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Department of Veterans Affairs Veterans Health Administration Washington, DC 20420

VHA DIRECTIVE 2007-004

January 12, 2007

COLORECTAL CANCER SCREENING

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy on providing colorectal cancer (CRC) screening and follow-up timelines for VHA facilities.

2. BACKGROUND

a. CRC is the second leading cause of cancer death in the United States (U.S.). A person at age 50 years has approximately a 5 percent lifetime risk of being diagnosed with CRC and a 2.5 percent chance of dying from it. More than 80 percent of CRCs arise from adenomatous polyps. Although less than 1 percent of adenomatous polyps smaller than 1 centimeter develop into cancer, at least 10 percent of adenomatous polyps greater than 1 centimeter become malignant within 10 years, and about 25 percent become malignant after 20 years. The prevalence of adenomatous polyps increases steadily with age from 20-25 percent at age 50, to 50 percent by age 75-80.

b. Twenty percent of CRC occurs in patients with specific risk factors, such as a family history of CRC and inflammatory bowel disease.

c. The increasing demand for colonoscopy as the primary method for CRC screening and prevention coupled with the cost of treatment for CRC make the issue of CRC screening in the Department of Veterans Affairs (VA) a high priority (see Att. C).

d. Based on a review of the evidence and recommendations from various organizations, all eligible veterans at average or high risk for CRC who may benefit from screening need to be offered CRC screening. Unless the primary screening method is colonoscopy, any positive screening test (fecal occult blood test (FOBT), flexible sigmoidoscopy, or double contrast barium enema (DCBE)) must be followed up with full colonoscopy, unless contraindicated.

(1) A veteran of any age with signs or symptoms that suggest the presence of CRC, polyps, or other gastrointestinal disease must be immediately offered an appropriate <u>diagnostic</u> evaluation. *NOTE:* Screening guidelines do not apply in this circumstance.

(2) In asymptomatic patients, the appropriate approach to screening begins by determining the individual's level of risk based on family and personal medical history. Screening options for CRC include:

(a) Home FOBT alone every year (three consecutive stool samples).

(b) Flexible sigmoidoscopy alone every 5 years.

(c) Home FOBT every year combined with flexible sigmoidoscopy every 5 years.

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(d) DCBE every 5 years.

(e) Colonoscopy alone every 10 years.

NOTE: Each method has advantages and disadvantages but none has clearly been proven to be superior. The choice of specific screening strategy (absent medical contraindications to a particular method) needs to be based on patient preferences.

e. Definitions

(1) **High-risk Veteran.** A high-risk veteran is one with a family history of CRC in first-degree relatives (refers to a parent, sibling, or child) and those with a personal history of adenomatous polyps or inflammatory bowel disease.

(a) Veterans with a first-degree relative with CRC diagnosed at age less than 60 years of age, or two first-degree relatives diagnosed with CRC at any age, are to be advised to have a screening colonoscopy (unless medically contraindicated) starting at age 40 years or 10 years younger than the earliest diagnosis in their family, whichever comes first. *NOTE:* A colonoscopy needs to be repeated at least every 10 years.

(b) Veterans with a first-degree relative with CRC or adenomatous polyps diagnosed at ≥ 60 year, or with two second-degree relatives (grandparent, aunt, or uncle) with CRC may be advised to be screened beginning at age 40.

(c) Veterans with a personal history of adenomatous polyps or inflammatory bowel disease need to have a screening colonoscopy (unless medically contraindicated) at a starting age and intervals recommended by their physicians. *NOTE: The veteran needs to be advised accordingly.*

(2) Average-risk Veteran. An average-risk veteran refers to veterans age 50 or older. Eligible veterans at average risk need to be offered screening for CRC beginning at age 50. *NOTE:* Discontinuing screening is reasonable in patients whose age or comorbid conditions limit life expectancy.

3. POLICY: It is VHA policy that each eligible veteran at average or high risk for CRC must be offered CRC screening.

4. ACTION:

The facility Director, or designee, is responsible for ensuring that:

a. Veterans are informed about different options for colorectal cancer screening, including the option of no screening. They need to make a shared decision with their provider. This may be accomplished through variety of methods, such as discussing one-on-one with a clinician, or providing a brochure or a video about screening choices. The practitioner may recommend any one of the five screening options, but the veteran has the option of rejecting the recommended method and instead choosing one of the other four alternatives, or none.

(1) Patients with severe cognitive, musculoskeletal, or neurological impairments may have difficulty with any of the screening methods. Patients who would have difficulty completing any particular method need to be offered alternative screening methods.

(2) FOBT screening for CRC requires good vision and is not suitable for patients with visual impairments. *NOTE:* A visually impaired veteran is defined as one who has low vision or is legally blind and would be unable to complete FOBT screening CRC. Visually impaired veterans must be offered alternative screening methods such as flexible sigmoidoscopy alone every 5 years, DCBE every 5 years, or colonoscopy alone every 10 years.

b. Follow-up for positive screening tests is provided and notification of screening test results is sent to patients.

(1) **Positive Screening Test.** For any positive screening test, the provider responsible for initiating follow-up must develop a follow-up plan or must document that no follow-up is indicated, within <u>14 calendar days</u> of the screening test (day of laboratory receipt of FOBT, day of test for sigmoidoscopy, or DCBE). If a diagnostic colonoscopy is indicated, the colonoscopy must be performed within <u>60 calendar days</u> of the positive screening test. If the patient desires colonoscopy more than 60 calendar days after positive screening, this must be documented in the medical record and the colonoscopy must be scheduled within <u>14 calendar days</u> of the patient's requested date.

(a) FOBT results (positive) must be conveyed to the patient in writing or orally within <u>14</u> calendar days from day of laboratory receipt of FOBT (see Att. A).

(b) Written reports of verbally-transmitted positive test results must be sent to the patient within <u>14 calendar days</u> of the test date, unless the patient has already been scheduled for follow-up of the positive test.

(2) **Sigmoidoscopy.** Initial findings of a sigmoidoscopy must be conveyed to the patient orally at the time of testing. If a biopsy is performed, receipt of results must be conveyed to the patient in writing or verbally within <u>14 calendar days</u> of the biopsy test results. For orally-transmitted results, written notification of results must be sent to the patient within <u>14 calendar days</u> of the biopsy test results, unless the patient has already been scheduled for follow-up of the positive test.

(3) **Double Contrast Barium Enema (DCBE).** Positive results of an DCBE must be conveyed to the patient in writing or orally within <u>14 calendar days</u> of the test date. For orally transmitted results, written notification of results must be sent to the patient within <u>14 calendar days</u> of the test date, unless the patient has already been scheduled for follow-up of the positive test.

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(4) **Colonoscopy (screening or diagnostic).** Initial findings of a colonoscopy must be conveyed to the patient orally at the time of testing. If a biopsy is performed, results must be conveyed to the patient in writing or orally within <u>14 calendar days</u> of the receipt of biopsy test results. Written reports of orally-transmitted colonoscopy or biopsy test results must be sent to the patient within <u>14 calendar days</u> of the biopsy result.

c. After a colon cancer is discovered, (e.g., positive pathology result), the patient should be seen in a general or colorectal cancer surgery clinic within 30 days.

d. VHA laboratory services must record results of FOBT performed within a VA laboratory as chemistry (CH-) subscripted tests, regardless of which laboratory section performed the testing.

e. The results must be documented under a specifically created Occult Blood Section of Laboratory Results display in Computerized Patient Record System (CPRS) Graphic User Interface (GUI).

(1) An OCCULT BLOOD Major Header in the Laboratory Reports Cumulative needs to be created for this purpose.

(2) All FOBT atomic tests must be mapped with appropriate Logical Observation Identifiers, Names, and Codes (LOINC) codes (see Att. B).

(3) Results must be entered using a standardized set of codes with text only entry (see Att. B).

5. **REFERENCES:** See Attachment D

6. FOLLOW-UP RESPONSIBILITY: The Office of Patient Care Services (11) is responsible for the contents of this Directive. Questions are directed to Medical-Surgical Strategic Healthcare Group at 202-273-8490.

7. RESCISSIONS: None. This VHA Directive expires January 31, 2012.

Michael J. Kussman, MD, MS, MACP Acting Under Secretary for Health

Attachments

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ATTACHMENT A

SAMPLE PATIENT LETTER FOR POSITIVE FECAL OCCULT BLOOD TEST (FOBT) RESULTS

(Date)

Mr. John J. Demo 1502 Harvard Street, NW Washington, DC 20017

Dear Mr. Demo,

I have reviewed the results of the Stool Cards (Screening test for Colorectal Cancer) testing you recently had done at the Veterans Affairs Medical Center, Washington, DC.

The results for your occult blood stool cards showed a small amount of blood in your stool. This result needs follow-up testing. Please call me at 202-745-8000 when you receive this letter to discuss the results and to review the next step in your evaluation.

Sincerely,

Joe Physician, MD Primary Care Clinic

ATTACHMENT B

LABORATORY REPORTING OF FECAL OCCULT BLOOD TEST (FOBT)

1. It is recommended that results for each of the three cards be reported separately (Occult Blood #1 (print name FOBT#1), Occult Blood #2 (print name FOBT#2) and Occult Blood #3 (print name FOBT#3)), with each result recorded as Positive or Negative. It is further recommended that the single card random determination needs to be a separate atomic test, but reported in the same manner. The term "trace" must not be used for tests performed within Department of Veterans Affairs (VA) laboratories. Tests performed by outside sources, such as commercial reference laboratories, must follow the reporting format of the specific reference laboratory for regulatory compliance reasons. In those circumstances, the term "trace" may be allowed if the non-VA performing reference lab still reports it. If only one or two cards are returned in a usable fashion, the results for the unreturned or un-interpretable cards must be canceled (using the asterisk (*) for canc) with a comment for "X3 set incomplete due to unreturned card" or "X3 set incomplete due to unacceptable or rejected card," respectively. This standardization allows a national collection of data on screening and follow-up of positive tests.

2. Implementation Notes

a. For the Laboratory Management Index Program (LMIP), only one billable workload code is allowed for data capture for the three card set. Only one workload tally is allowed regardless if one card is performed or all three of the set are completed. The billable verify workload code is to be placed on the panel test. The Recommended National Laboratory Test (NLT) codes for Occult Bloods are as follows (all codes may be suffixed according to site necessity):

- (1) Blood Occult Feces 82270.0000 for the three card set.
- (2) Blood Occult Feces spot test 82271.0000 for the single card random test.
- (3) Blood Occult Point of Care (POC) 82891.000 for Point of Care Occult Blood tests.

b. For Current Procedural Terminology (CPT) billing purposes, only one Primary Care Trust (PCT) code 82270, is used for billing for a three card set. If the X3 Occult Blood Panel of three separate atomic tests is used, the panel needs to be sent to American Medical Association (AMA) compliant YES so the one appropriate CPT code will pass from the panel only to Patient Care Encounter (PCE) for billing purposes if indicated.

- (1) 82270 for one to three card determination
- (2) 82272 for a single random determination
- (3) 82274 for one to three determinations using the immunoassay method.

c. For Logical Observation Identifiers Names and Codes (LOINC) codes the following may be used:

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(1) 14563-1

HEMOGLOBIN, GASTROINTESTINAL~1STSPECIMEN: ACNC: PT: STL: ORD

(2) 14564-9

HEMOGLOBIN, GASTROINTESTINAL~2NDSPECIMENT: ACNC: PT: STL: ORD

(3) 14565-6 HEMOGLOBIN,GASTROINTESTINAL~3RDSPECIMEN:ACNC:PT: STL:ORD

(4) 2335-8 HEMOGLOBIN, GASTROINTESTINAL: ACNC: PT: STL: ORD

3. For Decision Support System (DSS), the atomic tests of the FOBT need to be added to the Laboratory Results (LAR) extract. In addition the atomic tests need to have non-billable verify workload codes with the DSS Feeder key set to YES to have the count of the individual cards pass to the DSS Lab extract for DSS to equate the LAR results and the laboratory workload extract data. These extra counts are not counted in the lab and DSS must consider them stats-only counts. *NOTE: DSS recommends the use of the same NLT LMIP codes in subparagraph 2a.*

4. To standardize data entry format, the test input transform needs to be Set of Codes: Negative is to Negative and POSITIVE is to POSITIVE. *NOTE: Positive is intentionally in uppercase for impact.*

a. Enter data type of OCCULT BLOOD (#1): (N)umeric, (S)et of Codes, or (F)ree text ? S

b. INTERNALLY-STORED CODE://Negative WILL STAND FOR:// Negative

c. INTERNALLY-STORED CODE://POSITIVE WILL STAND FOR:// POSITIVE

5. If sites need to generate an Abnormal High (H) or Critical High (H*) flag, this may be done through the use of a Delta Check text alert such as the following:

a. Abnormal High Flag (H) XECUTABLE CODE: Q:\$D(LRGVP) I X["POSITIVE" S LRFLG="H"

b. Critical High Flag (H*) XECUTABLE CODE: Q:\$D(LRGVP) I X["POSITIVE" S LRFLG="H*"

6. For cards that are unacceptable for testing or unreturned, the result(s) must be canceled to ensure that workload is not accrued. If all three cards are unacceptable, then all must be canceled to ensure that the CPT code is not passed to billing inappropriately and that no workload is accrued. Comments for "X3 Set incomplete due to unreturned card" or "X3 Set incomplete due to unacceptable or rejected card" can be added as a laboratory description comments for use by the technical staff during the verification process.

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7. For Clinical Reminders, any POSITIVE result in any of the three card tests (or a single card positive test as well) needs to satisfy the reminder or three negative results for #1, #2, and #3 cards.

ATTACHMENT C

RECOMMENDATIONS FOR OPTIMIZING COLORECTAL CANCER (CRC) SCREENING IN PRACTICE

The success and stability of a CRC Program are dependent on adequate resources and an efficient infrastructure. Preliminary Department of Veterans Affairs (VA) studies have shown that providing veterans CRC screening and tracking the process can be accomplished in a resource efficient manner using different strategies. These strategies may include:

1. Group "prep" clinics: time set aside for preparing patients for colonoscopy.

2. Use of telemedicine to inform patients about screening options and preparation.

3. Mandatory view alerts of positive Fecal Occult Blood Test (FOBT) results: Computerized Patient Record System (CPRS) has the capability to set up view alerts to remind the provider of the results.

4. Appropriate consults for procedures between the various services.

5. Systematic review of consult requests: consults to be reviewed prior to the procedure for appropriateness and the time of the previous procedure whether done in the VA or outside the VA.

6. Use of a tracking system dedicated to ensure that each veteran's screening is completed and appropriately followed-up.

7. Nurse Managers to coordinate screening schedules, procedures, and ensure that all levels of the program are working together (e.g., review of consults, follow-up on requested information, retrieval of in-house and outside medical records, follow-up of no-shows, follow-up on positive FOBT tests, etc.).

8. Application Coordinators at each facility to implement standard templates within the Computerized Patient Record System (CPRS) for easy access to providers. This provides documentation within the medical record that a notification letter has been sent to the patient. *NOTE:* The text of the letter can be copied onto Veterans Health Administration (VHA) letterhead with a word processing program for a more professional appearance. Clinical Application Coordinators must work with the providers to ensure that the laboratory results are properly configured in CPRS (prioritize them based on normal and abnormal) so that the providers can view them and take action, if needed.

ATTACHMENT D

REFERENCES

1. Smith RA, von Eschenbach, AC, Wender, R, Levin, B, Byers, T, Rothenberger, D, et al. "American Cancer Society Guidelines for the Early Detection of Cancer: Update of Early Detection Guidelines for Prostate, Colorectal, and Endometrial Cancers," also: "Update 2001-Testing for Early Lung Cancer Detection." <u>CA: Cancer Journal for Clinicians.</u> 51:38-75:2001.

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5. "Screening for Colorectal Cancer in Adults at Average Risk: A Summary of the Evidence," <u>Agency for Healthcare Research and Quality (AHRQ)</u> Pub. No. O3-507A, August 2002.

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11. U.S. Prevention Services Task Force: http://www.ahrq.gov/clinic/uspstf/uspscolo.htm

12. U.S. Preventive Services Task Force Ratings: http://www.ahrq.gov/clinic/3rduspstf/ratings.htm.

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- 14. Centers for Disease Control and Prevention: http://www.cdc.gov/cancer/colorctl/index.htm.
- 15. VHA Quality Enhancement Research Initiative (QUERI): http://www.hsrd.research.va.gov/queri.
- 16. VA Cancer Homepage: http://www1.va.gov/cancer/.