



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Quality of Care Issues

**W. G. (Bill) Hefner VA Medical Center
Salisbury, North Carolina**

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Executive Summary

The VA Office of Inspector General (OIG), Office of Healthcare Inspections conducted an evaluation to determine the validity of allegations regarding quality of care issues at the W.G. (Bill) Hefner VA Medical Center (the medical center) Salisbury, North Carolina. The complainant alleged that his friend, who had a history of colon polyps, received inadequate care at the medical center and the Winston-Salem community based outpatient clinic. The patient was diagnosed with colon cancer by a private-sector physician in January 2005 and died 7 weeks later. While the complainant did not specifically allege wrongdoing, he questioned how the patient could progress from a “clean bill of health” to untreatable colon cancer in a short period of time.

We determined that the patient’s diagnostic testing was delayed on several occasions and that providers missed multiple opportunities over a period of years to diagnose the colon cancer. We believe that had providers followed-up with appropriate colonoscopy surveillance testing to remove polyps, it is possible that the patient’s developing colon cancer could have been detected and treated in time to prevent metastatic disease.

We recommended that the medical center require that patients with known risk factors for colon cancer receive appropriate and timely diagnostic testing and referrals in accordance with professional practice guidelines. We also recommended that the medical center require this case be evaluated for possible disclosure to the patient’s family.

The Veterans Integrated Service Network and Medical Center Directors agreed with our findings and recommendations and submitted appropriate action plans. We will follow up on proposed actions until they are completed.



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

TO: Director, W. G. (Bill) Hefner VA Medical Center, Salisbury, North Carolina (659/00)

SUBJECT: Healthcare Inspection – Quality of Care Issues, W.G. (Bill) Hefner VA Medical Center, Salisbury, North Carolina

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections evaluated allegations of inadequate care and failure to diagnose colorectal cancer (CRC) in a patient at the W.G. (Bill) Hefner VA Medical Center (the medical center). The purpose of our review was to determine whether the allegations had merit.

Background

The medical center is a tertiary care facility that provides medical, surgical, rehabilitative, and nursing home care to veterans in a primary service area that includes 23 counties in the Piedmont region of North Carolina. The medical center has 159 hospital beds and 270 long-term care beds, and operates community based outpatient clinics (CBOCs) in Charlotte and Winston-Salem. The medical center is part of Veterans Integrated Service Network (VISN) 6.

The complainant wrote to the Veterans Benefits Administration Regional Office in Winston-Salem on April 22, 2005, outlining his concerns about the care his friend received from providers at the medical center and the Winston-Salem CBOC (WSCBOC). It is unclear how the complaint letter was processed, but no apparent action was taken. In April 2007, the complainant resubmitted his letter to the VA OIG.

The complainant reported that the patient, who was his friend, told him about the care he received at the medical center and the WSCBOC. The patient, who had a history of colon polyps, complained to his providers in 2004 of “stomach problems.” He was allegedly told to take over-the-counter laxatives. In March 2004, a colonoscopy (an internal examination of the colon) was attempted but aborted because it was difficult to pass the colonoscope and painful for the patient. He did not receive a follow-up colonoscopy. On January 7, 2005, the patient was diagnosed with CRC by a private-sector physician; he died 7 weeks later.

While the complainant did not specifically allege wrongdoing, he questioned how the patient could progress from a “clean bill of health” to untreatable colon cancer in a short period of time, and why the difficult colonoscopy in March 2004 did not prompt further testing.

Scope and Methodology

We conducted a site visit September 25–26, 2007. We interviewed the complainant, the patient’s step-daughter, medical center clinical care providers, and administrative and other staff knowledgeable about the patient’s care. We consulted with a gastroenterologist and a radiologist not affiliated with the medical center or VISN 6. We reviewed relevant medical center and Veterans Health Administration policies, American College of Gastroenterology (ACG) and American Society for Gastrointestinal Endoscopy (ASGE) professional practice guidelines, as well as the patient’s medical records, patient advocate reports, and other clinical reviews of the patient’s care. This review was conducted in accordance with the *Quality Standards for Inspections* published by the President’s Council on Integrity and Efficiency.

Case Summary

The patient was a 69-year-old veteran treated at the medical center from 1995 through January 3, 2005. His past medical history was significant for coronary artery disease with open heart surgery in September 2002, atrial fibrillation,¹ severe dilated cardiomyopathy,² diabetes mellitus, gastric ulcer, chronic obstructive pulmonary disease,³ and colon polyps.⁴

During a colonoscopy in October 1995, the patient had two large polyps removed; however, both specimens were lost during the procedure and a pathology examination and diagnosis could not be made. The patient received annual colonoscopies at the medical center in 1996, 1997, and 1998, when he also had a polypectomy.⁵ On February 9, 2000, the patient had a colonoscopy with multiple polypectomies. The colonoscopy report indicated severe diverticular disease⁶ of the sigmoid colon and multiple sessile (flat) polyps of the ascending colon. This exam was not fully satisfactory due to stool in the colon. Four submitted specimens, each 3-4 millimeters in size, were found to be tubular adenomas.⁷

¹ A rapid irregular heart rhythm which involves the two upper chambers of the heart.

² Decreased function of the heart’s main pumping chamber associated with its dilatation.

³ A lung condition characterized by limitation of airflow.

⁴ A growth of tissue projecting from a mucous membrane in the intestine.

⁵ The removal of colon polyps by a surgical procedure during colonoscopy.

⁶ Mucosal outpouchings through the large bowel wall.

⁷ A benign epithelial tumor found commonly at colonoscopy. They are removed because of their tendency to become malignant.

The patient received close follow-up care at the medical center and WSCBOC between August 2000 and January 2004 for heart rhythm abnormalities, diabetes, and hypertension control. The medical records show 25 visits during this timeframe. The patient's primary care provider (PCP) at the WSCBOC noted on January 10, 2003, that a repeat colonoscopy would be needed within the next year. The PCP placed a surgical consultation request on May 21, but an evaluation for colonoscopy was not scheduled. He placed a second request on September 25. The surgeon evaluated the patient on January 2, 2004, and the patient's colonoscopy was scheduled for March.

The patient had an incomplete colonoscopy on March 16, 2004. The surgeon was unable to pass the colonoscope beyond 30–35 centimeters (cm) due to patient discomfort and colon stiffness. To follow up on the incomplete colonoscopy, the surgeon ordered a double contrast barium enema (DCBE). A DCBE involves instilling air into the colon in conjunction with barium contrast medium,⁸ along with x-ray examination of the colon and rectum.

Inexplicably, the patient's PCP ordered a barium enema (BE)⁹ on May 10, and then promptly discontinued the order. He then documented that the colonoscopy should be attempted again in July 2004, but he did not enter a consultation request for this service.

Despite the DCBE order, a single contrast BE was completed on June 24, 2004. The radiologist reported that the entire colon and a segment of the terminal ileum¹⁰ were visualized. Numerous diverticula were seen in the left colon, with no evidence of diverticulitis (acute inflammation of pouches). The surgeon discharged the patient from the surgery clinic on August 17 with the diagnosis of diverticulosis (chronic condition of diverticula). Follow-up care was delegated to the PCP; however, the patient was not seen until October 18, when he again complained of constipation despite taking a laxative and an over-the-counter stool softener.

The patient presented to a private hospital's emergency room (ER) on December 29 with complaints of abdominal pain and nausea. An abdominal computed tomography scan¹¹ showed possible colon cancer. Hospital providers notified the patient's PCP at WSCBOC of the findings and set up a follow-up appointment for January 2005.

The PCP evaluated the patient in clinic on January 3, 2005, and noted constipation, abdominal pain, rectal bleeding, and a 16-pound weight loss. The PCP's treatment plan included a high-fiber diet and laxatives. Despite his apparent knowledge of the CT scan results, the PCP did not mention this in his progress note or pursue an aggressive

⁸ A type of contrast that outlines specific areas inside the body, which creates a clearer image.

⁹ A special x-ray of the large intestine after barium sulfate is placed into the rectal area.

¹⁰ The most distal part of the small intestine before it joins the large intestine.

¹¹ A computerized x-ray procedure that produces cross-sectional images of the abdomen layer by layer.

gastrointestinal work-up. A follow-up clinic appointment was scheduled for 1 month later.

The patient was again evaluated in the private hospital's ER on January 4 for abdominal pain. A gastroenterologist attempted a colonoscopy but was unable to pass the colonoscope past the splenic flexure.¹² The patient underwent an exploratory laparotomy and bowel resection on January 7; pathology reports confirmed Stage IV¹³ colon cancer with metastasis to the stomach and local lymph nodes. The patient was placed under hospice care and expired February 25, 2005.

This case was evaluated as part of the medical center's peer review program.

Inspection Results

We determined that medical center and WSCBOC providers did not adequately monitor the patient despite his increased risk for CRC.

Issue 1: Delay in Follow-Up Testing After Incomplete Colonoscopies

We found that the patient did not receive timely follow-up testing after two incomplete colonoscopies. ACG guidelines recommend that patients with a history of multiple tubular adenomatous polyps have a colonoscopy with biopsy of polyps every 3 years. These guidelines were not met, as follows:

- On February 9, 2000, the patient had a colonoscopy with polypectomy. However, the exam was inadequate because of stool in the colon. Due to the poor preparation, a repeat colonoscopy should have been completed sooner than 3 years to ensure an accurate diagnosis.¹⁴
- The next colonoscopy (due no later than February 2003) was not requested until May 21, 2003. No apparent action was taken to schedule the patient, and the PCP requested the colonoscopy again on September 25. The patient was not seen in the surgical clinic until January 2004 and his colonoscopy was not attempted until March 16, 2004, about 10 months after the initial request and 13 months beyond the due date.
- The March 16, 2004, colonoscopy was aborted due to patient discomfort and the surgeon's inability to pass the colonoscope beyond 35 cm.

¹² The sharp right-angle bend of the transverse colon under the spleen as it becomes the descending colon.

¹³ Cancers that have often metastasized, or spread to other organs or throughout the body.

¹⁴ ASGE/ACG Taskforce on Quality in Endoscopy, *American Journal of Gastroenterology*; 101:873-885, 2006.

Issue 2: Appropriateness of Follow-Up Testing

To follow-up on the failed colonoscopy of March 2004, the surgeon ordered a DCBE; however, this test did not constitute an acceptable approach as defined by professional practice guidelines for high-risk patients. Further, an independent radiologist who reviewed the DCBE images and report identified errors in the completion and interpretation of this study, as follows:

- While the surgeon ordered a DCBE, a single contrast BE was actually performed. Compared with DCBE, BE is less likely to detect polyps.¹⁵
- The BE was mislabeled as a DCBE, an error unknown to the patient’s clinicians at the time they judged that no further testing was needed.
- The BE was technically inadequate inasmuch as the images did not include the entire colon (despite the radiologist’s report stating that he visualized the entire colon and a segment of the terminal ileum). We could not determine whether the radiologist was present during the BE, which could have allowed him to visualize the entire colon even though the images were not captured.

The radiologist who interpreted the BE in 2004 noted diverticulosis of the distal descending and sigmoid colon, and the surgeon discharged the patient from surgical clinic. During our on-site review, the new Chief of Imaging Service reviewed the case but did not mention that the study was mislabeled or that it was technically inadequate. She did note that most newly trained radiologists would have performed a DCBE. In addition to finding that the image was inadequate, our independent radiologist noted a possible abnormality.

Issue 3: Failure to Prevent Metastatic Colon Cancer

We determined that due to a series of missed opportunities, medical center providers failed to diagnose CRC in the early stages when it was potentially treatable. The patient had received annual colonoscopies from 1995–1998 and again in 2000, a frequency that exceeded community standards of care. Yet despite the patient’s history of adenomatous polyps and an incomplete colonoscopy in 2000, he did not receive timely follow-up colonoscopies. Instead, a medical center radiologist performed a BE, which was not the appropriate test, and that study was not adequately completed. When the patient complained about “stomach problems,” providers ordered a high-fiber diet and/or laxatives.

¹⁵ John H. Bond, MD, for the Practice Parameters Committee of the American College of Gastroenterology, Gastroenterology Section, Minneapolis Veterans Affairs Medical Center and University of Minnesota, Minneapolis, Minnesota, *American Journal of Gastroenterology* – Vol. 95, No. 11, 2000.

Medical center managers told us that prior to July 2004, the facility lacked adequate staffing and equipment to meet the demand for colonoscopies. For the period March 2003–March 2004, the average time from the request for surgical consultation to completion of the colonoscopy procedure was 135 days. In addition, there was no system in place to prioritize patients for colonoscopies based on their risk factors.

In July 2004, medical center managers hired a gastroenterologist to perform procedures previously completed by staff surgeons, established a dedicated gastroenterology (GI) suite, and obtained new colonoscopy equipment. Vendor contracts are now in place to refer patients for private-sector colonoscopies, which has improved timeliness. For example, in October 2005, there were 840 patients waiting for colonoscopies; by April 2006, there were only 4 patients on the waiting list. At the time of our review, the average time from GI consultation to completion of the colonoscopy had improved to 38 days.

Although the new GI suite was established in July 2004, the patient did not receive a follow-up colonoscopy at that time. Providers told us that they thought the BE was an adequate follow-up test for the incomplete colonoscopy. However, both the surgeon who performed the March 2004 colonoscopy and the Chief of Staff told us that they would handle the case differently today. Given currently available resources, they would repeat the colonoscopy onsite or refer the case to a private-sector colleague skilled in managing difficult colonoscopies.

Conclusion

We concluded that the patient’s diagnostic testing was delayed on several occasions and that providers missed multiple opportunities over a period of several years to diagnose CRC. The patient had two incomplete colonoscopies, neither of which was appropriately followed up. Optimal surveillance for patients with a history of multiple tubular adenomatous polyps consists of a repeat colonoscopy and removal of adenomas no less than every 3 years. Medical center providers did not repeat the March 2004 colonoscopy and instead opted for a DCBE, which was not indicated for this patient due to his increased risk for cancer. In addition, a BE was completed but it was not air-contrast as ordered and labeled, and was technically inadequate.

We believe that had providers followed-up with appropriate diagnostic testing starting with the first incomplete colonoscopy in 2000, it is reasonable to expect that the patient’s developing CRC could have been detected and treated in time to prevent metastatic disease.

Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Medical Center Director requires that patients with known risk factors for CRC receive appropriate and timely diagnostic testing and referrals in accordance with professional practice guidelines.

Recommendation 2. We recommended that the VISN Director ensure that the Medical Center Director requires that this case be evaluated for possible disclosure to the patient's family.

Assistant Inspector General Comments

The VISN and Medical Center Directors agreed with our findings and recommendations and provided acceptable improvement plans. Actions have been implemented to ensure patients with risk factors for CRC receive appropriate and timely diagnostic testing. The case will be disclosed to the family in March 2008. See pages 8–12 for the Directors' comments. We will follow up until the planned actions are completed.

(original signed by:)

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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: January 23, 2008

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

Subject: **Quality of Care Issues, W. G. (Bill) Hefner VA Medical Center, Salisbury, North Carolina**

To: Director of Health Care Inspections for Atlanta Regions

1. The attached subject report is forwarded for your review and further action. I have reviewed the responses and concur with the facility's recommendations.
2. Please contact Carolyn Adams, Director, Salisbury VAMC, at (704) 638-9000, extension 3344, if you have any further questions.

(original signed by:)

DANIEL F. HOFFMANN, FACHE

Medical Center Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: January 18, 2008

From: Director, W. G. (Bill) Hefner VA Medical Center, Salisbury,
North Carolina (659/00)

**Subject: Quality of Care Issues, W.G. (Bill) Hefner VA Medical
Center, Salisbury, North Carolina**

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

1. This is to acknowledge receipt and thorough review of the Office of Inspector General Follow-Up Evaluation draft report. I concur with all recommendations for improvement identified in the report.
2. The responses and action plans for each recommendation are enclosed.
3. Should you have any questions regarding the comments or implementation plans, please contact me at (704) 638-9000 ext. 3344.

(original signed by:)

CAROLYN L. ADAMS

Director, Salisbury VA Medical Center

Medical Center Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's Report:

OIG Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Medical Center Director requires that patients with known risk factors for CRC receive appropriate and timely diagnostic testing and referrals in accordance with professional practice guidelines.

Concur

Target Completion Date:

Completed

The facility has implemented the following processes and monitors to enhance clinical efforts to ensure that veterans with known risk factors for CRC receive appropriate and timely diagnosis and referral in accordance with professional practice guidelines.

1. Establishment and appointment of a Program Support position effective December 26, 2007 with the following responsibilities to monitor CRC screening: (a) Establishing a confidential electronic database to track all positive CRC screening results, (Fecal Occult Blood Tests - FOBT) and abnormal colonoscopy findings. Veterans that are treated outside of the facility will also be monitored for appropriate follow-up care. Veterans who are actively followed by the GI providers for specific conditions such as Crohn's and Ulcerative Colitis will also be monitored. (b) Collaborating with the Chief of Gastroenterology, the Endoscopy Nurse Manager and Medicine Administrative Officer to improve screening processes as needed. (c) Assisting the Medicine Service Administrative Officer and Program Specialist in the identification, development and monitoring of specific GI clinical indicators. These include, but are not limited to,

clinic wait times, physician procedure/clinic templates and schedules, C-4 Collaborative, and the endoscopy pre-procedure program.

2. A RN Case Manager position has also been established to track high grade dysplasia and cancer identified from endoscopies. The case manager is notified of these findings from pathology and all cases will be monitored for appropriate follow-up care. Patient and family involvement is a key component of this process improvement.

3. The facility established a Colorectal Cancer C-4 Collaborative Team during FY07. This Team is involved with the FY08 VHA monitor focusing on improving the timeliness from the time a veteran is FOBT positive until he/she has a colonoscopy. The GI Physician Staff, Medicine Service Administrative Officer, Endoscopy Nurse Manager and GI program support lead the efforts with this initiative. The C-4 Team will continue to review and enhance this patient care process for colorectal cancer screening throughout FY08. Colorectal Cancer screening remains a critical performance measure for FY08. The facility exceeded the goal for FY07 and is currently meeting the benchmark for FY08.

4. Medicine Service continues to have in place two GI service contracts with a Medical Center and Digestive Health Centers located in Charlotte and Winston Salem NC. The Service amended the contracts approximately three months ago to increase patient referrals from 80 per month to 110 / month for each vendor. The goal is to outsource approximately 220 screening colonoscopies monthly. A process has also been implemented to fast track FOBT+ veterans with contract vendors if additional access is needed to meet the service C-4 goals.

5. The facility continues to enhance staffing for the GI services. An additional Gastroenterologist entered on duty January 7, 2008. The facility will continue to recruit for two additional Gastroenterologists. A third Physician Extender was appointed in December 2007 and a fourth PA position has been advertised locally and nationally to assist physicians

with addressing the large volume of new referrals received monthly in GI (540 avg) .

Recommendation 2. We recommended that the VISN Director ensure that the Medical Center Director requires that this case be evaluated for possible disclosure to the patient's family.

Concur

Target Completion Date:

March 8, 2008

The facility will provide institutional disclosure to the patient's family per the facility policy which is based on the VHA Directive 2005-049. The facility has conferred with Regional Counsel who has provided guidance. The family will be offered appropriate options and will be made aware of the Tort Claim process and the 1151 Disability claim process. They will be provided with information concerning where to obtain assistance in filling out the necessary forms. The disclosure will be documented in the medical record.

OIG Contact and Staff Acknowledgments

OIG Contact	Victoria H. Coates Director, Atlanta Office of Healthcare Inspections (404) 929-5962
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Acknowledgments	David Griffith, Health Systems Specialist Jerome Herbers, M.D.
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Report Distribution

VA Distribution

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