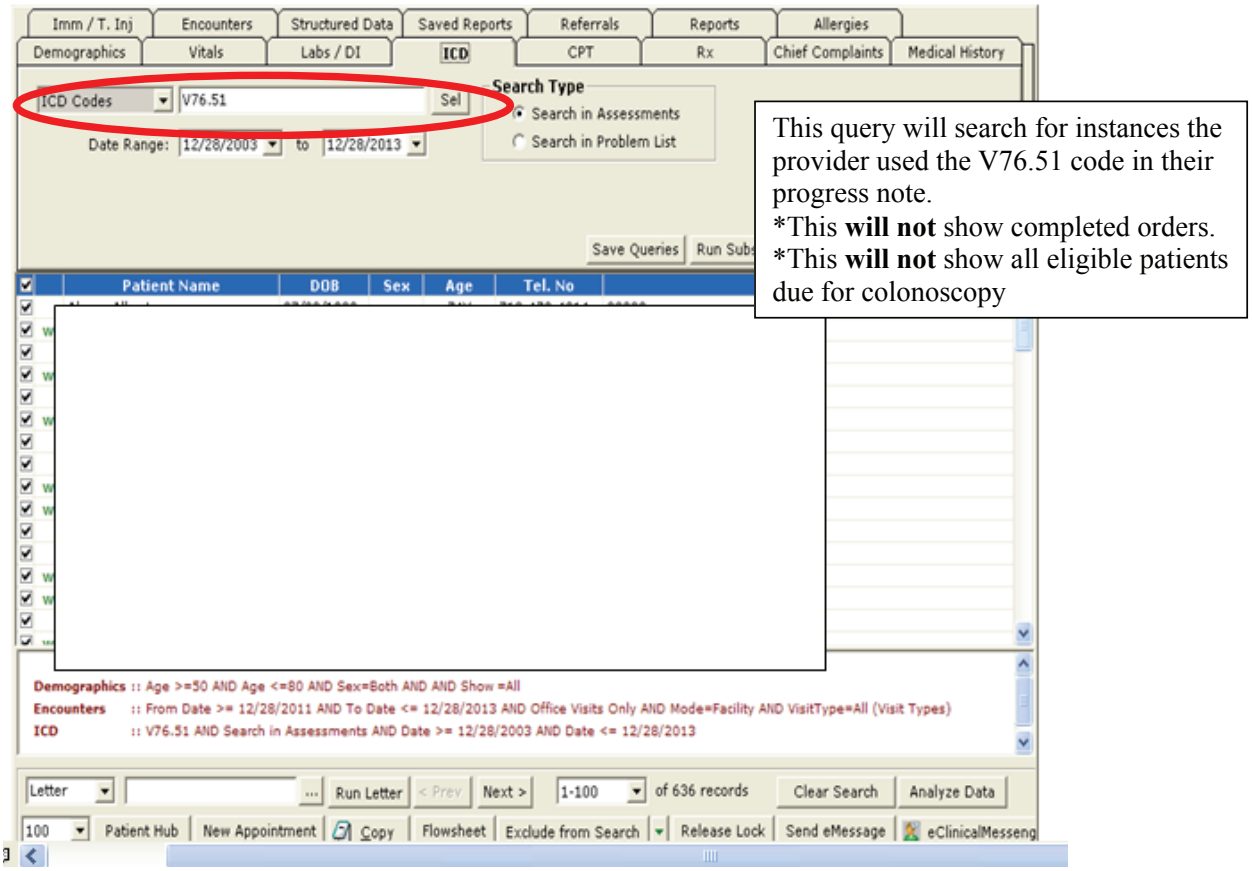


Click into Quality Measure Reports and search for the Colonoscopy report (701-CM).





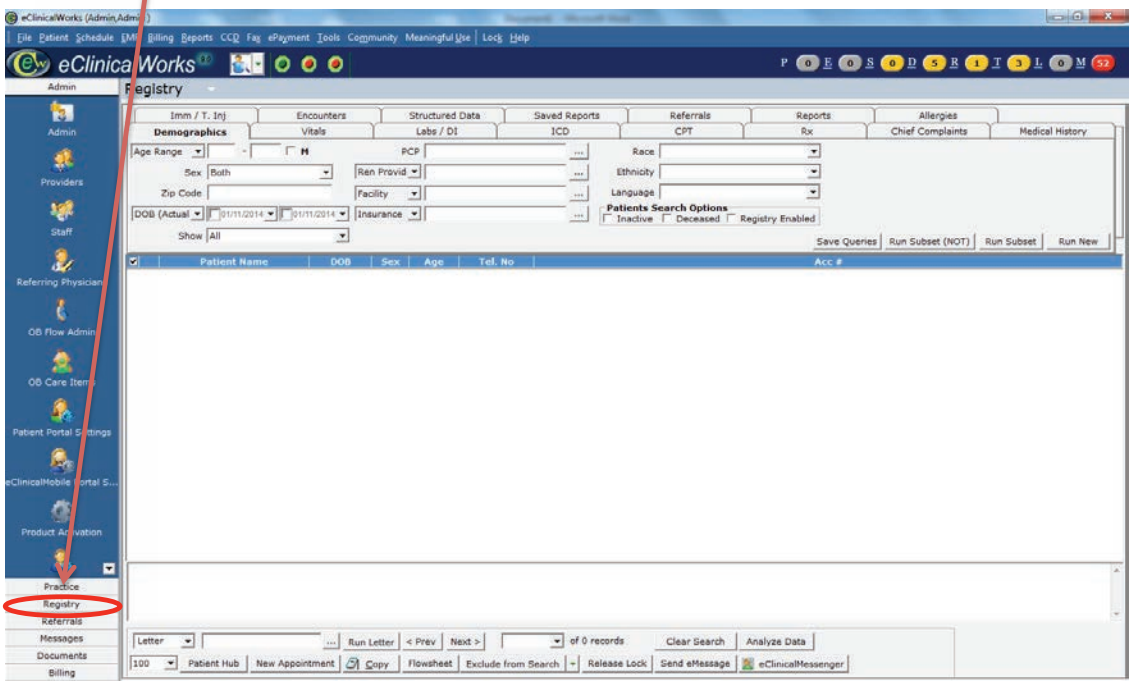
Building reports on Colonoscopy in the Registry section
This query is for ordering the colonoscopy (V76.51). This does not include completed orders or patients that refuse or don't see the specialty provider.



This query will search for instances the provider used the V76.51 code in their progress note.
*This **will not** show completed orders.
*This **will not** show all eligible patients due for colonoscopy

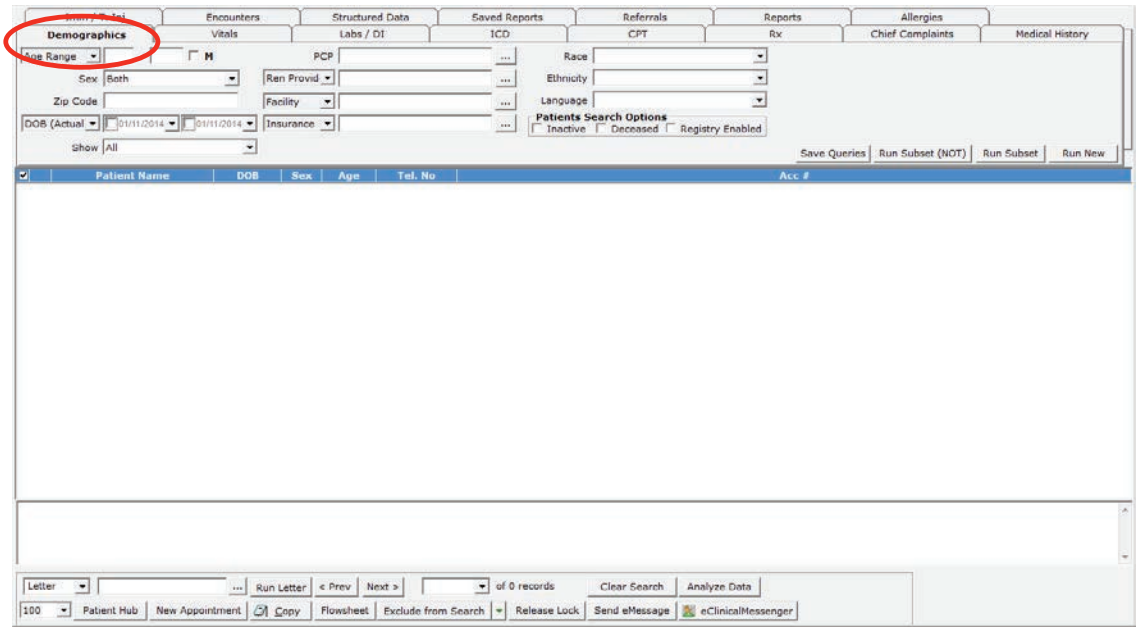
Running Reports for FOBT in ECW

Go to registry

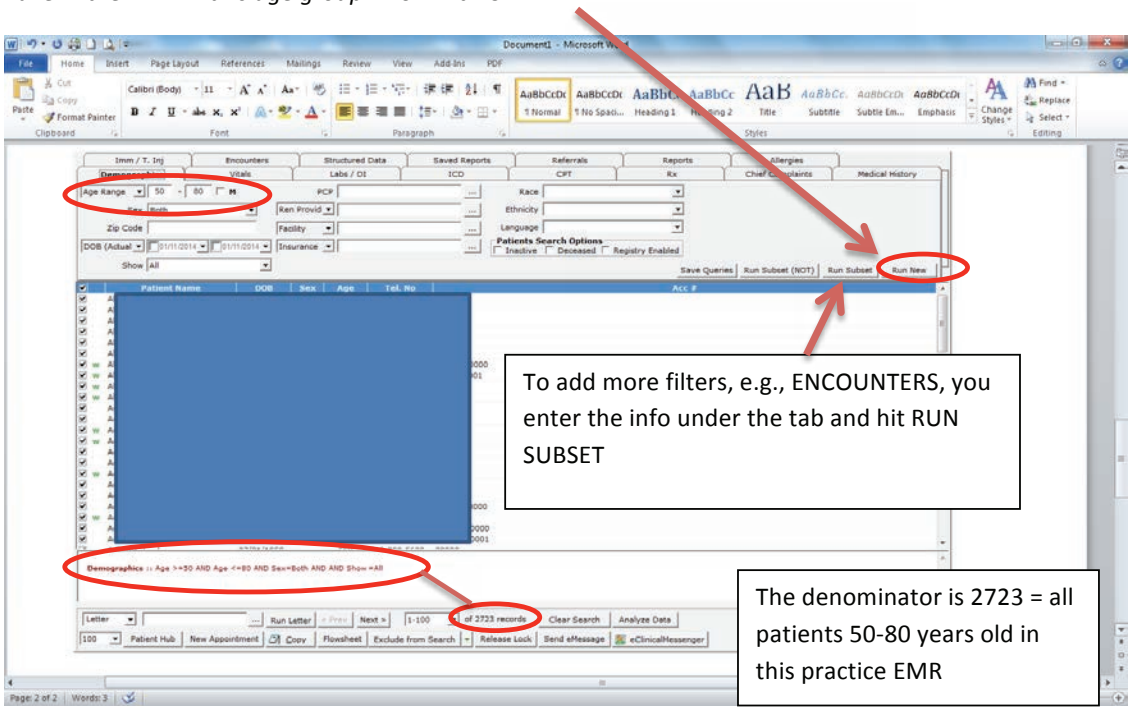


This window will appear. *Hint: Make sure you have access to the registry with your log in. otherwise you will get an admin error message.*

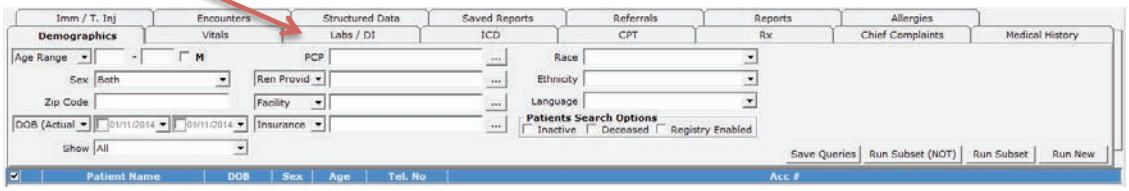
Now build you report by getting your group of all eligible patients for your denominator in the Demographics tab



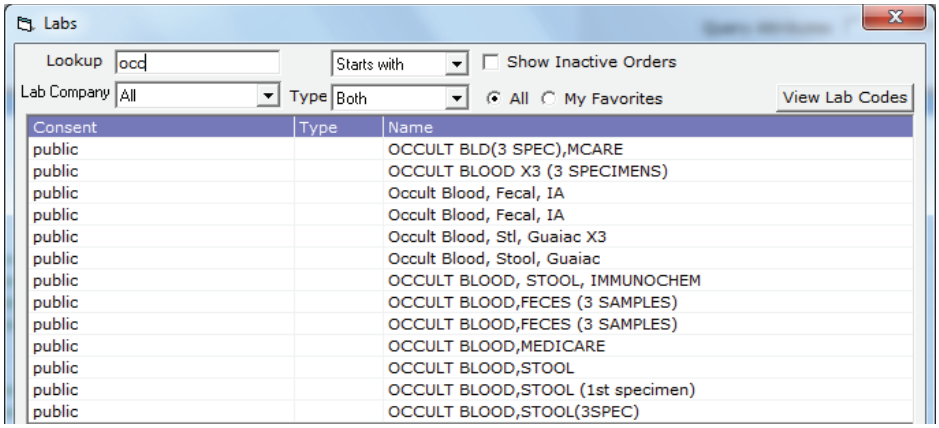
In this example we pulled all patients age 50-80. *Hint: You should also include patients that have had a office visit in the last 2 years since that will cleanup your denominator based on patients seen in the practice and not every patient you have in the EMR in this age group.* Now hit RUN NEW



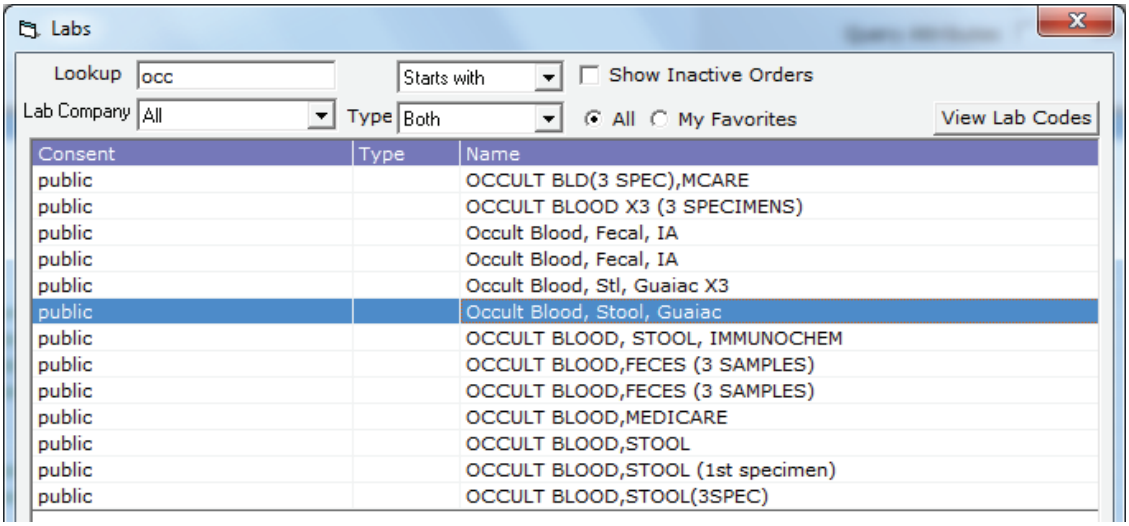
Once you've identified your population then you need to query for the service, e.g., FOBT lab test you click on the LABs/DI tab



This window will appear and you type in the first few letters of the lab that your practice selects when documenting the encounter

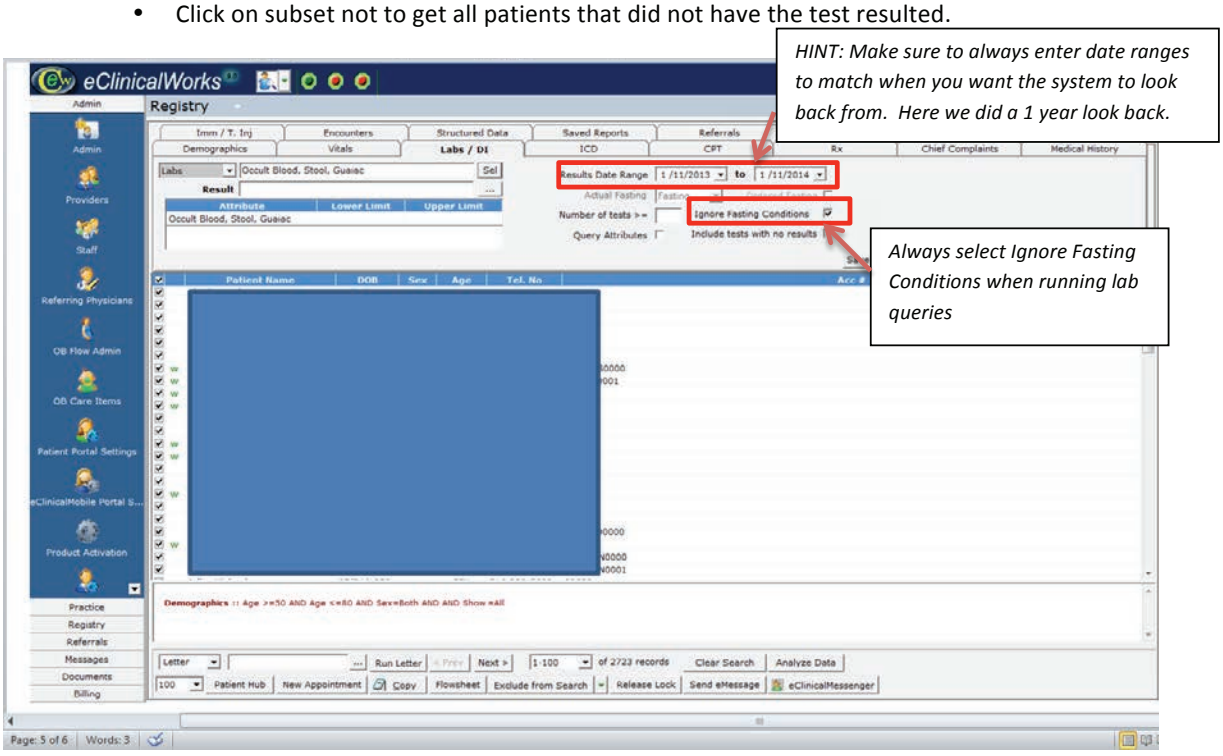


Here we selected Occult Blood Guaiac. *Hint- Ask your providers what they select when ordering these labs. You can query for several at a time to make sure you capture all patients that had the service*

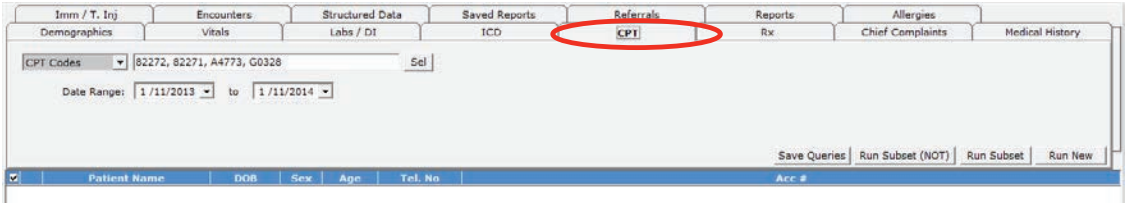


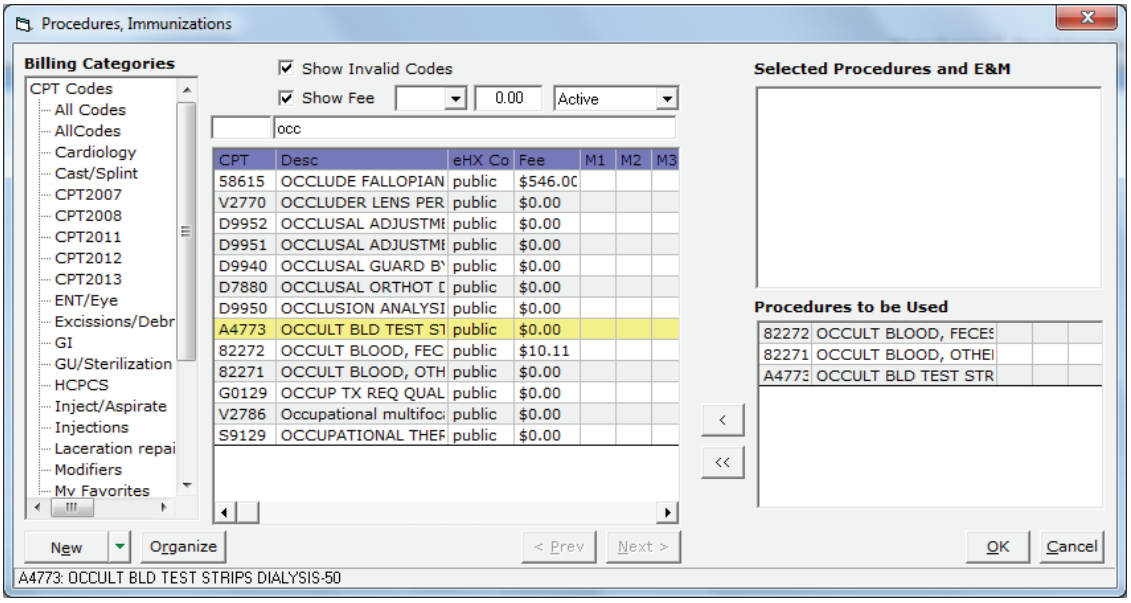
Now the query is ready to run for all 2723 patients that are 50-80 yrs old that had the occult blood test performed.

- Click on Run Subset to get everyone that had the test resulted for the past one year.
- Click on subset not to get all patients that did not have the test resulted.



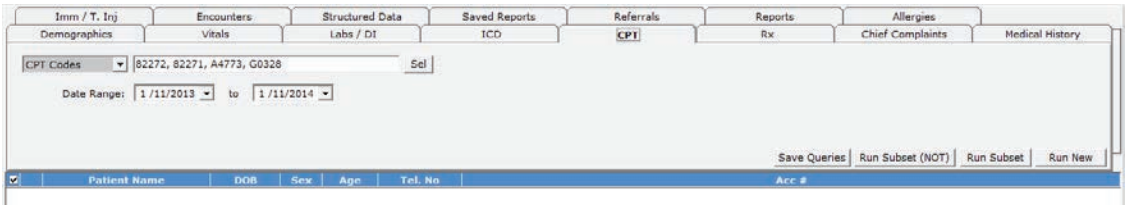
Alternatively a practice may run a query for FOBT's by searching CPT codes. Therfore follow the first step in identifiying your population and hit Run New. Then click on the CPT tab and query for all types of FOBT CPT codes.





After you enter your codes

- Click on Run Subset to get everyone that had the CPT code for the past one year.
- Click on Run Subset Not to get all patients that did not have the CPT entered in the past year



EXAMPLE OF "SCREENING POLICY"

XYZ HEALTH CENTER

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 age 50 and above can prevent and detect colorectal cancer at an early and curative stage, resulting in decreased mortality rates. Colorectal cancer is the second leading cause of cancer deaths in the United States. In keeping with XYZ Health Center's philosophy that information leads to good decisions and that we are a clinically integrated system of providers, we will implement a process for a comprehensive colorectal cancer screening program.

II. REFERENCE

The XYZ Committee has carefully considered several standards to use in the colorectal cancer screening program. The USPSTF & US Multi-Society Task Force guidelines were chosen because they were most appropriate to the target population in the community.

III. RESPONSIBILITY

It is the responsibility of all staff members to be familiar with the initiative, develop a practice based process for chart review, data abstraction, and accurate data entry and patient education for CRCS.

IV. **Procedure** (See attachment 1)

V. **Data Abstraction and Reporting** (See attachment 1)

VI. **Additional Data for Medical Review and Quality Audit** (See attachment 2)

ATTACHMENT 1 (CRCS Initiative)

IV. PROCEDURE

1. POPULATION

Target population: Number of patients at average risk between age 50 through 75.

UDS standard of care screening options[1]:

- Colonoscopy conducted during the reporting year or previous 9 years (total = 10 years)
- Flexible sigmoidoscopy conducted during reporting year or previous 4 years (total = 5 years
- Guaiac-based fecal occult blood test (gFOBT) or fecal immunochemical test (FIT) during the reporting year

2. **Interim GOALS**

X by 20XX

3. EXCLUSION

Patients who have or who have had colorectal cancer

may want to consider excluding patients receiving end of life care

4. DATA ENTRY

Practice managers will assure that new employees are oriented to this initiative and are provided with adequate orientation for data entry and appropriate scanning of documents.

V. DATA ABSTRACTION AND REPORTING

A. REPORTS

1. Report parameters: Number of active patients aged 51 through 74
2. Exclusions**:** Patients who have or who have had colorectal cancer
3. Reporting Frequency: Quarterly
4. Data Calculation:

$$\frac{\text{\# of active pts aged 51 through 74 who have had gFOBT/FIT <1 yr, flexible signomoscopy < 5 yrs, or colonoscopy <10 yrs}}{\text{Total \# of active patients who were aged 51 through 74}}$$

ATTACHMENT 2 (CRCS Initiative)

VI. ADDITIONAL DATA FOR MEDICAL REVIEW OR QUALITY AUDIT

An additional data field that includes ICD-9 code risk information may enhance the management of patients whose plan of care includes a higher rate of surveillance or diagnostics.

ICD-9	Diagnosis
V16.0	Family History of Colon Cancer
V10.05 – V10.06	History of Colon Cancer
V12.72	History of Colon Polyps
153.0 – 153.9	Malignant neoplasm of the colon
150 – 154.8	Malignant neoplasm of the rectum
197.4- 197.5	Secondary malignant neoplasm
211.2- 211.4	Benign neoplasm of the other digestive systems
230.3 – 230.6	Carcinoma in situ of digestive organs
235.2	Neoplasm of uncertain behavior
556 – 556.9	Ulcerative colitis
558.9	Other unspecified noninfectious colitis (inflammatory bowel disease)
569.0	Anal and rectal polyp

1. Bureau of primary health care: BPHC uniform data system manual. *Health Resources and Services Administration*. December 19, 2013.

Appendix C: 2 – Options for Stool-based Tests – **Coming Soon!**

Appendix C: 3 – Standard 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):				

Direct Referral For Screening Colonoscopy

Physicians: To assess patient fitness for direct referral for colonoscopy, fill out the form below. For patients who **are** appropriate candidates for direct referral: 1) fax this form to a participating endoscopist (see reverse for referral sites); 2) provide the patient with a copy of this form and the endoscopist contact information; 3) instruct patient to call the referral site to schedule their procedure and to receive bowel preparation instructions. For patients who **are not** appropriate candidates for direct referral: refer patient to a GI specialist for assessment prior to colonoscopy.

Date of Referral: _____/_____/_____

Reason for procedure:

☐ Asymptomatic person age 50 years and older

☐ 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: _____/_____/_____)

Patient Information or Label:

Name: _____

DOB: _____

Address: _____

_____

Phone: _____

Mobile: _____

Insurance Carrier: _____

Policy ID#: _____

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:**
Heme (+) stool, 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?			
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 an A.M. appointment. Advise patient on how much and when to take their oral diabetes medications, insulin or Exenatide (Byetta®) 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: _____

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

NYC Health

New York Citywide Colon Cancer Control Coalition

TO THE PATIENT:

You have been directly referred for a colonoscopy by your physician. Your physician will forward this form to the doctor who will perform your colonoscopy (an endoscopist) and will 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 prior to the procedure; (2) how to adjust your diet prior to the colonoscopy; (3) how to adjust your medications prior to the colonoscopy.

TO THE REFERRING PHYSICIAN:

Where to Directly Refer Patients for Colonoscopy in NYC:

The New York Society for Gastrointestinal Endoscopy (NYSGE) maintains a list of physicians that accept direct referrals for colonoscopy on their website: http://www.nysge.org.*

(*Note: This link is provided for informational purposes only; DOH does not recommend any doctor listed on NYSGE's website; NYSGE's list is entirely generated by NYSGE and does not include the names of all qualified specialists, but rather is a source, amongst many, covering doctors specializing in a particular area.)

In addition to the office-based practices noted above, a number of hospitals in New York City accept direct referrals for colonoscopy. To access a list of hospitals that accept direct referrals for colonoscopy, go to: www.nyc.gov/directreferral.

RESOURCES FOR UNINSURED AND UNDERINSURED PATIENTS:

311 is an important resource for patients seeking information about hospitals that provide colonoscopies, including patients who are not yet covered in a health insurance plan.

Appendix C: 5 – Sample Colonoscopy Appointment Letters in English and Spanish (Operation Access)

<Date>
<First Name> <Last Name>
<Address>
<City>, <State> <ZipCode>

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 – Sample Colonoscopy Appointment Letters in English and Spanish (Operation Access)

<Date>
<First Name> <Last Name>
<Address>
<City>, <State> <ZipCode>

Estimad <EndOfWordGenderSpanish> <FirstName>:

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 or to request an interpreter, 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!

Colonoscopy Screening 1st meeting

Name:		
Address:		
Email:		
Telephone #1: Telephone #2:	**Always attempt to get two phone #s**	
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, >5yrs since last colonoscopy		
Medication Review	**STOP Date**	**Don't STOP**
• Aspirin, Plavix (clopidogrel)***need MD clearance, ideally stop 5 days** Plavix (clopidogrel) Effient		
• Coumadin (warfarin) ***need MD clearance, ideally stop 4 days** Xarelto		
• Diabetes meds Metformin, Januvia, glyburide ***need MD clearance, usually hold oral agent morning of test** 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 laxative	
• 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 transportations plans (who, how): Name: Phone:	

Colonoscopy Screening 1-3 weeks before

Second face to face meeting mandatory if initial meeting > 5 weeks before colonoscopy	
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 laxative	
• 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	
• Patient's transportations plans (who, how): Name: Phone:	

Screening Colonoscopy – Telephone Calls

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	
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: Resolution:	
Patient concern/question: Resolution:	

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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.

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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"

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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.

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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 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.

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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.flu.fit.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

Tracking form for FIT/HSgFOBT follow-up

Patient Name/MR or DOB	Phone #	Date Test Given	Reminder Date (Phone/Mail)	Result: pos. or neg.	Date PCP Notified	Date colonoscopy scheduled	Reminder Date (Phone/Mail)	Date colonoscopy completed

CRC Screening Reminder Card[62]

ENGLISH	**Protect Yourself from Colon Cancer.** **Get Checked Every Year!** Your last test was normal. It was done on _____ You should have this test done again on _____ Talk with your doctor, or call Erie Family Health Center at xxx-xxx-xxxx and we will mail you a free test kit.
SPANISH	**Protéjase Contra Cáncer del Colon.** **¡Repita Su Chequeo Anualmente!** Su último chequeo salió normal. Lo hizo el _____ Le toca hacerlo de nuevo el _____ Hable con su médico o llame al Centro de Salud Erie al xxx-xxx-xxxx, y le enviaremos el equipo gratuito.

Patient Letter Included with Mailed FIT (for Never Screened Patients)[62]

English	Dear _____, At Erie Family Health Center, we want to do everything we can to protect your health. My records show that I have never tested you for colon cancer. I'm reaching out to my patients who have never been tested, because this is very important. Anyone can get colon cancer. Colon cancer is one of the most common cancers. Even if no one in your family has ever had it, you could get colon cancer. Your chance of getting colon cancer increases as you get older. I recommend that everyone age 50 and older get tested. Do the test, even if you feel fine. Colon cancer starts off as a small growth in your colon (large intestine). When it is small, you do not feel anything. The test can find cancer early. When we find cancer early, it is treated most successfully. The test is easy. Just follow the instructions I sent with the test. The test is free. We have paid for the postage. You can mail it to us at no cost. The test could save your life! Do it right away and mail it back to us. We will tell you the results in 2 weeks. If you have any questions about the test, call the colon cancer screening coordinator, <NAME>, at XXX-XXX-XXXX. If you see blood in your stool (or poop), do not do this test. Call Erie Family Health Center to make an appointment. Sincerely,
Spanish	Estimado(a) _____, En el Centro de Salud Erie, queremos hacer todo lo posible por proteger su salud. Su expediente indica que nunca se ha hecho la prueba de cáncer de colon. Me estoy poniendo en contacto con mis pacientes que nunca se han hecho la prueba, porque es muy importante. Cualquier persona puede contraer el cáncer de colon. El cáncer de colon es uno de los tipos de cáncer más comunes. Aun si nadie en su familia nunca ha tenido, usted puede contraerlo Su probabilidad de contraer el cáncer de colon aumenta con la edad. Le recomiendo que todas las personas de 50 años o más se hagan la prueba. Haga la prueba, aunque se sienta bien. El cáncer de colon comienza como una pequeña masa en el colon (intestino grueso). Cuando la masa es pequeña, no se siente. La prueba puede detectar el cáncer temprano. Cuando detectamos el cáncer temprano es cuando es más exitosamente tratable. Es fácil hacerse la prueba. Simplemente siga las instrucciones que le envié con la prueba. Esta prueba es gratuita. Hemos pagado los gastos de envío. Usted puede regresárnosla por correo sin costo. ¡Esta prueba podría salvarle la vida! Hágala de inmediato y regresárnosla. Le haremos saber los resultados en 2 semanas. Si tiene preguntas sobre la prueba, comuníquese con la persona a cargo de la coordinación de detección de cáncer de colon, <NAME>, al XXX-XXX-XXXX. Si ve sangre en su caca, no se haga esta prueba. Llame al Centro de Salud Erie para hacer una cita. Atentamente,

Patient Letter Included with Mailed FIT (for Repeat Screening)[62]

ENGLISH	Dear XXX, A year ago, you did a test to check for colon cancer. Your test was normal. But, colon cancer can start any time. And when cancer is starting, you do not feel anything. To protect yourself from colon cancer, you need to do this test every year. It is time to do the test again. Last time, you put some stool (poop) on three cards. The test checked for hidden blood in your stool, which is a sign of colon cancer. The test is much easier this year. You just need to collect stool one time, and you can eat whatever food you usually eat before the test. We have sent you the test kit with this letter. Just follow the instructions. Mail it back to us as soon as you have done the test. The test and the postage are free. This simple test could save your life. Do it and send it in right away! If you have any questions about the test or how to do the test, please call XXX, the colon cancer screening coordinator, at xxx-xxx-xxxx. Sincerely,
SPANISH	Estimado Don XXX, {or} Estimada Doña XXX, Hace un año atrás usted se hizo una prueba para detectar cáncer de colon. Esa prueba salió normal. Pero el cáncer de colon puede comenzar en cualquier momento. Y cuando el cáncer está empezando, uno no siente nada. Para protegerse del cáncer de colon, usted debe hacerse esta prueba cada año. Ahora le toca hacerse la prueba nuevamente. La última vez, usted puso un poco de materia fecal (caca) en tres tarjetas. La prueba buscó la presencia de sangre oculta en su materia fecal (caca), lo cual es una señal de cáncer de colon. Este año la prueba es mucho más fácil. Sólo tiene que recolectar su materia fecal (caca) una vez, y puede comer cualquier comida que usted por lo general come antes de la prueba. Le hemos enviado con esta carta el material para hacer la prueba. Simplemente siga las instrucciones. Envíenosla de regreso apenas haya hecho la prueba. La prueba y el costo de mandarla por correo son gratuitos para usted. Esta sencilla prueba podría salvarle la vida. ¡Hágala y envíenos su prueba de inmediato! Si tiene alguna pregunta sobre la prueba o sobre cómo se hace, por favor llame a XXX, coordinador bilingüe de pruebas de cáncer de colon, al teléfono xxx-xxx-xxxx. Atentamente,

Sample Patient Reminder Letter to Return Test

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 treated most successfully 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

Results Notification Letter Sent to Patients with Negative FIT[62]

English	Dear XXX Good news! The test for colon cancer that you sent in was normal. There was no blood. Just remember that to protect yourself you need to do this test every year. So write down that you should have this test done again in one year. We have included a reminder card with the date when you should have this done again. Now that you have been tested for colon cancer, help protect your family and friends! Everyone between the ages of 50 and 75 should be tested. Tell them how easy it is and encourage them to get tested. Sincerely,
Spanish	Estimado Don XXX, {or} Estimada Doña XXX, ¡Buenas noticias! La prueba del cáncer de colon que usted nos envió dio un resultado normal. No había sangre. Sólo recuerde que para protegerse tiene que hacerse esta prueba cada año. Por lo tanto anote que debe hacerse esta prueba nuevamente en un año. Hemos incluido una tarjeta como recordatorio, con la fecha en que debe hacérsela nuevamente. Ahora que ya se ha hecho la prueba del cáncer de colon, ayude a proteger a su familia y a sus amigos. Todas las personas entre las edades de 50 y 75 años deberían hacerse la prueba. Dígales lo fácil que es y anímelos a hacerse la prueba. Atentamente,

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
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Results: ______________________________

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Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

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Recommendation: age ≥ 50 years or family history
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Other ________________
Referral date: ______/______/______
Results: ______________________________

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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
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Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Is colon cancer screening needed?
____Yes ____No
Recommendation: age ≥ 50 years or family history
Type: Colonoscopy FOBT
Other ________________
Referral date: ______/______/______
Results: ______________________________

Appendix C: 14 – 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 aft 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:

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 • Several expert groups set a quality target of 90% or higher for cecal intubation rate • 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 • 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: 1 – Patient Education Materials

Centers for Disease Control and Prevention

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

cancer.gov/cancertopics/pdq/screening/colorectal/Patient

Patient information about colorectal cancer, colorectal cancer screening, and other topics

National Colorectal Cancer Roundtable

nccrt.org/tools/

Tools and Resources

Prevent Cancer Foundation

preventcancer.org/colorectal3c.aspx?id=1036

(Materials available in Spanish): Fact Sheet: Colorectal Cancer 2009 Fact Sheet

American Cancer Society

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 & Figures*, Journals

Appendix D: 2 – Guidelines

American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in People at Average Risk, Increased Risk, or at High Risk

cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations

2008 US Preventive Services Task Force Colorectal Cancer Screening Guidelines

uspreventiveservicestaskforce.org/uspstf/uspscolo.htm

Appendix D: 3 – Patient Navigation

Key considerations in designing a patient navigation program for colorectal cancer screening, Degroff et al, *Health Promotion Practice*

hpp.sagepub.com/content/early/2013/12/19/1524839913513587

Colonoscopy Patient Navigator Program Orientation Manual – New York City Government

nyc.gov/html/doh/downloads/pdf/cancer/orientation.pdf

Michigan Colorectal Cancer Early Detection Program – pages 14-29

michigancancer.org/Colorectal/PDFs/Manuals/FY14CRCManual.pdf

Colorado Patient Navigator Training Program

patientnavigatortraining.org/

Patient Navigation Research Program Center to Reduce Cancer Health Disparities, National Cancer Institute

crchd.cancer.gov/pnp/pnrp-index.html

Appendix D: 4 – Electronic Health Records

Use of Electronic Medical Records to Facilitate Colorectal Cancer Screening in Community Health Centers – National Colorectal Cancer Roundtable

http://nccrt.org/about/disparities/report-on-use-of-electronic-medical-records-to-facilitate-colorectal-cancer-screening-in-community-health-centers/

Use of Electronic Medical Records in Optimizing the Delivery of Colorectal Cancer Screening in Primary Care – National Colorectal Cancer Roundtable

nccrt.org/about/provider-education/electronic-medical/

Information on Meaningful Use of Electronic Health Records – Centers for Disease Control and Prevention

cdc.gov/ehrmeaningfuluse

HRSA Reporting and Technical Assistance

bphc.hrsa.gov/healthcenterdatastatistics/reporting/index.html

Appendix D: 5 – Practice Management

National Cancer Institute Research Tested Intervention Programs (RTIP) – list of evidence-based screening programs, many of which can be adopted and implemented by CHCs

rtips.cancer.gov/rtips/programSearch.do

Interactive Web-based Toolkit: How to Increase Colorectal Cancer Screening Rates in Practice

www5.cancer.org/aspx/pcmanual/default.aspx

Options for Increasing Colorectal Cancer Screening Rates in North Carolina Community Health Centers – UNC Lineberger Comprehensive Cancer Center

ncspeed.org/sites/default/files/CRC_Toolkit.pdf

Agency for Healthcare Research and Quality – Patient Centered Medical Home

pcmh.ahrq.gov/portal/server.pt/community/pcmh__home/1483

Health Resources and Administration (HRSA) – Information on the Uniform Data System

bphc.hrsa.gov/healthcenterdatastatistics/index.html

CDC Guide to Community Preventive Services Website – resource to help you choose programs and policies to improve health and prevent disease in your community

thecommunityguide.org/index.html

New Hampshire Colorectal Cancer Screening Program

cancer.dartmouth.edu/gi_pancreatic/nh_colorectal_screening.html

Project Access

chattmedsoc.org/about-us-project-access

Cancer Coalition of South Georgia

sgacancer.org

Operation Access

operationaccess.org

Volunteers in Medicine

vim-chatt.org/vim16/

New York Citywide Colon Cancer Control Coalition

c5nyc.org

CDC Colorectal Cancer Control Program (CRCCP)

cdc.gov/cancer/crccp/

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