Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Quality of Care Issues
Clement J. Zablocki VA Medical Center
Milwaukee, Wisconsin

Report No. 07-00569-212 **September 26, 2007**

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 allegations made by an anonymous complainant regarding the quality of care provided to patients by a clinician on the Palliative Care Unit (PCU) at the Clement J. Zablocki VA Medical Center in Milwaukee, WI. Patients are admitted to this unit for end of life care. The complainant alleged that four patients were denied pain medications during the last stage of life, and another patient was given the wrong medication that caused the patient's premature death.

While we substantiated that a patient's daughter expressed concerns regarding the patient's condition and wanted the treatment plan changed to avoid further pain, after the physician explained his reason for not changing the treatment plan, the daughter agreed with his decision. We substantiated that a patient died before the order for a morphine sulfate intravenous drip was initiated and that a patient was given the wrong medication. However, we did not substantiate that the medication error caused this patient's death.

Additional PCU concerns regarding patient confidentiality and storage of hazardous cleaning products were identified during our on-site inspection, and managers took immediate action to correct these deficiencies.

We did not substantiate that the patients named in the allegations were denied pain medications and allowed to suffer during the last stage of their life while on the PCU. Further, we did not substantiate that the clinician told a patient's family member that the patient was not in pain or that a patient's son had to convince the clinician to administer morphine sulfate so that his father could be comfortable during the last stage of his life.

We made recommendations that management should ensure that:

- All PCU staff use the Bar Code Medication Administration system when administering medications and all clinical disclosures are conducted according to Veterans Health Administration policy.
- All PCU staff comply with patient confidentiality and computer security policies.
- All PCU staff comply with medical center policy and Joint Commission's Environment of Care Standards for storing hazardous cleaning products.

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

TO: Director, Veterans Integrated Service Network 12 (10N12)

SUBJECT: Healthcare Inspection – Quality of Care Issues, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin

Purpose

The purpose of this inspection was to determine the validity of allegations made by an anonymous complainant regarding the quality of care provided to patients by a staff member (hereafter identified as the clinician) on the Palliative Care[1] Unit (PCU) at the Clement J. Zablocki VA Medical Center (the medical center). It was alleged that four patients were denied pain medications during the last stage of their life. The complainant also alleged that a fifth patient was given the wrong medication by the clinician which caused the patient's premature death.

Background

The medical center is a tertiary care facility that is part of Veterans Integrated Service Network (VISN) 12 and provides a broad range of inpatient and outpatient care services including medical, surgical, mental health, geriatric, rehabilitation services, and spinal cord injury care. The medical center serves a veteran population of approximately 235,000 in a primary service area that includes 15 counties in the eastern part of Wisconsin. The medical center is affiliated with the Medical College of Wisconsin and supports 142 medical resident positions in 34 training programs.

An anonymous complainant contacted the Office of Inspector General Hotline with the following allegations regarding the quality of care provided to patients by a clinician on the PCU:

- The clinician denied pain medication to patient A, allowing the patient to suffer for days during the last stage of his life. The family was told by the clinician that the patient was not in pain and could sit up in the chair.

[1] Palliative care can afford relief of the pain of a patient whose disease is not responsive to curative treatment.

- A family member of patient B had to convince staff to administer morphine sulfate (also referred to as MSO_4, which is the chemical symbol) to regulate the patient's breathing and to reduce the severe pain the patient was experiencing during the last stage of his life.

- The clinician and other staff failed to administer pain medication to patient C during the last stage of his life. The patient's daughter expressed concerns with the care her father received during his last 48 hours of his life.

- Patient D's son screamed and begged in despair for the clinician to order MSO_4 so his father could be comfortable during the last stage of his life. The MSO_4 drip[2] was ordered, however, it arrived on the PCU after the patient died.

- Patient E died prematurely after the clinician administered the wrong medication. According to the allegation, when the family asked the clinician about this error, they were told the medication would not harm the patient.

Scope and Methodology

On May 1–3, 2007, we conducted a site visit at the medical center. We interviewed managers and staff, and conducted an environment of care inspection of the PCU. Prior to the site visit, we reviewed electronic medical records for the five patients named in the complaint, medical center documentation, policies, and quality management data.

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

Inspection Results

Patient A Case History and Findings

Patient A was a 77-year-old male veteran, who transferred from a community facility to the medical center's medical unit on September 14, 2006, with diagnoses of lung cancer and pneumonia. He was transferred to the Intensive Care Unit (ICU) 2 days after admission for worsening respiratory status. On September 27 the patient was transferred to the PCU with an overall poor prognosis. Pain management orders included MSO_4 5 mg sublingual (under the tongue) every hour as needed for difficult breathing or pain.

On October 10 the patient's pain level was scored as 8 out of a possible 10, with 10 being the highest pain level. He received pain medication as needed. Later, when the patient refused to get up in the chair, the clinician suggested that he should try to sit up as much

[2] The continuous introduction of an intravenous (IV) fluid into a vein, a drop at a time.

as possible to regain his strength. She encouraged the patient to get into a wheelchair so that he could visit with his wife off the unit when she arrived. The patient agreed and was assisted with transfer to the wheelchair.

On the morning of October 16 the patient was noted to be very lethargic. Documentation shows that he had been getting medications as ordered for complaints of "pain all over." Because of the patient's lethargy and often vague complaints regarding his discomforts, his pain medication intervals were increased from every 1 hour to every 3 hours. At lunchtime, the patient was awake and eating well when fed. The patient was monitored closely for comfort during the next 24 hours. The care plan was to keep him comfortable and responsive.

October 17, the clinician documented that the patient was agitated and moaning in discomfort. The patient's wife was notified by telephone that the patient's condition was deteriorating and that he would be more comfortable with a continuous MSO_4 IV drip for pain. The wife stated that she knew this was coming and that she and other family members agreed with the clinician's suggestion to begin this comfort measure.

We did not substantiate that patient A was denied pain medications and comfort care during the last stage of his life or that the clinician had told the family or the patient that he was not in pain.

Patient B Case History and Findings

Patient B was a 60-year-old male veteran with a history of diabetes and morbid obesity[3] who was transferred to the medical center on October 10, 2006, from a community facility. The patient was admitted to the ICU with hypoglycemia (low blood glucose), blood in his stool, and severe abdominal pain. General Surgery and Gastroenterology consultations were ordered on admission to the ICU. The gastroenterologist performed a colonoscopy on the same day. The colonoscopy identified several polyps and one large polyp that was actively bleeding. Biopsies were positive for adenocarcinoma, and it was believed that the patient was in hepatic (liver) failure. General Surgery physicians recognized the need for an operative intervention, but the patient's co-morbidities (poor liver function, obesity, and renal insufficiency) necessitated medical clearance. The patient received medical clearance, and surgeons performed a partial left colon resection on October 13. The surgeons found the tumor had spread to the patient's liver. The patient was readmitted to the ICU after surgery. On October 19 at 4:14 p.m., the patient was transferred to the PCU with orders for a MSO_4 IV drip for pain management. The MSO_4 IV drip was started at 4:47 p.m. on October 19 and was continued until the patient's death at 6:45 p.m. that same evening.

[3] Sometimes called "clinically severe obesity"; this is defined as being 100 pounds or more over the ideal body weight or having a Body Mass Index [BMI] of 40 or higher.

We did not substantiate patient B was denied pain medications and allowed to suffer during the last stage of his life on the PCU.

Patient C Case History and Findings

Patient C was a 61-year-old male veteran who was diagnosed with lung cancer in April 2006. He was admitted to the medical center on October 22 with symptoms of nausea, vomiting, weight loss, and unsteadiness. Further testing revealed that the lung cancer had metastasized (spread) to the patient's brain. The patient was transferred to the PCU on October 24 for end of life care. The patient received radiation treatments for the metastatic brain lesions from October 16 to October 30.

On October 24 the physician ordered MSO_4 15 mg by mouth every 3 hours as needed for pain. The patient received the first dose on October 27 at 11:06 p.m. and the last dose on November 5 at 4:53 a.m.

On November 3, the patient told the nurse that he was getting weaker; however, he denied being in any pain at that time. He expressed a desire to participate in a parade the following day. The patient's family had ambivalent feelings about taking him out of the medical center on a pass, but they decided that they would take it minute by minute.

On November 4 at 3:00 a.m. the patient's daughter voiced concerns regarding the appearance of the patient's urine. The patient's urine was very concentrated and dark amber in color. The nurse told the daughter that the reason the urine was so dark in color was most likely due to the fact that the patient had a decrease in oral intake. The patient denied any pain or burning upon urination. The daughter was concerned that the patient might have a urinary tract infection and wanted to have her father treated with antibiotics before they leave for the parade the next day to avoid further pain. The nurse notified the physician on call and relayed the daughter's concerns. The physician did not feel antibiotics were needed at this time and advised that treating the patient's pain would be the foremost thing to do at this point. The daughter was agreeable to this plan, and no new orders were given.

On November 4 at 9:15 a.m., the patient left the medical center with his family to attend the parade. The patient and his family returned to the medical center at 11:11 a.m. The patient seemed proud of his accomplishment and denied being in any pain at that time. His appetite was poor, the nurse noted that he only consumed 10 percent of his lunch, and his family stated that he had vomited outside. The patient refused medications offered for vomiting. On November 5 at 3:54 a.m., the patient experienced pain and anxiety and was given pain medication as ordered. At 4:45 a.m. the physician was notified that the medication only provided short term relief, and the patient's nonverbal pain was now

assessed at 10 on the pain scale.[4] At 4:53 a.m. the patient was given MSO_4 4 mg by intramuscular injection for pain. He died at 5:14 a.m.

We did not substantiate that patient C was denied pain medications and allowed to suffer during the last stage of his life on the PCU. While we substantiated that the patient's daughter expressed concerns regarding the patient possibly having a urinary tract infection, the daughter agreed to the physician's recommended treatment plan of care.

Patient D Case History and Findings

Patient D was a 75-year-old male veteran admitted to the medical center on October 26, 2006, for an open lung biopsy for interstitial lung disease.[5] The patient developed pneumonia and other respiratory complications and was transferred to the ICU. The biopsy identified a type of pulmonary fibrosis with poor response to treatment. The patient's family considered caring for him at home; but after discussions with staff, they chose palliative care with do not resuscitate, intubate or re-hospitalize orders. The patient was admitted to the PCU by the clinician on October 26. Documentation shows that the patient was alert and mildly dyspneic (short of breath) with no pain. The patient was aware that his lung condition was terminal. The clinician documented a family discussion about his terminal condition and that his life expectancy was predicted as days to weeks. The patient told the clinician he was hesitant about taking MSO_4 for pain as it made him "hazy." The clinician informed the patient and family that the medication would be available as needed.

During the night of November 6, the patient removed his ambient oxygen supply, and his pulse oximetry level (an indirect, noninvasive assessment of oxygen in the blood) dropped to 54 percent (normal 95–100 percent). The response team was notified and after administering MSO_4 the patient was able to relax and sleep. The patient's pulse oxygen leveled off at 76 percent. On November 7, the patient was alert with a good appetite and stated that he "felt great." However, the patient quickly became fatigued, with his pulse oxygen levels fluctuating in the 70s and 80s. The patient was alert and denied any discomfort. The daughter was at his bedside, and the clinician discussed the patient's deteriorating status with her.

On November 7 at 10:57 a.m., the clinician told the family that the patient would soon require a MSO_4 drip and or other medications to help him relax and breathe easier. At 11:41 a.m. the clinician suggested to the family that the patient be started on a MSO_4 IV drip. The family agreed with this plan. The patient continued to get MSO_4 IV push (injected into the line going directly into the vein and blood stream) as needed, while waiting for the MSO_4 IV drip to be started. The MSO_4 IV drip was ordered at 1:09 p.m.

[4] Pain is assessed using the 0–10 numerical rating scale, with 10 being the worst.
[5] A group of inflammatory and scarring processes that affect the gas exchanging area of the lungs.

While the IV team was attempting to obtain IV access in another site for the MSO_4 drip, the patient relaxed, became somnolent, and suddenly stopped breathing. He was pronounced dead at 2:15 p.m. The MSO_4 IV drip was never started.

We did not substantiate that patient D's son had to scream and beg the clinician to administer MSO_4 for the patient's comfort. Documentation shows that the clinician involved the patient's family in treatment decisions including decisions regarding pain management immediately prior to the patient's death. There are no documented conversations with the patient's son, and the clinician could not recall any personal communication with the son.

We substantiated that the MSO_4 IV drip arrived on the PCU after the patient's death. However, the patient received MSO_4 IV push for pain as needed prior to his death.

Patient E Case History and Findings

Patient E was an 81-year-old male veteran admitted to an acute care unit at the medical center on September 16, 2006, with diagnoses of progressive dyspnea, chronic obstructive pulmonary disease, congestive heart failure, chronic lymphocytic leukemia, and a 40-pound weight loss. He was transferred to the PCU for end of life care.

Admission medication orders included a daily oral dose of 20 mEqs (milliequivilents) of potassium chloride. On September 27, a nurse, who was assigned to care for the patient that day, administered an additional oral dose of 40 mEq potassium chloride to the patient. The nurse told us that the patient's potassium level was at a low normal that day, and when she saw a potassium chloride tablet with the patient's name on it arrive on the unit, she assumed it was for him. However, there were two patients on the unit that day with the same last name. Later, when another nurse asked if the potassium chloride that had been ordered for her patient had arrived, the nurse in question realized she had given another patient's medication to Patient E.

The nurse did not use the medical center's Bar Code Medication Administration (BCMA) system machine, which is required by policy. The BCMA system is designed to reduce the chance of medication error through a verification process that ensures that the right patient gets the right medication at the right time by the right route, and of the right dose. To start the verification process, the BCMA system requires staff to scan the barcode on the patient's armband before administering any medication. Use of the BCMA system might have prevented this error.

When the nurse became aware of the medication error, she immediately notified the clinician. She also informed the patient of the error and told him he would be monitored. The clinician examined the patient, reviewed his recent laboratory values, and ordered repeat laboratory testing for the following morning. The clinician told us that since the

patient's potassium level was at low normal, she did not feel the urgency to repeat it any earlier. The laboratory results the following day remained within normal range.

The nurse appropriately informed the patient, initiated an incident report, and submitted the report to her immediate supervisor. However, she did not document this extra dose in the patient's medical record. The nurse made an addendum to the medical record to document the extra dose during our site visit.

At the time of the medication error, managers took immediate action, and the nurse was counseled regarding medication administration procedures and the use of the BCMA system for all medication administration.

We substantiated that patient E was given an extra dose of medication that was not ordered. However, the medication was given by a nurse not the clinician. There was no documentation in the patient's medical record that the clinician informed the patient's family of the medication error, and the clinician did not recall discussing this incident with them, as required by Veterans Health Administration (VHA) Handbook 1050.1. [6]

We did not substantiate that the medication error caused the patient's premature death. The patient died 13 days after the error, and laboratory results indicated the patient's potassium level was within normal limits at that time.

Palliative Care Unit Inspection:

We inspected the PCU on May 2 and found the unit to be clean and appropriately maintained. However, we identified two concerns that required management's immediate attention.

The unit nurse manager's office door was open, and a set of keys was lying on the table. Sensitive patient documents were on the desk and the computer terminal was open with sensitive information on the screen. Staff was unaware of the office being open during our inspection of the unit. Since the unit manager was unavailable, we requested that the office door be immediately locked to safeguard the keys and sensitive information.

We observed that the housekeeper's storage room door was open, and the housekeeper was not in the immediate area. Because hazardous cleaning products are stored in this room that may be harmful to patients, we requested that the door be immediately closed and locked.

[6] VHA Handbook 1050.1, *VHA National Patient Safety Improvement Handbook*, issued 01/30/2002.

Recommendations

Recommendation 1. The VISN Director should ensure the Medical Center Director takes action to require all PCU staff to use the BCMA system when administering medications and all clinical disclosures are documented according to VHA Handbook 1050.1 and medical center policy.

Recommendation 2. The VISN Director should ensure that the Medical Center Director takes action to ensure all PCU staff comply with patient confidentiality and computer security policies.

Recommendation 3. The VISN Director should ensure that the Medical Center Director takes action to ensure PCU staff comply with medical center policy and Joint Commission's Environment of Care Standards for storing hazardous cleaning products.

Comments:

The VISN and Medical Center Directors agreed with the findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, page 10–13 for the full text of their comments.) We will follow up on the planned actions until they are completed.

(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: August 7, 2007

From: VISN Director (10N12)

Subject: **Healthcare Inspections: Quality of Care Issues, Clement J. Zablocki VA Medical Center Milwaukee, Wisconsin**

To: Director, Chicago Regional Office of HC Inspections

Attached please find responses from Milwaukee VAMC to all recommendations. I have reviewed and concurred with the responses and action plans. Thank you.

James W. Roseborough, FACHE

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: August 6, 2007

From: Acting Medical Center Director (695/00)

Subject: **Healthcare Inspections: Quality of Care Issues, Clement J. Zablocki VA Medical Center Milwaukee, Wisconsin**

To: Verena Briley-Hudson, Director, Chicago Regional Office of Healthcare Inspection, Office of Inspector General

I have reviewed the draft report and concur with the recommendations. The potential patient safety issues noted in the draft report merit our attention. Thank you for the opportunity to review the draft report and provide the improvement that is needed.

Attached are the actions we plan to take in order to improve the quality of care we provide to those we serve.

If you have any questions please contact Jodi J. Johnson, Manager, PI (PI/695) at (414) 384-2000 ext. 42517.

(original signed by:)

Larry L. Berkeley

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

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

OIG Recommendation(s)

Recommendation 1. The VISN Director should ensure the Medical Center Director takes action to require all PCU staff to use the BCMA system when administering medications and all clinical disclosures are documented according to VHA Handbook 1050.1 and medical center policy.

Concur **Target Completion Date:** 9/30/07

The Medical Center has been fostering a culture of patient safety related to medication administration and disclosure and as such has previously taken actions to promote understanding and compliance with these vital efforts.

(a) We have concluded that the finding in May 2007 related to by-passing of the Bar Code Medication Administration (BCMA) system was related to individual compliance and perception of the nurse on the PCU. The nurse involved in the medication event on PCU was counseled by her supervisor and appropriate action was taken. The Clement J. Zablocki VA Medical Center (ZVAMC) will monitor all medication events on the PCU for proper use of BCMA during Quarter 4, 2007. Each event related to BCMA will be aggregated and reviewed for common themes (shift, nurse, medication type, etc) so that unit-specific follow up (re-education, etc) can be provided.

(b) ZVAMC has a medical center disclosure policy that follows VHA Handbook 1050.1. At the time of the May 2007 OIG review educational activities related to disclosure continued to take place. All PCU staff have been notified of the local policy with regard to disclosure. Performance Improvement/ Risk Management will conduct a concurrent review of any adverse events in PCU for evidence of disclosure and provide real-time feedback in order to meet the intent of the Handbook.

Recommendation 2. The VISN Director should ensure that the Medical Center Director takes action to ensure all PCU staff comply with patient confidentiality and computer security policies.

Concur **Target Completion Date:** 9/30/07

The Medical Center has taken the following immediate actions to correct this finding:

Follow up training for PCU staff was provided locally regarding information security of patient records (bedside clip boards and computer work stations). The Associate Director for Patient/ Nursing Services led a review to ensure that sensitive data was removed from non-secured areas. The Program Manager involved with this finding in May 2007 has been counseled and appropriate action has been taken. Ongoing monitoring will continue via PI driven facility tracers and Environment of Care Rounds. Findings will be shared with leadership and medical center councils and immediate corrective actions will be taken as needed. Due to the amount of information that is used in healthcare, ZVAMC will continue to monitor the security of information on an ongoing basis.

Recommendation 3. The VISN Director should ensure that the Medical Center Director takes action to ensure PCU staff complies with medical center policy and Joint Commission's Environment of Care Standards for storing hazardous cleaning products.

Concur **Target Completion Date:** 9/30/07

The housekeeper working in the PCU received immediate education related to specific chemicals stored in housekeeping closets and the rationale for securing them. This training will be added to annual housekeeper competency review for FY 2008.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Verena Briley-Hudson, MN, RN, Director Chicago Office of Healthcare Inspections (708) 202-2672
Acknowledgments	Wachita Haywood, RN, Associate Director Michael Shepherd, MD, Medical Consultant Judy Brown, Program Support Assistant

Appendix D

Report Distribution

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