



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 14-04754-407

Healthcare Inspection

Alleged Colorectal Cancer Screening and Administrative Issues VA Palo Alto Health Care System Palo Alto, California

July 9, 2015

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:

Telephone: 1-800-488-8244

E-Mail: vaoighotline@va.gov

Web site: www.va.gov/oig

Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection at the request of Congresswoman Jackie Speier in response to complaints about the colorectal cancer screening process and other administrative issues at the VA Palo Alto Health Care System (system), Palo Alto, CA. The purpose of this inspection was to determine the merit of the allegations.

The complainant alleged that the use of fecal immunochemical test (FIT) was substandard care for colorectal cancer screening, that the nearby community medical groups did not use it, and that FIT was a poor substitute for colonoscopy. We found the system implemented FIT for screening and that the use of FIT was consistent with current literature and VA and community recommendations.

The complainant alleged that an erroneous letter implying that FIT and colonoscopy were equal tests was sent to patients with the purported author's signature block but without the individual's permission. We substantiated this allegation. Patients no longer receive this letter as of January 2014.

The complainant alleged that the FIT machine sensitivity was low and can be manipulated. We did not substantiate this allegation, as the value was pre-set by the manufacturer.

The complainant alleged that patients were not given a choice of FIT or colonoscopy for colorectal cancer screening. We did not substantiate this allegation, as primary care providers discussed the risks and benefits of both modalities with patients during clinic encounters before ordering tests.

We recommended that the System Director implement procedures to prevent the unauthorized use of individuals' signature blocks on form letters.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendation and provided an acceptable action plan. (See Appendixes B and C, pages 15–17 for the Directors' comments.) We consider the recommendation closed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection at the request of Congresswoman Jackie Speier. The purpose of the review was to assess the validity of allegations about the colorectal cancer (CRC) screening process and other administrative issues at the VA Palo Alto Health Care System (system), Palo Alto, CA.

Background

VA Palo Alto Health Care System

The system provides a wide range of tertiary care services in northern California, including colorectal cancer screening. It comprises three inpatient facilities in Palo Alto, Menlo Park, and Livermore¹ and seven community based outpatient clinics (CBOCs) located in San Jose, Fremont, Capitola, Monterey, Stockton, Modesto, and Sonora. Geographically, the catchment area spans 131 miles east from the Palo Alto hospital to the Sonora CBOC and 83 miles south to the Monterey CBOC.² It operates almost 900 inpatient beds, including three nursing homes and a 100-bed domiciliary, serving 85,000 enrolled veterans and is part of Veterans Integrated Service Network (VISN 21).

The VA Palo Alto Hospital (facility) is a teaching facility in the system, partnering with nearby Stanford University to provide a range of patient care services including medicine, surgery, psychiatry, rehabilitation, neurology, oncology, dentistry, geriatrics, and extended care. The Gastroenterology (GI) Section falls under the medicine department and has five full-time and three part-time physicians with two consultants. Four of these physicians perform colonoscopies. At the time of the site visit, the medicine department was recruiting for a chief of the GI Section.

Colorectal Cancer Screening

CRC is the third most commonly diagnosed cancer and third leading cause of cancer deaths in the United States regardless of gender. In 2014, about 136,830 people were predicted to be diagnosed while 50,310 people were predicted to die of the disease according to the American Cancer Society.³ In recent years, the mortality from CRC has been steadily decreasing. From 2008 to 2010, incidence rates have decreased by greater than 4 percent per year. These findings are generally attributed to the increased screening and detection for CRC.

The United States Preventive Services Task Force (USPSTF)⁴ lists a grade A

¹ VAPAHC website, <http://www.paloalto.va.gov/about/index.asp>. Accessed 10/7/2014.

² Google Map. Accessed 10/7/2014.

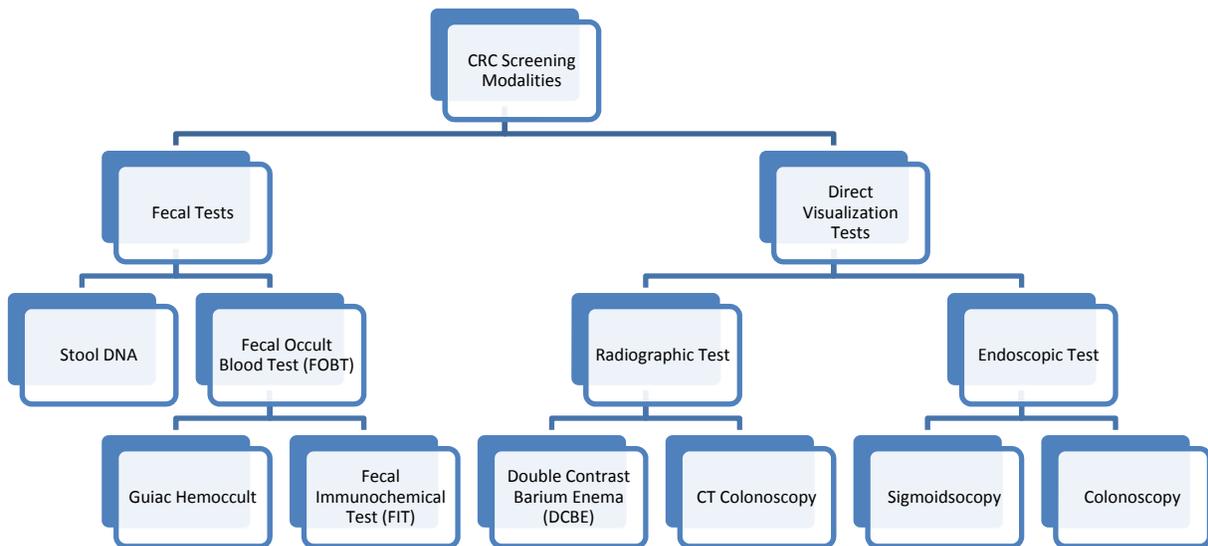
³ American Cancer Society. *Colorectal Cancer Facts & Figures 2014–2016*. Atlanta: American Cancer Society, 2014.

⁴ The USPSTF includes experts in primary care that make evidence-based recommendations to guide clinicians and patients on best practices in preventive medicine.

recommendation⁵ for colorectal screening for all adults ages 50–75.⁶ USPSTF recommends against routine screening in adults ages 76–85, but it may be considered on an individual basis. USPSTF also recommends against screening patients older than 85. High risk patients with a history of CRC cancer, inflammatory bowel disease, or an inherited family history of colon cancer are excluded from the guideline.

Screening methods fall broadly into two groups (Figure 1). One category collects stool specimens for fecal testing to detect CRC, while the other directly visualizes the large intestine to detect CRC and premalignant changes. All fecal tests that are positive require a follow-up colonoscopy for confirmation and biopsy. Some precancerous polyps⁷ may be detected on follow-up colonoscopy, but the opportunity for prevention of CRC using stool testing is limited. In contrast, the other category involves direct visualization tests that can examine the structure of the colon and detect more precancerous polyps and CRC.⁸

Figure1. Colorectal Cancer Screening Modalities



Source: OIG analysis of relevant literature⁹

⁵ Healthcare practice guidelines use four grades of recommendations that are based on the strength of the research. Grade A is the strongest recommendation, taken typically directly from several randomized clinical control trials.

⁶ U.S. Preventative Services Task Force (USPSTF). *Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement*. Ann Intern Med. 2008; 149:627–637.

⁷ Polyps are small clumps of cells on the lining of the colon. Most are harmless, but some develop into cancers.

⁸ Bernard Levin, et al. Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline From the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. Gastroenterology 2008; 134 (5): 1570–1595.

⁹ USPSTF. *Recommendation Statement*, 2008; Robert Fletcher. *Tests for Screening for Colorectal Cancer: Stool Tests, Radiologic Imaging, and Endoscopy*. http://www.uptodate.com/contents/tests-for-screening-for-colorectal-cancer-stool-tests-radiologic-imaging-and-endoscopy?source=search_result&search=colorectal+cancer+screening&selectedTitle=3%7E65. Accessed: 9/26/2014

Fecal Testing. Fecal tests include DNA tests and fecal occult blood tests (FOBT). Both are noninvasive with minimal adverse effects. Stool DNA tests look for precancerous or cancerous DNA changes in the cells, but the USPSTF concludes that there is currently insufficient outcomes data to support the use of the test.¹⁰ FOBT screens for occult blood and needs to be repeated yearly.

The two types of FOBT are guaiac hemoccult and fecal immunochemical test (FIT). (Some literature, including the VA CRC screening directive, uses the terms FOBT and guaiac hemoccult interchangeably.) The older guaiac hemoccult tests use the resin of the guaiacum tree to detect the presence of bleeding, without discriminating between animal and human hemoglobin (a component of blood), and requires three samples.

In contrast, FIT is a newer type of stool test that only screens human blood, needs a single sample, and is not limited by diet or anticoagulant use. Unlike hemoccult testing, which is subject to the technician's interpretation of the color change, FIT is quantitatively measured, but the results are qualitatively reported by a machine with a preset threshold as positive or negative.

Direct Visualization Testing. For all direct visualization tests, patients must take a bowel preparation medication to clean out the stool. One type of direct visualization test includes radiologic tests such as double contrast barium enema (DCBE) and computerized tomography (CT) colonoscopy (also known as virtual colonoscopy).

The other type of direct visualization test includes endoscopic tests that involve inserting a small, long, flexible tube with a camera at the tip into the anus to visualize the inside of the colon. Patients must stop taking anticoagulants prior to the procedure to limit the risk of bleeding. For sigmoidoscopy, the camera examines the portion of the colon closest to the anus while in a colonoscopy, it traverses the entire colon. Colonoscopy is generally performed by a gastroenterologist who can excise any visualized abnormalities for biopsy. Although this test is diagnostic and therapeutic for the detection and prevention of CRC, patient adherence rates are low. Adverse events with this invasive test are higher than other CRC screening tests. A 2008 report of pooled data from 12 prospective studies indicated that serious complications occurred 2.8 times per 1,000 procedures.¹¹ Adverse events occurred more frequently in patients who required polyp removal, older patients, and those with diabetes, stroke, lung disease, and heart failure.¹²

CRC Screening. While CRC screening has resulted in large declines in cancer incidence and mortality in recent years, only 59 percent of patients meeting criteria for

¹⁰ Evelyn Whitlock, et al. *Screening for Colorectal Cancer: A Targeted, Updated Systematic Review for the U.S. Preventative Services Task Force.* Ann Intern Med. 2008; 149:638–658.

¹¹ Whitlock, et al. 2008. Pooled data from 12 prospective studies evaluated significant complications from screening colonoscopy on predominately asymptomatic individuals. Serious complications were defined as perforation, bleeding, heart problems, diverticulitis (infection of the intestinal wall), severe abdominal pain, or death.

¹² Fletcher. Accessed 9/26/2014.

screening reported having testing consistent with the current guidelines.¹³ Clear recommendations on the screening population exist, but there is little consensus on how best to screen for CRC. The US Multi-Society Task Force on Colorectal Cancer, American Cancer Society, and American College of Radiology recommend one of the following methods:¹⁴

- guaiac hemoccult or FIT annually,
- colonoscopy every 10 years,
- other direct visualization tests every 5 years, or
- stool DNA testing at an unspecified interval.

In contrast, the USPSTF, finding insufficient evidence to recommend direct visualization tests other than colonoscopy, recommends one of the following methods:¹⁵

- annual FOBT,
- flexible sigmoidoscopy every 5 years with FOBT every 3 years, or
- colonoscopy every 10 years.

The American Gastroenterological Association recommends colonoscopy as the preferred test for CRC screening, as “It is the strong opinion of this expert panel that *colon cancer prevention* should be the primary goal of CRC screening.”¹⁶

Regarding which screening test is best, USPSTF recommends:

Because several screening strategies have similar efficacy, efforts to reduce colon cancer deaths should focus on implementation of strategies that maximize the number of individuals who get screening of some type. The different options for colorectal cancer screening tests are variably acceptable to patients; eliciting patient preferences is one step in improving adherence. Ideally, shared decision making between clinicians and patients would incorporate information on local test availability and quality as well as patient preference.”¹⁷ Higher patient participation rates with fecal testing may ultimately increase rates of CRC detection.¹⁸

¹³ American Cancer Society. 2014.

¹⁴ Fletcher. Accessed 9/26/2014.

¹⁵ USPSTF *Recommendation Statement*. 2008.

¹⁶ Levin, et al. 2008.

¹⁷ U.S. Preventative Services Task Force. 2008.

¹⁸ Enrique Quintero, et al. *Colonoscopy versus Fecal Immunochemical Testing in Colorectal-Cancer Screening*. N Engl J Med 2012;366:697–706.

Veteran's Health Administration (VHA) Directive 2007-004 on CRC screening does not specify the preferred modality for CRC screening. Rather, it describes options for CRC screening in asymptomatic patients, which include:¹⁹

- three consecutive FOBT every year,
- flexible sigmoidoscopy every 5 years,
- home FOBT every year plus flexible sigmoidoscopy every 5 years, or
- double contrast barium enema or colonoscopy every 10 years.

While not in effect at the time of the events of this report, an updated VHA CRC screening directive was published emphasizing more flexibility in screening options and the importance of shared decision making between patients and providers.²⁰ It explicitly states: "there is insufficient evidence to recommend one screening strategy over another as each strategy has certain advantages and disadvantages." It also clarified that patients with positive screening tests (other than colonoscopy) should have a follow-up colonoscopy. The updated directive included methods for monitoring colonoscopy quality and optimizing bowel preparation to limit missed abnormalities.

Allegations

On June 20, 2014, OIG received allegations about the GI Section at the system. After a phone call and an in-person meeting with the complainant, we refined the allegations to:

- The use of FIT is substandard care; community medical groups did not use FIT.
- A signed letter was sent to patients without the purported author's permission, implying that FIT and colonoscopy were equal.
- FIT machine sensitivity is low and can be manually manipulated.
- Patients are not given a choice of FIT or colonoscopy for CRC screening.

The complainant made a fifth allegation regarding work environment and personnel issues that we did not address, as it was outside our purview.

Scope and Methodology

We interviewed the complainant by phone on September 2 and in-person on September 23, 2014, to better understand the allegations. We visited the facility from September 23 to 24, 2014. We interviewed relevant clinical and administrative personnel including the Chief of Staff, Deputy Chief of Staff, Medicine Service Chief, two staff gastroenterologists, two Chiefs of Primary Care, the Chief of Pathology and

¹⁹ VHA Directive 2007-004, *Colorectal Cancer Screening*.

²⁰ VHA Directive 1015, *Colorectal Cancer Screening*.

Laboratory Medicine Services, and the Lab Manager. We reviewed the CRC screening recommendations at the system and discussed the process of obtaining screening. We also conducted a phone interview with the VA National Director of Gastroenterology.

We further determined the screening practices at nearby facilities through interviews, local news articles, and published journal articles. We reviewed the VA recommendations for CRC screening in effect at the time of the complaint. We performed a literature review of the current national recommendations for CRC screening, specifically focusing on FIT and colonoscopy.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Use of FIT for CRC Screening

We found that the system implemented FIT for CRC screening. We did not substantiate that the use of FIT was substandard care.

We found that, historically, colonoscopy had been the modality of choice for CRC screening at the system. However, when the number of patients requiring screening began to increase, staff expressed concern that the system did not have enough gastroenterologists to perform the number of colonoscopies needed. As a result of this concern, in the first half of 2013, the system's primary care and GI medical sections jointly agreed to offer either FIT or colonoscopy to patients despite resistance from some GI physicians. On June 7, 2013, FIT with the Polymedco OC Auto Micro 80 machine was approved for use in the lab.

To implement this new policy, physician staff developed a CRC screening clinical reminder in the Computerized Patient Record System (CPRS) to assist primary care providers in screening eligible patients (see Appendix A). Primary care providers were informed of the policy changes during monthly staff meetings. With the new process, patients were given a choice between FIT and colonoscopy, and they could choose the modality after having informed discussions with their primary care providers. If the FIT was positive, the ordering provider would be alerted in CPRS, and he/she would order a colonoscopy for follow-up.

The complainant alleged that the system was not following community practice patterns. We found that CRC screening practices in non-VA northern California health care groups were not consistent. Northern California Kaiser members ages 50–75 receive a mailed FIT as the primary screening modality. After instituting this practice, the Kaiser medical group found that colorectal cancer screening rates went from less than

40 percent in 2005 to greater than 80 percent in 2012.²¹ Those who have a positive FIT receive a follow-up colonoscopy. The nearby Stanford Health Care Group follows the Kaiser model. In contrast, Palo Alto Medical Foundation, the largest multispecialty private practice group in the area, recommends colonoscopies for screening.²²

VA facilities also employ different modalities of screening (Table 1). Data from OIG's 2013 *Combined Assessment Program Summary Report on Evaluation of Colorectal Cancer Screening and Follow-Up in Veterans Health Administration Facilities*²³ found that 16 out of 53 VA facilities in the country use FIT as the preferred screening modality, either alone or in combination with other modalities. Because VA recognizes a number of different CRC screening methods, differences in screening methods at the facility level do not violate VA policy.

Table 1. Preferred CRC Screening Modalities in VA Facilities

Preferred Modality for CRC Screening	Number of Facilities	Percentage of Total Inspections
FOBT* only	17	32%
FIT only	11	21%
FOBT + Colonoscopy	9	17%
Colonoscopy only	7	13%
FIT + Colonoscopy	3	6%
FOBT + Sigmoidoscopy	2	4%
FIT + FOBT + Colonoscopy	1	2%
FOBT + FIT	1	2%
FOBT + DCBE + Colonoscopy	1	2%
FOBT + DCBE + Sigmoidoscopy	1	2%
Total Facilities	53	**

Source: VAOIG

*FOBT refers to guaiac hemocult testing. **May not add up to 100% due to rounding.

The USPSTF, US Multi-Society Task Force on Colorectal Cancer, American Cancer Society, and American College of Radiology support the use of FIT for CRC screening.

²¹Sandy Kleffman. Kaiser Permanente research method has potential to transform U.S. Health Care System. http://www.mercurynews.com/News/ci_23416589/Kaiser-Permanente-research-method-has-potential. Theodore Levin. A Systematic Approach to Colorectal Cancer Screening. <http://www.gastro.org/journals-publications/aga-perspectives/februarymarch2014/a-systematic-approach-to-colorectal-cancer-screening#27>. Both Accessed 9/26/2014.

²² Palo Alto Medical Group Colon Cancer Screening and Prevention. <http://www.pamf.org/gastroenterology/services/screenings.html>. Accessed 2/9/2015.

²³ Report No. 13-01741-215, June 12, 2013.

According to the VA national GI program director, a VA clinical trial (“CONFIRM”) is currently underway which will provide more information on the effectiveness of FIT compared to colonoscopy.²⁴

Issue 2: Unauthorized Letters Sent to Patients

We substantiated the allegation that letters were sent to patients with the purported author’s signature block without the individual’s review and approval of the content or permission to use the signature. From June 1, 2013, to January 31, 2014, letters with the signature block were sent to 1,442 patients advising them of the need for CRC screening. The letter stated:

Dear Veteran,

Your primary care doctor has prepared a consult recommending that you receive colon cancer screening using either a stool test (FIT test) or a colonoscopy.

Please call the Palo Alto GI Endoscopy Center within 7 business days of receipt of this letter to indicate if you are interested in having the test done.

Our phone number is 650-493-5000, [extension]. If you call when the office is closed, you may leave a message on voicemail with the following information:

- Your first and last name.*
- The last 4 numbers of your social security number.*
- Your phone number including area code.*
- The best time to reach you at home.*

Thank you,

[name and title]

While the textual content of the letter was appropriate for informing patients about testing options, it implied that FIT and colonoscopy were equal tests—a position that the author did not support. The author believed that colonoscopy should continue to be the system’s primary CRC screening modality, as it could prevent cancers and had been the traditional practice at the system and nearby VA San Francisco.

We determined that GI physicians composed the letter under the auspices of the Chief of Medicine. According to one physician, the letter was automatically sent to every patient who had a GI consult placed for CRC screening by his/her PCP. However, that

²⁴ CONFIRM stands for Colonoscopy versus FIT in Reducing Mortality from colon cancer. It will randomize 50,000 veterans to either FIT or colonoscopy for CRC screening and follow them for 10 years to determine the rates of colon cancer mortality. It is currently enrolling patients and anticipates completion of the study by 2025. <http://www.clinicaltrials.gov/ct2/show/NCT01239082?term=CONFIRM&rank=20>. Accessed 10/15/2014.

practice has since been changed. Now, when a patient needs CRC screening, the primary care physician places the order for FIT or colonoscopy. Patients no longer receive the GI screening letter.

We substantiated that the individual whose name and title appeared on the letter did not authorize the use of the name or title. We received information confirming the System Director's acknowledgement of this practice, instructions to appropriate personnel to curtail the practice, and eventual apology to the purported author for the unauthorized use of that individual's name.

Issue 3: Sensitivity of FIT Machine and Manipulation of FIT Results

We did not substantiate the allegation that the FIT machine sensitivity was low and that the results could be manipulated.

The complainant alleged that the FIT machine threshold for a positive test could be manually manipulated, which could lead to a decreased number of positive results. The Chief of Pathology and the lab manager at the system confirmed that the Polymedco machine threshold could not be manually adjusted. The sensitivity threshold of 100ng/ml (nanograms per milliliter) was pre-set by the company. The complainant further alleged that FIT only had a sensitivity of 80 percent, but the Polymedco data submitted to the US Food and Drug Administration stated that at the pre-set 100ng/ml threshold, the sensitivity²⁵ was 96.11 percent and specificity²⁶ 99.33 percent.²⁷

Issue 4: Patients Not Given a Choice of FIT or Colonoscopy for CRC Screening

We did not substantiate the allegation that patients were not given a choice between FIT and colonoscopy for CRC screening.

According to multiple primary care physicians, the Chief of Medicine, and the Deputy Chief of Staff, patients were given a choice. During the primary care clinic visit, the provider discussed the risk and benefit of each modality and jointly decided the most appropriate test with the patient. The CRC Screening Clinical Reminder presents choices for screening including FIT and colonoscopy. It alerts the provider to discuss the choice with the patient (see Appendix A). The CRC screening letter sent to patients from June 2013 to January 2014 also stated patients have a choice between FIT and colonoscopy.

Conclusions

We did not substantiate the allegation that use of FIT constituted substandard care. CRC screening using FIT was consistent with VHA policy and national screening

²⁵ Sensitivity denotes a test's ability to find true positives.

²⁶ Specificity denotes a test's ability to find true negatives.

²⁷ Polymedco OC Auto Micro 80 Analyzer FDA Summary.

http://www.accessdata.fda.gov/cdrh_docs/reviews/K041408.pdf. Accessed 2/9/2015

guidelines. The system has followed USPSTF recommendations that: “Efforts ... should focus on implementation of strategies that maximize the number of individuals who get screening of some type.”²⁸

We substantiated the allegation that a letter was sent to patients using the purported author’s name without permission implying that FIT and colonoscopy were equally effective. There was a valid concern that the author’s name was used on a letter that suggested a position that the author did not support.

We did not substantiate that FIT machine sensitivity was low and the threshold could be manipulated. We also found that patients were given a choice between FIT and colonoscopy for CRC screening.

Recommendation

1. We recommended that the System Director implement procedures to prevent the unauthorized use of individuals’ signature blocks on form letters.

²⁸ U.S. Preventative Services Task Force. 2008.

CRC Screening Clinical Reminder

COLORECTAL CANCER SCREENING PROTOCOL 6/2013

Click for screening guidelines (FIT vs colonoscopy)

Record outside procedures or uncoded procedures at VAPAHCS (Note: figure after procedure is duration of time after which average risk veteran (age <75) would need next screening given no abnormal findings.)

Colonoscopy (10 years)
 Flexible Sigmoidoscopy (5 years)
 FIT X 1 (1 year)
 FOBT X 3 (1 year)
 Barium enema (5 years)
 CT colonography (5 years)

Order screening now, set interval for future screening, or choose other options.

Order FIT now
 Order colonoscopy now.
 Request GI service to recommend need for screening or screen interval, or to discuss FIT vs colonoscopy with veteran (choose E-consult).

Clear Clinical Maint Visit Info < Back Next > Finish Cancel

Colorectal Cancer Screen:
Colorectal Cancer Screen

<No encounter information entered>

* Indicates a Required Field

Continued on next page

COLORECTAL CANCER SCREENING PROTOCOL 6/2013

[Click for screening guidelines \(FIT vs colonoscopy\)](#)

Recommendations

****Average CRC risk, no special considerations:**

Fecal immunochemical testing (FIT) q1y or colonoscopy q10y

****Increased risk due to positive family history (excluding familial colon cancer syndromes):**

Colonoscopy q5y; annual FIT is reasonable alternative. Screening should begin at age 40, or 10 years before the youngest relative's diagnosis, whichever is earlier.

(Definition of a positive family history: A single first-degree relative diagnosed with CRC or an advanced adenoma (≥ 1 cm, or with high-grade dysplasia or villous elements), or two or more first degree relatives with CRC or advanced adenomas at any age)

****Highest risk (including familial colon cancer syndromes, prior personal history of colon cancer, inflammatory bowel disease):**

Colonoscopy is preferred

****Patients on warfarin, direct thrombin inhibitors, clopidoprel, and aspirin/dipyridamole:**

FIT is preferred

****Patients at increased risk from conscious sedation (includes recent MI and stents):**

FIT is preferred

Continued on next page

Order a Lab Test

Available Lab Tests: OCCULT BLOOD FIT (x1SCREEN)
 OCCULT BLOOD FIT (x1SCREEN) ▲
 OCCULT BLOOD Guaiacx1 R1
 OCCULT BLOOD Guaiacx1 S1
 OCCULT BLOOD(InPTorSTAT
 OCULAR LARVA MIGRANS <
 Oculopharyngeal muscular dys
 OGTT <GTT (HYPOGLYCE
 OGTT <2HR OGTT*(FOR C >

OCCULT BLOOD FIT (x1SCREEN)

Collect Sample: FIT COLLECTIOI
 Specimen: FECES
 Urgency: ROUTINE

Collection Type: Ward Collect
 Collection Date/Time: NOW
 How Often?: ONE TIME
 How Long?:

0  Fecal Immunochemical Test (iFOBT). Colorectal cancer screen. No dietary/medicinal restrictions, 1 sample. Replaces 3 card quaiac (qFOBT) panel.

Accept Order
 Quit

Colorectal Cancer screening guidelines for average risk patients:

- 1) Age 50-75: Fecal Immunochemical Test (FIT) every year, or Colonoscopy every 10 years
- 2) Age 76-85: no routine colorectal screening indicated: there may be considerations that support colorectal cancer screening in an individual patient.
- 3) > age 85: no colorectal cancer screening indicated
- 4) Severe comorbidities (advanced CHF, COPD, life expectancy < 5 years): no routine colorectal screening indicated, potential harm may outweigh benefits
- 5) Recent event which may increase risk of colonoscopy or sedation (MI, PE, etc): Perform FIT, or defer colonoscopy, if possible.

Continued on next page

SCREENING/SURVEILLANCE: Veteran needs non-urgent colon cancer screening, including surveillance because of prior adenomatous polyps or cancer.

Click for screening guidelines (FIT vs colonoscopy)!

Annual fecal immunochemical testing (FIT) and Colonoscopy (q 10 years for average risk) and are both considered effective screening modalities for colorectal cancer. The advantages of FIT are lower risk (risk of perforation with colonoscopy is 1 in 2000), no patient discomfort, and lower cost/resource utilization. Unlike the FOBT test, FIT only requires submission of a single specimen, and no dietary restrictions are needed. The advantages of colonoscopy are a somewhat higher sensitivity, especially for advanced adenomas, the ability to remove polyps at the time of screening, and the need for less frequent screening.

FIT is generally the preferred procedure for patients on warfarin, direct thrombin inhibitors, clopidogrel, or aspirin/dipyridamole, and for patients who may be at increased risk from sedation or an invasive procedure (e.g. recent MI). FIT may also be preferred for patients who tolerate Golytely poorly, who have had suboptimal preps in the past, or who have concerns about the risks or discomfort associated with colonoscopy.

Colonoscopy is the preferred procedure for the highest risk patients (familial colon cancer syndrome, prior personal history of colon cancer, IBD) and for surveillance of patients who had the removal of more than 2 adenomas, or large (> 1 cm) adenoma(s) at their previous colonoscopy. Colonoscopy may also be preferred for other veterans at increased risk, including patients with a family history of cancer or advanced adenomas in a first degree relative, but if the veteran prefers FIT, this is a reasonable alternative.

Request colonoscopy (To order FIT, please cancel this consult and enter Lab order)

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: April 17, 2015

From: Director, Sierra Pacific Network (10N21)

Subj: Healthcare Inspection—Alleged Colorectal Cancer Screening and Administrative Issues, VA Palo Alto Health Care System, Palo Alto, California

To: Director, Los Angeles Office of Healthcare Inspections (54LA)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. Thank you for the opportunity afforded to the VA Palo Alto Health Care System leadership to review the draft report regarding the subject above.
2. They have instituted a process that will require approval by the Service/Section Chief prior to use of a signature block on patient notification letters, which will prevent this from occurring in the future.
3. If you have any questions, please contact Terry Sanders, Associate Quality Manager for V21 at (707) 562-8370.

(original signed by:)

Sheila M. Cullen

Attachments

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 16, 2015

From: Director, VA Palo Alto Health Care System (640/00)

Subj: Healthcare Inspection—Alleged Colorectal Cancer Screening and Administrative Issues, VA Palo Alto Health Care System, Palo Alto, California

To: Director, Sierra Pacific Network (10N21)

1. I have reviewed the report and concur with the recommendations. Corrective action has been implemented to comply with the recommendations.

(original signed by:)

Elizabeth Joyce Freeman

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendation in the OIG report:

OIG Recommendation

Recommendation 1. We recommended that the System Director implement procedures to prevent the unauthorized use of individuals' signature blocks on form letters.

Concur

Target date for completion: Completed

Facility response: On January 16, 2014, the Health System Director instructed the Clinical Applications Coordinator to remove the name of the physician from notification letters sent from the Gastroenterology Department. No letters have been mailed with the unauthorized signature block since that date. The Chief of Staff Office has since instituted a requirement that patient letters used by a service will have the approval of the Section or Service Chief prior to the letters being used. Ongoing compliance with this requirement will be reported to the Medical Executive Board on, at least, an annual basis.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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