



THE SECRETARY OF VETERANS AFFAIRS  
WASHINGTON

May 10, 2002

Ms. Elaine Kaplan  
U.S. Office of Special Counsel  
1730 M Street, NW  
Washington, DC 20036-4505

Dear Ms. Kaplan:

This is in response to your letter dated November 29, 2001, regarding public health and safety issues reported by an employee of the Department of Veterans Affairs (VA) Medical Center in Pittsburgh, PA (OSC File No. 01-1111). The letter was received in the Office of the Secretary on January 9, 2002.

The VA Office of the Medical Inspector (OMI) has investigated the allegations of the employee and prepared a report pursuant to the requirements of 5 U.S.C. § 1213(c). The investigation consisted of a clinical peer review of eleven patient cases referenced by the employee, a review of all facility policies and procedures concerning respiratory patients, and a review of all other facility documents that pertained to the patients in question. A site visit was also conducted. Participants in the site visit included a physician who specializes in the treatment of pulmonary disease, and two registered nurses from the OMI. Two physicians who specialize in pulmonary disease and two respiratory therapists performed the peer and document reviews. I have reviewed the report, and now submit it to the Office of Special Counsel for your review.

Thank you for the opportunity to respond to these issues. If you have further questions about the investigative process, please contact Dr. Clark T. Sawin, Medical Inspector at 202-273-8940.

Sincerely yours,

  
Anthony J. Principi

Enclosure

**OFFICE OF THE MEDICAL INSPECTOR  
REPORT TO OFFICE OF SPECIAL COUNSEL**

**Report of Complaint File No. DI-01-1111  
Office of Special Counsel**

Prepared by:  
The Office of the Medical Inspector (10MI)  
Department of Veterans Affairs  
Veterans Administration  
810 Vermont Avenue, NW  
Washington, DC 20420



Report Date: **March 29, 2002**

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## **Executive Summary**

The Office of the Medical Inspector (OMI) was asked to review the clinical issues related to a complaint lodged with the Office of Special Counsel by a respiratory therapist at the VA Pittsburgh Healthcare System (VAPHS), University Drive Division. The review consisted of a review of pertinent medical records, and documents from the VAPHS, a site visit to the VAPHS and personal conversations with the complainant. The OMI found that the respiratory care provided by VAPHS is within acceptable standards and does not represent a threat to veterans treated at VAPHS.

## **I. Introduction and Summary of Complainant's Allegations**

The Office of the Medical Inspector (OMI) was asked to review the clinical issues related to a complaint lodged with the Office of Special Counsel (OSC) by a respiratory therapist at the VA Pittsburgh Healthcare System (VAPHS), University Drive Division (UDD). The complaint alleges that pulmonary patients did not receive proper medical care and attention, which resulted in a high number of patient transfers and six deaths. More specifically, the complaint alleges that the VAPHS does not have the properly trained staff, the proper supplies and equipment (oxygen regulators, suction supplies, and resuscitator bags), or a designated unit to manage pulmonary patients. According to the complaint, 11 pulmonary patients were transferred more than 72 times between units from December 1999 through November 2000. Of these 11 patients, 6 died due to either respiratory arrest or pulmonary complications.

## **II. Facility Profile**

The VAPHS is a fully integrated delivery system serving a veteran population of over 360,000 throughout the Tri-State area of western Pennsylvania, Ohio, West Virginia, and counties in western Maryland. VAPHS is part of VISN 4 (Veterans Integrated Service Network), which covers Pennsylvania, Wilmington, Delaware and Clarksburg, West Virginia. The mission of the VAPHS is fourfold: patient care, education, research, and primary backup to the Department of Defense health care system in time of national emergency as Western Pennsylvania's Coordination Center for the National Disaster Medical System. VAPHS has been designated as a National Liver and Renal Transplant Center, a Regional Cardiac Surgery Center, an Oncology Network Center, and a Dialysis Center. The VAPHS has earned the recognition as a National Center of Clinical Excellence in Women Veterans Health Programs and Renal Dialysis.

VAPHS consists of three Divisions operating under one management:

*The UDD* is located in the Oakland District of Pittsburgh adjacent to the University of Pittsburgh and is categorized as a specialty referral center for critical care and psychiatry. UDD serves as the acute care facility and has approximately 146 beds distributed among Medicine, Surgery, Neurology and Critical Care Services. It has an average daily census of 110. The UDD has primary care outpatient clinics that are located in St. Clairsville, OH, Aliquippa, PA, Washington, PA, and Greensburg, PA. As a large tertiary facility, UDD serves as the primary referral site for VAPHS as well as for less complex facilities in the VISN. The VAPHS also supports three Veterans Outreach Centers in Pittsburgh and McKeesport, PA, and Wheeling, WV. As a result, UDD acts as a hub facility with many spokes, and it experiences a high number of admissions and discharges through transfers from other facilities.

*The H. John Heinz, III Progressive Care Center* has 336 Nursing Home Care beds with an average daily census of 299. Programs supporting the Progressive Care Center include Primary Care, Adult Day Health Care, and Hospice Care.

*The Highland Drive Division* provides acute and long-term care, psychiatric treatment, (substance abuse, post-traumatic stress disorder, and schizophrenia), and a Homeless Program. Highland Drive has an average daily census of 179 in 210 beds including a 101 bed Homeless Domiciliary. It is also a Regional Center for the treatment of former prisoners of war.

### **III. Methods for Conducting the Investigation**

The OMI contacted the VAPHS Director to inform him of the complaint and the OMI's plan to investigate this matter. The Director and his staff provided their full cooperation to the OMI. The OMI's investigation included a clinical peer review of the 11 patient cases cited, a review of all VAPHS policies and procedures concerning respiratory patients, a review of all other VAPHS documents that pertained to the patients in question, and a site visit to UDD. A physician who specializes in the treatment of pulmonary disease and two registered nurses from the OMI conducted the site visit on March 20 – 21, 2002. Two physicians who specialize in the treatment of pulmonary disease and two respiratory therapists performed the peer and document reviews.

### **IV. Summary of the Evidence**

#### **A. Case Reviews**

The patient's names relevant to the complaint were obtained from the Chief, Disclosure Unit, at the Office of Special Counsel (OSC); the patients' records were obtained from UDD. Four of the patients had a primary respiratory diagnosis; however, one was admitted for abdominal pain and underwent gall bladder surgery. Four others had terminal cancer, and the remaining three had other long-term debilitating diseases. Of the six deaths, four were from cancer (one of whom died suddenly but not from a respiratory condition). Another patient who died requested a "do not resuscitate" (DNR) order after being diagnosed with inoperable mesenteric ischemia. The last person who died did so later in the VAPHS nursing home. The reviewing physicians commented that these patients were elderly and quite sick and that only one of them died unexpectedly. The reviewers determined that the care provided met the standard of care. However, they noted that in some cases the documentation in the medical record could be improved and that two of the patients might have been transferred to the nursing home too soon. Those two patients, in fact, had been transferred back to acute care and treated appropriately. Otherwise the transfers that occurred for these patients were found to be appropriate.

#### **B. Document Reviews**

In addition to the medical records, the VAPHS submitted its policies on respiratory care, a report of an external review of Post Operative Respiratory Occurrences, and a

memorandum from the Director. These documents were reviewed and considered in the overall investigative process. Policy and procedures were found to be appropriate and to address the delivery of respiratory care by respiratory therapists and registered nurses. However, a site visit was required to evaluate their application. After a thorough review of medical center and VHA policy a “VA Interim and Interdisciplinary Care Plan” as alleged by the complainant was not found. A copy of two documents both titled “Interim and Interdisciplinary Care Plan” was provided to the OMI by the Office of Special Counsel. It appears to be a standard form used for overprint. The 1<sup>st</sup> forms cover the care of tracheotomy/ventilator patients and the 2<sup>nd</sup> airway clearance. According to staff at VAPHS, they are not familiar with these documents, have never used them, and are not aware of any requirement to do so. As mentioned in the case review section, the care of the patients cited by the complainant was peer reviewed and found to meet the standard of care.

### **C. Site Visit**

The site visit was conducted by a physician specializing in pulmonary and intensive care medicine and two registered nurses on March 20 –21, 2002. The findings are as follows:

#### **1. Respiratory Care Services**

At the VAPHS, respiratory patients are cared for on the medical-surgical units or in the Critical Care Center, which consists of four units (MICU, CCU, SICU, and Step-Down).

Four beds on one of the medical-surgical units have been set aside for a high level of observation of patients at highest risk for respiratory compromise. The nurse/patient ratio for the patients in the “high observation” beds is 1:4 and a separate nurse workstation is just outside these rooms. The nurses receive special training and require specific competencies to meet the needs of these patients.

A full-time outcomes coordinator, a nurse, is assigned to the Critical Care Center to conduct utilization review. Prior to the designation of the “high observation” beds, many patients stayed in critical care beds even after they no longer met InterQual criteria due to their need for closer observation than could be provided on the medical-surgical units. The number of such patients is increasing, and the facility leadership plans to increase the “high observation” beds from four to eight.

The Respiratory Care Service is under the leadership of a physician manager from the critical care service line. UDD had 6 respiratory therapists FTEE for the medical-surgical units (average daily staffing 4.12) and the Critical Care Center had 13 (average daily staffing 8.7). One FTEE is designated to provide respiratory therapy training to all staff at VAPHS. The OMI team members reviewed the certifications/licenses and competencies of the respiratory therapists. In all cases, the certifications/licenses were current and unrestricted. Competencies are reviewed yearly and are on file for the previous four years.

The nursing service policy states that "in the absence of a respiratory therapist" the nurse should provide respiratory care to patients. According to both respiratory therapists and nurses this happens only rarely. The Chief of the Respiratory Care Service is responsible for ensuring that nurses are trained to provide these treatments and this training is evident in the nurses' continuing education record. As mentioned earlier, there is one respiratory therapist designated full-time to provide training to all staff at the three Divisions of the VAPHS.

VAPHS has designed a care delivery system for respiratory care that ensures that patients at risk for respiratory compromise are closely observed by staff, both nurses and respiratory therapists, who are competent to do so. Based on the document review on site, this delivery system pre-dates the period referred to by the complaint (December 1999 – November 2000). However, the designation of the "high observation" beds occurred in July 2000.

## **2. Peer Reviews/Quality and Performance**

The patient care review process in place at VAPHS provides several opportunities for peer review. Cases may be generated through automated occurrence screens (which includes all deaths), adverse/unexpected outcomes, service line monitors, VISN or external peer reviews, and Medical Staff Committee Reviews. Fact-finding is first conducted by a clinical reviewer with a practitioner from the service line. A standard of care is then determined for each patient and the care is given a safety assessment code score in accordance with patient safety policy. Provider practice issues are peer reviewed, and, if necessary, the service-line Director intervenes. These cases are presented at the integrated Medical/Administrative Executive Board and the Director approves or disapproves their actions/recommendations.

System issues are reviewed by the director and/or chief of staff and root cause analyses conducted when indicated. The Adverse Event Review Committee as well as the Clinical/Administrative Executive Board meets regularly to review these events and make recommendations. Administrative Boards of Investigation (AI) are also a part of the process and can be initiated at any point in the review.

The review process is dynamic; any case or a specific aspect of a case may be reviewed as a provider practice issue, a system issue, and/or concurrently as an AI. OMI team members reviewed the minutes of the Adverse Event Review Committee and found no trends, patterns, or concerns regarding respiratory care.

Reviews are conducted of all transfers for quality care concerns and they are discussed daily at the leadership meeting of all three Divisions of the VAPHS.

VAPHS' peer review/quality and performance process meets the intent outlined in VHA policy. Although many of the processes were in place prior to the submission of this complaint, VAPHS has refined the process by flow-charting and integrating the roles of its various committees.

### **3. Equipment and Supplies**

The Chief, Critical Care Service line presents requests for pulmonary equipment and supplies to the integrated Clinical/Administrative Executive Board, of which the Chief is also a member. Staff could not recall a time when a request had been denied. The OMI site visit team toured several units and the respiratory care equipment section. All equipment was inspected and tagged by biomedical engineering for preventative maintenance and no expired dates were found. Several crash carts were inspected for equipment, supplies, and drugs and were all found to be current and checked according to VAPHS policy. Cardiopulmonary Resuscitation (CPR) critique sheets were reviewed for 1-year and there was no evidence of equipment failure or non-availability during cardiopulmonary resuscitation. The respiratory care department is staffed with a technician responsible for equipment cleaning and monitoring and a back-up system is in place to rent equipment such as ventilators if a shortage is anticipated.

There was no evidence of failure, non-availability, or shortages of any equipment including that listed by the complainant.

### **4. Staff Interviews**

Interview sessions were held with nurses and physicians from the critical care center, the "high observation" unit, and the respiratory therapy staff (the complainant was present during this interview). Both groups indicated that the staffs on these units operate as an interdisciplinary team with good communication as they provide care. Staff felt that all needed supplies and equipment were available to them in the delivery of care. The critical care units are well staffed and currently have no nursing or physician vacancies. The "high observation" unit had one vacancy and the respiratory care service has two vacancies. Approval has been given to fill all three vacancies.

The nurses confirmed that they receive the proper training in providing respiratory treatments. Both groups expressed a high level of respect for the Chief, Critical Care Center. Care is driven by the patient's condition, and ongoing team monitoring and consultation takes place at the bedside and is documented in the progress notes.

An OMI team member spoke with the complainant by phone on March 26, 2002 at 2:14 pm. The complainant indicated that over the last year there has been a great improvement in the delivery of respiratory care. The complainant's concern now is that the nurses at the Heinz Division be properly trained to provide respiratory care and that protocols be developed for respiratory therapist to use in patient care. Both of these concerns have been addressed by the Chief of Critical Care and the complainant is satisfied that the issues previously of concern to her have been resolved.

It appears from the interviews with staff that there has been and currently is good coordination of care provided to respiratory patients at the VAPHS. It also appears that the concerns expressed by the complainant have been resolved.

## V. Conclusions

The OMI team found that the respiratory care provided by VAPHS is within acceptable standards and does not represent a threat to veterans treated at VAPHS. Based on our review, no violations of clinical practice or apparent violations of any law, rule or regulation were found.

### Planned Actions

No actions will be taken by the OMI at this time. Other than those actions mentioned above, i.e., refinement of peer review/quality and performances processes by VAPHS, no actions are required of the VAPHS.

More specifically, with respect to the specific complaints registered by the complainant as outlined in the letter from the OSC to Secretary Principi, the OMI finds as follows:

- (1) Complaint: Pulmonary patients do not receive proper medical care and attention according to the VHA Interim and Interdisciplinary Care Plan.  
*Review of the medical records of the cases cited by the complainant and interviews with staff has provided evidence that there has been good coordination of care and that proper care was provided.*
- (2) Complaint: There have been a high number of deaths.  
*Review of the data and medical records by expert consultants has shown that of the 6 patients who died who were cited by the complainant, none of the deaths was attributable to substandard respiratory care.*
- (3) Complaint: There has been inadequate training of staff to provide respiratory care treatments.  
*Review of documents and interviews has shown that the nurses' continuing education records show that there has in fact been training in respiratory care; and that the respiratory therapists have yearly competency evaluations; that the records are complete and satisfactory for the four years the reviewers examined.*
- (4) Complaint: There is inadequate equipment.  
*Review of documents and interviews has shown that equipment requests are and have been handled appropriately and there was no evidence of lack of equipment or equipment maintenance.*
- (5) Complaint: There is no pulmonary unit.  
*There has been a careful planning of units to provide appropriate levels of care based upon level of acuity of illness, with a "high observation" unit to include patients with pulmonary care needs.*

(6) Complaint: There were many patient transfers.

*The cases reviewed showed appropriate transfers. The facility conducts regular quality reviews on all transfers.*