Department of Veterans Affairs

Office of Inspector General

Healthcare Inspection

Quality of Care in the Intensive Care Unit
VA Northern Indiana Health Care System
Fort Wayne, Indiana

Report No. 10-02816-200 **June 20, 2011**

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections (OHI) conducted an inspection to determine the validity of allegations regarding quality of care at the VA Northern Indiana Health Care System (the facility) in Fort Wayne, IN.

An anonymous complainant alleged that a physician was responsible for several patient deaths and that no action was taken following peer review assessments; a patient (Patient 1) died because the physician delayed transfer to a community hospital; and in March 2010, three ventilators were in simultaneous operation in violation of policy, with no backup ventilators available for emergencies.

During the course of this inspection, the OHI received additional allegations regarding the physician. First, the physician allegedly prescribed medication which "fried a patient's kidneys" and disregarded computer notification warnings about the use of a medication for the patient (Patient 2). Second, the physician allegedly removed a patient (Patient 3) from a ventilator prematurely and the patient needed to be transferred to a community hospital.

An additional allegation was that a patient (Patient 4) with a large blood clot in his leg was inappropriately transferred from the Marion campus to the Fort Wayne campus, and his care was poorly managed after transfer.

We found inadequate management, documentation, and review of Patient 1's cardiopulmonary arrest and inadequate Intensive Care Unit (ICU) monitoring of Patient 2. We also found that Patient 3 should not have been accepted in transfer from a community hospital. We identified no quality of care issues in the care of Patient 4.

We did not substantiate that the physician was responsible for patient deaths, delayed transfer of Patient 1, inappropriately prescribed a medication for Patient 2, or prematurely removed Patient 3 from a ventilator.

We substantiated that in March 2010 there were two intervals when three patients in the ICU received mechanical ventilator therapy concurrently. We did not substantiate that there were no backup ventilators in the facility or that the use of three ventilators simultaneously was in violation of facility policy.

During a 6-month period, we found 23 days with time periods ranging from 4 to 15 hours during which there were no staff in the facility with demonstrated competence in out-of-operating room (OR) airway management.

In addition, we found that Medical Officers of the Day were routinely providing care to patients in the emergency department and to inpatients, including the ICU, contrary to Veterans Health Administration (VHA) policy.

We recommended that the System Director:

- Ensure that peer review assessments of the care issues identified for Patients 1–3 are conducted and that action is taken as necessary.
- Confer with Regional Counsel regarding adverse event disclosure to the family of Patient 1.
- Ensure that care provided in response to cardiopulmonary arrests is documented and reviewed in accordance with facility policy.
- Ensure that staff with demonstrated competence and clinical privileges or scope of practice are available at all times to provide out-of-OR airway management.
- Ensure that ICU physician coverage complies with VHA policy.

The VISN and System Directors concurred with the inspection results. We will follow up on the planned actions until they are complete.

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

TO: Director, Veterans In Partnership (10N11)

SUBJECT: Healthcare Inspection – Quality of Care in the Intensive Care Unit, VA Northern Indiana Health Care System, Fort Wayne, Indiana

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) conducted an inspection to determine the validity of allegations regarding quality of care at the VA Northern Indiana Health Care System, Fort Wayne, IN.

Background

The VA Northern Indiana Health Care System, part of Veterans Integrated Service Network (VISN) 11, is comprised of two campuses located in Fort Wayne and Marion, IN. The Fort Wayne campus (the facility) has 22 medical/surgical and 4 intensive care unit (ICU) beds. The Marion campus provides long term care and acute and chronic psychiatric care, serving as the psychiatric referral hospital for veterans throughout the state of Indiana. The Fort Wayne and Marion campuses are located approximately 56 miles apart.

An anonymous complainant contacted the OIG Hotline Section on May 19, 2010. The complainant alleged that:

- A physician (Physician X) at the facility was responsible for several patient deaths during the past 2 years and that no action was taken following peer review assessments.
- In March 2010, a patient (Patient 1) died because Physician X delayed transfer to a community hospital.
- In March 2010, three ventilators were in simultaneous operation in violation of policy, with no backup ventilators available for emergencies.

During the course of this inspection, the OHI received the following additional allegations:

- Physician X prescribed medication which "fried a patient's kidneys." The patient (Patient 2) was transferred to a community hospital for emergency dialysis and died.
- Physician X disregarded computer notification warnings about the use of theophylline for Patient 2.
- Physician X removed a patient (Patient 3) from a ventilator prematurely, and the patient needed to be transferred to a community hospital.
- A patient (Patient 4) with a large blood clot in his leg was inappropriately transferred from the Marion campus to the Fort Wayne campus, and his care was poorly managed after transfer.

Scope and Methodology

We conducted onsite inspections on July 26–28 and September 20–23, 2010. We reviewed facility and Veterans Health Administration (VHA) policies, committee minutes, quality management data and documentation, and other applicable facility documents. Also, we evaluated facility data from the VHA Inpatient Evaluation Center. We interviewed employees and managers with knowledge of or the responsibility for administrative controls related to these allegations.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of Inspectors General on Integrity and Efficiency.

Case Summaries

Patient 1

The patient had a history of myocardial infarction, congestive heart failure, carotid artery disease, and diabetes mellitus. He had previously undergone coronary artery bypass surgery, carotid artery surgery, and placement of an implantable cardioverter defibrillator.

The patient was admitted to the facility in early March 2010 after presenting with shortness of breath and chest pressure. Echocardiography revealed "markedly decreased left ventricular systolic function." He improved following intravenous (IV) treatment with a diuretic and was discharged home after 3 days.

Ten days after discharge, the patient presented to the facility emergency department (ED) with 2–3 days of worsening shortness of breath and less than 1 day of left calf swelling and pain. Computed tomography (CT) of the thorax showed no evidence of pulmonary

embolism. The patient was admitted to the general medical ward and treated with IV fluids and the antibiotic ceftriaxone for possible pneumonia.

On the following morning, after the patient's blood pressure (BP) was found to be low (86/50 mm Hg), the rate of IV fluids was increased and two of the patient's usual medications (furosemide and carvedilol) were discontinued. Also on that morning, laboratory personnel reported that blood cultures obtained in the ED on the previous afternoon were growing gram positive cocci, and antibiotic therapy was changed to piperacillin/tazobactam and clindamycin.

The patient was transferred to the ICU and evaluated by surgical consultants, who noted that there was no crepitation of the left leg on physical examination and that ultrasonography obtained that day had revealed no evidence of deep vein thrombosis. The consultants indicated that the patient had "cellulitis with sepsis" and recommended the addition of a third antibiotic, vancomycin. Because of persistent hypotension, the patient was also treated with dopamine.

Nursing documentation describes that the patient became increasingly lethargic and had decreased urine output, and that the patient's family requested transfer to another facility. A nursing report was called to a local community hospital, but at that time no bed was available. Approximately 1 hour later, the receiving hospital was ready to accept the patient and ambulance transportation was initiated. Approximately 30 minutes later, the patient's breathing was judged to be ineffective, and a code blue was called. The cardiac rhythm recorded at the time the patient deteriorated was ventricular tachycardia. The physician who responded wrote that the patient "did not have a pulse or BP during the code." Advanced Cardiac Life Support protocols were reportedly implemented "for about 40 minutes," but the patient did not survive. The death certificate states that death was due to "streptococcus pyogenes septic shock and congestive heart failure."

Patient 2

The patient was transferred from a community hospital to the facility in mid-february 2009 with severe chronic obstructive pulmonary disease and pneumonia. On hospital day (HD) 2, he was moved to the ICU for continuous nebulizer treatment and closer monitoring. He received IV fluids only as necessary for administration of an antibiotic, but these were discontinued by HD 3. Nursing documentation indicated that he was eating less than half of each meal. During the hospitalization, physicians received routine electronic notifications warning of the potential for interactions among the patient's medications.

On HD 6, he was noted to have mental status changes and decreased urine output. Laboratory tests revealed markedly worsened kidney function when compared with the most recent tests 5 days earlier. A private nephrologist was consulted and the patient was transferred to a community hospital for urgent hemodialysis.

The patient died 3 days later. Medical records obtained from the private hospital revealed that the patient had worsening respiratory distress but had "regained his normal renal function." The death certificate states that death was due to "end-stage chronic lung disease."

Patient 3

The patient was transferred to the facility from a community hospital in mid-October 2009 for continued treatment of acute respiratory failure and sepsis. He was morbidly obese and had recently been treated with chemotherapy for non-Hodgkin's lymphoma. At the time of transfer, he was intubated and receiving IV medication to maintain a normal BP. He was admitted to the facility ICU and treated with broad spectrum antibiotics. Over the next few days, his condition gradually improved.

On the morning of HD 5, the patient expressed that he wished to have the endotracheal tube (ETT) removed. That afternoon, a respiratory therapist (RT) wrote that the "patient became anxious coughing up pink frothy mucus via ETT." The RT was unable to pass a suction catheter and notified Physician X of a possible kink in the ETT. Physician X ordered that the patient be extubated and placed on BiPAP.[1] The patient subsequently developed respiratory distress, and an anesthesiologist was notified of the need for emergent intubation. The anesthesiologist was unable to intubate, noting "significant airway edema" and that "the decision was made to transfer patient to a facility with backup for a surgical airway due to risk of increasing airway edema and loss of airway with continued airway manipulation." Later that evening, the patient was transferred to a community hospital (different from the original transferring hospital) and successfully intubated.

At the community hospital, the patient was extubated the following day, hospitalized an additional 3 days, and transferred back to the facility. He was then discharged home after 1 day. At the time of this report, 17 months after discharge, the patient was ambulatory and attending clinic visits at the facility.

Patient 4

The patient presented to the urgent care clinic at the Marion campus in late September 2010 with 4 days of pain involving his entire left leg. His medical history was significant for hypertension, diabetes mellitus, arthritis, and a remote history of left leg deep vein thrombosis. Ultrasonography at a local hospital revealed extensive left proximal iliac vein thrombosis, and the patient was treated with the anticoagulant enoxaparin and transferred to the Fort Wayne facility. At Fort Wayne, he was admitted to a general

[1] BiPAP is a form of positive airway pressure commonly used in critically ill patients. The patient wears a sealed mask by which oxygen is delivered at a higher pressure during inspiration than during expiration.

medical ward and then to the ICU because he was considered to be at high risk for pulmonary embolism.

Approximately 6 hours after admission, the patient developed chest pain and shortness of breath, and CT revealed bilateral pulmonary emboli. With remobilization occurring despite anticoagulation, the patient was felt to require placement of an inferior vena cava (IVC) filter, and he was transferred to a community hospital. An IVC filter was placed without complication and the patient was discharged home after 3 days. At the time of this report, 7 months later, the patient was ambulatory and attending clinic visits at the facility.

Inspection Results

Issue 1: Quality of Care for Specific Patients

In the care of Patient 1, we found inadequate management of cardiopulmonary arrest. At the time of arrest, the patient's initial cardiac rhythm was ventricular tachycardia. Although this abnormal rhythm should have been treated with immediate electrical cardioversion, we found no evidence that this treatment was provided for at least 20 minutes.

Facility policy[2] states that the ICU Nurse Manager or Nursing Officer of the Day, during non-administrative hours, is responsible for coordinating a critique of code blue management with those involved in the code as soon as possible. Findings and recommendations are to be reported to the Critical Care Committee (CCC). The CCC is to review critiques of medical codes and out-of-operating room (OR) airway data.[3]

In this case, concurrent documentation of code activities was inadequate and there was no post-code assessment. Further, the CCC did not review available cardiac rhythm recordings.

Patient 2 was inadequately monitored during his ICU stay. The patient was eating poorly, physicians documented no clinical assessment of his fluid requirements during 3 days in the ICU, and there was no laboratory assessment of kidney function.

Patient 3 should not have been accepted in transfer from the community hospital. At the time of transfer, he required mechanical ventilation and IV medication for BP support. Moving such a patient between facilities subjects the patient to risks that are appropriate only if the receiving facility can provide critical services not otherwise available.

We identified no quality of care issues in the care of patient 4.

[2] VA Northern Indiana Health Care System Policy Number 11-46, *Emergency Response Code Blue*, April 25, 2008.
[3] VA Northern Indiana Health Care System Policy Number 11-07-10, *Critical Care Committee*, February 17, 2010.

Issue 2: Quality of Care Provided by Physician X

We did not substantiate that Physician X was responsible for patient deaths. A review of deaths at the facility during fiscal years (FYs) 2009–2010 revealed no association with patient care management by Physician X. Further, reports for the facility generated by VHA's Inpatient Evaluation Center for quarters 3 and 4 of FY 2010 revealed no excess mortality.

We did not substantiate that Physician X delayed transfer of Patient 1, inappropriately prescribed theophylline for Patient 2, or prematurely removed Patient 3 from a ventilator. Physician X received notifications and considered the possibility of interactions between Patient 2's medications. However, we identified no inappropriate use of medications, and no untoward consequences resulted from the combination of medications prescribed.

Issue 3: Out-of-Operating Room Airway Management

A facility anesthesiologist is on call to assist with airway management in out-of-OR settings during non-administrative hours, but this physician does not remain in the facility and is only required to arrive within 1 hour of being contacted. To ensure that competent staff are always available to provide airway management in out-of-OR settings, facility policy requires the Chief of Staff to assess the number and type of clinical staff whose expected duties include these procedures.[4] We found that no assessment had been completed.

The facility hired contract physicians to work as Medical Officers of the Day[5] (MODs). The MOD contract in effect from February 1, 2010, through January 31, 2011, stipulated that MODs complete a written test on emergency airway management and demonstrate competence in emergency airway management to facility staff.

A review of the training records and credentialing and privileging files of the 10 MODs who provided medical coverage at the facility during non-administrative hours revealed that only 2 of the MODs had passed the written test, had demonstrated competency, and were privileged to perform out-of-OR airway management.

Facility RTs who agreed to provide out-of-OR airway management were provided opportunities to establish competence. At the time of our review, 14 RTs were employed at the facility and 6 (43 percent) of them were identified as being competent to perform out-of-OR airway management. There were no RTs who were deemed competent to perform out-of-OR airway management assigned to work the evening shift at the time of our review.

[4] VA Northern Indiana Health Care System Policy Number 11-51, *Out-of-Operating Room Airway Management*, August 6, 2008.

[5] The Medical Officer of the Day is a designated responsible physician who is physically present in an inpatient facility during periods when the regular medical staff is not on duty. These periods generally include evenings, nights, weekends, and holidays, but may be required in other circumstances.

We reviewed MOD and RT schedules for March–August 2010. We found 23 days with time periods ranging from 4 to 15 hours during which there were no staff in the facility deemed competent to perform out-of-OR airway management.

Issue 4: Critical Care Issues

ICU Physician Staffing. Facility policy states that all physicians with ICU privileges will share an on-call schedule covering 24 hours a day, 7 days a week, to assure that one physician with ICU privileges is always available for consultation.[6] Physicians without specific ICU privileges, including MODs, can admit patients to ICU. When a practitioner without ICU privileges admits patients to ICU, he/she is to contact the attending physician to discuss the clinical condition and treatment plan.

At the time of our review, the facility had 10 contract MODs and only 4 of them had privileges to provide ICU care. Management of ICU patients within the first 24 hours of admission was largely provided by MODs, many of whom lacked privileges to provide ICU patient care and whose primary responsibility was to provide patient care in the ED.

According to VHA policy, a properly trained, experienced, credentialed, and privileged emergency physician must be present in the ED at all times and must not be expected to cover the inpatient unit or respond to emergencies outside of the ED.[7]

The facility hired contract physicians to work as MODs. One MOD was scheduled to work from 4:30 p.m. to 8:00 a.m., Monday through Friday. On Saturday and Sunday, one MOD was scheduled to work a 12-hour shift (8:00 a.m.–8:00 p.m. or 8:00 p.m.–8:00 a.m.). Most of the time the MOD was on duty, he/she was the only physician in the facility.

The MOD contract stated that the care of inpatients during non-administrative hours is the responsibility of the MOD, and that he/she should visit all wards, including ICU, and personally see all seriously ill patients and other patients as requested by charge nurses or staff physicians.

Ventilator Management. We substantiated that in March 2010 there were two intervals when three patients in the ICU received mechanical ventilator therapy concurrently. We did not substantiate that there were no backup ventilators in the facility; three portable ventilators were available for use in the event there was a need for another due to mechanical failure or additional patient care requirements.

[6] VA Northern Indiana Health Care System Policy Number 11-16, *Intensive Care Unit (ICU)*, January 26, 2007.
[7] VHA Directive 2010-010, *Standards for Emergency Department and Urgent Care Clinic Staffing Needs in VHA Facilities*, March 2, 2010.

We did not substantiate that the simultaneous use of three ventilators was in violation of facility policy. We found no guidance limiting the number of ventilators that can be used concurrently.

Conclusions

We found inadequate management, documentation, and review of Patient 1's cardiopulmonary arrest and inadequate ICU monitoring of Patient 2. We also found that Patient 3 should not have been accepted in transfer from a community hospital. We identified no quality of care issues in the care of patient 4.

We did not substantiate that Physician X was responsible for patient deaths. We also did not substantiate that Physician X delayed transfer of Patient 1, inappropriately prescribed theophylline for Patient 2, or prematurely removed Patient 3 from a ventilator.

During a 6-month period, we found 23 days with time periods ranging from 4 to 15 hours during which there were no staff in the facility with demonstrated competence to perform out-of-OR airway management.

MODs were routinely providing care to patients in the ED and to inpatients, including the ICU, contrary to VHA policy.

We substantiated that in March 2010 there were two intervals when three patients in the ICU received mechanical ventilator therapy concurrently. We did not substantiate that there were no backup ventilators in the facility or that the use of three ventilators simultaneously was in violation of facility policy.

Recommendations

Recommendation 1. We recommended that the System Director ensure that peer review assessments of the care issues identified for Patients 1–3 are conducted and that action is taken as necessary.

Recommendation 2. We recommended that the System Director confer with Regional Counsel regarding adverse event disclosure to the family of Patient 1.

Recommendation 3. We recommended that the System Director ensure that care provided in response to cardiopulmonary arrests is documented and reviewed in accordance with facility policy.

Recommendation 4. We recommended that the System Director ensure that staff with demonstrated competence and clinical privileges or scope of practice are available at all times to provide out-of-OR airway management.

Recommendation 5. We recommended that the System Director ensure that ICU physician coverage complies with VHA policy.

Comments

The VISN and System Directors concurred with the inspection results (See Appendixes A and B, pages 10–14, for the full text of the Directors' comments). We will follow up on the planned actions until they are complete.

(original signed by:)

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

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: May 2, 2011

From: Director, Veterans In Partnership (10N11)

Subject: **Healthcare Inspection – Quality of Care in the Intensive Care Unit, VA Northern Indiana Health Care System, Fort Wayne, Indiana**

To: Director, Chicago Office of Healthcare Inspections (54CH)

Thru: Director, Management Review Service (10B5)

Attached is the response from VA Northern Indiana Healthcare System to the Quality of Care in the ICU at Ft. Wayne. If you have any questions, please contact Kelley Sermak, Acting QMO, at 734-222-4302.

Michael S. Finegan
Director, Veterans In Partnership (10N11)

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: April 28, 2011

From: Director, VA Northern Indiana Health Care System (610A/4)

Subject: **Healthcare Inspection – Quality of Care in the Intensive Care Unit, VA Northern Indiana Health Care System, Fort Wayne, Indiana**

To: Director, Veterans In Partnership (10N11)

1. The Leadership has reviewed the draft inspection report of the Review of Quality of Care conducted by the Office of Healthcare Inspections. Our response to the recommendations is attached.

2 We appreciate the completeness of the review that was conducted for these cases involving Veterans treated in the Intensive Care Unit. We concur with the recommendations and have implemented changes to increase patient safety in the Intensive Care Unit.

(*original signed by*:)
Helen Rhodes, Acting Director for and in the absence of:

Daniel Hendee, FACHE, Director
Director, VA Northern Indiana Health Care System (610/A4)

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 Recommendations

Recommendation 1. We recommended that the System Director ensure that peer review assessments of the care issues identified for Patients 1–3 are conducted and that action is taken as necessary.

Concur: **Target Completion Date: June 30, 2011**

Facility's Response:

Peer reviews were completed on each of these patients. These Internal Peer Reviews have been sent for External Peer Review in order to validate Internal Peer Review findings.

Status: Initial Facility Peer Reviews Completed on May 20, 2010. External Peer Reviews Results and Peer Review Committee Reviews should be completed by June 30, 2011.

Recommendation 2. We recommended that the System Director confer with Regional Counsel regarding adverse event disclosure to the family of Patient 1.

Concur: **Target Completion Date: June 30, 2011**

Facility's Response:

Regional Counsel was conferred with on April 21, 2011, regarding adverse event disclosure to the family of Patient 1. It was decided that an institutional disclosure was not warranted at this time but would be reevaluated after completion of an External Peer Review.

Status: Completed initial conference on April 21, 2011. External Peer Review Results and Peer Review Committee Reviews should be completed by June 30, 2011.

Recommendation 3. We recommended that the System Director ensure that care provided in response to cardiopulmonary arrests is documented and reviewed in accordance with facility policy.

Concur: **Target Completion Date: May 31, 2011**

Facility's Response:

VA NIHCS complies with VA NIHCS Policy 11-46-11, Emergency Response Code Blue, and VHA Directive 2008-063. Cardiopulmonary resuscitative events and their immediate Code Critiques are monitored on a monthly basis by the Acute Care Committee (formerly, the Critical Care Committee) for completeness and quality of care. Codes are critiqued by the code team members and then reviewed by an Intensive Care Unit RN for recommendations which are forwarded to the Patient Safety Manager (this is transitioning to Quality Management) who prepares the code report for the monthly review by the Acute Care Committee and compiles data per the directive for trending in a quarterly Cardiopulmonary report. Issues and non-compliance are identified, recorded, and sent out to appropriate managers for action. Actions are followed up by Patient Safety (transitioning to Quality Management) who reports the data to the committee for tracking and trending. The Acute Care Committee aggregates and analyzes the data looking for opportunities for improvement and reports go to the Clinical Executive Board.

In the March 2010 code review, the code was not documented according to facility policy and records could not be found. The code members were questioned regarding their recollection of the event. The lack of documentation issue for this code was discussed during the April 2010 Critical Care Committee and the decision was made to make the ICU Nurse Manager responsible to ensure that code records and code critiques are completed according to VA NIHCS policy. During the July 2010 OIG review, the code record and strips were found. These were then reviewed by the Critical Care Committee at their August 2010 meeting. In an effort to provide oversight into tracking the code blue responses and appropriate documentation, Quality Management will discuss all code blue events on an ongoing basis during morning report. Quality Management will track follow-up of all code blue events by placing the information on the morning report tracking log and will ensure that all documentation is completed according to VA NIHCS policy. This oversight will also include ensuring that the code blue documentation and strips have been scanned into the medical record.

Status: Open

Recommendation 4. We recommended that the System Director ensure that staff with demonstrated competence and clinical privileges or scope of practice are available at all times to provide out-of-OR airway management.

Concur: **Target Completion Date: January 20, 2011**

Facility's Response:

All Fort Wayne MODs covering the ICU have established competencies with out-of-OR airway management and have been credentialed and priviledged to do so. A second MOD was added for non-administrative hours, including holidays, so that one is available at all times to provide out-of-OR airway management.

Status: Completed.

Recommendation 5. We recommended that the System Director ensure that ICU physician coverage complies with VHA policy.

Concur: **Target Completion Date: October 12, 2010**

Facility's Response:

A second MOD was added for non-administrative hours, including holidays, so that ICU physician coverage complies with VHA policy.

Status: Completed.

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General (202) 461-4720
Acknowledgments	Verena Briley-Hudson, NP, Chicago Regional Director Roberta Thompson, LCSW, Team Leader Paula Chapman, CTRS Jerome Herbers, Jr., MD JoDean Marquez, RN Jennifer Reed, RN Wachita Haywood, RN Judy Brown, Program Support Assistant

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