Department of Veterans Affairs

Office of Inspector General

Healthcare Inspection

Colorectal Cancer Detection and Management in Veterans Health Administration Facilities

Report No. 05-00784-76 **February 2, 2006**

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DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Under Secretary for Health (10/10B5)

SUBJECT: Healthcare Inspection — Colorectal Cancer Detection and Management in Veterans Health Administration Facilities

Purpose

The Department of Veterans Affairs Office of Inspector General's (OIG) Office of Healthcare Inspections (OHI) evaluated the effectiveness of colorectal cancer detection and management at Veterans Health Administration (VHA) facilities. The evaluation was conducted to determine whether VHA clinicians: (1) appropriately screened patients for colorectal cancer, (2) provided diagnostic evaluations and treatments efficiently, (3) effectively managed patients with positive screening results and/or active symptoms, (4) properly notified patients of their cancer diagnoses, and (5) coordinated care between all involved disciplines.

Background

Colorectal cancer (CRC) is defined as cancer of the colon or rectum. According to the American Cancer Society (ACS), CRC is the second leading cause of cancer deaths in the United States. The ACS estimates that 145,290 new cases will be diagnosed and 56,290 deaths will occur due to colorectal cancer in 2005.[1]

Screening for CRC is crucial since it is one of the most treatable cancers, if detected early. When CRC is detected at an early stage, the 1-year survival rate is about 90 percent. Ninety-three percent of CRC occurs in men and women age 50 years or older.[2] The U.S. Preventive Services Task Force, a panel of experts in prevention and primary care, strongly recommends that clinicians screen adults age 50 and older with one of the following procedures:[3]

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[1] Overview of Colon and Rectum Cancer, American Cancer Society, 2005. http://www.cancer.org/docroot/CRI/CRI_2_1x.asp?rnav=criov&dt=10

[2] Cancer Prevention and Control. Centers for Disease Prevention and Control, reviewed May 10, 2005. http://www.cdc.gov/cancer/screenforlife/fs_professional.htm

[3] U.S. Preventive Services Task Force. Screening for Colorectal Cancer: Recommendations and Rationale. July 2002. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/3rduspstf/colorectal/colorr.htm

- Fecal Occult Blood Test (FOBT) annually. This test detects blood that is not visible in a stool sample.

- Flexible sigmoidoscopy examination every 5 years. This procedure allows physicians to visually inspect the interior walls of the rectum and the lower part of the colon using a thin, flexible, lighted tube called a sigmoidoscope.

- Double-contrast barium enema every 5 years. This procedure is a series of x-ray images of the colon and the rectum taken after the patient is given an enema containing barium dye followed by an injection of air.

- Colonoscopy examination every 10 years. This procedure allows physicians to visually inspect the interior walls of the rectum and the entire colon using a thin, flexible, lighted tube called a colonoscope.

In 2000, VHA established a national performance measure target of screening 72 percent of patients over age 51 for CRC using any of the four screening options defined above. In the fourth quarter of fiscal year (FY) 2004, VHA reported that national compliance with the CRC screening measure achieved an average of 74 percent, with individual facilities ranging from 46 to 100 percent. This performance compares favorably with the private sector Health Plan Employer Data and Information Set performance in 2003 of 50 percent.

However, in an analysis of FY 2002 data, the VHA Quality Enhancement Research Initiative found that 54 percent of veterans with positive FOBT results failed to receive complete diagnostic evaluations within 6 months.[4] On May 16, 2005, VHA issued guidance indicating that, unless the primary screening method is colonoscopy, any positive screening test needs to be followed up with colonoscopy. Patients with positive screening results must have prompt diagnostic evaluations, usually by colonoscopy, and expeditious treatments for optimal outcomes. Surgery is the most common initial treatment for CRC, and chemotherapy and/or radiation treatment may also be used.

Scope and Methodology

The scope of this inspection included 10 Combined Assessment Program (CAP) visits at VHA medical facilities from January 1, 2005, through June 15, 2005. The review included analyses of Veterans Integrated Service Network (VISN) and facility performance measure scores for colorectal cancer screening and waiting times, evaluations of patients' medical records, and results of interviews with key clinical staff at each facility. This report includes the results of the first 10 sites; however, the reviews continued on CAP visits through October 2005. The 10 sites included in this report are:

[4] Kochevar, Laura. Colorectal Cancer QUERI, Department of Veterans Affairs, March 2005.

Central Arkansas	Northern California (Sacramento)
Detroit	Salt Lake City
Northern Arizona (Prescott)	San Juan
Providence	West Palm Beach
Puget Sound	Wilmington

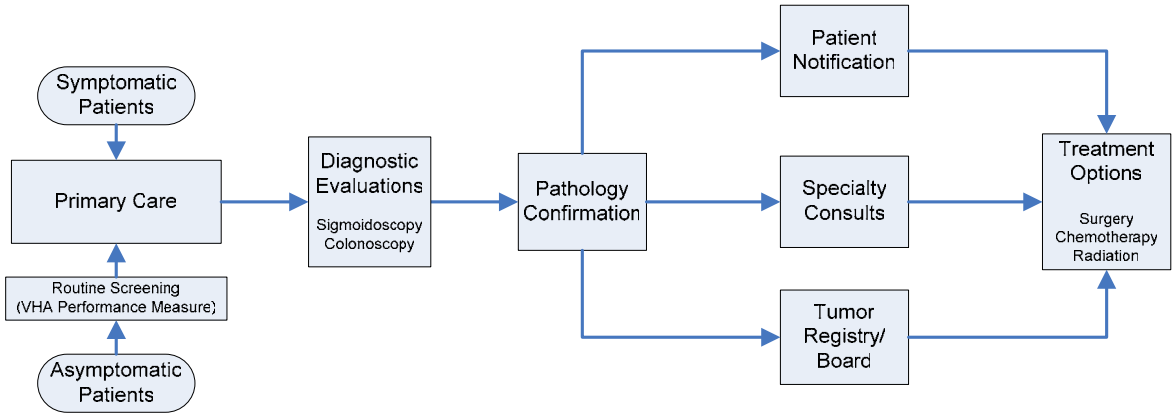
Each facility provided a list of patients diagnosed with CRC in FY 2004. We randomly selected approximately 10 patients per site between ages 51 and 80. If fewer than 10 patients were diagnosed with CRC in FY 2004 at a facility, we expanded the population to include patients diagnosed in FY 2003. The actual number of patients per facility varied from 7–12, depending upon the scope of services provided. For example, some facilities offered primary care only and referred patients to other facilities for gastroenterology (GI), surgery, and/or oncology care. The initial number of patient cases used in this report was 100. Upon detailed analysis, 10 cases were eliminated from the final sample for the following reasons: (1) the patients did not have CRC, (2) they had disorders that did not offer the opportunity for FOBT screening, or (3) they received a substantial amount of their care outside VHA.

Of the 90 patients in the final sample, 26 (29 percent) presented with bowel symptoms that led to diagnosis. We defined this as the symptomatic group. The remaining 64 patients (71 percent) did not have symptoms, but were initially evaluated via a screening methodology. In this asymptomatic group, 36 patients (56 percent) initially had FOBT, 23 patients (36 percent) had colonoscopies, and 5 patients (8 percent) had sigmoidoscopies.

Denominators vary in the following calculations because some patients were screened, diagnosed, or treated in non-VA facilities.

We conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

CRC Process Flow Diagram



Results

A. Screening

Seven of the 10 sites met the VHA National Performance Measure goal of 72 percent in the fourth quarter of FY 2004. Of the 90 patients in our sample, 83 (92 percent) were either screened appropriately or screening was not applicable (age younger than 51 or had not received prior care at a VHA facility).

B. Diagnostic Evaluations and Treatments

1. Length of Time from Presentation to Diagnosis was Excessive

Patients presented to a VHA facility either for screening or with symptoms. Reviews of medical records showed the following results:

Length of Time from Presentation to Diagnosis		
	Symptomatic Group	**Asymptomatic Group**
Number of cases:	26	64
Range in days:	0-536	0-815
Mean days:	106	199

A diagnosis of CRC is reliably made when tissue is obtained. There is no standard in the medical literature that defines the appropriate length of time from the determination that a screening test is positive to the CRC diagnosis, usually by colonoscopy. Absent a definitive standard, it is our opinion that 3 to 6 months is an unacceptable time interval between presentation and diagnosis.

C. Clinical Management

1. Management of Patients with Symptoms and/or Positive Screening Results Needed Improvement

On August 4, 2003, a primary care provider gave a patient FOBT cards. On August 6, 2003, the results showed that the patient's FOBT was positive, and the provider sent a consult to GI. The patient was scheduled for a colonoscopy on January 21, 2004, but he was unable to keep the appointment and called the clinic on January 22, 2004, to reschedule. On April 20, 2004, he underwent the colonoscopy. He was diagnosed with CRC on April 26, 2004. In May and June 2004, the patient was seen by surgery, GI, oncology, and radiation oncology. He received chemotherapy and radiation treatments until August. On October 12, 2004, he underwent surgery. Pathology analysis showed that the tumor was quite advanced. It is possible that this patient might have had a better outcome if the screening and diagnostic colonoscopy had occurred earlier.

a. High Priority Patients Needed to Receive Timely Colonoscopies

High-priority patients are those with symptoms and/or positive screening tests. They need to be evaluated according to their clinical conditions and receive priority diagnostic colonoscopies. Patients with symptoms and/or positive screening results who cancelled or failed to show up for their colonoscopy appointments were often administratively dropped to the bottom of the waiting list rather than being appropriately clinically prioritized, resulting in delays of 6 months or more. To address this problem, one facility implemented a nurse practitioner clinic to contact and follow up with patients who cancelled or failed to show up for their colonoscopy.

Facility managers need to continually assess the demand for and supply of colonoscopies. Some facilities' primary care providers requested far more routine screening colonoscopies than the facilities had the capacity to perform. One GI chief, facing overwhelming requests for routine screening colonoscopies, set the following criteria for expedited colonoscopy:

- Positive FOBT
- Iron deficiency anemia
- Family history of CRC
- Age greater than 40 years with blood in the stools
- Chronic inflammatory bowel disease

GI clinicians perform the majority of diagnostic colonoscopies with general surgery providing the remainder. Each site we visited had different arrangements of staff, space, and equipment. To function efficiently, GI sections need all of the following:

- Sufficient numbers of gastroenterologists to perform and/or supervise colonoscopies.
- Enough nurses or trained technicians to prepare patients, perform colonoscopies, provide monitoring during and after the colonoscopies, and to clean the rooms and equipment after the procedures.
- Adequate numbers of procedure rooms.
- Ample adjacent space for recovering patients after the procedures.
- Appropriate numbers of colonoscopes and other equipment.

Facilities' staff provided several reasons to explain lengthy delays in providing diagnostic colonoscopies. Chiefs of staff in some facilities complained of difficulties in recruiting gastroenterologists because the VA salary is not competitive with the community. Limitations in space and support staff were also cited. Several GI chiefs told us that their workload had increased steadily over the past several years without commensurate increases in resources. For example, in one facility consults to GI numbered 4,439 in FY 2002 and 5,458 in FY 2004—an increase of 23 percent. In another facility, GI procedures numbered 1,943 in FY 2003 and 2,495 in FY 2004—an increase of 28 percent. Most GI chiefs told us that the section runs procedure clinics 5 days per week. Three facilities had extended their clinic hours from 7:00 a.m. to 5:30 p.m. to attempt to better manage the increased demand.

Senior facility managers inconsistently used fee basis funds to refer patients to non-VA providers. One facility GI chief told us that if high-priority patients cannot be scheduled for an appointment within 30 days, they are referred for fee-basis services. Chiefs of staff in several other facilities told us that fee basis resources were too limited to use to address extensive GI backlogs.

Further analysis is needed to determine the most efficient, cost-effective way to provide timely diagnostic colonoscopies for these patients. The analysis should include prioritization criteria; necessary resources in staff, equipment, and space; and criteria for use of fee-basis funds. While some standardization is necessary, each VHA facility has unique needs and may require different solutions.

b. A Metric for the Timeframe for Obtaining Diagnostic Colonoscopy is Needed.

We could not locate any standards for the optimum timeframe from positive screening results to colonoscopy. Many facilities had policies, procedures, or service agreements with specific goals for obtaining colonoscopies. These documents varied in their timeframes from 30 days to 1 year, with 30 days being the most common. GI chiefs and chiefs of staff told us that they considered 30–45 days as an acceptable length of time. A 2004 VHA national performance measure assessed the percent of next available GI appointments that were scheduled within 30 days. In the fourth quarter of FY 2004, only

3 of the 10 facilities reviewed met the goal of 80 percent of next available GI appointments scheduled within 30 days.

Metrics affect organizational behavior, and the current performance measure has been very successful in increasing CRC screening. Implementation of metrics that emphasize the need for high-priority patients to receive timely colonoscopies and that measure progress toward improving timely diagnosis is needed. Metrics could focus upon the length of time from presentation to diagnosis, the percent of newly diagnosed cases with more benign pathology, survival statistics, or other discrete markers. The VHA performance measure for CRC should move from screening to diagnosis with the recognition that the metric will be adjusted in the future as necessary.

2. Length of Time from Request for Specialty Consultations until Evaluation was Acceptable

Medical records reviews of patients who were referred to Surgery and/or Oncology for evaluation produced the data in the table below. Some patients received no referrals.

Length of Time from Request for Specialty Consultations until Evaluation		
	Surgery	**Oncology**
Number of cases:	76	47
Range in days:	0-47	0-80
Mean days:	11	19.7

3. Length of Time From Diagnosis to Earliest Treatment was Acceptable

Medical records reviews of patients who received treatment from Surgery, Oncology, and/or Radiation Therapy produced the following data. Some patients received no treatment. In the symptomatic group, the surgeons were often involved with the cases prior to the date of diagnosis.

Length of Time From Diagnosis to Earliest Treatment	
Number of cases:	87
Range in days:	0-212
Mean days:	39.6

Two patients experienced lengthy waits for surgery. Both had been evaluated by surgeons and scheduled for surgery in about 100 days. One of the two patients needed cardiology clearance prior to surgery.

D. Patient Notification

Of the 90 cases, evidence that clinicians notified patients of their CRC diagnoses was present in only 58 cases (64 percent). For those 58 cases, the mean length of time from diagnosis to notification was 9 days.

No VHA regulations require clinicians to notify patients of their CRC diagnoses within any specified timeframe or to document this communication. Progress notes revealed that two of the patients in the sample learned of their diagnoses in less than optimal ways. In one case, a nurse assumed that the patient knew and casually mentioned it; and in another case, the patient repeatedly called trying to find out his biopsy results.

In contrast, patient notification requirements regarding breast cancer are very clear in terms of timeframes and methods of notification. For example, each certified VHA mammography site is required to establish a documented procedure to provide a summary of the written mammography report to the patient. The interpreting physician must document letters, reports, and/or verbal communication with the patient in the patient's medical record. The mammography report content must be communicated to the patient in terms easily understood by a layperson within 30 days from the date of the procedure. Documentation of letters and/or verbal communication with the patient must be entered into the medical record.

All patients undergoing any type of cancer screening and diagnostic testing should be notified about the results in a timely manner and the notification should be documented in the medical record.

E. Coordination of Care

Evidence that treatment planning was coordinated across involved disciplines was documented in 89 cases. Clinicians in some facilities referred these patients to their facilities' Tumor Boards. We found Tumor Board discussions to be excellent interdisciplinary mechanisms and encourage the inclusion of CRC patients.

F. Tumor Registries

Tissue analyses indicative of cancer are generally captured by the facilities' tumor registries. VHA policy requires that all VHA facilities establish a tumor registry.[5] Although not a major focus of our review, we noted wide variation across facilities in implementation and data management. We suggest that further review of this important data repository be initiated to address consistency and data validation.

[5] VHA Directive 2003-034 "National Cancer Strategy," June 20, 2003.

Conclusions

VHA has stressed CRC screening, and our findings were consistent with the VHA performance measure data. Surgery and oncology clinicians appropriately responded to requests for evaluations, and the length of time from diagnosis to earliest treatment was acceptable. Treatment planning appeared to be coordinated across involved disciplines.

The length of time from presentation to diagnosis was excessive. Timely diagnostic colonoscopies for patients with symptoms or positive screening results are essential for optimum early detection and treatment. VHA has not yet set any timelines for this important diagnostic step to occur. GI clinicians provide the majority of diagnostic colonoscopies; also GI resources, scheduling processes, prioritization criteria, and referral practices need to be addressed. To provide the best possible outcomes, primary care and GI providers need to better manage patients with symptoms or positive screening results.

Patients were not consistently notified of their CRC diagnoses within a reasonable amount of time. VHA has not set any timelines for when notification should occur or how it should be documented.

Recommendations

The Under Secretary for Health needs to:

a. Establish appropriate metrics to evaluate and improve the timeliness of CRC diagnosis.

b. Implement prioritization processes to ensure that high-priority patients receive diagnostic colonoscopies according to their clinical needs.

c. Implement a consistent notification requirement for patients undergoing CRC diagnostic testing, including timeliness and documentation.

Under Secretary for Health Comments

The Under Secretary for Health concurred with the findings and recommendations. The Under Secretary for Health plans to collect data and establish timelines, which will be utilized to calculate performance measures and supporting indicators to monitor the timeliness of CRC diagnosis. He plans to update the Colorectal Cancer Screening Information Letter to include a clarification of prioritization processes to ensure that high-priority patients receive diagnostic colonoscopies according to their clinical needs. This information letter will then be reissued as a directive, which will also include specific requirements for patient notification of CRC screening results, including a timeline and documentation standards.

Inspector General Comments

The Under Secretary for Health's comments and implementation plans were responsive and met the intent of the recommendations. We will monitor the implementation of these recommendations.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

Undersecretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: January 20, 2006

From: Under Secretary for Health (10/10B5)

Subject: **OIG Draft Report, Healthcare Inspection: *Colorectal Cancer Detection and Management in VHA Facilities*, Project No. 2005-00784-HI-0109 (EDMS 334359)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed this draft report, and I am pleased the report acknowledges that the Veterans Health Administration (VHA) has consistently stressed the importance of and met the performance measures for colorectal cancer (CRC) screening and care coordination. I realize, however, that as effective as VHA's screening and care coordination are, there are opportunities for improvement in the timely diagnosis, prioritization, and consistent notification of patients for positive screens. I appreciate your efforts in helping us provide better patient care and concur with the findings and recommendations of this draft report.

2. I will ensure that the VHA Deputy Under Secretary for Health for Operations and Management (DUSHOM) widely disseminates your report across our networks and reaffirms the commitment to improving CRC detection and management. I expect that the findings and recommendations in the report will have a positive impact on VHA's ongoing initiatives to improve the quality of care for patients with a positive CRC screen. Attached is VHA's complete plan of corrective action. The plan provides a summary of specific initiatives that appropriately address each of the report's recommendations.

3. As reflected in your report, clearly VHA must improve the timeliness of diagnostic colonoscopies for patients with symptoms suggestive of colorectal cancer or positive screening results in order to optimize early CRC detection and management. As an organization, we are well aware of this shortfall, and despite the lack of private sector benchmarks, we have already initiated quality improvement efforts to decrease this time interval. One such initiative is the External Peer Review Program (EPRP), which is a VHA-wide effort coordinated by the Office of Quality and Performance (OQP) to provide medical facilities with diagnostic and procedure-specific quality of care information in order to improve the overall level of patient care. This is accomplished by abstracting information from a random sample of paper and electronic medical records and compiling it into a database for analysis and comparison of clinical care. For colorectal cancer care, EPRP will abstract data on the follow-up testing of positive, non-colonoscopy, CRC screening tests with time intervals in order to analyze factors that are unnecessarily delaying CRC diagnosis.

4. Another cutting-edge quality improvement initiative directly focused on CRC management is the Colorectal Cancer Care Collaborative (C4), which is a joint project involving OQP, the DUSHOM Advanced Clinical Access program, and the Office of Research and Development Quality Enhancement Research Initiative. C4 is a pilot project involving 21 volunteer facility teams (one per network) that meets regularly to share measures and practices to continuously improve facility-level CRC quality of care. Through the C4 project, I ultimately hope that VHA can decrease unnecessary delays and increase adherence to evidence-based care in the screening, diagnosis, and treatment of colorectal cancer-related patients. The C4's strategy in this endeavor is to develop and test useful improvement and monitoring measures; identify, package, and disseminate key change concepts and tools; develop a plan for spreading

effective practices; and evaluate the pilot project to aid future efforts related to CRC care management.

5. Lastly, as you may already be aware, I issued the Colorectal Cancer Screening Information Letter (IL 10-2005-009) in May 2005, which provides information regarding the provision of CRC screening within VHA. Coupled with the information we continue to collect through EPRP and C4, I believe this information letter can be updated to include a clarification of prioritization processes to ensure that high-priority patients receive diagnostic colonoscopies according to their clinical needs. The guidance will also address consistent notification requirements for patients undergoing CRC testing, as recommended. After updating the information letter, I plan to reissue it as a directive. I anticipate publication of the new directive by September 30, 2006.

6. Thank you for the opportunity to review the draft report. If you have any questions, please contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 565-7638.

(original signed by:)
Jonathan B. Perlin, MD, PhD, MSHA, FACP

Attachment

VETERANS HEALTH ADMINISTRATION
Action Plan
OIG Draft Report, Healthcare Inspection: Colorectal Cancer Detection and Management in VHA Facilities, Project No. 2005-00784-HI-0109

Recommendations/ Actions	Status	Completion Date

We recommend that the Under Secretary for Health:

Recommended Improvement Action(s) a: Establish appropriate metrics to evaluate and improve the timeliness of CRC diagnosis.

Concur

We agree that the establishment of appropriate metrics to evaluate and improve the timeliness of colorectal cancer (CRC) diagnosis offers VHA an opportunity to identify and decrease unnecessary diagnostic delays for persons with positive CRC screens. To facilitate this effort, the Office of Quality and Performance (OQP) will utilize the External Peer Review Program (EPRP) to abstract data on the follow-up testing of positive, non-colonoscopy, CRC screening tests with time intervals in order to calculate performance measures and supporting indicators and analyze internal and external factors that are unnecessarily delaying CRC diagnosis. OQP will report data on diagnostic delays quarterly, providing the mean time from a positive, non-colonoscopy, CRC screen to colonoscopy as a metric to track VHA-wide delays and improve the timeliness of CRC diagnoses. Results for the First Quarter of Fiscal Year (FY) 2006 will be available in March 2006.

In addition to EPRP, OQP has developed facility-wide metrics to evaluate the effectiveness of quality improvement efforts currently being conducted through the Colorectal Cancer Care Collaborative (C4). Currently, participants in the C4 projects are capturing three core measures to improve the quality of care and increase adherence to evidence-based

care in the diagnosis of CRC: time from positive fecal occult blood test (FOBT) to colonoscopy performed or paid for by VA (for colonoscopies within one year); the number of colonoscopies performed or paid for by VA within 90 days after positive FOBT (for colonoscopies within one year); and the number of positive FOBTs without a follow-up colonoscopy. C4 is scheduled to conclude its work in September 2006 and will utilize the collected data set to set up and refine performance measures for CRC diagnosis.

As stated, there are no private sector benchmarks regarding performance measures for timeliness of CRC diagnosis. In an effort to establish a professional consensus on timeliness, the VHA Office of Patient Care Services (PCS) is in the process of soliciting input from the practitioners in the field, including the Field Advisory Committee members in Oncology and Gastroenterology, on best practices for timelines. A measure of the time from a positive stool guaiac to flexible sigmoidoscopy/colonoscopy is included in the survey. In addition, PCS is also reviewing the United Kingdom National Health Service's Cancer Plan for such timelines. PCS expects to produce these timelines in draft form by the end of March 2006. These timelines, along with the data collected by C4 through September 2006, will be utilized to set up and refine performance measures to improve the timeliness of CRC diagnosis.

In Process 9/30/06

<u>Recommended Improvement Action(s) b</u>: Implement prioritization processes to ensure that high-priority patients receive diagnostic colonoscopies according to their clinical needs.

Concur

PCS will utilize the information captured in EPRP and C4 to assist in the development and implementation of processes for the prioritization of diagnostic colonoscopies. The Colorectal Cancer Screening Information Letter already defines priorities in the screening of CRC patients. Coupled with the information collected through EPRP and C4, which is scheduled to conclude in September 2006, this information

letter will be updated to include a clarification of prioritization processes to ensure that high-priority patients receive diagnostic colonoscopies according to their clinical needs. After this information letter is updated, PCS will reissue it as a directive.

In Process 9/30/06

Recommended Improvement Action(s) c: Implement a consistent notification requirement for patients undergoing CRC diagnostic testing, including timeliness and documentation.

Concur

PCS will address this by consolidating input from the survey of practitioners in the field on best practices for timelines. These timelines will include reporting positive tests for cancer screening to patients to definitive diagnosis and treatment, including surgery, chemotherapy, and/or radiation. This information will be utilized to establish specific requirements for patient notification of CRC screening results, a timeline, and documentation standards and will be included in the updated Colorectal Cancer Screening Information Letter to be reissued as a directive. The directive will state that all patients will be notified of their screening results (positive and negative) within 7 working days, and the notification will be required to be documented in the chart. If a test is positive, there must be documentation of the discussion with the patient and its outcome.

In Process 9/30/06

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Julie Watrous, Director, Los Angeles Regional Office of Healthcare Inspections (310) 268-3005
Acknowledgments	Elizabeth Bullock Dorothy Duncan Jeanne Martin Annette Robinson Carol Torczon John Tryboski Sue Zarter

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