Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged End of Life Care Issues
VA Palo Alto Health Care System
Palo Alto, California

Report No. 08-00509-103 **March 25, 2008**

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The purpose of this inspection was to determine the validity of the following allegations regarding patient care and administrative issues at the VA Palo Alto Health Care System (VAPAHCS):

- The deaths of four terminally ill cancer patients in the intensive care unit (ICU) were intentionally hastened through the use of high dosages of narcotics and too little oxygen.
- End of life care policies were not clear or comprehensive.
- Patient flow into and out of the medical-surgical ICU was inappropriately influenced by upcoming major surgeries.

We did not substantiate that any of the four patients' deaths were intentionally hastened. In each case, the family members, after consultation with the clinical team, had requested that clinicians withhold any further interventions and provide comfort care only. The orders were changed, interventions (including oxygen) were withheld or withdrawn, and sedative medications were provided for comfort.

We substantiated that the policies that discuss end of life care issues were not clear and allowed for wide-ranging interpretations. Because end of life care is not the norm and is infrequently given on the ICU, written guidelines for the ICU will likely reduce the levels of disagreement between staff members. Upon receipt of the complaint, the Deputy Chief of Staff (COS) had assigned the task of drafting comfort care guidelines to the VAPAHCS Bioethics Committee Chairman.

We did not substantiate the allegation that patient flow into and out of the ICU was inappropriately influenced by upcoming major surgeries. However, the Deputy COS acknowledged that bed utilization issues throughout the VAPAHCS, including the ICU, have been identified and that several task forces are actively working to address them.

We recommended that the VAPAHCS complete and implement the end of life care guidelines and provide training to all staff on all shifts in the ICU. Also, the Chief Nurse Executive should add end of life care competency to the initial and annual ICU nurse skills checklists.

The Veterans Integrated Service Network 21 and VAPAHCS Directors concurred with the findings and recommendations. They submitted acceptable action plans, which include completing the comfort care guidelines, providing training, and adding end of life care to the ICU nurse skills checklists. We find the action plans acceptable and will follow up until the plans have been implemented.

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

TO: Director, Veterans Integrated Service Network 21

SUBJECT: Healthcare Inspection – Alleged End of Life Care Issues, VA Palo Alto Health Care System, Palo Alto, California

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections reviewed allegations regarding patient care and administrative issues at the VA Palo Alto Health Care System (VAPAHCS). The purpose of this inspection was to determine the validity of the following allegations:

- The deaths of four patients in the intensive care unit (ICU) were hastened through the use of high dosages of narcotics and too little oxygen.
- End of life care policies were not clear or comprehensive.
- Patient flow into and out of the ICU was inappropriately influenced by upcoming major surgeries.

Background

The complainant, an employee, voiced her concerns to the ICU nurse manager and the Chief of Quality Management, who alerted senior managers, who contacted the OIG.

The VAPAHCS is a tertiary medical center with 903 beds and 2,820 employees. It has an operating budget close to $500 million. The VAPAHCS is part of Veterans Integrated Service Network (VISN) 21.

The following terms used in the report are defined below and on the next page.

Palliative care. "Palliative care is both a philosophy of care and an organized, highly structured system for delivering care to persons with life-threatening or debilitating illness. Palliative care is patient and family-centered care that focuses upon effective management of pain and other distressing symptoms, while incorporating psychosocial and spiritual care according to patient and family needs, values, beliefs,

and cultures. The goal of palliative care is to prevent and relieve suffering and to support the best possible quality of life for patients and their families, regardless of the stage of the disease or the need for other therapies. Palliative care can be delivered concurrently with life-prolonging care or as the main focus of care."[1] Palliative care is also known as end of life care or comfort care.

- **Withholding and/or withdrawal of life-sustaining treatment.** Patients have the right to have unwanted life-sustaining treatment withheld and/or withdrawn even if this action results in death. The attending practitioner participates in the discussion of the withholding and/or withdrawal of life-sustaining treatment with the treatment team and recommends that life-sustaining treatment be withheld and/or withdrawn in a signed and dated progress note in the medical record.[2]

Scope and Methodology

We interviewed the complainant by phone. We conducted a site visit at the VAPAHCS January 8–9, 2008, and interviewed staff nurses, staff physicians, a respiratory therapist, a pharmacist, and several managers. We reviewed documents, including medical records, policies, meeting minutes, and reports. The scope of our review was limited to the allegations made by the complainant.

We conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Inspection Results

Case Reviews

Patient A

The patient was a male in his late 50's. In July 2006, he was diagnosed with lung cancer that had metastasized to the brain. In September 2007, he had a blood clot in his left leg that resulted in a below the knee amputation in October. Two weeks later, he suffered a hemorrhage into the right side of his brain. Clinicians initiated aggressive treatment, including mechanical ventilation, but his condition did not improve. The prognosis was extremely poor. In early November, after consultation with the clinical team, the family decided that clinicians should provide comfort care only. At 10:30 a.m., clinicians disconnected the ventilator but left the endotracheal (ET) tube in place for airway support. The patient was given an intravenous (IV) injection of 10 milligrams (mg) of morphine, and over the next 4 hours, the morphine was increased to 20 mg of morphine per hour by IV infusion.

[1] National Comprehensive Cancer Network "Clinical Practice Guidelines in Oncology," *Palliative Care*, v.1.2007, p. 1, http://www.nccn.org/professionals/physician_gls/PDF/palliative.pdf.
[2] VHA Handbook 1004.1, *VHA Informed Consent for Clinical Treatments and Procedures*, January 29, 2003, p 10.

Two days later, the family requested that the ET tube be removed. The patient's oxygen saturation[3] fell from an average of 95 percent to a range of 54–85 percent. The patient's heart rate increased from an average of 100 beats per minute (bpm) to 154 bpm. At approximately 4:00 p.m. that day, the assigned nurse felt that additional sedation was needed to address the higher heart rate and, after discussion with the physician, increased the morphine to 30 mg per hour. Morphine continued at this rate for about 5 hours, and the heart rate decreased. At approximately 9:30 p.m., the assigned nurse on the next shift felt that the 30 mg per hour dosage might be too much and that supplemental oxygen would increase the oxygen saturation and might make the patient more comfortable. She obtained a physician's order to administer oxygen and began supplemental oxygen. The patient's oxygen saturation increased, and the nurse decreased the morphine gradually to 9.5 mg per hour during the morning of the next day. The patient died at 8:50 a.m. the day after the ET tube was removed.

Patient B

The patient was a male in his mid 60's. In August 2006, he was diagnosed with advanced lung cancer that was treated with chemotherapy. In July 2007, he was admitted with renal failure, pneumonia, and sepsis. Clinicians initiated aggressive treatment, including a chemotherapy drug, antibiotics, mechanical ventilation, and medication to maintain effective blood pressure. None of these interventions improved the patient's condition. A week after admission, after consultation with the clinical team, the family decided that clinicians should provide comfort care only. Clinicians continued mechanical ventilation with room air and discontinued the medications supporting the patient's blood pressure. The patient died at 2:45 p.m. the same day.

Patient C

The patient was a male in his mid 60's. In early July 2007, he was diagnosed with advanced lung cancer and scheduled for radiation treatment beginning approximately 2 weeks later. However, he was admitted to the VAPAHCS a week after diagnosis with respiratory distress, pneumonia, and sepsis. Clinicians initiated aggressive treatment, including antibiotics and mechanical ventilation, but there was no improvement in the patient's condition. After approximately a week of treatment and after consultation with the clinical team, the family requested that clinicians provide comfort care only. Clinicians continued mechanical ventilation with room air and reduced the medications supporting the patient's blood pressure. The patient died at 6:28 p.m. that same day, which was the same day as patient B died.

[3] The maximum amount of oxygen that can be carried by the blood under the existing environmental conditions.

Patient D

The patient was a male in his mid 50's. In July 2006, the patient was diagnosed with colon cancer that had metastasized to his liver and was treated with chemotherapy. In July 2007, he presented with respiratory failure, sepsis, and low blood pressure. Clinicians initiated aggressive treatments, including antibiotics, mechanical ventilation, and medication, to maintain effective blood pressure. None of these interventions resulted in improvement in the patient's condition. At approximately noon the day after his admission, and after consultation with the clinical team, the family requested that clinicians provide comfort care only. Clinicians discontinued the medication to support the patient's blood pressure, and he died at 4:45 p.m. that day. This was also the same day that patients B and C died.

Issue 1: Deaths of four patients were intentionally hastened through the use of high dosages of narcotics and too little oxygen.

We did not substantiate that any of the four deaths were intentionally hastened through the use of narcotics or the lack of oxygen. All four patients were terminally ill cancer patients with additional systemic failures. In all four cases, the family members, after consultation with the clinical team, had requested that clinicians designate the patients as "Do Not Resuscitate," withdraw and/or withhold interventions, and provide comfort care only. The orders were changed, the interventions were withheld or withdrawn, and sedative medications were provided. Other than the complainant, none of the staff members interviewed felt that the deaths were intentionally hastened. None of the deaths was considered unexpected, and no peer reviews or autopsies were performed.

All four patients were unresponsive, so the assigned nurses assessed the available data, such as heart rate, oxygen saturation, and the extent to which breathing appeared labored. Given the same data, different nurses believed different approaches would provide more comfort.

Regarding Patient A, the complainant alleged the following specific issues with the end of life care.

- The dosage of 30 mg per hour of morphine was much higher than usual and intended to hasten the patient's death.

The physicians interviewed had differing opinions about sedative dosages for comfort care, but all stated that 30 mg per hour could be appropriate depending on the patient's level of discomfort and tolerance to sedatives. The ICU pharmacist stated that 20 mg per hour of morphine was considered to be the usual maximum dose for pain relief. However, dosages can be increased for comfort care at the physician's discretion. The actual written order at 9:30 p.m. the evening before the patient's death was "morphine for comfort care only titrate 1–40 mg per hour." The assigned nurse increased the patient's

morphine from 20 to 30 mg per hour at approximately 4:00 p.m. She stated that she discussed the patient's increasing heart rate with the assigned physician and had verbal agreement to proceed with the morphine dosage change.

- The patient should have had supplemental oxygen administered as a comfort measure.

The physicians interviewed had differing ideas about the use of oxygen as a comfort measure, particularly in an unresponsive patient. Some stated that oxygen is considered an intervention and would be contraindicated when the family requested no interventions. Others felt that oxygen could be tried, and perhaps, less sedation would be needed. In this case, when oxygen was initiated, the patient's heart rate remained around 120 bpm, the saturation increased to 100 percent, and the morphine dose was decreased gradually to 9.5 mg per hour.

With regards to the remaining three patients, the complainant specifically alleged that medications to maintain blood pressure should not have been withdrawn. The physicians interviewed all stated that they considered such medications to be interventions. They told us they discussed the withdrawal of these medications with the patients' family members as part of the change from aggressive treatment to comfort care.

We interviewed seven staff nurses and four physicians who had provided care to the four patients during their last days. We found differing opinions among the clinicians about sedative dosages, use of oxygen, and continuation of other medications, such as those that maintain blood pressure.

A review of recent literature indicates that comfort care has wide-ranging interpretations across all health care settings, including ICUs. Guidelines on sedation in dying ICU patients state that "terminal sedation represents another means of alleviating pain and suffering at the end of life and is not euthanasia" and "the physician's intent when administering these drugs (sedatives) was seen as the distinguishing factor between palliative care and euthanasia."[4] Similarly, VHA's National Ethics Committee reported that "palliative sedation is intended to relieve the patient's suffering and is unlikely to hasten death."[5] "Physicians should administer drugs in sufficient amounts to relieve pain and suffering because the importance of palliative care cannot be overemphasized."[6] The amount of medication required is based on individual need. In a review of end of life ICU pain control, the median morphine dosage was 25 mg per hour.[7] While it is

[4] Laura A Hawryluck et al., "Consensus Guidelines on Analgesia and Sedation in Dying Intensive Care Unit Patients," *BMC Medical Ethics 2002*, 3:3, August 12, 2002, http://www.biomedcentral.com/1472-6939/3/3.
[5] National Center for Ethics in Health Care, "The Ethics of Palliative Sedation," *A Report by the National Ethics Committee of the Veterans Health Administration*, March 2006, p. 3.
[6] Charles L. Sprung, M.D. et al., "Relieving Suffering or Intentionally Hastening Death: Where Do You Draw the Line?" *Crit Care Med*, Vol. 36, No. 1, 2008, p. 13.
[7] Sprung, p. 9.

preferable to provide palliative sedation to patients who can consent to it themselves, it may be provided to patients who lack decision-making capacity with the consent of the surrogate decision maker.[8] Regarding oxygen, palliative care guidelines suggest that oxygen therapy for the dying patient is indicated if the patient reports relief.[9] In terminating mechanical ventilation, a common approach is to turn off oxygen in favor of room air and use narcotics for comfort.[10]

We concluded that while there were specific differences in clinicians' approaches to providing comfort care, there was no evidence to substantiate that any clinician provided incorrect or unethical care.

Issue 2: End of life care policies were not clear or comprehensive.

We substantiated that the policies that discuss end of life care issues were not clear and allowed for wide-ranging interpretations. Given that aggressive intervention is the norm in the ICU and that comfort care is provided only sporadically, written guidelines would be useful in decreasing differences in practice between clinicians. Upon receipt of the complaint, the Deputy Chief of Staff (COS) had assigned the task of drafting end of life care guidelines to the VAPAHCS Bioethics Committee Chairman. Therefore, we recommended that the ICU medical and nursing leaders, the Bioethics Committee, and the Palliative Care Team collaborate to complete the task of creating written guidelines for comfort care in the ICU. Once the guidelines are complete, we recommend that training be provided to all staff on all shifts in the ICU. We also recommended that end of life care competency be added to initial and annual ICU nurse skills checklists.

Issue 3: Patient flow into and out of the ICU was inappropriately influenced by upcoming major surgeries.

We found no evidence to substantiate the complainant's allegation that the three patient deaths on the same day were intentionally hastened to make room for the following Monday's surgical patients. As discussed previously, all three patients were terminally ill cancer patients with additional systemic failures, and the family members had requested that clinicians provide comfort care only. Other than the complainant, none of the staff members interviewed stated that deaths were intentionally hastened in the ICU.

The following Monday, five surgeries were scheduled, and the planned destination for the five patients was the ICU. Everyone we interviewed agreed that for three patient deaths to occur on any single day was very unusual. The mortality analysis for fiscal year 2007 showed 56 deaths in the ICU, which was an average of one death every 6.5 days. The

[8] National Center for Ethics in Health Care, p. 7.
[9] National Comprehensive Cancer Network, p. 10.
[10] J. Randall Curtis, M.D., M.P.H.,"Interventions to Improve Care During Withdrawal of Life-Sustaining Treatments," *J Palliative Medicine,* Vol. 8, Supp 1, 2005, p. 126.

number of deaths in the ICU has been on a decreasing trend. No other trends were identified in the mortality analysis.

The managers we interviewed acknowledged that ICU beds are in high demand and that triaging decisions are made daily regarding which patients can be moved to different units. Such triaging decisions are made by the designated triage physician in consultation with the surgeons and other clinical managers. All staff we interviewed stated that the surgery schedule does not influence their patient care practices. We noted that the ICU occupancy rate for 1 week in July and 1 week in November ranged from 73–100 percent, with an average of 89 percent.

Utilization Management (UM) staff review patient care throughout the VAPAHCS to determine if patients are in the most appropriate location. We reviewed the data and UM Committee meeting minutes and noted considerable discussion about bed utilization and patient flow issues. For example, in the August 2007 meeting minutes, clinicians discussed the feasibility of moving stable terminal patients from acute units to the hospice unit, the surgeons' preference to keep stable patients in the ICU longer than necessary, and alternative levels of care for mental health patients.

The Deputy COS acknowledged that bed utilization issues throughout the VAPAHCS, including the ICU, have been identified and that several task forces are actively working to address them. Some of the actions that have been implemented include facilitating the discharge process, improving tracking of elective surgeries and ER admissions, and initiating an orthopedic surgery critical pathway to improve efficiency.

We concluded that while ICU bed availability is a frequent discussion and decision point, staff nurses and physicians focus on caring for the patients assigned to them and are somewhat isolated from such decisions. We suggest that the Deputy COS continue with robust efforts to improve the identified bed utilization issues.

Recommendations

Recommendation 1. We recommended that the VISN Director require the VAPAHCS Director to ensure that ICU medical and nursing leaders, in conjunction with the Bioethics Committee and the Palliative Care Unit managers, complete the task of creating written guidelines for comfort care in the ICU.

Recommendation 2. We recommended that the VISN Director require the VAPAHCS Director to ensure that end of life care training be provided to all staff on all shifts in the ICU.

Recommendation 3. We recommended that the VISN Director require the VAPAHCS Director to ensure that end of life care competency be added to initial and annual ICU nurse skills checklists.

Comments

The VISN 21 Director concurred with the findings and recommendations and submitted acceptable action plans, which include completing the comfort care guidelines, providing training, and adding end of life care to the ICU nurse skills checklists. We find the action plans acceptable and will follow up until the plans have been implemented.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: February 26, 2008

From: Director, VA Sierra Pacific Network (10N21)

Subject: **Healthcare Inspection – Alleged End of Life Care Issues, VA Palo Alto Health Care System, Palo Alto, California**

To: Director, Los Angeles Regional Office of Healthcare Inspections, Office of Inspector General (54LA)

Thru: Director, Management Review Service (10B5)

1. I appreciate the opportunity to provide comments to the draft report on the alleged end of life care issues at the VA Palo Alto Health Care System (VAPAHCS). I have discussed this draft report and the recommendations of the Healthcare Inspection Team with the leadership of VAPAHCS. We concur with the recommendations and have taken steps to ensure that these recommendations are implemented in a timely fashion (see attached comments).

2. I thank the Healthcare Inspection Team for their efforts in reviewing this alleged incident at VAPAHCS. The VAPAHCS leadership and staff viewed the review as instructive and as an opportunity for process improvement. We hope that the training and guidelines VAPAHCS staff develop may prove to be useful to other facilities within the VA.

3. If you have any questions regarding our responses and actions to the recommendations in the draft report, please contact me at (707) 562-8350.

(original signed by:)
Robert L. Wiebe, M.D., M.B.A.

VISN Director's Comments to Office of Inspector General's Report

The following comments from the VISN 21 Director are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the VISN Director require the VAPAHCS Director to ensure that ICU medical and nursing leaders, in conjunction with the Bioethics Committee and the Palliative Care Unit managers, complete the task of creating written guidelines for comfort care in the ICU.

Concur. The Chair of the VAPAHCS Bioethics Committee and the Director of the Palliative Care Unit have worked with ICU medical and nursing leadership to develop guidelines for comfort care within the ICU. These guidelines are in the process of being finalized and will be complete March 31, 2008.

Target Completion Date: March 31, 2008

Recommendation 2. We recommended that the VISN Director require the VAPAHCS Director to ensure that end of life care training be provided to all staff on all shifts in the ICU.

Concur. With the guidelines for comfort care completed on March 31, 2008, this end of life training will be complete on April 30, 2008, and will include all staff on all shifts of the ICU. The training will occur on all shifts as recommended.

Target Completion Date: April 30, 2008

Recommendation 3. We recommended that the VISN Director require the VAPAHCS Director to ensure that end of life care competency be added to initial and annual ICU nurse skills checklists.

Concur. The Chief Nurse for Acute Medicine and Surgery will add end of life care competency to the initial and annual ICU nurse skill checklists. The upcoming training on end of life care will serve as the initial determination of competency.

Target Completion Date: April 30, 2008

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Julie Watrous, RN, Director Los Angeles Office of Healthcare Inspections (213) 253-2677 ext. 4972
	Nancy Albaladejo, Healthcare Inspector

Appendix C

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