Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Patient Safety on a Critical Care Unit
Malcom Randall VA Medical Center
Gainesville, FL

Report No. 12-01475-222

July 16, 2012

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding a nurse's practice on a Critical Care Unit at the Malcom Randall VA Medical Center in Gainesville, FL.

In January 2012, OIG received allegations that a Registered Nurse (RN) did not obtain blood glucose levels as ordered for a patient on a continuous insulin infusion and entered fictitious blood glucose levels into the electronic health record, did not titrate a patient's insulin infusion per facility protocol, and was practicing medicine without a license. Further allegations were that the RN did not document vital signs and other clinical information on this patient and one other patient until the end of the shift, failed to provide pain medication to a hospice patient, and had falsified documentation on blood glucose levels on a patient in July 2011. It was also alleged that no action was taken on these or other issues that allegedly had been reported to the unit's nurse manager (NM) regarding the RN's provision of patient care.

We substantiated the allegations that the RN falsified documentation and did not administer insulin as ordered for a patient. We did not substantiate the allegation that the RN was practicing medicine without a license. We did not substantiate the allegation that patient care was not documented until the end of a shift. We did not substantiate the allegation that the RN failed to provide pain medication for a patient; however, the RN did not provide pain medication as ordered nor adhere to local policy for pain management. We substantiated the allegation that previous concerns about the RN were reported to the NM, but not that nothing was done. However, we found that there was a pattern of quality of care issues associated with the RN, and that the NM did not address the issues following appropriate managerial protocol.

An Administrative Investigative Board (AIB) was conducted by the facility for review of the allegations, as well as additional allegations brought to light during the course of this inspection. We reviewed the results of the AIB, and concurred with its findings, conclusions, and recommendations.

We recommended that the System Director follow through with recommendations made by the AIB, and request that Regional Counsel evaluate relevant documents to determine if criteria are met to report the RN's actions to state licensure governing boards.

The VISN and System Directors concurred with our recommendation and provided an acceptable action plan. We will follow up on the planned actions until they are completed.

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

TO: Director, VA Sunshine Healthcare Network (10N8)

SUBJECT: Healthcare Inspection – Patient Safety on a Critical Care Unit, Malcom Randall VA Medical Center, Gainesville, FL

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection at the Malcom Randall VA Medical Center (the facility) in Gainesville, Florida, to assess the merit of allegations concerning patient care in the facility's Medical Intensive Care Unit (MICU).

Background

The facility, part of Veterans Integrated Service Network 8, is in the North Florida/South Georgia Veterans Health System, which includes the Malcom Randall VA Medical Center in Gainesville, FL, and the Lake City VA Medical Center in Lake City, FL. The facility has acute medical, surgical, and specialty services, with 222 operating beds, including a 12 bed MICU.

We received allegations that a registered nurse (RN) in the MICU did not properly care for patients, and that the nurse manager (NM) of the MICU was aware of concerns regarding this RN's patient care but did not take appropriate action. Specifically, the allegations were that:

- In January 2012, the RN did not obtain blood glucose levels as ordered for a patient on a continuous insulin infusion and entered fictitious blood glucose levels into the electronic health record (EHR).
- The RN was practicing medicine without a license.
- The RN did not titrate (adjust) a patient's insulin infusion per facility protocol.

- The RN did not document vital signs and other clinical information on this patient and one other patient until the end of the shift.
- The RN failed to provide pain medication to a hospice patient.
- The RN had falsified documentation on blood glucose levels prior to January 2012, but no actions were taken.
- "Many" reports of contact (ROC) have been submitted to the NM concerning the RN but appropriate actions were not taken.

Documentation of Patient Care in the MICU

Components of patient care documentation in the MICU include three different systems: the Computerized Patient Record System (CPRS), CareVue[1], and Bar Code Medication Administration (BCMA). Entries into all three systems are password protected for each facility employee.

CPRS. The CPRS medical record contains progress notes, medication history, vital signs, and results of laboratory, radiology, and other tests. When specific tests (such as blood glucose levels) are performed at the bedside of the patient, the results are automatically uploaded to CPRS when the blood glucose monitor (glucometer) is placed in a docking station. The actual date, time, and name of the person performing the test are transferred from the glucometer to the EHR when the monitor is docked, and entries cannot be altered.

CareVue. CareVue is an electronic flow sheet used in the MICU. Current vital signs and other data, such as infusion rates of intravenous fluids and medications, can be automatically uploaded from the patient's bedside monitor into CareVue at frequencies determined by the care provider. Other entries, such as documentation of therapies and treatments, can also be automatically uploaded into the record at frequencies determined by the caregiver. Narrative entries documenting patient condition and care may be made into the record well after the fact but indicate the actual time of events or care given. However, the actual date and time the narrative entry was made cannot be altered.

BCMA. When medications are administered to a patient, the patient's armband and the medication are scanned with a bar code reader, and relevant information is automatically transmitted to CPRS, including the medication given, time, and name of the individual giving the medication.

[1] A software system designed to centralize documentation of patient information into one form.

Insulin Treatment in the ICU

Hyperglycemia (elevated blood glucose level) requires aggressive treatment in the ICU setting. Patients in the ICU are more likely to have hyperglycemia, and control of glucose levels is associated with improved patient outcomes, particularly in the setting of sepsis (bloodstream infection). Physicians may achieve improved glucose level control with a continuous intravenous infusion of insulin. Ideally, blood glucose levels are maintained within a range of 140 to 180 milligrams/deciliter (mg/dl). Glucose levels below 140 mg/dl may increase the risk of severe hypoglycemia (decreased blood glucose level), while levels above 180 are considered inadequate control.[2] Intravenous insulin affects blood glucose levels rapidly, so hourly monitoring and titration in the ICU is required.

The Yale protocol[3] is a well-established nurse controlled algorithm used to calculate the appropriate insulin infusion rate based on the patient's rate of change in blood glucose levels. The nurse monitors blood glucose levels hourly and adjusts the insulin dose as indicated by protocol calculations. Multiple dosage calculator tools are available on-line; when the current and previous hour's blood glucose levels are entered, the correct insulin infusion rate is displayed. When the blood glucose levels remain above the target range, the insulin dose is increased. Once the target range is achieved, the current insulin dose is maintained, and the blood glucose levels are monitored hourly. If the blood glucose levels decrease below the desired range, the insulin dose is lowered or stopped altogether to prevent hypoglycemia.[4]

Scope and Methodology

During a site visit conducted from January 31 through February 3, 2012, we interviewed facility staff, service managers, and facility leaders. We conducted a detailed review of EHRs for two patients cared for by the subject RN, and other relevant documents. We also reviewed policies, procedures, and all reports of contact (ROC) related to the MICU for the last 2 years.

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.

[2] Diabetes Facts and Guidelines, 2011/2012. Silvio E. Inzucchi, M.D.
[3] Yale protocol information, guidelines, protocols, and calculators are widely available on the internet.
[4] van den Berghe, G., P. Wouters, et al. (2001). "Intensive insulin therapy in critically ill patients." N Engl J Med 345(19): 1359-1367.

Inspection Results

Issue 1: Improper Delivery of Care by an RN

We substantiated the allegations that the subject RN documented fictitious blood glucose levels in the EHR, and did not follow physician orders for the titration of a continuous insulin infusion. We did not substantiate the allegation that the RN was practicing medicine without a license. No medications were given or actions taken without physician supervision, direction, or control. Instead, the RN failed to follow written physician orders. We did not substantiate the allegation that patient care documentation was not performed until the end of the shift on two patients. Entries were made in the EHR of both patients throughout the shift; however, the majority of documentation was completed at the end of the shift. While it is prudent practice to continually document care rendered throughout a shift, on occasion circumstances and patient care responsibilities may prevent timely documentation.

We did not substantiate the allegation that the subject RN failed to provide any pain medication to a hospice patient; however, we found that the RN did not adequately treat the patient's pain and failed to follow physician orders and local policy for pain management.

Case Review

Patient 1: Falsification of Documentation in the EHR and Failure to Follow Physician Orders

The patient was a critically ill female in her sixties with multiple chronic health problems, including diabetes, liver failure, and high blood pressure. She was admitted to the MICU in mid-January 2012 with abdominal pain, low blood pressure, and sepsis. The subject RN cared for the patient from 12:00 a.m. to 8:00 a.m., and was responsible for all aspects of patient care, including obtaining hourly blood glucose levels and adjusting the continuous insulin infusion according to the results and pre-established protocol. Physician orders for blood glucose monitoring and insulin regulation for the patient were to follow the Yale protocol. The patient was transferred out of MICU the next day, and was discharged to home ten days later.

A review of the CPRS and CareVue blood glucose levels and insulin infusion rates showed the following:

Date and Time of Entry	Blood Glucose Level		Insulin Infusion Rate (Units/Hr as noted in CareVue)
	CPRS Documentation (blood glucose levels are automatically entered)	CareVue Documentation (blood glucose levels are manually entered)	
12:00		458	6.5
12:22	458		
1:00 a.m.		343	6.5
2:00 a.m.			6.5
3:00 a.m.		353	6.5
03:58	353		
03:59	343		
4:00 a.m.		321	6.5
4:12 a.m.	321		
5:00 a.m.			6.5
6:00 a.m.		236	6.5
6:50 a.m.	261		
7:00 a.m.		201	6.5

In summary, the RN should have performed eight hourly blood glucose tests during her shift; the time-stamped glucometer showed that five were done. Of these, three were done within 14 minutes of each other (between 3:58 a.m. and 4:12 a.m.). The patient did not receive glucose monitoring for over 3.5 hours (between 12:22 a.m. to 3:58 a.m.), and again for over 2.5 hours (between 4:12 a.m. to 6:50 a.m.). The insulin infusion rate was never adjusted during the entire 8-hour shift. However, the RN documented hourly glucose readings in CareVue, except at 2 a.m. and 5 a.m.

Results

We found that the subject RN's documentation did not match the time-stamped glucometer readings. In addition, we found that the RN did not follow physician orders to titrate the insulin infusion rate. Based on the facility's protocol and the patient's documented blood glucose levels, the insulin infusion rate should have been much more aggressively titrated, as the patient remained hyperglycemic the entire shift. The RN involved told us that she could not find the Yale protocol calculator on the computer the night she was caring for the patient. She did not have an explanation for the disparities in documentation of blood glucose levels between the CPRS and CareVue records, or the lack of compliance with hourly blood glucose levels and insulin titration, despite the fact that her documentation in CPRS reflects that hourly blood glucose levels were done and the Yale protocol was followed. Despite these practices, we found no evidence that the RN's actions resulted in patient harm.

We noted that the narrative portion of documentation in CareVue for the shift was performed at the end of the shift between 7:06 and 7:13 a.m. for this patient, and at 8:36 a.m. for patient 2 (described below). Ideally, documentation should be done throughout the shift for optimal recall of care and timely access to patient information by other health care providers. We learned that a charge nurse had previously told the RN not to wait until the end of a shift to document in CareVue, because other providers would not have timely information regarding the patient's condition. The charge nurse documented this conversation with the RN in a ROC dated September 2010.

Patient 2: Inadequate Documentation of Pain Management for a Hospice Patient

Case Review

The patient, a male in his fifties with a diagnosis of pneumonia and stage IV lung cancer, was admitted to MICU overnight for symptom management (pain and air hunger[5]), and transferred to the palliative care unit the next day.

Results

We found that the RN did not follow physician orders for treatment of severe pain; or local policy for documentation of pain assessment, actions to be taken, and medication effectiveness.

Local policy requires that "assessment for and documentation of the presence of pain will occur before and after pain medications are administered. Documentation will include the location and intensity using the 0 to 10 scale, the intervention provided, and the patient's perceived relief. If pain intensity remains 4 or greater after the prescribed intervention(s) without effect, the provider will be notified." Our review of the EHR showed the following physician orders:

- "Morphine sulfate 2-4 mg intravenously every 2 hours as needed for severe pain or severe dyspnea (shortness of breath), and to only use 4 mg if he does not respond to 2 mg."

- "Lorazepam 2 mg intravenously every hour as needed for anxiety or air hunger."

At 12:35 a.m., the subject RN documented in CPRS "Medicated with 4 mg Morphine Sulfate and 2 mg Lorazepam slow IVP (IV push) as per prn order per patient request. Will monitor for effectiveness." At the same time (12:35 a.m.), the RN also documented in CPRS "PAIN - Able to verbalize pain and discomfort. Hospice patient (prior to coming to the hospital) Comfort measures in progress." The RN documented hourly pain assessments in CareVue as "eyes closed," except at 3:00 a.m., when "10" was documented, but no pain medication was given at that time. The RN documented

[5] An acute sensation of feeling breathless, characterized by labored breathing.

"10" again at 07:00 a.m. The patient did not receive another dose of pain medication until 07:41 a.m., when the RN administered 4 mg of morphine. The RN documented effectiveness for both the 12:25 a.m. and 7:41 a.m. doses in BCMA at 7:42 a.m., and indicated only that the medication was "effective," with no further details.

Issue 2: Management Unresponsiveness

We substantiated the allegation that ROCs had been submitted to the NM about the subject RN's patient care. We did not substantiate the allegation that no actions were taken; however, the NM's discussions with the subject RN and actions taken were not appropriately documented, and managerial concerns were not reflected in the RN's performance appraisals.

In our inspection, we could not validate that the subject RN falsified documentation of blood glucose levels in July 2011. The subject nurse denied that that occurred. However, the NM told us that she discussed this very issue with the subject RN at that time and followed up with periodic checks of her documentation of blood glucose levels.

Results

We interviewed the NM, who was aware of the July 2011 event, and stated she discussed concerns about missing blood glucose readings with the RN. According to the NM, it was unclear whether blood glucose monitoring equipment failed or the blood glucose levels had actually not been done. Further review of documentation provided by the facility showed that there might have been equipment problems with uploading data from the glucometer into CPRS during that shift. The NM stated she periodically reviewed the RN's documentation of blood glucose levels for patients on insulin drips for several months after the incident, and had not found any discrepancies. The periodic reviews were not documented, a ROC provided to us documenting the discussion the NM had with the RN was not dated, and the contents of the ROC indicated that it was completed well after the event.

A ROC produced by the NM described an incident that occurred in September 2011, involving the subject RN's care of a patient with a small bore feeding tube.[6] According to the information given to us, the RN reported that she gave medications to the patient through the tube. When questioned about how she did this with the stylus[7] in place, she first stated that she gave medications through another port in the tube, and then stated that the patient had partially pulled the tube out, so she reinserted the stylus and repositioned the tube. A guide wire or stylus should never be inserted or repositioned in a feeding tube that is already in place in a patient,[8] because of

[6] A small bore, flexible silicone tube is usually inserted into the nose with a weighted tip that should be inserted past the pylorus valve of the stomach into the small intestine.
[7] A thin wire inside the tube used to guide the tube into place.
[8].www.kendallpatientcare.com April 2012.

the risk of penetration through the tube into surrounding organs and tissue. It was noted by the RN who assumed care of the patient that the tube was leaking, and ultimately had to be removed and replaced.

We found the NM was aware of this incident, and told us she had the nurse educator review with the subject RN the proper care for a patient with a small bore feeding tube. No documentation of the discussion or training with the RN could be produced.

Conclusions

We substantiated the allegations that the subject RN falsified documentation and did not administer insulin as ordered on a patient. We did not substantiate the allegation that the RN was practicing medicine without a license. We did not substantiate the allegation that patient care was not documented until the end of a shift. We did not substantiate the allegation that the RN failed to provide pain medication for a patient; however, the RN did not provide pain medication as ordered or adhere to local policy for pain management. We substantiated the allegation that previous concerns about the RN were reported to the NM, however, we did not substantiate the allegation that nothing was done. We found that there was a pattern of quality of care issues with the RN, and the NM did not address the issues following appropriate managerial protocol, including documentation of events and progressive discipline.

The facility conducted an Administrative Investigative Board (AIB) to review the allegations, as well as other allegations brought to light in the course of our inspection. We reviewed the results of the AIB, and concurred with its findings, conclusions, and recommendations.

Recommendation

We recommended that the System Director follow through with recommendations made by the AIB, and have Regional Counsel evaluate relevant documents to determine if criteria are met to report the nurse's actions to state licensure governing boards.

Comments

The VISN and System Directors concurred with our recommendation and provided an acceptable action plan (See Appendix A and B, pages 10-12 for the full text of the Directors' comments). We will follow up on the planned actions until they are completed.

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

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 21, 2012

From: Director, Veterans Sunshine Health Network (10N8)

Subject: **Healthcare Inspection –** Patient Safety on a Critical Care Unit, Malcom Randall VA Medical Center, Gainesville, FL

To: Associate Director, Bay Pines Office of Healthcare Inspections (54SP)

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

1. The recommendations made during the VA Inspector General Office of Healthcare Inspections review conducted in response to allegations regarding a nurse's practice on a Critical Care Unit has been reviewed and I concur with the findings and recommendations.

Thank you,

Nevin M. Weaver

Nevin M. Weaver, FACHE
Director, Veterans Sunshine Health Network (10N8)

Appendix B

Facility Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 18, 2012

From: Director, North Florida/South Georgia Veterans Health System (573/00)

Subject: **Healthcare Inspection –** Patient Safety on a Critical Care Unit, Malcom Randall VA Medical Center, Gainesville, FL

To: Director, Veterans Sunshine Health Network (10N8)

1. The recommendations made during the VA Inspector General Office of Healthcare Inspections review conducted in response to allegations regarding a nurse's practice on a Critical Care Unit has been reviewed and I concur with the findings and recommendations. Our comments and implementation plans are attached.

2. If you have any questions or require additional information, please contact Ms. LeAnne Whitlow, Associate Director, Nursing Service, at (352) 374-6050.

Thomas Wisnieski, MPA, FACHE
Director, North Florida/South Georgia Veterans Health System (Station 00/573)

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

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

OIG Recommendation

We recommended that the System Director follow through with recommendations made by the AIB, and have Regional Counsel evaluate relevant documents to determine if criteria are met to report the nurse's actions to state licensure governing boards.

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

Facility's Response:

An Administrative Investigative Board was convened on February 7, 2012. The findings, conclusions and recommendations resulting from the investigation were approved on April 2, 2012. Allegations of professional misconduct and substandard clinical practice against the subject RN and allegations of lack of adequate supervisory response by the RN Manager were substantiated. Proposed corrective actions for each employee will be issued on or before the target completion date. Additionally, the reporting process to the State Licensing Board of the subject RN was initiated on May 14, 2012.

Status: Pending

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720
Acknowledgments	Carol Torczon, RN, ACNP, Project Leader Monika Gottlieb, MD Eric Lindquist, Investigator

Appendix D

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