Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-03298-20

Healthcare Inspection

Alleged Delay in Gastroenterology Care Durham VA Medical Center Durham, North Carolina

November 6, 2014

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine whether a patient received appropriate and timely diagnostic testing for colorectal cancer (CRC) at the Durham VA Medical Center, Durham, North Carolina (the facility).

We confirmed that almost 8 months elapsed between the patient's initial gastrointestinal-related complaints in January 2011 until his colonoscopy in August. We did not find that this 8-month timeframe represented a clinically significant delay in care.

The patient's clinical presentation was unusual for a patient with CRC for both the early age of onset as well as the short time period from initial symptoms to the discovery of advanced cancer. None of the providers were suspicious for CRC given the patient's age at presentation and no known family history. Because the symptoms of inflammatory bowel disease are similar to CRC, providers reasonably considered inflammatory bowel disease as the more likely cause of the patient's symptoms. At each visit, providers evaluated the patient's condition and initiated appropriate laboratory and other diagnostic tests as indicated.

When the patient reported recurrence of blood-streaked diarrhea in April, his primary care provider requested a routine Gastroenterology (GI) Clinic appointment, which was scheduled in early June. The emergency department provider told us that he attempted to expedite the GI appointment (via an "added comment" in the consult) because of the patient's anxiety (not because there was a clinical urgency); we found no documented evidence that the request was reviewed and considered by a GI provider at the time.

At the time of the June visit, the GI provider evaluated the patient and ordered a routine colonoscopy, which was scheduled for mid-August. We could not say with certainty that the patient's outcome would have been different had he received the diagnostic colonoscopy sooner. The colonoscopy and subsequent computerized tomography scan revealed the patient had a large mass and advanced CRC with metastasis to the liver. As CRC is typically a slow-growing cancer, the patient likely had advanced CRC at the time of his initial presentation with symptoms. The patient subsequently transferred his medical care to a non-VA provider. He died a little over 2 years later.

We made no recommendations.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the report. (See Appendixes A and B, pages 6–7 for the Directors' comments.) No further action is required.

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 a review to determine whether a patient received appropriate and timely diagnostic testing for colorectal cancer (CRC) at the Durham VA Medical Center (facility), Durham, NC.

Background

The facility is a 271-bed tertiary care center affiliated with Duke University School of Medicine and provides medical, surgical, and psychiatric services. The facility is part of Veterans Integrated Service Network (VISN) 6 and serves veterans from North Carolina, southern Virginia, northern South Carolina, and eastern Tennessee.

Inflammatory Bowel Disease (IBD). IBD represents a number of conditions that result in inflammation of the intestines. These conditions typically occur in individuals in their 20s and 30s but can occur at almost any age. Symptoms from IBD include abdominal pain, diarrhea, blood in the stools, and weight loss.[1]

CRC. CRC occurs when tumors form in the lining of the large intestine. It is common in both men and women, and the risk of developing CRC rises after age 50. Overall, 90 percent of new cases and 94 percent of deaths occur in individuals 50 and older.[2] Other risk factors include colorectal polyps, a family history of CRC, ulcerative colitis, Crohn's disease, or a diet high in fat.[3] Symptoms include a change in bowel habits, such as diarrhea, constipation, or narrowing of the stool that lasts for more than a few days; rectal bleeding, dark stools, or blood in the stool; cramping or abdominal pain; weakness and fatigue; and unintended weight loss.[4]

In most cases, CRC develops from pre-cancerous polyps (abnormal growths) in the colon or rectum. Screening tests can detect polyps and/or bleeding from polyps so that they may be removed before they turn into cancer. A physician uses a colonoscope—a thin, flexible, lighted tube—to visually inspect the interior walls of the rectum and the entire colon. Samples of tissues or cells may be collected for closer examination, and most polyps may be removed.[5]

CRC is often a slow growing cancer that takes years to progress. For this reason, the general recommendation for non-high-risk patients is an interval of 10 years between colonoscopy screenings.

[1] http://www.gastro.org/patient-center/digestive-conditions/inflammatory-bowel-disease, retrieved July 21, 2014.
[2] http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-028312.pdf, retrieved July 17, 2014.
[3] http://www.nlm.nih.gov/medlineplus/colorectalcancer.html, retrieved May 26, 2014.
[4] http://www.nlm.nih.gov/medlineplus/colorectalcancer.html, retrieved July 14, 2014.
[5] http://www.cancer.gov/cancertopics/factsheet/detection/colorectal-screening, retrieved July 14, 2014.

Scheduling. The facility's Gastroenterology (GI) Clinic outpatient scheduling process for routine consults is as follows:

- The requesting provider (usually the primary care provider [PCP]) enters a GI consult into the computerized patient record system.
- The GI Clinic medical support assistant forwards the consult to a GI provider for clinical review.
- The GI provider reviews the consult within 5–7 days and determines the course of treatment, which may include referral to the GI Clinic for evaluation or direct referral for a procedure. The GI provider then forwards the consult back to the medical support assistance with guidance on when to schedule the appointment (for example within 2–4 weeks for urgent care or 3–6 months for routine care).
- The medical support assistant contacts the patient and schedules the appointment based on the patient's preference and the GI provider's recommended timeframe.

Concerns. The spouse of a patient who died of CRC reported that her husband complained to his PCP in January 2011 of abdominal pain and bloody stools. The wife further stated that the patient went to the emergency department (ED) five times complaining of similar symptoms. The patient underwent a colonoscopy in August 2011. Biopsy and imaging studies confirmed the presence of Stage 4 CRC.[6] The wife was concerned about an 8-month delay in performing the colonoscopy.

Scope and Methodology

We conducted a site visit June 26, 2014. We interviewed the Chief of GI and the PCP; the patient's GI physician and endoscopist; several GI medical support assistants and ED physicians; and others with knowledge about these concerns.

We reviewed relevant Veterans Health Administration, VISN, and facility policies related to CRC, consult management, and appointment scheduling; the patient's electronic health record; quality management documents; and consult management reports.

The patient care described in this report occurred in 2011, and several of the involved providers have since taken positions at other medical facilities and were unavailable for interviews.

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.

[6] Stage 4 CRC is when the cancer has spread through the blood and lymph nodes to other parts of the body, such as the lung, liver, or abdominal wall.

Case Summary

The patient was in his early 30s when he began receiving primary care services at the facility in 2007. The same PCP followed the patient through early 2011, primarily for musculoskeletal and general medical issues.

In January 2011, the patient reported a new complaint of diarrhea with blood-streaked stools since December 31, 2010. He denied any changes in weight or appetite and denied excessive fatigue. The PCP advised the patient to modify his diet and to provide a stool sample. The PCP scheduled a follow-up appointment in 4 weeks; however, the patient was unable to keep a February appointment and indicated he would call back to reschedule.

The patient followed up with his PCP in early April. His chief complaint during this appointment was anxiety and depression but noted that he was feeling better after restarting his anti-depressant medication. The patient also reported that his GI symptoms had improved with probiotic over-the-counter supplements, but they had not fully resolved. The patient continued to have 2–3 bowel movements per day but denied blood in the stool, extreme fatigue, and weight loss. The PCP noted that a lab test completed during the January appointment was negative for *H. pylori*.[7] The patient was to follow up in 6 months; however, he called back a week later to report bright red blood in his stools. After hearing of this symptom, the PCP requested a routine GI consultation that was scheduled for early June.

The patient called back 10 days later to request an earlier GI appointment. The PCP spoke with the patient and noted that although he continued to have loose stools, there was no blood in the stool at that point, and the patient's appetite remained good. The patient had not yet provided a stool sample for culture to look for infectious causes. The PCP advised the patient to keep his GI appointment but to go to the ED if his symptoms worsened.

The patient presented to the ED at the end of April with ongoing symptoms. The ED physician was unsure as to the exact cause of the patient's symptoms. For this reason, as well as the patient appearing anxious, the ED physician entered a comment on the existing consult to expedite the patient's GI appointment.

The patient provided a stool specimen in early May and presented to the ED in mid-May after being notified he had white blood cells in his stool.[8] The ED physician considered several possible diagnoses including IBD and infectious diarrhea. The ED physician treated the patient empirically for infectious agents and noted the GI appointment scheduled for June.

[7] *H. pylori* is a bacterium that causes chronic inflammation of the inner lining of the stomach.
[8] Diseases such as IBD may cause white blood cells in stool samples.

During the June appointment, the GI provider noted that the patient had weight loss in addition to diarrhea. His stool tests to date had not shown an infectious cause of symptoms. The GI provider recommended colonoscopy with further evaluation dependent upon the results of that procedure. The colonoscopy was scheduled for mid-August.

In July, the patient presented to the ED with escalation in his abdominal cramping and more episodes of diarrhea. He also noted decreased appetite and additional weight loss. The decision was made to treat him symptomatically and await the results of his colonoscopy.

The patient underwent a colonoscopy in August where a large mass was discovered and biopsied. Three days later, computerized tomography scan showed the mass as well as enlarged lymph nodes and lesions on the liver that were suspicious for metastasis.[9]

The patient subsequently saw a general surgeon who recommended additional testing, resection of the mass, and probable chemotherapy.

The patient transferred his care to University of North Carolina Hospitals and Clinics and underwent surgery in the beginning of September. Genetic testing revealed that the patient had Lynch syndrome, an inherited condition that increases the risk of colon cancer as well as other types of cancer.[10] He continued to receive non-VA care for almost 2 years and died in late Fall 2013.

Inspection Results

We confirmed that almost 8 months elapsed from the time the patient initially complained of GI symptoms and completion of his diagnostic colonoscopy. We further confirmed that the patient presented to the ED multiple times in the interim complaining of GI-related issues. We did not find, however, that the 8-month timeframe represented a clinically significant delay in care.

The patient was in his mid-30s and had no known family history of CRC. Because the symptoms of IBD are similar to CRC, providers reasonably considered IBD as the more likely cause of the patient's GI symptoms. At each visit, providers evaluated the patient's condition and initiated appropriate laboratory and other diagnostic tests as indicated. In addition, diet changes and supplements early in the treatment course improved the patient's symptoms.

[9] Metastasis is the spread of a cancer from one organ to another.

[10] Lynch syndrome, often called hereditary nonpolyposis colorectal cancer (HNPCC), is an inherited disorder that increases the risk of many types of cancer, particularly cancers of the colon (large intestine) and rectum, which are collectively referred to as colorectal cancer. Variations in certain genes (MLH1, MSH2, MSH6, PMS2, or EPCAM) increase the risk of developing Lynch syndrome. http://ghr.nlm.nih.gov/condition/lynch-syndrome, retrieved August 13, 2014.

When the patient reported recurrence of blood-streaked diarrhea in April, the PCP requested a routine GI appointment, which was scheduled for 49 days later. The patient and one provider subsequently made unsuccessful attempts to reschedule that appointment to an earlier date. The ED provider told us that he made this request (via an "added comment" in the consult) because of the patient's anxiety, not because there was a clinical urgency. We found no documented evidence that the request was reviewed and considered by a GI provider. After evaluating the patient in June, the GI provider ordered a routine colonoscopy, which was completed about 11 weeks later. The GI provider noted the patient had symptoms consistent with IBD, including bloody diarrhea, cramping, abdominal pain, and weight loss. He provided the patient with information about IBD.

According to the facility, the 78-day wait time from the GI clinic appointment to the colonoscopy fell within the GI Service's expected wait timeframes. The facility reported an average wait time of approximately 90 days for routine procedures, while urgent cases could be completed within 2 weeks depending on scheduling and patient availability.

We could not determine whether the patient's outcome would have been different had he received the diagnostic colonoscopy sooner. The colonoscopy and subsequent computerized tomography scan revealed the patient had a large mass and advanced CRC with metastasis to the liver. As CRC is typically a slow-growing cancer, the GI providers and the general surgeon told us that the patient probably had CRC for the past several years.

Conclusions

We confirmed that almost 8 months elapsed between the patient's initial complaints of symptoms consistent with CRC until his colonoscopy. We did not find that there was a clinically significant delay in care.

The patient's clinical presentation was unusual for a patient with CRC for both the early age of onset as well as the short time period from initial symptoms to the discovery of advanced cancer. None of the providers were suspicious for CRC given the patient's age at presentation and no known family history, and reasonably considered IBD as the more likely diagnosis.

We could not say with certainty that the patient's outcome would have been different had he received the diagnostic colonoscopy sooner. The colonoscopy and subsequent computerized tomography scan revealed the patient had a large mass and advanced CRC with metastasis to the liver. As CRC is typically a slow-growing cancer, the patient likely had advanced CRC at the time of his initial presentation with symptoms.

We made no recommendations.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: August 22, 2014

From: Director, VA Mid-Atlantic Health Care Network (10N6)

Subj: **Draft Report** – Healthcare Inspection—Alleged Delays in Gastroenterology Care, Durham VA Medical Center, Durham, NC

To: Director, Atlanta Regional Office of Healthcare Inspections (54AT)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. The attached subject report is forwarded for your review and further action. I have reviewed the response of the Durham VA Medical Center, Durham, NC and concur with the absence of recommendations.

2. If you have further questions, please contact Lisa Shear, VISN 6 QMO, at (919) 956-5541.

(original signed by:)

DANIEL F. HOFFMANN, FACHE

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: August 22, 2014

From: Director, Durham VA Medical Center (558)

Subj: **Draft Report** – Healthcare Inspection—Alleged Delays in Gastroenterology Care, Durham VA Medical Center, Durham, NC

To: Director, VA Mid-Atlantic Health Care Network (10N6)

1. I concur with the Office of Inspector General Alleged Delay in Gastroenterology Care at the Durham VA Medical, Durham, NC. Durham received zero recommendations.

2. Thank you for the opportunity to review the draft report.

(original signed by:)

DEANNE M. SEEKINS, MBA, VHA-CM

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Joanne Wasko, LCSW Victoria Coates, LICSW, MBA Sheyla Desir, RN, MSN Tishanna McCutchen, MSPH, MSN Toni Woodard, BS Robert Yang, MD George Boyles, Office of Investigations

Appendix E

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