



Clinical Screening Program Preparation

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Introduction

Previous chapters of this toolkit focus on promoting colorectal cancer screening and prevention in tribal communities. This chapter is about Northwest tribal clinics, existing cancer and screening rates, and potential improvement areas for clinics and community health workers, as identified in our focus group and key informant interviews. This chapter includes a brief overview of Indian Health Services' Improving Patient Care (IPC) model, as well as resources for improving CRC screening- and other services- through team-based approaches for patient care, building clinic capacity for prevention, screening and increasing patient tracking. Lastly, examples from two regional clinics that have successfully improved their screening rates will be described in detail.

Northwest Tribal Clinics

There are 43 federally recognized tribes in the Northwest Portland Area Indian Health Board service area of Washington, Oregon and Idaho. There are 39 tribal clinics in this service area. Each clinic is different and there is a wide range of clinic capacity. Some are large, well-staffed clinics with over 10 full primary care providers (including both doctors and nurse practitioners). Other tribal clinics are extremely small, rural and have primary care providers on a rotating schedule. In Indian country, there is a wide variety in clinic capacity so there is no one, single method for increasing CRC screening. There are many resources, including utilizing the IPC model, that are outlined below, however example success stories may be more effective in guiding your community's clinic in increasing screening rates.

What are the keys to your clinic's success in colorectal screening ?

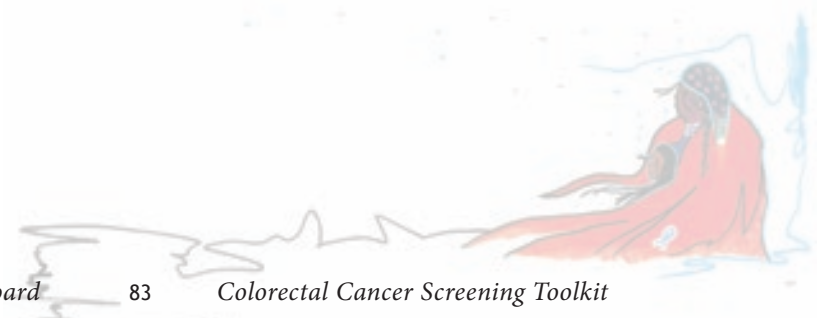
The Electronic Health Record reminder, puts CRC screening in the face of provider and nursing staff;

IFOBt vs. old cards has also become easier for patients because it is only one test;

Brightly colored envelopes are used for kits so that they stand-out at home;

Having GPRA and IPC objectives help to improve screening;

And, also receiving individual feedback regarding the GPRA scores help



Overview of Recommended Screening Tests

Fecal Immunochemical Test (FIT): This is a recent improvement over the traditional, guaiac-based FOBT. It uses a different immunochemical process to detect fecal occult blood that is more sensitive than the guaiac-based FOBT. It only requires one sample instead of three, includes a small plastic vial filled with liquid in which the stool sample is placed and does not have the dietary restrictions of the FOBT. Because of these characteristics, the FIT test is preferred over the FOBT for those clinics that offer stool testing for CRC screening. The FIT test is more expensive than traditional FOBT, but improves completion rates by patients. Despite better test performance characteristics, FIT tests have not been shown to be any more cost effective than guaiac-based FOBT¹.

Regardless of which type of stool-based test is used—the traditional FOBT or the newer FIT—it is important to keep in mind that these tests must be repeated annually in order to sufficiently screen patients and that any positive test result must have a complete colonoscopy performed. Pitfalls in stool-based screening include: failure to re-screen annually, failure to adequately educate the patient to collect the sample, failure of patients to return all samples properly or to follow dietary restrictions and failure of clinicians to follow-up on a positive test. For these reasons, and the fact that stool-based screening is not specific for CRC, endoscopic screening for CRC is preferred where cost is not a barrier for average risk patients.

Flexible sigmoidoscopy (FS): This screening method requires a trained endoscopist using a 30cm sigmoidoscope. The patient must undergo a bowel preparation that includes a low residue diet, laxatives and enemas. FS can be performed in an office or clinic setting and requires no anesthesia. The test can visualize adenomatous polyps in the first 30 cm of the rectum and descending colon, where approximately 2/3 of colorectal cancers occur. Adequate screening with this method requires that it be repeated every five years and that any positive examination is followed by a complete colonoscopy. Disadvantages of FS over stool-based tests are the increased need for patients to be educated and motivated to undergo a test that requires bowel preparation and

acceptance of a screening test that is invasive.

Colonoscopy: This screening method is the gold standard against which all other CRC screening tests are measured. Colonoscopy utilizes a 60 cm endoscope that fully visualizes the entire colon and rectum. Colonoscopy also allows for removal of adenomatous polyps, the pre-cursors to cancer, and allows for biopsy of suspicious areas. Unlike flexible sigmoidoscopy, colonoscopy does require anesthesia and must be performed in a clinical setting with adequate anesthesia and recovery services such as an ambulatory surgery suite or hospital. CRC screening with colonoscopy must be repeated every 10 years if no suspicious lesions are found. Screening by endoscopy (FS or colonoscopy) is approximately three times more likely to detect advanced CRC compared with fecal tests².

Other available tests: There are other available tests that may be helpful in screening for CRC but at present none of these tests have been recommended by the US Preventive Services Task Force (USPSTF) to screen for or prevent CRC.

Stool DNA Test: This test uses a stool sample to screen for cancerous cells. These tests along with tests that detect RNA and certain proteins associated with CRC show promising advantages over the FOBT or FIT tests in that they have increased sensitivity and specificity for detecting malignant cells and in some cases, cells from adenomatous polyps. However, a recent review did not find that these tests were cost-effective compared to currently available screening methods¹. Further evidence is needed from large clinical trials before these tests can be fully recommended.

CT Colonography (CTC): CTC can be a useful option for certain patients who are unable to undergo colonoscopy because of prior surgery or other reasons, but who still meet criteria for screening. CTC produces high-quality, three dimensional images of the entire colon. The preparation required is the same as that for colonoscopy, however there is no requirement for anesthesia. Advantages of CTC include higher patient acceptance of CTC compared to colonoscopy or double contrast barium enema (DCBE) in some studies, increased ability to detect advanced polyps (>10mm) compared to DCBE and decreased rate of missed cancers compared to DCBE. The rate for detection of CRC and advanced polyps is similar to that of colonoscopy,



however colonoscopy is superior in the detection of smaller (< 6 mm) adenomatous polyps and flat lesions (< 3mm in vertical height). The primary disadvantage of CTC is the necessity to undergo a second procedure, colonoscopy, in the event of a positive CTC. The inadvertent findings of extra-colonic pathology, which leads to additional diagnostic tests or procedures, is perceived as both an advantage and a disadvantage. In the case of identification of asymptomatic aortic aneurysm, there could be an advantage in decreased mortality and enhanced cost-effectiveness; while in the case of the identification of other conditions, including other cancers, the cost-effectiveness may be negated by the additional diagnostic and treatment procedures that patients undergo, which may or may not decrease mortality³.

Double Contrast Barium Enema (DCBE): DCBE is another radiologic method for viewing the colon and is still endorsed as a primary screening option by the American Cancer Society, US Multi-Society Task Force on Colorectal Cancer and the American College of Radiology. Because of superior performance of CTC compared with DCBE, The UK Department of Health no longer includes DCBE in its CRC screening program. DCBE requires colonic preparation as do CTC and endoscopy, offering no patient comfort advantages. Another factor affecting DCBE as an acceptable alternative is the relative lack of experience in performing and interpreting DCBE among radiologists in practice today.

The table below summarizes the recommendations for screening by two consensus guideline groups: 1) the joint statement of the American Cancer Society, US Multi-Society Task Force on Colorectal Cancer; and 2) the American College of Radiology (ACS/USMSTF/ACR) and the US Preventive Services Task Force (USPSTF).

From:

<http://www.cancer.org/Healthy/InformationforHealthCareProfessionals/ColonMDCliniciansInformationSource/ColorectalCancerScreeningandSurveillanceGuidelines/comparison-of-colorectal-screening-guidelines>



Age to Begin and End Screening, and Test Prioritization

Recommendation	ACS/USMSTF/ACR ⁴	USPSTF ⁵
Age to begin and end screening in average risk adults	Begin at age 50 and end screening at a point where curative therapy would not be offered due to life-limiting co-morbidity	Begin screening at age 50. Routine screening between ages 76-85 is not recommended. Screening after age 85 is not recommended.
Screening in high risk adults	Detailed recommendations based on personal risk and family history	No specific recommendations for age to begin testing or type of testing
Prioritization of tests	Tests are grouped into those that (1) primarily are effective at detecting cancer, and (2) those that are effective at detecting cancer and adenomatous polyps. Group 2 is preferred over group 1 due to the greater potential for prevention.	No specific prioritization of tests, though recommendations acknowledge that direct visualization techniques offer substantial benefit over fecal tests
Stool Testing, Guaiac based FOBT (gFOBT)	Annual screening with high sensitivity guaiac based tests	Annual screening with high sensitivity guaiac based tests
Stool Testing, Immunochemical-based FOBT (FIT)	Annual screening	Annual screening
Stool Testing, Stool DNA (sDNA)	sDNA is an acceptable option	Insufficient evidence to recommend for or against sDNA
Flexible Sigmoidoscopy	Screening every 5 years. Screening every 5 years, with annual gFOBT or FIT is an option	Screening every 5 years, with gFOBT every 3 years
Colonoscopy	Screening every 10 years	Screening every 10 years
CT Colonography	Screening every 5 years	Insufficient evidence to recommend for or against CT colonography
Double Contrast Barium Enema (DCBE)	Screening every 5 years	Not addressed



Determining Levels of Screening

Recommendations for CRC screening are based on the natural history of disease and the relative health of the patient. Some patients may have conditions that place them at higher risk to develop CRC or could cause CRC to occur at a younger age. In developing a clinical practice, it is recommended to focus on a stratified CRC screening approach that identifies three risk levels: those at average risk, those at increased risk and those at high risk for CRC. Finally, some patients may be severely ill from co-morbid conditions and may not be candidates for CRC screening. Screening algorithms should be flexible enough to account for this patient group, as well.

Level 1: Average-risk

Men and women aged 50—80: Patients in this age group have no first-degree relatives with a history of CRC or adenomatous polyps.

Level 2: Increased Risk

Patients at increased risk either have a personal history or a family history of adenomatous polyps or CRC. These patients should NOT be screened with FOBT/FIT or FS tests but should be screened directly with colonoscopy. Because the incidence of adenomatous polyps increases with age, the proportion of individuals who fall into this category also increases with age, from around 20 to 25% at age 50 to 50% by age 75.

Level 3: High Risk

Patients at high-risk for CRC have one of three recognized hereditary syndromes that are associated with early onset and high probability of developing CRC. These syndromes include: hereditary nonpolyposis colorectal cancer (HNPCC), familial adenomatous polyposis (FAP), and attenuated FAP (AFAP). Patients with one of these three syndromes should be referred to specialty care for early and more intensive surveillance for CRC. Identifying these patients in the primary care setting can be challenging and requires careful elicitation of family history for any relative with the following:

- CRC or adenomas diagnosed prior to age 50
- Endometrial cancer diagnosed prior to age 50



- Two or more HNPCC-related tumors in a family or in an individual*
- Multiple colorectal adenomas (usually 10 or more) diagnosed over one or more exams

* HNPCC-related tumors include colorectal, endometrial, stomach, ovarian, pancreas, ureter and renal pelvis, biliary tract, brain (most often glioblastoma), small bowel, pancreatic, sebaceous gland adenomas and keratoacanthomas.

Building An Effective Office-Based CRC Screening Program

To build an effective office-based CRC screening program, it is important to identify what resources are available to support screening (i.e. availability of colonoscopy, financial resources), to clearly delineate who is responsible to initiate screening, to assign responsibility for follow-up of incomplete and positive screening tests and to determine how screening will be forecast and tracked for your patient population. Clear office policies for each of these areas will help achieve success in meeting CRC screening goals.

Identifying Resources

In the Indian Health system, which includes IHS, Tribal and Urban Indian Health Clinics (I/T/U), colonoscopy is generally not available except through referral to outside providers. Some areas, for example Alaska Area, have a network of trained mid-level providers who can perform flexible sigmoidoscopy. In the Northwest, the I/T/U clinics only provide outpatient services at free-standing ambulatory care clinics. Payment of referral care services is arranged through Contract Health Services (CHS), through other public sources (Medicare, Medicaid) or through private insurance. Because CHS funds can only be used to pay for the care of Tribal members living within the Contract Health Service Delivery Area (CHSDA) of a specific clinic, many AI/AN living in the Northwest may not be covered under this system. It is also a system that is severely underfunded leading to prioritization of care based on the severity of the condition. Under the current prioritization system, most clinics allocate almost their entire CHS budget to patients with Priority I, defined as “life or limb-threatening” conditions. Given the importance of early detection and treatment of CRC and pre-cancerous polyps, there has been interest in considering designation of screening tests such as colonoscopy as Priority I procedures in the Portland Area.



For those patients who are not eligible for CHS funded services, public or private insurance resources can be utilized to pay for CRC screening services. Patients over the age of 65 or who are disabled qualify for Medicare, which does pay for CRC screening (see table below).

Approved Medicare Colorectal Cancer Screening Tests

Screening Test	Frequency	Recommended Population	Payment
Fecal Occult Blood Test (FOBT)	Once every 12 months	Average risk	Patient pays nothing for the test, but you generally have to pay 20% of the Medicare-approved amount for the doctor visit
Flexible Sigmoidoscopy	Once every 48 months	Average risk or 120 months after a previous screening colonoscopy if remain average risk	Patient pays 20% of the Medicare-approved amount with no Part B deductible. If the test is done in a hospital, outpatient department, or an ambulatory surgical center, you pay 25% of the Medicare-approved amount
Screening Colonoscopy	once every 120 months	Average risk or 48 months after a previous flexible sigmoidoscopy	Patient pays 20% of the Medicare-approved amount with no Part B deductible. If the test is done in a hospital, outpatient department, or an ambulatory surgical center, you pay 25% of the Medicare-approved amount
	once every 24 months	High risk	
Barium Enema	every 48 months	Average risk	Patient pays 20% of the Medicare-approved amount with no Part B deductible. If the test is done in a hospital, outpatient department, or an ambulatory surgical center, you pay 25% of the Medicare-approved amount.
	every 24 months	High risk	

Adapted from information available at: <http://www.medicare.gov/navigation/manage-your-health/preventive-services/colon-cancer-screening.aspx?AspxAutoDetectCookieSupport=1>



For those eligible for Medicaid, covered procedures may vary from state to state⁷. States participating in Medicaid are not required to provide CRC screening services. Clear disclosure of specific coverage of which CRC screening tests from each state was not readily available in an on-line search. For example, in ID, the Medicaid program provides payment for screening examinations currently recommended by the USPSTF^{8,9,10}. In Oregon, state law requires coverage of ACS recommended screening tests; in Washington, the law requires coverage for USPSTF or CDC recommended screenings⁹. It is recommended that providers and patients contact the Medicaid program in their states to be sure that screening costs will be covered. For those who are not eligible for any of the above and are uninsured, additional resources may be available¹⁰.

The conversation about paying for preventive services, like CRC screening, is changing rapidly with the passage of the Affordable Care Act (ACA). This legislation will ensure that CRC screening and other preventive services are provided by all plans participating in the health insurance exchanges *without charging co-pays*. At the time of this publication, State-based health insurance exchanges are not yet available for enrollment. Information about ACA covered preventive services can be found at:

<https://www.healthcare.gov/what-are-my-preventive-care-benefits/>

For state-specific information, check the following websites for details:

Idaho: <http://www.yourhealthidaho.org/>

Oregon: <http://www.coveroregon.com/>

Washington: <http://www.wahealthplanfinder.org/>



Clinic Staff Roles and Responsibilities

The majority of Northwest I/T/U clinics use RPMS to collect patient information, including information about CRC screening, risk factors and related diagnoses. Although some clinics use commercially available systems, expertise on the capabilities of these systems is not widely available and there is no specific support for any other clinical data system other than RPMS at this time. For I/T/U clinics utilizing the RPMS Electronic Health Record (EHR) and for many other EHR systems, the use of clinical reminders is an effective tool for knowing when to recommend CRC screening. Forecasting logic in the RPMS system considers patient age, prior screening, prior diagnoses and family history if this information has been entered into the patient's medical record. For example, an average-risk patient who is 50 years old with no prior screening history will be forecast to receive some form of CRC screening. If the patient successfully completes an FOBT, he will be forecast for screening again in 12 months. However, if he undergoes colonoscopy and the result is negative, he will not be forecast to be screened again for 120 months (10 years).

For an office with EHR, the following roles and responsibilities should be considered: (see table on next page)



Role	Responsibility
Maintenance of Information Technology Infrastructure: computer systems, current version of RPMS/EHR	Information Technology Site Manager
Display of Clinical Reminders	Clinical Applications Coordinator (CAC)
Training in use of EHR, including clinical reminders	CAC
Review of CRC Clinical Reminders at every visit	RN/LPN or MA/NA interacting with patient during clinic visit
Initial offer of CRC screening	RN/LPN or MA/NA interacting with patient during clinic visit
Follow-up of CRC Screening offered	RN or LPN case manager
Follow-up of refusals	Primary Care Provider
Discussion of positive results, referral for specialty care or further testing as needed	Primary Care Provider in collaboration with RN/LPN case manager
Patient Education	Entire care team has a responsibility to educate the patient according to the patient's readiness to learn
Pre-test	RN/LPN or MA/NA interacting with patient during clinic visit
Post-test	Primary Care Provider in collaboration with RN/LPN case manager

Even without EHR, clinics using RPMS can readily assign and perform these same roles and responsibilities if they make use of the Health Summary at each visit. The Health Summary is a feature within RPMS that can be customized to display the latest information on a variety of clinical conditions, including recommended screenings. In the absence of a full EHR with clinical reminders, a fully optimized health summary for each patient with up to date clinical information can be quickly reviewed at the start of every clinic visit to determine the need for CRC screening.

Ideally, care teams are established that provide a mechanism for good collaboration between nurses, medical/nursing assistants and primary care providers. Patients are assigned to these teams making it clear which primary care team is responsible for routine screenings, including CRC screening. Methods can be optimized within each team to provide



appropriate education, testing, referral and follow-up. The key to effective care teams is open communication in addition to each team member understanding his or her roles and responsibilities. Data can provide opportunities to discuss completeness and adequacy of screening, identify areas where improvement is needed and motivate all team members to do their best to provide optimal preventive care.

Overcoming Barriers

Patients will often identify barriers to screening if asked during the clinic visit. Common barriers include: misunderstanding of how to collect samples (FOBT/FIT), embarrassment regarding handling of stool samples (FOBT/FIT), discomfort related to bowel preparations (flexible sigmoidoscopy, colonoscopy, barium enema, CT colonography), fear or discomfort related to the test itself (flexible sigmoidoscopy, colonoscopy) fear of the test result (all forms of screening).

To overcome these barriers, the care team members must first develop a relationship of trust with the patient. Once rapport is established, education and materials can be provided. For some, the best form of education is through the use of models or other demonstrations. For others, brochures, drawings or other materials work best. Multimedia resources that show AI/AN people talking about their experience and the importance of screening have been used successfully in many communities. A questionnaire to help identify a patient's stage of readiness to accept CRC screening is available in the tool box, 8.1.4

Developing Screening Program Measures and Goals

Goals for CRC screening may be developed according to local needs but may also be dictated by external mandates such as GPRA or Meaningful Use. Examples of local measures that could be tracked include:

- Number of patients eligible for screening seen in one month (by any test or by a specific test)
- Percent of eligible patients screened in one month (by any test or by a specific test)
- Number/percent of refusals
- Number/percent of FOBT/FIT test kits not returned in one month

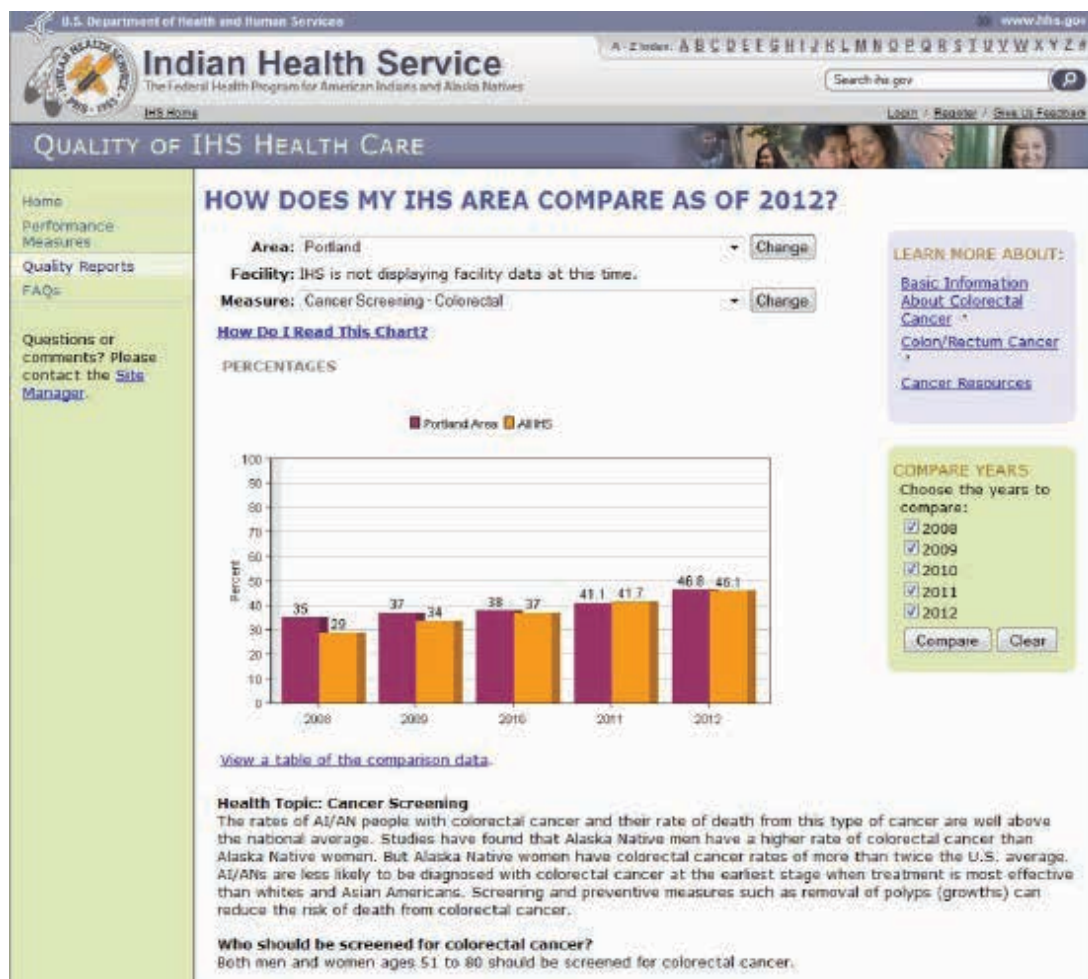


- Percent of patients referred for colonoscopy who complete the exam within 30 days

Local measures such as these can help track progress on important steps in the process of CRC screening.

The primary external measures for CRC screening developed through GPRA are displayed in the Appendix at the end of this chapter. These measures are reported for all IHS sites and many Tribal sites and can be found aggregated by area on the IHS Quality of Care website at:

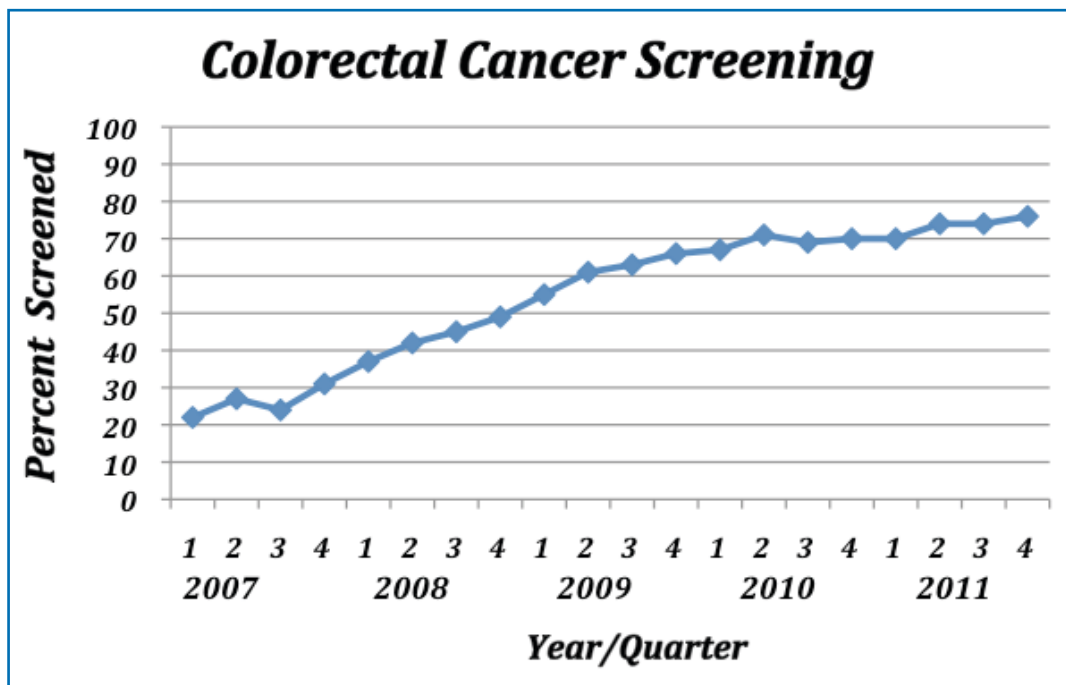
<http://www.ihs.gov/qualityofcare/index.cfm>



Tools for Improvement

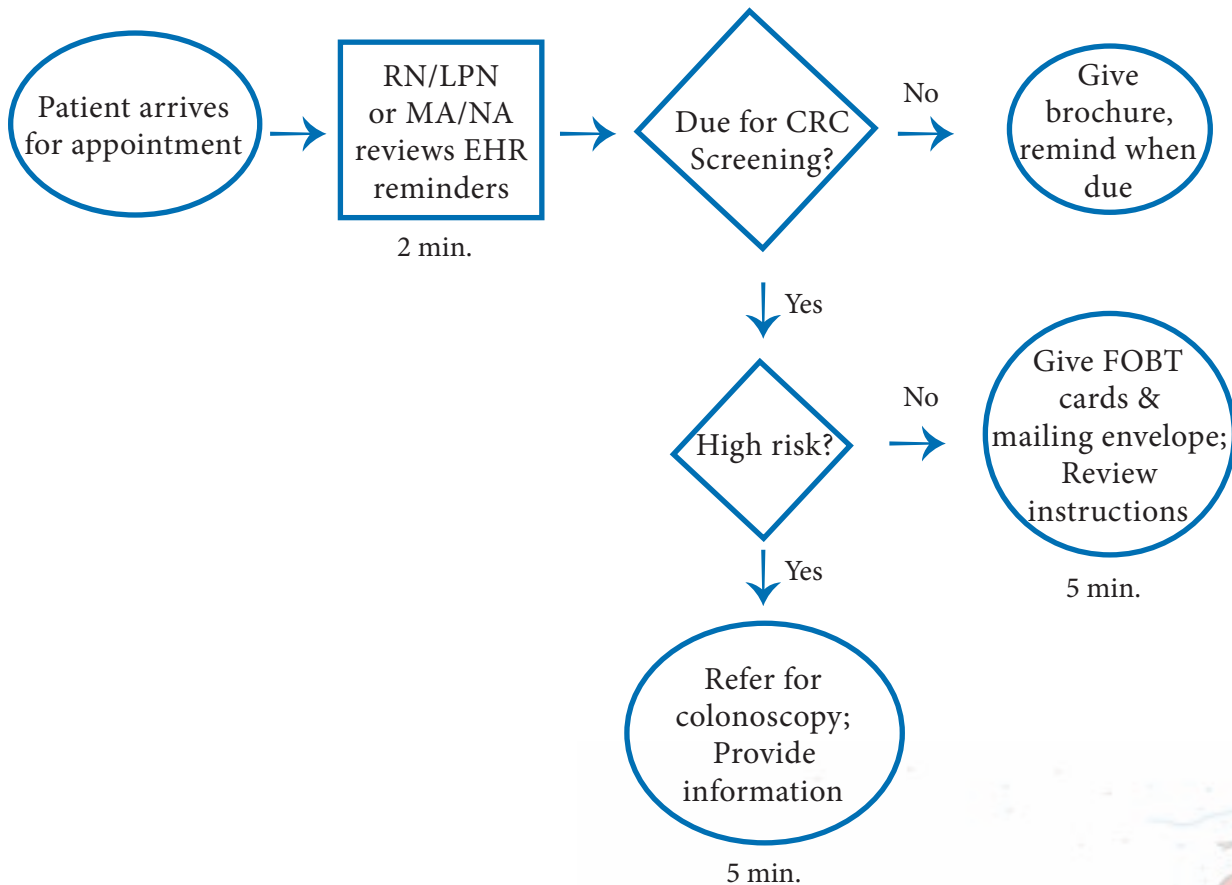
Data: The RPMS application, iCare, was developed to facilitate the management of patients assigned to a care team or to manage groups of patients with the same disease conditions such as diabetes, hypertension, rheumatoid arthritis, asthma and many more. Clinics with established primary care teams have successfully used iCare to identify patients in their panels who are in need of a variety of screenings, diagnostic tests or treatment regimens. By reviewing these patient panels with iCare, those patients who have not been in the clinic recently but who are due for CRC screening can be identified. Letters or phone calls can then be used to encourage them to be screened.

Data generated from iCare or from custom RPMS queries using QMAN can be exported to programs like Microsoft Excel to create graphs showing screening rates over time by provider or care team. These graphs can be used to provide valuable information for teams to improve their performance.



Process Mapping: Process mapping is a technique in which a clinical process such as patient registration, immunization services or screening is mapped out showing each individual step that must occur to complete the process. Once a process is mapped, the care team can evaluate the complexity of the process and look for opportunities to streamline. One way to start mapping a process is to walk through a typical clinic visit as a patient, either by shadowing a patient or giving a patient a form to fill in the steps and times for each step. Once the initial data is obtained, a visual map is created showing each step in the process and the amount of time taken. Tool 8.2.1 is a worksheet for process mapping.

Sample of Process Map

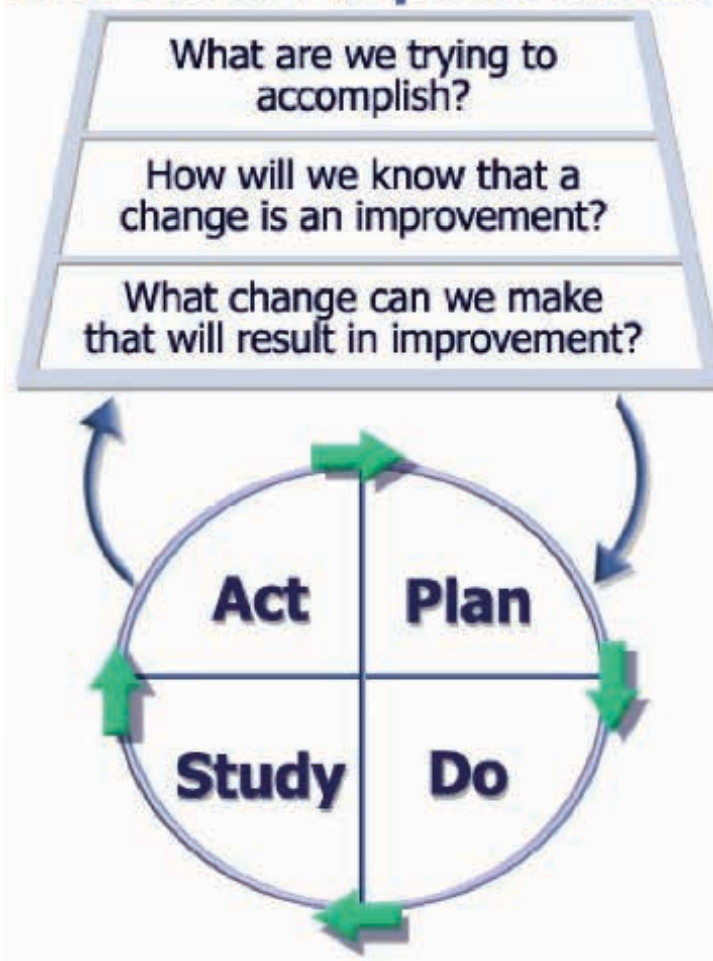


Model for Improvement: The Model for Improvement asks three fundamental questions of any improvement effort:

1. What are we trying to accomplish?
2. How will we know that a change is an improvement?
3. What change can we make that will result in an improvement?

A key strategy in quality improvement is to make small changes, sequentially, on small numbers of patients until a process is refined and ready to be implemented. This can be done through the Plan-Do-Study-Act cycle. Tool 8.2.2 is a worksheet for planning and documenting PDSA cycles. Key points for using the Model for Improvement are to be very specific, focus on small tests with just a few patients over just 1 or 2 days. It is vitally important to include a prediction

Model for Improvement



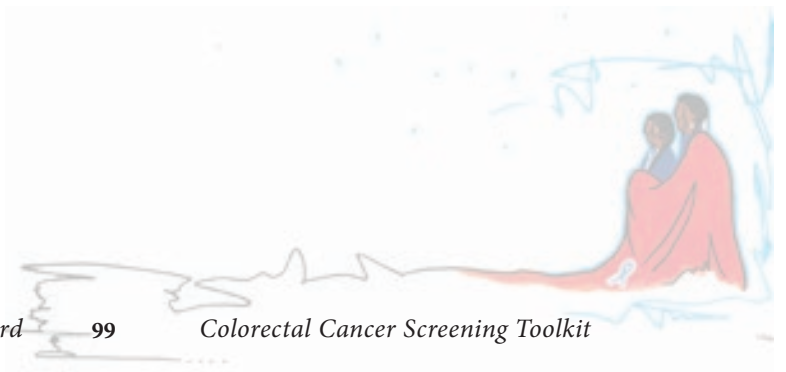
of what will happen before performing the test cycle and to include measureable data that can be readily collected and easily analyzed¹¹.

Section Summary

This section provides the rationale and descriptions of recommended methods for CRC Screening from a clinical perspective. To build a successful CRC screening program, it is important to identify resources to pay for screening, assign team roles and responsibilities, overcome barriers and develop measures for tracking progress. Helpful tools for developing a CRC screening program, specifically, as well as general quality improvement steps were included.

Additional Resources

1. Colorectal Cancer Screening Algorithm. Harvard University. Available at: <https://www.rmhf.harvard.edu/Clinician-Resources/Guidelines-Algorithms/2010/Colorectal-Cancer-Screening-Algorithm>
2. How to Increase Colorectal Cancer Screening Rates in Practice: A Primary Care Clinician's* Evidence-Based Toolbox and Guide 2008. American Cancer Society. Available at: <http://www.cancer.org/healthy/informationforhealthcareprofessionals/colonmdcliniciansinformationsource/cancerscreeningactionplan/index>
3. National Conference of State Legislatures: Colorectal Cancer Screening: What are States Doing? Updated: August 2011. Available at: <http://www.ncsl.org/default.aspx?tabid=14328>



Tool Box Description

8.1 _____

Colorectal Cancer Screening Tools

These tools include screening checklist and algorithms that can be given to providers or posted in exam rooms

8.1.1 Colorectal Cancer Screening Checklist

8.1.2 Risk-based Colorectal Cancer Screening Algorithm

8.1.3 Algorithm for FOBT/FIT-Based Colorectal Cancer Screening

8.1.4 Brief Questionnaire Identify Decision Stage- this tool can help determine a patient's readiness to make a decision about CRC screening. Also available at

<http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-028273.pdf>

8.2 _____

Quality Improvement Tools

These tools can be used to help improve any clinical process and may be especially helpful for identifying and guiding quality improvement initiatives to improve Colorectal Cancer Screening.

8.2.1 Process Mapping Worksheet

8.2.2 Plan-Do-Study-Act (PDSA) Worksheet

8.2.3 Clinical Reporting System measures for CRC screening, Version 13. Full documentation available at:

http://www.ihs.gov/RPMS/PackageDocs/BGP/bgp_1300.01u_logicselected.pdf

