Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Quality of Care and Patient Safety Issues
Martinsburg VA Medical Center
Martinsburg, West Virginia

Report No. 11-02756-201

June 13, 2012

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:
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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine the validity of allegations received from a complainant. The allegations addressed perioperative patient safety and administrative oversight of processes at the Martinsburg VA Medical Center (the facility), Martinsburg, WV.

We did not substantiate that the facility failed to take appropriate action when surgical instruments were found to have discoloration, and when surgeons observed the presence of microfibers in the surgical field during cataract surgeries.

We did not substantiate allegations that a surgeon was responsible for higher than expected blood loss during surgery, falsely documented operative reports, or that the facility failed to provide appropriate oversight of surgery. We substantiated that the facility did not remove a surgeon from duty following a sentinel event; however, we found no requirement for removal. We recommended that the Facility Director conduct a risk assessment to determine whether local policies related to sentinel events should be modified to include providing temporary relief from duty for staff.

We did not substantiate delays in diagnosis and surgical mismanagement of two patients; however, we identified a lack of medical record documentation. We recommended that the Facility Director strengthen processes to ensure that practitioners outline their treatment decision-making process in the medical record.

We substantiated a delay in patient transport from the operating room, although we did not substantiate actual risk. We recommended that the Facility Director ensure that ICU, OR, and PACU staff receive training on any newly purchased beds and ensure that OR staff receive training on reporting near-miss and patient safety incidents.

We did not substantiate that the facility added additional surgery services without planning for the necessary support services and staff the additions would require. We substantiated canceled or delayed surgeries due to lack of beds; however, the facility acted to ensure bed availability. Therefore, we made no recommendations.

We substantiated allegations of clinical and administrative mismanagement of Rapid Response Team (RRT) and Cardiac Arrest Team (CAT) activity. We did not substantiate allegations regarding oversight of patient deaths. We recommended that the Facility Director strengthen policies regarding response to changes in clinical conditions and monitor adherence to policy; comply with VHA standards for ED physicians; and designate one committee with responsibility for reviewing all CAT and RRT processes.

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

TO: Veterans Integrated Service Network(10N5) Director

SUBJECT: Healthcare Inspection – Healthcare Inspection – Quality of Care and Patient Safety Issues, Martinsburg VA Medical Center, Martinsburg, West Virginia

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to determine the validity of allegations of compromised patient safety at the Martinsburg, WV, VA Medical Center (the facility).

Background

The facility, part of Veterans Integrated Service Network 5, has 70 inpatient beds, 121 Community Living Center (CLC) beds, 8 Compensated Work Therapy Transitional Housing beds, and 312 domiciliary beds. It provides a broad range of inpatient and outpatient health care services including medical, surgical, mental health, geriatric, and rehabilitation services. The facility serves approximately 138,235 veterans in a primary service area that includes 23 counties in West Virginia, Maryland, Virginia, and Pennsylvania.

Allegations

A complainant contacted OIG's Hotline with quality of care and patient safety concerns. The complainant alleged mismanagement of patient care and poor oversight of hospital processes, resulting in actual or potential harm to patients. Specifically, the complainant alleged that:

• The facility failed to take appropriate action when surgical instruments were found to have discoloration, and when surgeons observed the presence of microfibers in the surgical field during cataract surgeries.

• A surgeon was responsible for higher than expected blood loss during surgery and that the facility failed to take action. In addition, the surgeon allegedly falsely documented the amount of blood loss in operative reports.

• The facility failed to provide immediate relief from duty for a surgical team after a sentinel event.[1]

• Delays in diagnosis and mismanagement of care for two surgical patients resulted in significant postoperative complications.

• A patient was placed at risk for harm immediately following surgery because of a delay in transport from the operating room (OR) to the Intensive Care Unit (ICU) due to his bed not fitting into the elevator.

• The facility added additional surgical services without planning for the necessary support services and staff the additions would require.

• Unavailability of inpatient beds caused delays and cancellations in surgeries.

• Delays in recognition of worsening clinical conditions resulted in failure to activate the rapid response team or cardiopulmonary resuscitation team in a timely manner. Further, the facility failed to take action regarding deaths among these patients.

• The facility failed to provide oversight of cardiopulmonary resuscitation and rapid response team processes.

• Management was advised of safety issues and failed to take action. In addition, senior management created an environment that discouraged staff from voicing concerns.

Other allegations related to personnel concerns were reported that did not fall under the purview of the Office of Healthcare Inspections and we did not address them in this review.

Scope and Methodology

We conducted a site visit July 18-22, 2011. We interviewed facility leadership, physicians, clinicians, nurses and support staff. We reviewed patients' medical records, quality management documents, credentialing and privileging documents, facility and Veterans Health Administration (VHA) policies, committee meeting minutes, preventative maintenance documents, service records and OR schedules. In addition, we consulted with ophthalmic surgeons, vendors of ophthalmic surgical packages, and experts in urologic surgery, and toured the facility's Central Instrument Processing (CIP) suite/unit.

[1] The Joint Commission (JC) defines a sentinel event as an unexpected occurrence involving death or serious physical or psychological injury (including loss of limb or function), or the risk thereof.

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

Inspection Results

Issue 1: Patient Safety

The complainant alleged that the facility failed to take appropriate action when surgical instruments were discovered to have discoloration, and when surgeons observed the presence of microfibers in the surgical field during cataract surgeries. We did not substantiate this allegation.

Discolored Surgical Instruments

In April 2011, the Chief of CIP noticed discolorations on some reprocessed surgical instruments. Discoloration spots/stains/rust can indicate damage to the coating of the instrument which can harbor microscopic bioburden. The discolorations were removed by additional hand scrubbing with a specialized cleaning compound, and the instruments were re-sterilized. The Chief of CIP also notified the manufacturer of the machine used to sterilize the instruments and the facility's biomedical and operations services and requested assistance in addressing the discolorations.

While the discoloration problem did not resolve after the manufacturer's service representative came to the facility and serviced the machines, the discoloration did stop after the facility's operations foreman and a biomedical engineering technician disassembled and cleaned the water holding tanks and replaced water filters. The Chief of CIP reported these events to the CIP's oversight committee, and the facility leadership reported these events to the VISN and VHA Central Office.

The Chief of CIP continued to monitor the process and in May, ordered an inspection of all recently reprocessed instruments. During the inspection they found discolored instruments and CIP staff hand-scrubbed and re-sterilized the instruments.

The discolorations reappeared at the end of June, more visible than before. An inspection of water quality in the holding tanks showed high levels of conductivity and iron, suggesting the water was not deionized.

Most surgical instrument manufacturers recommend deionized water for the final rinse after washing, in order to prevent mineral deposits on instruments. Deionization is the process of removing minerals (for example, calcium or iron) from water. Water can be deionized by exposure to specially treated plastic beads which capture and withdraw ions from the water.

The facility produced deionized water by utilizing water tanks containing plastic beads. The deionizer tanks retained the beads with mesh screens that allowed passage of water but not beads. The water supply for the washers flowed through two deionizer tanks, then into a primary holding tank. From this primary tank, deionized water flowed into secondary holding tanks located inside the washers.

The facility's inspection revealed a damaged mesh screen inside a deionizer tank. Beads had been flowing out of the deionizer tanks into the holding tanks inside the washers. When the water was heated in the washers, the plastic beads melted and released iron and other minerals into the water, resulting in increased conductivity and discolorations on the instruments.[2]

The deionizing system was dismantled and cleaned, and new component parts and extra water filters were added to capture any loose beads and to prevent recurrence. During this repair, three surgeries were performed at the facility using only instruments that had been hand-scrubbed prior to sterilization. All other surgeries were cancelled. The facility leadership notified VISN and VHA Central Office personnel about the reappearance of the discoloration and the actions taken for resolution. The VHA Sterile Processing Program director determined that veterans had not been placed at risk. The surgery schedule resumed the following day. At the time of our inspection, there had been no further instances of discolored instruments.

We found that although the facility did not cancel all surgeries while evaluating the causes for discolored instruments, they acted promptly to ensure all instruments were appropriately reprocessed prior to use. The Chief of CIP implemented a process for re-cleaning and sterilizing surgical instruments and prioritized the release of useable instrument trays from CIP. During this process, the facility Chief of Staff (COS) and Chief of CIP cancelled surgeries that could not be performed with hand-scrubbed instruments in order to provide for safe patient care while maintaining facility operations.

Microfibers observed during Cataract Surgeries.

The complainant alleged that the facility failed to cancel surgeries when an ophthalmologist performing cataract surgeries noted microfibers intermittently present in the surgical field. We substantiated that the facility did not cancel surgeries when surgeons noted microfibers during some cataract surgeries; however, cancellations were not warranted.

Ophthalmologists perform cataract surgery using a microscope and highly specialized instruments. The surgery involves entering the front portion of the eye, removing the existing lens, and inserting an artificial lens in its place. There are multiple sources of potential contamination by microfibers during eye surgery. Microfibers can shed from

[2] The washers heated the water to >180 degrees. The manufacturer of the plastic beads informed the facility's Operation foreman that the beads melted at temperatures >160 degrees.

gauze, surgical field drapes, and instrument wrappings. While not completely avoidable, preventive measures can reduce the frequency of microfibers. Surgical instruments can be irrigated with sterile fluid and wiped with a fiber free sponge or a lint-free instrument wipe.

Some high precision instruments are too sensitive to tolerate rinsing or wiping. These instruments are generally prepared with ultrasonic cleaning or other sterilization process. Some surgical vendors supply specially prepared, pre-packaged 'fiber-free' trays to reduce the likelihood of microfibers.

Despite these precautions, the ophthalmic surgical literature indicates that retained intraocular microfibers during cataract surgery do occur.[3] Process improvement measures focus on reducing the incidence of the occurrence. It is common practice to irrigate the eye if microfibers are noted. However, even irrigation may not eliminate fibers completely. Retained fibers are well tolerated and do not cause complications. The fibers are inert and sterile, and have not been associated with post-operative infections, inflammation, or vision loss.[4]

Facility staff told us that they observed microfibers during some cataract surgeries. The fibers were removed by irrigating the surgical field with sterile fluid. The staff reported these observations to the facility's surgical oversight committee. In response, CIP staff worked to reduce the occurrence of microfibers by removing sterile cloth drapes from the surgical instrument trays. When episodes reoccurred, CIP purchased pre-packaged fiber-free surgical instrument trays. At the time of our inspection, there had been no further reoccurrences.

We found that facility staff acted appropriately to ensure patient safety when they discovered discolorations on surgical instruments and microfibers in the cataract surgical field.

Issue 2: Surgical Competence

The complainant alleged that a surgeon was responsible for higher than expected blood loss during surgery, resulting in complications for three patients and that the surgeon allegedly underreported the amount of blood loss in his operative reports. Further, it was alleged that facility leadership failed to take corrective actions. We did not substantiate these allegations.

The three patients were identified and their surgical histories are discussed below. Facility leadership reviews of these cases were timely with appropriate actions.

[3] Yuen H K L, Lam RF, et al. (2005). "Retained presumed intraocular cotton fiber after cataract operation: Long-term follow-up with in vivo confocal microscopy." Journal of cataract and refractive surgery **31**(8): 1582-1587.
[4] Ibid.

Case Summary - Patient 1: The patient, a man in his mid nineties with a history of cardiovascular disease and benign prostate hypertrophy,[5] presented to the facility's Urology Clinic with acute urinary retention. A urologist performed a cystourethroscopy[6] and inserted a Foley catheter[7] for chronic use. The patient returned a few weeks later complaining of discomfort from the catheter. The urologist outlined treatment options and warned the patient that because of his large prostate, surgery was likely to result in significant blood loss, and might be ineffective. After reviewing the risks, benefits, and alternatives, the patient requested surgery.

In March 2010, the patient underwent a suprapubic prostatectomy[8]. The surgeon noted bleeding during the procedure, and documented an estimated blood loss of 2500 cubic centimeters (cc). Postoperatively, the patient had persistent bleeding resulting in hypovolemic shock.[9] During the first 24 hours after surgery, he required multiple blood product transfusions. The patient remained in the ICU for 10 days after surgery. In addition to the intraoperative bleeding noted above, he had multiple postoperative complications including acute renal failure, elevated sodium levels, and inadequate nutritional intake.

The patient was transferred to the medical floor on postoperative day 11. However, he was unable to participate in physical therapy, could not tolerate oral food, and was unable to communicate. He developed a urinary tract infection and further deteriorated, requiring re-admission to the ICU 3 days later. After discussions with his surrogate decision maker regarding prognosis, the patient was transferred to the palliative care program, where he died in mid-May.

Finding: We noted that this patient had pre-existing risks (including age and prostate size) for bleeding and other complications prior to surgery, and substantial intra-operative and post-operative bleeding is a known complication of this procedure.[10] The surgeon's documented estimate of blood loss was at the high end of the range expected for the procedure. The patient developed multiple post-operative complications despite

[5] Benign prostatic hypertrophy refers to enlargement of the prostate gland, potentially slowing or blocking the urine stream.
[6] Cystourethroscopy is a procedure to visualize portions of the urinary tract. A small tube with a camera is inserted into the bladder through the urethra.
[7] Indwelling urethral catheters used for bladder drainage. They are also used for management for patients with chronic urinary retention who are refractory to, or not candidates for, other interventions (e.g., transurethral resection of the prostate (TURP)). Urethral catheters are inserted through the tip of the urethra.
[8] Suprapubic prostatectomy is the surgical removal of an enlarged prostate through an incision made through the lower abdomen. After surgery, a catheter is placed into the bladder through the incision to help irrigate the bladder with fluid, and another catheter is placed in the urethra for bladder drainage.
[9] Hypovolemic shock is a consequence intravascular volume loss, such as, blood loss.
[10] Hedican SP, Walsh PC: Postoperative bleeding following radical retropubic prostatectomy. J Urol 1994; 152:1181–1183.

aggressive and appropriate treatments. The patient's course, while unfortunate, was not indicative of substandard surgical care.

Case Summary - Patient 2: The patient, a man in his eighties, had a long history of benign prostate hypertrophy with difficulty voiding. He had prior urology consultations and procedures, including a transurethral resection of the prostate (TURP) in 2001, and had intermittent episodes of urine retention requiring Foley catheters over several years.

In February 2010, the patient presented to the facility's Emergency Department (ED), again requiring a Foley catheter for urine retention and blood in his urine. Subsequent outpatient treatments were unsuccessful in stopping the bleeding.

The patient developed complications from persistent blood loss and was admitted in March requiring continuous bladder irrigation, blood transfusions, and supportive care. A cystourethroscopy and TURP to identify and treat the bleeding source were scheduled for 1 week later, after all pre-operative evaluations were completed.

Prior to the scheduled surgery, the patient developed clots in his bladder, which obstructed his Foley catheter. The patient's urethra was then inadvertently injured during attempts to irrigate his catheter, causing further bleeding. An emergent cystourethroscopy to evacuate the clots was performed, but he continued to bleed and required more blood transfusions.

In April, the patient underwent a cystourethroscopy with TURP. In his pre-operative note, the surgeon noted the patient's enlarged prostate and anticipated high intra-operative blood losses.

During the procedure, the patient experienced complications due to blood loss and required blood transfusions. The urologist documented an estimated blood loss of 750 cc. The anesthesiologist documented an estimated blood loss in the range of 2500 to 3000 cc. Postoperatively, the patient continued to bleed. He was given blood products and transferred to the ICU. A hematologist was consulted and attributed the patient's excessive bleeding to abnormal fibrinolytic activity[11] from the patient's large prostate gland. After starting a medication to promote clotting, the patient's bleeding slowed down and he was discharged home 1 week after surgery.

Finding: We found that this patient had a prolonged course with persistent symptoms associated with a large, obstructing prostate and anemia. Initially, non-surgical approaches were attempted, but were unsuccessful. Prior to the scheduled TURP, the patient had urethral trauma, further exacerbating his bleeding. Hematuria (blood in the

[11] A process by which blood clots dissolve prematurely.

urine) caused anemia severe enough to require blood transfusions prior to surgery. Even with these transfusions, the patient was still anemic prior to surgery.

This patient had a large prostate, which increased the probability of excessive intraoperative bleeding. However, without surgery, bleeding related to urethral injury would have persisted, and he had developed complications associated with persistent blood loss.

The surgeon's and anesthesiologist's estimations of blood loss did not coincide. Estimation of blood loss during this procedure is difficult, and variation between individual estimates is not uncommon. During the procedure, the surgeon irrigates the site continuously. The mixture of blood and irrigant cannot be measured because it flows directly from the suction catheter into a drain. Additionally, postoperative bleeding complications are difficult to control after TURP, and when the prostate is large there can be significant bleeding. Overall, we found no evidence that higher than expected blood loss occurred or that the surgeon intentionally underreported intraoperative blood loss.

Case Summary - Patient 3: A male patient in his sixties was diagnosed with prostate cancer in October 2009. The surgeon reviewed the treatment options with him, but the patient deferred treatment, stating that he was not ready to make a decision. In January 2010, the patient agreed to proceed with a recommended radical prostatectomy. The urologist reviewed with the patient the potential risks of surgery including significant bleeding and/or infection.

The urologist performed the prostatectomy in March 2010. In his operative note, the surgeon documented significant bleeding that was difficult to control. He estimated a total of 2700 cc of blood loss. During the procedure, the patient received five units of blood. He had very low blood pressure in the recovery room, and was transferred to the facility's ICU. Three days after surgery the patient received an additional two units of blood. He had no further bleeding and was discharged home 9 days after surgery.

Finding: Radical prostatectomy is associated with bleeding complications. Such cases can be associated with up to 2000-3000 cc of blood loss. Bleeding can be higher in older patients. The amount of bleeding documented in this case was within the range associated with this type of surgery. [12,13]

[12] McCullough, T. C., J. V. Roth, et al. (2004). "Estimated blood loss underestimates calculated blood loss during radical retropubic prostatectomy." Urologia Internationalis **72**(1): 13-16.

[13] Hedican SP, Walsh PC: Postoperative bleeding following radical retropubic prostatectomy. J Urol 1994; 152:1181–1183.

Issue 3: Sentinel Event Management

The complainant alleged that the facility failed to remove a physician from duty following a performance of a wrong site surgery. We substantiated this allegation.

The Joint Commission (TJC) defines a sentinel event as an unexpected occurrence involving death or serious physical or psychological injury (including loss of limb or function), or the risk thereof. TJC requires that leaders make support systems available for staff involved in an adverse or sentinel event. VHA policies and TJC standards have no requirement to relieve physicians or other staff of their work duties following a sentinel event, including wrong site surgery.

Case Summary - Patient 4: The patient was a man in his sixties with a history of severe back pain which prevented him from lying on the surgical table in the usual position for the proposed surgery. The surgical team took the required pre-operative safety measures and marked the surgical site. The orientation of the site was altered because of the patient's unusual position on the surgical table. The surgeon performed surgery on the wrong side. When he realized his error, he became very distressed and after completing the surgery, he immediately notified facility leadership. Leadership offered psychological services to the surgeon that day, however he declined. The surgeon resumed surgery as scheduled later the same day and performed two more procedures.

The following morning, facility leadership reviewed the surgical schedule and allowed the surgeon to perform three previously scheduled procedures. When those cases were completed, the surgeon took planned annual leave. At the time of our site inspection, the surgeon had received psychological counseling.

Findings

We found that facility leadership took appropriate administrative steps regarding disclosure, documentation, and investigation into the sentinel event. Medical records of the five patients the surgeon operated on following the sentinel event contained no documentation of intraoperative or postoperative complications.

Although the facility did not remove the physician from duty after a sentinel event, there was no requirement to do so and the provider was offered the opportunity for support services. The surgical team told us that the incident caused them emotional distress; however, facility leadership told us that they did not fully recognize the impact of the event on the team.

Professional agencies, such as the Institute for Healthcare Improvement (IHI) and Catholic Healthcare Partners, have published guidelines for responding to serious adverse events. IHI notes that "When patients are harmed, the empathy and sense of responsibility that defines caregivers also increases the likelihood that the emotional toll of these events may render the caregiver less capable of carrying on their immediate

responsibilities." The guidance encourages that immediately following a serious adverse event, leaders evaluate the impact of the event and address patient care loads or "provide temporary relief from assignment," so that involved staff have time to adjust and cope with the situation.[14,15]

We found that the facility took appropriate actions; however, the surgical staff were not given sufficient time to adjust and cope with the situation.

Recommendation 1: We recommended that the facility conduct a risk assessment to determine whether local policies related to sentinel events should be modified to include providing temporary relief from duty for staff.

Issue 4: General Surgery Quality of Care

The complainant alleged that delays in diagnosis and mismanagement of care for two surgical patients resulted in significant postoperative complications. We did not substantiate this allegation.

Case Summary - Patient 5: In May 2011, the patient, a man in his fifties, with a history of chronic low back pain treated with narcotics, went to the facility's ED with complaints of abdominal pain, nausea, and constipation.

On initial assessment in the ED, the patient was afebrile and had leukocytosis.[16] Findings on an abdominal computed tomography (CT) scan were suggestive of a small bowel obstruction.[17] After reviewing the CT scan with a radiologist, the surgeon admitted the patient and treated him with intravenous (IV) fluids, pain control, and bowel rest.

When the patient did not improve over the next 3 days, the surgeon consulted another surgeon who recommended exploratory surgery. Both surgeons took the patient to the OR later that day, found ischemic bowel,[18] and removed portions of the small and large bowel. The following day, additional portions of bowel were removed. The patient developed a leak at the initial surgical site and returned to surgery for a bypass ileostomy.[19] Three weeks later the patient was discharged home.

[14] Conway J, Federico F, Stewart K, Campbell MJ. Respectful Management of Serious Clinical Adverse Events. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2010. (Available on www.IHI.org).
[15] Catholic Healthcare Partners, Guidelines for Responding to Serious Adverse Events, 2010.
[16] Leukocytosis is an increase in white blood cells, often associated with an infection or inflammation.
[17] Small bowel obstruction is a blockage of the small intestine, causing a buildup of air and fluid often seen on imaging.
[18] Ischemic bowel occurs when there is a loss of blood supply to the intestine. This can be a late complication of small bowel obstruction, or other etiology.
[19] The small bowel is connected to an opening through the abdominal wall, to allow for the passage of stool into a plastic pouch attached to the skin.

Finding: We determined that the patient had significant co-morbidities, placing him at a high surgical risk. Thus, efforts at more conservative therapies were prudent. The initial CT scan did not show evidence of bowel ischemia, which would have prompted urgent surgical intervention. When conservative treatment efforts were not successful, exploratory surgery resulted in a definitive diagnosis and treatment for ischemic bowel. Medical literature supports that bowel ischemia is difficult to diagnose, particularly in patients without significant risk factors for this condition. [20,21]

Case Summary - Patient 6: After having been diagnosed with rectal cancer in 2009, the patient, a man in his fifties, initially decided against staging or treatment. He then presented in May 2011, requesting surgery. The surgeon discussed treatment options with an oncologist and another surgeon. Based on the patient's psychosocial and medical co-morbidities they recommended tumor removal without further diagnostic or therapeutic interventions.

The operative report documented a large tumor with only limited bowel available for reattachment following tumor removal. Post-operatively, the patient developed a fever and bloody stool. The surgeon ordered a CT scan, which did not show evidence of a leak at the surgical site. Because the patient's condition continued to decline, the surgeon performed emergency exploratory surgery. He discovered a leak at the surgical site, which he repaired and performed a diverting colostomy.[22] The patient developed multiple complications requiring prolonged ICU care. He was discharged home 6 weeks after his initial surgery.

Finding: We found that the patient presented for surgical treatment of a large rectal tumor with a high post-operative risk of morbidity and mortality secondary to multiple co-existing medical and social factors. Our interview with the surgeon, review of the medical records and review of expert opinions did not substantiate surgical mismanagement.

While the surgeon could have pursued other management options, he incorporated the complexities of this patient's conditions into his management approach. He demonstrated a patient-centric approach to surgical management by incorporating the patient's request to avoid a colostomy. In addition, the surgeon incorporated the recommendations of multiple subspecialists in the decision process. However, he did not document his decision making process in his progress notes.

[20] Howard, T. J., L. A. Plaskon, et al. (1996). "Nonocclusive mesenteric ischemia remains a diagnostic dilemma." The American Journal of Surgery **171**(4): 405-408.
[21] Park, W. M., P. Gloviczki, et al. (2002). "Contemporary management of acute mesenteric ischemia: Factors associated with survival." Journal of Vascular Surgery **35**(3): 445-452.
[22] A portion of the large intestine is connected to an abdominal wall opening to divert the passage of stool from a portion of the intestine, allowing the diverted section to heal.

Recommendation 2: We recommend that the facility strengthen processes to ensure that practitioners outline their treatment decision-making processes in the medical record.

Issue 5: Patient Flow

Delay in transporting from OR

The complainant alleged that a patient was at risk for harm immediately following surgery because of a delay in transfer from the operating room to the ICU when his bed did not fit into the elevator. We substantiated that there was a delay in transporting a patient to the ICU following surgery when the patient's bed would not fit in the elevator. However, we did not substantiate that he was at risk for immediate harm.

Case Summary - Patient 7: In May 2011, the patient, a man in his fifties, was admitted to the facility, for a total knee replacement. The surgery proceeded without incident, ending in the evening. The patient was moved directly from the OR table onto an ICU bed prior to transport to the ICU for recovery. Ordinarily, the patient would have recovered in the Post-Anesthesia Care Unit (PACU) and PACU staff would have transported him to the ICU. However, the PACU was closed during the evening shift, so an OR nurse and anesthesiologist transported him in the ICU bed and encountered difficulty loading the bed into the elevator. Eventually, they were able to retract the ends of the bed to a size the elevator could accommodate. The patient arrived in the ICU 25 minutes later. During transport, the patient was alert and his vital signs remained stable. The patient had a routine recovery in the facility and was discharged home 4 days later.

Finding: We found that the facility had purchased new beds for the ICU. The PACU staff were trained in the use of these beds but the OR nurses were not. The OR nurses received training on the new beds while we were on site.

Local policy required staff to report incidents where patient safety is compromised. No report was filed regarding this incident, and facility managers were unaware of the incident until our inspection.

Recommendation 3: We recommended that the facility ensures that ICU, OR, and PACU staff receive training on any newly purchased beds.

Recommendation 4: We recommended that the facility ensures that OR staff receive training on reporting near-miss and patient safety incidents.

Vascular Surgery

The complainant alleged that the facility added vascular surgery services without planning for the necessary support services and staff. We did not substantiate this allegation.

The facility is rated at an intermediate complexity level. VHA requires this level of facility to have a vascular surgeon available and able to respond by phone within 15 minutes or on-site within 60 minutes.[23] In order to maintain their current complexity level the facility was required to add vascular surgery services. The facility applied for and received approval from both the VISN and VHA Central Office to add the service. New equipment was added to the OR to support vascular surgery. The facility ensured that OR staff received training on the new equipment. All appropriate facility staff received training on care of the vascular surgery patient.

Delays and cancellations in surgeries

The complainant alleged that the facility lacked available inpatient beds, causing delays and cancellations in surgeries. We substantiated the allegation.

In February and March 2010, the facility's ICU underwent renovations to add additional beds. During this time, there were only four ICU beds available. Some surgeries require the availability of an ICU bed post surgery. We reviewed the surgical schedule and found seven surgeries were cancelled due to lack of inpatient beds. On February 28, three of the four ICU beds were occupied, necessitating the cancellation of three elective surgical procedures. During this time period, the facility cancelled four additional elective surgeries due to lack of inpatient medical beds. We reviewed the medical records of the seven patients whose surgeries were cancelled and determined that no patient harm occurred due to the cancellation of surgeries.

In addition to the cancelled surgeries, 29 surgeries in a 6-month period were delayed up to 2 hours due to lack of an inpatient bed. Eight of the delays were due to lack of an ICU bed, 14 were due to lack of a surgical bed, 4 due to lack of an observation bed, and 3 were delayed due to lack of a general medical bed.

We determined that the facility canceled or delayed surgeries due to lack of inpatient beds; however, in February 2010 an additional four ICU beds were added and renovations were underway to open a step-down unit for patients requiring less intensive care than provided in the ICU, but more intensive care than available on a medical-surgical unit. The facility had taken actions to ensure that additional medical and ICU beds were available.

Issue 6: Cardiopulmonary Resuscitation and Rapid Response Processes

The complainant alleged that delays in recognition or response to patients' worsening clinical conditions resulted in failure to activate the Rapid Response Team (RRT) or Cardiac Arrest Team (CAT) team in a timely manner, and that the facility failed to take

[23] VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010

appropriate actions regarding deaths among these patients. We substantiated that facility staff failed to activate the CAT or RRT in a timely manner in some cases. We did not substantiate that the facility failed to take appropriate actions regarding these deaths.

Alleged Delays in Recognition or Response to Worsening Clinical Conditions

VHA recognizes that rapidly responding to a potential emergency is a mechanism to reduce the number of in-hospital cardiopulmonary arrests and that prevention of in-hospital cardiac arrests may reduce mortality.[24] The IHI promotes several strategies to prevent avoidable patient deaths, including deploying rapid response teams (RRT).[25] TJC requires a process for recognizing and responding to changes in a patient's condition, although the use of RRTs is not specifically required.

RRTs bring critical care expertise to the patient's bedside before cardiopulmonary arrest has occurred. An RRT intervenes when a patient's vital signs or mental status begins to worsen and may be called when a staff member becomes "worried" about the patient. A Cardiac Arrest Team (CAT) typically responds when a cardiopulmonary arrest has occurred, and includes a physician with the skill and authority to place a patient on mechanical ventilation.

Case Summary - Patient 8: A male patient in his seventies with advanced peripheral vascular disease, congestive heart failure (CHF), and chronic obstructive pulmonary disease was admitted to the facility's Community Living Center (CLC) in August 2010, for care of chronic bilateral lower extremity ischemic ulcers.

During daily rounds in November 2010, the CLC staff observed mental status changes and discovered left upper lobe pneumonia, prompting admission to the inpatient medical unit.

The inpatient physician requested a palliative care consult. He was concerned that the patient would not survive the pneumonia because of his multiple cardiopulmonary comorbidities and limited functional and nutritional status. After conferring with the palliative care consultant, the patient's surrogate decision maker requested full treatment and full resuscitation in the event of cardiopulmonary arrest ("full code"). The patient's clinical condition continued to decline despite antibiotic and antifungal therapies, and he became progressively less responsive.

[24] VHA Directive 2008-063, *Oversight and Monitoring of Cardiopulmonary Resuscitative Events and Facility Cardiopulmonary Resuscitation Committees*, October 17,2008.

[25] Institute for Healthcare Improvement, "How-to Guide: Deploy Rapid Response Teams," http://www.ihi.org/knowledge/Pages/Tools/HowtoGuideDeployRapidResponseTeams.aspx, accessed on December 22, 2011.

Eight days after admission, the patient suddenly became unresponsive and stopped breathing shortly after nursing staff unsuccessfully attempted to place a nasogastric tube. The staff immediately began CPR and alerted the CAT. Resuscitation efforts, including intubation and mechanical ventilation, were unsuccessful and the patient died.

Case Summary - Patient 9: The patient, a man in his nineties with diabetes and significant cardiopulmonary disease, was hospitalized for atrial fibrillation in February, 2010. The patient remained hospitalized throughout February due to additional cardiopulmonary complications. He was admitted to the CLC for rehabilitation in March. On the second day of admission to the CLC, his blood glucose level was low at 28 mg/deciliter (dl).[26] He was treated with serial doses of IV glucagon, followed by a meal. About 3 hours later, he developed hypotension with rapid atrial fibrillation, requiring transfer to the ICU.

Approximately 8 hours later, the patient developed cardiopulmonary arrest and was placed on life support. The patient's family arrived not long afterward and requested removal of life support. The patient died later that evening.

Case Summary - Patient 10: A male patient in his eighties fell at home, fractured his arm and went to the facility's ED. During x-ray examinations looking for additional fractures, a large lung mass, suspicious for cancer, was noted on his x-rays. While in the ED, the patient received a narcotic for pain control and was assessed as awake and cooperative. On arrival to the medical floor about 30 minutes later, he was unresponsive and required CPR. After successful resuscitation, his condition stabilized. Later in the hospitalization, he was diagnosed with advanced-stage lung cancer. He chose to receive hospice care, and died in the facility's CLC about 2 months later.

Case Summary - Patient 11: The patient, in his eighties with non-Hodgkins lymphoma, was a resident in the facility's CLC in July 2009, when he fell and fractured his hip, prompting transfer to the inpatient surgical unit. Surgical intervention was delayed because of multiple cardiovascular complications, including atrial fibrillation with rapid ventricular rates and a myocardial infarction. Prior to the fall, Do Not Resuscitate (DNR) orders had been issued. During his surgery and immediate post-operative recovery, the physician suspended the DNR orders, as required by facility policy.[27]

When the patient returned to the CLC a week later, his DNR orders resumed. Despite treatment and rehabilitative therapy attempts, the patient's clinical and functional condition declined. He was unable to walk or perform minimal activities without assistance, or consistently follow simple commands. While initially refusing participation in therapies, soon the patient was physically incapable of participating in

[26] The facility's reference range for normal blood glucose was 74-118 mg/dl.
[27] Per policy, DNR orders were cancelled when a patient transferred from one level of care to another, and were rewritten after transfer to the new level.

them. Over the next several days, he became progressively more lethargic, despite adjustments to his narcotics and other medications.

A week later, the patient became unresponsive. A nurse notified his family of his change in condition, but did not call the physician. After the patient died, later that night, the nurse called the physician to report his death.

Case Summary - Patient 12: The patient, a man in his seventies with cardiovascular disease, chronic renal failure and diabetes, was admitted to the facility in October 2010, for treatment of pneumonia and herpes zoster (shingles) on his chest. Despite IV drug treatments and management by multiple subspecialists, the patient's condition continued to decline during the hospitalization. By hospital day 10, he developed progressive hypoxia. The next evening, a nurse notified the covering hospitalist that his breathing was acutely worse. A hospitalist evaluated the patient, reviewed the results of recent diagnostic studies, including a chest x-ray and echocardiogram, and adjusted IV fluids. About 3 hours later, the patient developed cardiopulmonary arrest. A CAT attempted resuscitation, but was unsuccessful and the patient died.

Case Summary - Patient 13: A male patient in his seventies with severe spinal stenosis[28] was admitted with progressive lower extremity weakness and pain. The next day he developed sudden vomiting, aspirated,[29] and became acutely hypoxic.[30] The nurse notified a hospitalist and a respiratory therapist. The patient was transferred to the ICU and emergently intubated. Over the next 2 days, he developed life-threatening complications with sepsis and acute lung injury. After discussions with his family, life support was withdrawn and the patient died.

Case Summary - Patient 14: The patient, in his nineties with CHF, chronic kidney disease and lung disease, was admitted to the CLC February 2010, for short-term rehabilitation after hospitalization for acute CHF exacerbation.

In March, a nurse practitioner noted that his weight had increased and adjusted his diuretic dose. Several hours later, a nurse found the patient sitting on the side of his bed with his oxygen mask off and hypoxic. After assisting him back into bed, the patient became unresponsive. The nurse called the RRT and the patient was intubated and transferred to the ICU. He was diagnosed with pleural effusion, which was drained.[31] Although his breathing improved, he continued to have complications from his chronic kidney and heart disease.

[28] Spinal stenosis is a narrowing of the vertebral canal within the spinal column.
[29] Pulmonary aspiration is the entry of food, drink or stomach contents from the mouth or gastrointestinal tract into the larynx and lower respiratory tract.
[30] Hypoxia is a pathological condition in which the body is deprived of adequate oxygen supply.
[31] Pleural effusion refers to fluid trapped in the lining of the lung, which can collapse adjacent lung tissue. Treatment can include insertion of a needle into the fluid sac to drain the fluid and re-expand the lung.

The physician informed the patient's family about his prognosis and treatment options. The family requested hospice care and the patient died 2 days later.

Case Summary - Patient 15: The patient, a man in his sixties with multiple sclerosis, post traumatic stress disorder and chronic pain, resided in the facility's long-term CLC. He had been noncompliant with medications and often rejected patient care efforts offered by facility nurses.

In February 2010, the patient refused to get out of bed into his wheelchair unless allowed to order food from outside the facility. A physician spoke with the patient, who eventually agreed to get into his wheelchair. Later that afternoon, a nurse found the patient in his room, not breathing, with a partially eaten sandwich on his table.

The nurse immediately called the physician, who unsuccessfully attempted to clear the patient's airway by performing abdominal thrusts. The physician then called for assistance from the CAT. While intubating the patient, the physician removed a large piece of meat from the patient's airway. The patient was without a pulse for an estimated 30 minutes during the resuscitation efforts.

The following day, the patient remained unresponsive. The ICU physician was concerned about brain injury due to a lack of oxygen because of the extended time needed to regain a pulse during CPR. The physician ordered an electroencephalogram (EEG) and requested a neurology consult. The EEG indicated severe, irreversible brain damage, consistent with lack of oxygen to the brain.

The neurologist discussed the EEG results with the patient's family and recommended withdrawal of life support if there was no improvement within 24-48 hours. Three days later, the patient's condition had not changed. The patient's family requested withdrawal of life support and comfort care measures. The patient died 2 days later with his family at the bedside.

Findings:

We found that the facility reviewed these eight patient deaths in accordance with VHA policies. However, we identified areas that needed improvement. We found that poor documentation and communication during patient transitions to different levels and areas of care (patients 10 and 14), and during staff shift changes (patients 8, 11 and 12) led to delays in recognition of changes in patients' clinical conditions. In the care of patient 13 and 15, we found that the nurse called the patients' attending physicians rather than activating the RRT or CAT, resulting in delay of care. Staff told us they inadvertently assumed Patient 11 was receiving only palliative interventions so when his clinical condition deteriorated they assumed the decline was expected and, therefore, did not activate the CAT.

The facility's policy combined the CAT and RRT into one team. During our interviews, we identified staff confusion regarding:

- whether to notify the CAT/RRT team or notify an individual physician
- which providers would respond when the CAT/RRT was called
- how to transfer authority for managing resuscitation efforts from the unit staff to the CAT/RRT when they arrived
- when to call a provider and which type of provider to call due to differences between nursing and facility policies

At the time of our inspection, the facility had drafted new policies separating the CAT from the RRT and initiated training for staff on the new policies. However, these policies had not been activated due to delays in procuring paging equipment. Further, the new CAT policy includes an ED physician as a responder; however, VHA policy states the ED provider must not be expected to cover inpatient units, or respond to emergencies outside of the ED.[32]

Recommendation 5: We recommended that the facility strengthen policies regarding response to changes in clinical conditions and monitor adherence to policy.

Recommendation 6: We recommended that the facility comply with VHA standards for ED physicians.

Issue 7: Administrative Oversight of Cardiopulmonary Resuscitation and Rapid Response Processes

The complainant alleged that the facility failed to provide oversight of the cardiopulmonary resuscitation and rapid response team processes. We substantiated this allegation.

VHA requires that each facility ensure that a CPR Committee reviews each episode of care where resuscitation was attempted, for the purpose of identifying problems, analyzing trends, and benchmarking, in order to identify opportunities to improve both process and outcomes.[33] VHA requires each CPR event to be reviewed for the presence of:

- Clinical issues or patient care issues such as failure to rescue, which may have contributed to the occurrence of a cardiopulmonary event, and
- Delays in initiating CPR both in-house, and problems in obtaining the assistance of Emergency Medical Services.

[32] VHA Directive 2010-010, *Standards For Emergency Department and Urgent Care Clinic Staffing Needs in VHA Facilities*, March 2, 2010

[33] VHA Directive 2008-063,*Oversight and Monitoring of Cardiopulmonary Resuscitative Events and Facility Cardiopulmonary Resuscitation Committees*, October 17,2008.

We found that although the committee reviewed resuscitation events, it did not review clinical or patient care issues which may have contributed to their occurrence. In addition, we identified two committees with differing responsibilities for code oversight. We found that there was confusion between committees concerning who was responsible for reviewing which aspects of code processes. For example, the Surgical Invasive Procedures Committee (SIPRC) was responsible for reviewing the circumstances leading up to and including intubations that occurred during a code; however, the CPR Committee members told us they thought that SIPRC was doing a complete code review. The Critical Care Committee noted technical delays but no CPR or RRT data had been analyzed or trended. In addition, the committee noted delayed participation by physicians in responding to codes. Action plans included communication with these physicians, but it was unclear whether implementation of the action plan occurred.

Recommendation 7: We recommended that the facility designate one committee with responsibility for reviewing all CAT and RRT processes in accordance with VHA requirements.

Issue 8: Leadership

The complainant alleged that senior leaders failed to act when notified of safety issues and created an environment that discouraged staff from voicing concerns. We did not substantiate the allegation.

We identified issues affecting patient safety and found that facility leadership had taken steps to ensure problem resolution and patient safety prior to our inspection. Staff at every level told us that they felt comfortable reporting issues to supervisors and confident that issues were followed through to resolution. We found no evidence that that leadership discouraged staff from reporting issues or that leadership failed to act after becoming aware of potential patient safety issues.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans (see Appendixes A and B, pages 19–23, for the full text of their comments and actions). We will follow up on the planned actions for recommendations 1, 2, and 4–7 until they are completed, and we consider recommendation 3 closed.

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

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: May 7, 2012

From: Director, VA Capitol Healthcare Network, VISN 5 (10N5)

Subject: **Healthcare Inspection – Quality of Care and Patient Safety Issues, Martinsburg VA Medical Center, Martinsburg, West Virginia**

To: Associate Director, Washington, DC, Office of Healthcare Inspections (54DC)

Director, Management Review Service (VHA 10A4A4 Management Review)

1. I have reviewed and concur with the Martinsburg VAMC response to the Quality of Care and Patient Safety Issues draft report. Thank you for this opportunity of review as a process to ensure that we continue to provide exceptional care to our Veterans.

2. Attached please find the facility concurrences and responses to the seven recommendations from the draft report.

3. I concur with the facility actions and monitoring plan they have developed.

(signed by Guy Richardson, Deputy Network Director, for:)
Fernando O. Rivera, FACHE
Network Director, VISN 5
VA Capitol Health Care Network

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: April 27, 2012

From: Director, Martinsburg VA Medical Center (613/00)

Subject: **Healthcare Inspection – Quality of Care and Patient Safety Issues, Martinsburg VA Medical Center, Martinsburg, West Virginia**

To: Director, VA Capitol Healthcare Network, VISN 5 (10N5)

1. I have reviewed the issues outlined in the draft report and concur with the seven recommendations.

2. Our response to the recommendations is attached. I appreciate the comprehensive review and efforts to ensure high quality of care to our Veterans.

3. If you have additional questions or require additional information, please contact V. Denise O'Dell, Chief of Quality Management at 304-263-0811 ext. 4035.

(original signed by:)
Ann R. Brown, FACHE
Medical Center Director

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 facility conduct a risk assessment to determine whether local policies related to sentinel events should be modified to include providing temporary relief from duty for staff.

Concur **Target Completion Date:** June 11, 2012

Facility's Response
The facility Risk Manager will coordinate a risk assessment of local policies related to sentinel events to determine if revision is indicated and will include possible temporary relief from duty for staff. The facility Risk Manager will share the results of the risk assessment with leadership for approval.

Recommendation 2: We recommend that the facility strengthen processes to ensure that practitioners outline their treatment decision-making process in the medical record, particularly if it deviates from an ideal approach.

Concur **Target Completion Date:** June 29, 2012

Facility's Response
The facility Chief of Staff during the upcoming Medical Staff meeting will stress to practitioners to outline their treatment decisions in the medical record, particularly if the provider decision is to pursue other management options that are concurrent with the patient's wishes.

Recommendation 3: We recommended that the facility ensures that ICU, OR, and PACU staff receive training on any newly purchased beds.

Concur **Target Completion Date:** Completed

Facility's Response
The ICU and PACU staff had received training on the newly purchased beds but not the OR staff who choose to transport the Veteran to ICU. The OR staff were trained on the new beds while the OIG team was on site.

Recommendation 4: We recommended that the facility ensures that OR staff receive training on reporting near-miss and patient safety incidents.

Concur **Target Completion Date:** June 29, 2012

Facility's Response
The facility Patient Safety Coordinator and Risk Manager provide ongoing staff training for reporting close calls and patient safety incidents. A special training session will be provided to the OR staff to include the facility policy and procedure relating to reporting near-miss and patient safety incidents.

Recommendation 5: We recommended that the facility strengthen policies regarding response to changes in clinical conditions and monitor adherence to policy.

Concur **Target Completion Date:** September 1, 2012

Facility's Response
The Patient Safety Coordinator and Risk Manager will develop a medical record monitoring tool which will include documentation of changes in clinical condition in progress notes and care plans. They will randomly select 30 open medical records for review of Veterans transferred between levels of care. The results will be shared with Clinical Services Chiefs. Then the Patient Safety Coordinator and Risk Manager will conduct a review of current facility policies regarding response to changes in clinical conditions and make recommendations to strengthen the process. Clinical staff will be informed if those processes change.

Recommendation 6: We recommended that the facility comply with VHA standards for ED physicians.

Concur **Target Completion Date:** Completed

Facility's Response
We will confer with the National Program Office to explore obtaining a waiver from the National Directive.

Recommendation 7: We recommended that the facility designate one committee with responsibility for reviewing all CAT and RRT processes in accordance with VHA requirements.

Concur **Target Completion Date:** Completed

Facility's Response
The facility CPR Committee reviews all CAT and RRT episodes and outcomes according to VHA Directive 2008-063. The committee was in place and fulfilling those responsibilities at the time of the review; however, subsequent to the review, the committee has made even greater strides in the analysis of all CAT and RRT events for the purpose of identifying problems, analyzing trends, and identifying opportunities for improvement. When problems are determined they recommend specific actions and ensure those actions are implemented. Reviews of episodes of individual cases could be better explained in the committee minutes. In order to strengthen those minutes, the CPR Committee will include documentation of discussions and analysis of individual clinical incidents that may have contributed to the occurrence of RRT or CAT events.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720
Acknowledgments	Randall Snow, J.D., Project Leader Katharine Foster, RN, Team Leader Shirley Carlile, BA Jennifer Christensen, DPM Myra Conway, RN Donna Giroux, RN Kathy Gudgell, RN, J.D. Monica Gottlieb, M.D., Physician Consultant Natalie Sadow-Colón, MBA, Lead Program Assistant

Appendix D

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