



# **Department of Veterans Affairs Office of Inspector General**

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## **Healthcare Inspection**

### **Alleged Poor Surgical Care and Mismanagement of Adverse Events VA Medical Center West Palm Beach, Florida**

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## **Executive Summary**

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to an anonymous survey respondent's allegations of poor surgical care and mismanagement of adverse events at the West Palm Beach VA Medical Center, West Palm Beach, Florida.

We did not substantiate that three patients experienced adverse outcomes because an Ear, Nose, and Throat (ENT) surgeon did not possess the necessary qualifications or competence to care for otolaryngology patients. We also did not substantiate that the surgeon exercised poor judgment. The ENT surgeon met competency expectations, he was appropriately privileged to perform the surgeries in question, and his performance was periodically reviewed as part of the reprivileging process.

We found that reporting and evaluation of adverse events needed improvement. Surgical staff did not appear to understand the requirement to report serious adverse events or to use the correct disclosure template. We made two recommendations related to staff training and disclosure of adverse events.



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

**TO:** Director, VA Sunshine Health Care Network (10N8)

**SUBJECT:** Healthcare Inspection – Alleged Poor Surgical Care and Mismanagement of Adverse Events in Surgical Service, VA Medical Center, West Palm Beach, Florida

## **Purpose**

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a Combined Assessment Program (CAP) review at the West Palm Beach VA Medical Center (the facility), West Palm Beach, Florida, during the week of December 5, 2011. As part of the CAP, we conducted an Employee Assessment Review (EAR) survey, which is an anonymous employee survey that offers all VA medical center and outpatient clinic staff the opportunity to express their opinions about the quality of care provided at the facility. An anonymous survey respondent alleged that three surgical patients suffered adverse outcomes related to a surgeon's poor judgment and questionable qualifications and competence.

The Office of Healthcare Inspections reviewed the allegations. The purpose of the review was to determine whether the allegations had merit.

## **Background**

This tertiary care facility provides a broad range of inpatient and outpatient medical, surgical, and long term care services. It operates 140 acute care beds and 120 community living center (CLC) beds. Outpatient care is also provided at six community based outpatient clinics in Boca Raton, Delray Beach, Ft. Pierce, Okeechobee, Stuart, and Vero Beach, FL. The facility is part of Veterans Integrated Service Network 8 and serves a veteran population of about 177,300 throughout Indian River, Okeechobee, St. Lucie, Martin, Glades, Hendry, and Palm Beach counties in Florida.

Otolaryngology (commonly referred to as Ear, Nose, and Throat [ENT]) is a surgical subspecialty that focuses on diseases, deformities, disorders, and injuries of the ears, respiratory and upper alimentary systems, the face, jaws, and other head and neck systems.

An anonymous EAR complaint alleged that:

- A specific surgeon (the surgeon) did not possess the necessary qualifications, competencies, or judgment to assure safe patient care and, as a result, three patients experienced adverse outcomes.
- Facility managers did not ensure that the aforementioned three cases were appropriately evaluated as required by VHA guidelines.

Facility policy<sup>1</sup> requires that incidents of patient harm or potential harm be reported to the facility's Chief of Staff through its Quality Management (QM) office. Patient incidents and adverse events are evaluated to determine if significant trends specific to type of harm, severity of injury, and location of incident exist in order to redesign processes and, where possible, prevent future incidents and adverse events.

Facility policy also requires providers to disclose incidents and adverse events to patients under certain conditions, and to document the disclosure using a specified template in the patient's medical record. While some surgical complications are minor and do not require reporting and disclosure, other surgical complications must be reported to QM and disclosed to patients and their families.

## Scope and Methodology

We reviewed facility and Veterans Health Administration (VHA) policies, directives, and handbooks; select patient medical records; QM documents; patient advocate reports; staff credentialing and privileging records; and The Joint Commission (JC) standards. We interviewed the Chief of Staff, Chief of Surgery, subject surgeon, other facility ENT surgeons and Surgical Service staff, and additional clinical and administrative staff knowledgeable about the issues.

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.

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<sup>1</sup> MCM 548-99-256, *Patient Incident Review Program*, November 2009.

## Case Summaries

### Case 1

In April 2011, a man in his sixties with metastatic thyroid cancer underwent surgery to remove his thyroid and have a tracheotomy performed (placement of a tube in the neck to facilitate breathing). While the surgeon was aware prior to surgery that one of the patient's jugular veins required removal because of cancer, he did not discover until the patient was in the operating room that the cancer had spread to both jugular veins. The surgeon made the decision to remove both internal jugular veins during this procedure. He also made the decision to delay the tracheotomy as he did not want to create an opening from the exterior of the neck to the area where the cancer had been removed. The airway was being maintained by a temporary breathing tube.

The patient experienced a significant amount of blood loss during the procedure, and severe facial and tongue swelling after surgery. Immediately after surgery, the patient's breathing tube was removed, but due to low oxygen saturation of his blood, hypoxemic shock, an abnormally rapid heart rate and low blood pressure, the tube had to be reinserted. The surgeon disclosed to the patient and his family that the facial swelling was related to both internal jugular veins being removed. The surgeon also explained that because of the blood loss during surgery, the patient's blood had a diminished capacity to carry oxygen which also contributed to the patient's post-surgical complications.

The patient was transferred to the Surgical Intensive Care Unit (SICU) for close monitoring of his breathing and signs of multiple organ injury due to shock. He was started on a steroid to reduce his swelling. He received supportive treatment for his medical conditions, and his swelling improved over time as his circulatory system adjusted to the removal of the jugular veins.

On post-operative day (POD) 8, the patient's condition stabilized and he underwent a tracheotomy for permanent airway management, and a nasogastric tube was placed to provide nutritional support. During the patient's SICU stay, his facial swelling continued to improve and he began working with the speech pathologist. On POD 21,<sup>2</sup> the facial swelling resolved and he was discharged home in stable condition with home health support.

### Case 2

In January 2011, a man in his fifties with advanced cancer of the neck and lungs presented to the facility's emergency department (ED) with a complaint of difficulty

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<sup>2</sup> Elapsed days from the first surgery involving the thyroidectomy.

breathing. A tracheotomy was performed the same day to assist him with breathing. However, the surgeon advised the patient and his family that his condition was terminal and the breathing tube would not change the progression of the cancer. The surgeon documented that the trachea tube placement was difficult because of the cancer and prior tissue damage resulting from earlier radiation therapy. Further, medical record documentation stated that the patient's pleura (a membrane surrounding the lung) was visible, which was an unusual occurrence during this type of surgery. After surgery, the patient's right lung collapsed due to the exposure of the pleura and the patient required placement of a chest tube (used to drain air which allows the lung to expand). The patient remained in the SICU for 5 days until the collapsed lung had resolved and his breathing improved. He was discharged home in stable condition.

The patient returned to the facility's ED the following day due to bleeding around his trachea which occurred after a violent episode of coughing. He was readmitted and a larger endotracheal tube was placed to bypass and control the bleeding. The patient's physician met with the patient's family to discuss palliative care. Upon concurrence from the patient and his family, a palliative care consult was initiated. Palliative care planning was in progress when the patient experienced profuse bleeding from around the trachea tube and bleeding in his mouth. His oxygen saturation decreased to the point that he required mechanical ventilation to support his breathing. Shortly thereafter, he experienced two episodes of cardiac arrest for which he was resuscitated. After discussion with the family, the patient's code status was changed to Do Not Resuscitate (DNR), and he passed away shortly thereafter.

### Case 3

In February 2010, a man in his seventies was diagnosed with chronic right maxillary sinusitis and a nasal polyp with medial wall displacement. In late March, he had outpatient endoscopic sinus surgery. The medical record reflects that throughout the procedure, the floor of the orbit (area surrounding the eye) appeared to be intact and at the termination of the procedure, the orbit was soft by palpation (touch). The surgeon documented that at discharge from the post-operative recovery room, the patient said he could see an examination light. He was then discharged home.

On POD 2, the patient's daughter notified staff in the facility's ENT clinic that her father had a fever. She was instructed to continue monitoring him and call back if his symptoms worsened. On POD 3, the patient was admitted to a private-sector hospital for fever and loss of vision in his right eye. A computed tomography scan showed a crack in the orbit of the right eye. On POD 6, he was discharged from the private facility on 10 days of home intravenous antibiotic therapy for a urinary tract infection. He was seen for follow-up in the facility's ENT clinic the next day. The surgeon noted that the patient's right orbit was firm and mildly bulging and that the patient was unable to see a bright examination light. The surgeon told the patient and his family that, at this point, the

vision loss would probably be permanent. He disclosed that the bleeding around the eye, which resulted in the patient's vision loss, was a delayed but known complication of the surgery. Loss of vision and permanent blindness were listed on the informed consent for the patient's surgery as a known complication associated with the endoscopic sinus surgery the patient underwent.

In January 2011, the patient returned to the facility from his summer home and was seen for follow-up in the Ophthalmology Clinic. The provider noted that the patient would not regain sight in his right eye.

## **Inspection Results**

### **Issue 1: Qualifications, Competence, and Judgment**

We did not substantiate that three patients experienced adverse outcomes because an ENT surgeon did not possess the necessary qualifications or competence to properly care for otolaryngology patients. We also did not substantiate that the surgeon exercised poor judgment.

The surgeon possessed the background and qualifications to care for otolaryngology patients as required by VHA. He is specialty-trained in otolaryngology and has been practicing in the field for many years.

The surgeon met competency expectations and his performance, including surgical complication rates, was periodically reviewed as part of the facility's reprivileging process. The surgeon was appropriately privileged to perform the surgeries in question. He has current medical staff privileges to perform thyroid surgery with radical neck dissections, tracheotomies, and endoscopic sinus surgery. The past 2 years of VA Surgical Quality Improvement Program (VASQIP) reports did not reflect any deficiencies or outliers for ENT surgeries.

In case 1, we found the surgeon's decision to remove both internal jugular veins and delay the tracheotomy to be reasonable. The surgeon told us that his rationale for removing both internal jugular veins was that he did not want to risk leaving any cancer behind. He also told us that he delayed placement of the tracheotomy to avoid the risk of creating an opening from the exterior of the neck to the area where the cancer had been removed. Both procedures were reviewed for quality of care. Another ENT surgeon indicated that the bilateral neck dissection could have been performed in stages rather than removing both jugular veins at once. There is, however, literature that supports that bilateral neck dissection is an acceptable and proper treatment for metastatic cancer from



a primary lesion of the head and neck.<sup>3</sup> There were no concerns related to the second procedure.

In case 2, the patient's poor health status, along with prior tissue damage from chemotherapy and radiation therapy, left him vulnerable to airway obstructions. Medical record documentation reflected multiple discussions with the patient and his family that the tracheotomy was palliative, not curative. Another ENT surgeon indicated that the patient would have "suffocated to death" had it not been for his surgeon's intervention.

In case 3, one of the uncommon but severe complications of endoscopic sinus surgery is loss of vision with possible permanent blindness<sup>4</sup>. The possibility of blindness was listed on the informed consent signed by the patient. The medical record reflected that the surgery progressed according to plan and that throughout the procedure, the floor of the orbit appeared to be intact. After completion of the procedure, the orbit was soft by palpation and the patient reported he could see an examination light. The orbit fracture did not present itself until several days after the patient was discharged.

We found no evidence that the surgeon exercised poor judgment related to these patients' care. While the identified patients experienced serious but known complications, the surgeon had properly informed them of the risks associated with the surgical procedures and appropriately disclosed complications to the patients and families when they occurred. In case's 1 and 2, complications were arguably associated with the patients' underlying medical conditions.

## **Issue 2: Reporting and Evaluation of Adverse Events**

We substantiated that facility managers did not ensure that the cases were appropriately evaluated as required by VHA guidelines.

While the surgeon disclosed, discussed, and documented relevant complications with the patients and their families, he did not use the disclosure template note required by local policy. The template note, if completed, prints out in the risk manager's office and serves as a way to alert facility leadership that an adverse event has occurred. The risk manager then initiates appropriate quality of care reviews, if indicated. Although the risk manager did not receive a disclosure alert, she became aware of cases 1 and 2 through occurrence screens<sup>5</sup> (case 1 because of return to the OR within 30 days of surgery and case 2 because of death within 30 days of the surgery). Quality of care reviews were initiated accordingly; however, the review of case 1 was not critically analyzed and was not referred to the appropriate oversight committee for further evaluation.

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<sup>3</sup> Ahn C, Sindelar WF. *Bilateral Radical Neck Dissection: Report of Results of 55 patients*, J Surg Oncol, 1989 Apr; 40(4): 252-5

<sup>4</sup> Endoscopic sinus surgery world articles [http://www.entusa.com/endoscopic\\_sinus\\_surgery.html](http://www.entusa.com/endoscopic_sinus_surgery.html)

<sup>5</sup> Predetermined list of criteria that warrants further review for quality assurance purposes.

Case 3 did not meet criteria for an occurrence screen. Although multiple surgical staff members were aware of and documented the complication that occurred in case 3, no one notified facility leadership that this serious adverse event occurred. Facility leadership learned of the complication as a result of our review. Quality of care and morbidity and mortality reviews have now been completed.

## Conclusions

We did not substantiate that the surgeon did not possess the necessary qualifications or competency to care for patients, or that he exercised poor judgment, which resulted in adverse outcomes for the patients discussed in the case summaries. The surgeon met all VHA requirements and was privileged to perform the surgeries in question. Provider privileging and VASQIP data did not reflect unexpected deficiencies or outliers.

We substantiated that reporting and evaluation of adverse events needed improvement. Surgical staff did not appear to understand the requirement to report serious adverse events or to use the disclosure template.

## Recommendations

**Recommendation 1.** We recommended that the facility Director ensure that all surgical staff receive training on reporting and disclosure of adverse events.

**Recommendation 2:** We recommended that the facility Director discuss the case in which the patient suffered permanent blindness with Regional Counsel to ensure appropriate reviews and disclosures are completed.

## Comments

The VISN and Facility Directors concurred with our recommendations and provided an acceptable action plan. We consider both recommendations closed.



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

## VISN Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** 05/08/2012

**From:** Director, VA Sunshine Healthcare Network (10N8)

**Subject:** Healthcare Inspection—Alleged Poor Surgical Care and Mismanagement of Adverse Events, VA Medical Center, West Palm Beach, Florida

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

**Thru:** Director, VHA Management Review Service (10A4A4)

1. I have reviewed and concur with the recommendations in the report regarding the above referenced Healthcare Inspection of the West Palm Beach VA Medical Center, West Palm Beach, FL.
2. Appropriate action has been completed, as detailed in the attached report.

*(original signed by:)*

Nevin M. Weaver, FACHE

Director, VA Sunshine Healthcare Network (10N8)

## Facility Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** 05/08/2012

**From:** Director, West Palm Beach VA Medical Center (548/00)

**Subject:** Healthcare Inspection—Alleged Poor Surgical Care and Mismanagement of Adverse Events, West Palm Beach VA Medical Center West Palm Beach, Florida

**To:** Director, VA Sunshine Healthcare Network (10N8)

Thank you for your consultation and review conducted of the West Palm Beach VA Medical Center.

We concur with all of the recommendations and appreciate the time and expertise of the OIG team.

*(original signed by:)*

Deepak Mandi, MD

Acting Director, West Palm Beach VA Medical Center  
(548/00)

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 the facility Director ensure that all surgical staff receives training on reporting and disclosure of adverse events.

Concur

Target Completion Date: Completed

**Facility's Response:** On 11/9/11, the requirement for self-reporting including intraoperative and postoperative complications was discussed with staff by the Chief of Surgical Service at the Surgical Service staff meeting. The importance of filling out and submitting a patient incident worksheet was also discussed. On 2/8/12, requirements for self reporting and using the patient incident worksheet was again discussed with the surgical staff and the Chief of Surgical Service at the Surgical Service staff meeting. On 3/16/12, a meeting was held with the ENT surgeon, the Chief of Surgical Service and the Clinical Coordinator for Surgical Service, to discuss this case. Self reporting requirements, patient incident worksheet and the Disclosure of Adverse Events policy and procedure were reviewed. On 4/11/12, a formal training on Disclosure of Adverse Events, including clinical and institutional disclosures, the peer review process and completing patient incident worksheets, was presented by the Risk Manager to all surgical staff. The importance of using the disclosure template for the reporting of the Disclosure of Adverse Events was emphasized. The Risk Manager reviewed the steps to access the disclosure template with the staff utilizing a PowerPoint presentation.

**Status:** Completed

**Recommendation 2.** We recommended that the facility Director discuss the case in which the patient suffered permanent blindness with Regional Counsel to ensure appropriate reviews and disclosure are completed.

Concur

Target Completion Date: Completed

**Facility's Response:** The facility Acting Director and Risk Manager discussed this case with the Regional Counsel after contact was made with the veteran's daughter on 03/06/2012. This contact with the veteran's daughter, who is the health care surrogate for her father who has advanced Alzheimer's disease, was documented in the medical record. It was during this discussion that the daughter declined our request for a face to face meeting to further discuss the particulars of this incident and to complete a formal institutional disclosure. She further declined our offer to have Regional Counsel send the information regarding the right to file a Tort Claim. Our Regional Counsel reviewed this documentation and stated that he found that all of the appropriate reviews and disclosures were completed. He did not recommend any further action regarding review or disclosure to this family, related to this incident.

**Status:** Completed

## **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	Karen Sutton, BS, Project Leader Victoria Coates, LICSW, MBA Robert Yang, MD

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