Department of Veterans Affairs
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Office of Healthcare Inspections

Report No. 13-00670-265

Healthcare Inspection
Review of Circumstances Leading to a Pause in Providing Inpatient Care
VA Northern Indiana Healthcare System
Fort Wayne, Indiana

August 2, 2013

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection at the request of Senator Joe Donnelly and Congressman Marlin Stutzman regarding the suspension (pause) of all inpatient admissions at the Fort Wayne campus (the facility) of the VA Northern Indiana Healthcare System (VANIHCS), Fort Wayne, IN, in October 2012. The OIG was asked to review overall quality of care and management at the facility, define what issues led to suspension of inpatient care, and determine what measures need to be taken to return the facility to normal operations.

We reviewed medical records and nursing administrative documents and identified issues with quality of inpatient care in multiple cases. Several factors likely contributed to the circumstances that allowed this to happen: the facility did not effectively and consistently fill upper and mid-level leadership positions, there were lapses in clinical judgment by individual providers, and there was limited compliance in maintaining nurse competencies. Managers that were in place often did not provide necessary leadership. Some prior budget deficits had been addressed, at least in part, by not filling key staff positions.

As of May 2013, inpatient operations had not resumed at full capacity but are being phased in. We determined that the facility, Veterans Integrated Service Network (VISN) 11, and Veterans Health Administration (VHA) could have improved communication to stakeholders regarding the pause. In view of recurring qualitative issues relating to patient care, lack of long-term stability in upper and mid-level leadership positions, and workload, VISN 11 may need to consider the scope of services the facility is capable of reliably providing, namely, the appropriate designation for ICU level care in the near term and whether an ICU is viable in the long-term.

We recommended that VHA develop policy and guidance for facilities when major clinical services are paused; that the VISN Director ensure the assigned ICU level of care is commensurate with facility capabilities, and that the VANIHCS Director ensure that recruitment efforts continue for vacant leadership positions, that nurse competencies are consistently completed and validated, and that the nurse staffing methodology is fully implemented.

Comments

The Under Secretary for Health and VISN and Facility Directors concurred with the inspection results (see Appendixes A, B, and C, pages 16–22, for the full text of their comments). We will follow up on the planned actions until they are completed.

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Purpose

At the request of Senator Joe Donnelly and Congressman Marlin Stutzman, the VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection regarding the suspension (pause) of all inpatient admissions to the acute medical unit and intensive care unit (ICU) at the Fort Wayne campus (the facility) of the VA Northern Indiana Health Care System (VANIHCS).

In November 2012, Senator Donnelly and Congressman Stutzman requested that the OIG undertake a review regarding the decision made by leaders of Veterans Integrated Service Network (VISN) 11 to pause all facility inpatient care. The Senator and Congressman were concerned that problems existed within the fundamental quality control structure, not just for inpatient services but, possibly, throughout the facility. They were also concerned that VA has not fully identified the specific measures that need to be taken in order to return the facility to normal operations.

Specifically, the OIG was asked to review the following:

- Overall quality of care at the facility
- Overall management at the facility
- Issues leading to the suspension of inpatient care
- Measures to be taken in order to return the facility to normal operations

Background

The VANIHCS consists of two campuses located in Fort Wayne and Marion, IN, and is part of VISN 11, Veterans in Partnership. The facility provides outpatient primary care and inpatient medical, surgical, and ICU care. There are a total of 26 authorized beds—22 medical/surgical and telemetry beds on the acute care unit and 4 ICU beds. Veterans Health Administration (VHA) designated the ICU as a level 3 on a scale of 1–4, with level 1 the most complex and level 4 offering basic services.[1] The Marion campus provides long-term care and acute and chronic psychiatric care. The pause did not involve the Marion campus.

On October 11, 2012, admissions to the ICU and telemetry beds were paused but patients were still admitted to the acute medical unit. On October 22, all admissions to the acute medical unit were paused.

Since 2007, several external reviews identified quality of care issues that led to selective services being paused at the facility. In 2007, surgery services were paused and in 2009, reusable medical equipment services were paused. In the present case, VISN leaders cited several reasons why they decided to pause all inpatient admissions to the facility, including the previous external reviews and subsequent findings, the lack

[1] Almenoff, P., Sales, A., Rounds S., et al. *Intensive care services in the Veterans Health Administration*. Chest 2007, 132:1455-62.

of documented staff competencies, and quality of care concerns regarding inpatient care.

During the pause, outpatient services at the facility remained unaffected and veterans who required inpatient medical or surgical care were referred for community-based care or to other VA facilities within a 2–3 hour driving distance.

Scope and Methodology

Our review was limited to operations at the Fort Wayne campus of the VANIHCS.

We conducted site visits on December 3, 2012, and again from January 28–31, 2013. We interviewed the VISN Director, Chief Medical Officer (CMO), and Quality Management Officer. We interviewed the Acting Associate Director for Operations at the facility and the Acting VANIHCS Director at the time of the pause. We also interviewed the current VANIHCS Director, Chief of Staff (COS), Associate Director for Patient Care Services, Quality Manager, and Associate Director for Operations at the Marion campus. We conducted interviews with mid-level managers, clinicians, and front-line employees.

We evaluated patient care areas, including outpatient and designated inpatient areas. We reviewed VHA directives, electronic health records (EHR), facility policies and procedures, administrative documents, nurse training records, and quality management data and documents. A team from the VHA Office of the Medical Inspector (OMI) visited the facility in October 2012 and issued an extensive patient focused internal review for the VA Under Secretary for Health. We reviewed the OMI report but also conducted an independent inspection and review of EHRs.

To gather information from facility employees, we conducted an Employee Assessment Review (EAR) survey regarding patient safety and quality of care. Facility staff received an e-mail invitation on December 3, 2012, to respond anonymously through a dedicated OIG internet portal. Individuals responding to the survey could, if they wished, provide specific details of their concerns and their contact information. There were 102 responses to the EAR survey through January 14, 2013, and 25 employees provided additional information or requested an interview. We reviewed individual comments and followed up on specific concerns. We aggregated the data and discussed the results with the VANIHCS Director.

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.

Inspection Results

Issue 1: Quality of Care

Case Reviews

Of the 20 cases we reviewed, we selected three to offer as examples of the facility's failure to consistently engage sound clinical judgment and deliver quality inpatient care. These three cases do not define the limits of the quality of care concerns we had after reviewing a larger number of cases at the facility. However, these cases are offered as examples of the facility's failure to consistently engage sound clinical judgment and deliver quality inpatient care.

Case 1

A man in his early 60s presented to the facility's Emergency Department (ED) for a perirectal abscess[2] with cellulitis[3].

Five days earlier, the patient had been seen as an outpatient at another VA medical facility with fever and flank pain and placed on an antibiotic. One day earlier, he had been seen at a non-VA facility, documented to have a marked elevation in white blood cell count[4] and had an imaging report interpreted to show a large perirectal abscess. Upon presentation to the facility, the patient was admitted, seen by general surgery, and underwent an urgent drainage of the perirectal abscess without immediate complications.

Postoperatively, the patient was initially clinically stable, including a normal blood pressure (BP) 133/65 mm Hg[5], and was treated on the acute medical unit with physician orders to resume maintenance BP lowering drugs and to obtain vital signs every 4 hours over the next 24 hours. Execution of the vital sign orders was not fully complied with by nurses. The only documented vital signs during the first post-operative night were pulse and respiratory rate. No BP readings were recorded for over 16 hours, at which time the patient was found to have rapid heart rate, fever, low blood pressure, and a low urine output[6]. The Rapid Response Team (RRT)[7] was called to evaluate the patient.

[2]Perirectal abscess is a collection of pus in the tissues surrounding the anus.
[3]Cellulitis is a skin infection caused by bacteria.
[4] White blood cell is a type of blood cell that, when present in increased numbers, often reflects inflammation somewhere in the body, frequently on the basis of infection.
[5] Blood pressure is recorded in "millimeters of mercury" (mm Hg), a measure of the pressure of blood on the vessels when the heart beats. Normal blood pressure values range approximately from 100-135/60-90.
[6] Low urine output may be an indication of reduced blood flow coming to the kidney.
[7] Rapid Response Team is a group of medical providers who may be called to a patient's bedside, usually on a general medical or surgical floor, to immediately assess and treat the patient with the goal of preventing intensive care unit transfer, cardiac arrest, or death.

The RRT assessed the patient to be clinically unstable, possibly septic[8], and requiring urgent transfer to a nearby non-VA hospital for ICU care. Nursing notes reference "lower BP's" in the hours before the RRT was called but a series of specific BP readings is not documented. Despite the apparent low BP readings in the hours prior to his transfer to the non-VA ICU, the patient had been given his regular doses of two different BP lowering drugs. The physician's post-operative orders did not contain guidance for notifying providers of abnormal BP levels or parameters for withholding BP lowering drugs. There were no BP readings documented at the times the nurses gave the anti-hypertensive drugs.

Case 2

A man in his early 70s presented to the facility's ED complaining of shortness of breath, chest pain, lightheadedness, and a "racing heart." The patient had a known medical history of coronary artery disease, hypertension, and atrial fibrillation[9]. Vital sign assessment upon arrival in the ED showed a rapid pulse rate,[10] 135 beats/min., and a low BP of 87/54 mm Hg. An electrocardiogram (EKG)[11] confirmed the heart rhythm to be atrial fibrillation. The patient received medication to lower his heart rate and intravenous fluids to improve BP.

After being stabilized in the ED, the patient was admitted to a telemetry bed[12] in a non-ICU setting. There, further management included a dosage increase in an antiarrhythmic drug, oral sotalol, which the patient was already taking for heart rate control. Over the course of the rest of the day, the patient continued to have atrial fibrillation, but at an acceptable ventricular rate, and with normal BP readings.

After 1 day in the hospital, and 16 hours following the sotalol dosage increase, the admitting physician assessed the patient as "ready for discharge." At the time of the physician's orders for discharge, the patient's heart rate was in the normal range at 82 beats/min. However, within 2 hours, while still at the facility and waiting to be picked up to go home, a telemetry technician noted the patient to have a rapid heart rate of 122 beats/min. while at rest, increasing to 140 beats/min. when walking. There is no documentation that a nurse or physician was informed as to the patient's increased heart rates while waiting to go home. No cardiology consultation was obtained during the entirety of the hospitalization.

Therefore, the patient, admitted to the hospital on the prior day for the consequences of a rapid heart rate (135 beats/min.), was being sent home having a heart rate which was

[8] Septic (sepsis) is a serious infection, usually caused by bacteria, that can progress very quickly, involves organ failure, and, in some cases, leads to death.
[9] Atrial fibrillation is an irregular, often rapid, heart rhythm that may cause poor blood flow to the body. During atrial fibrillation, the heart's two upper chambers (the atria) beat chaotically and irregularly, out of coordination with the two lower chambers (the ventricles).
[10] A normal resting heart rate in an adult is 60-100 beats/minute (min.)
[11] Electrocardiogram is a recording of the heart's electrical activity in a graphic form demonstrating findings to include rate and rhythm.
[12] Telemetry is a device that allows a patient's heart rate and rhythm to be under continuous electronic monitoring, and usually observed by a medical provider from a remote location.

actually higher than when he was admitted. The patient did go home and, in less than 2 hours, returned to the facility's ED complaining again of chest pain, lightheadedness, and a rapid heart rate. Following stabilization and further assessment, the patient was transferred to a non-VA facility the next day for additional cardiac evaluation, though the precise reason for transfer is not clear.

Case 3

A man in his mid-80s presented to the facility's ED with complaints to include shortness of breath and diarrhea of months duration. He had a past medical history of cardiomyopathy[13], coronary artery disease, abdominal aortic aneurysm, and chronic obstructive pulmonary disease. The patient's ED assessment was notable for a low BP of 92/56 mm Hg and low serum levels of calcium and magnesium[14]. He was admitted to a non-ICU telemetry bed. Over the next several days, the patient's presenting symptoms and laboratory abnormalities were addressed.

On the fifth hospital day, the patient suddenly developed a rapid, irregular heartbeat. He was transferred to the ICU, treated supportively and with anti-arrhythmic agents, and was observed to convert to a normal sinus (regular) heart rhythm[15] within 2 days, though with a persisting rapid rate and low BP readings. Later that day, the patient became lethargic and responsive only to painful stimulation, suggesting decreased blood flow to the brain. The RRT was not informed of the patient's changed clinical status. Rather, the Medical Officer of the Day[16] was called and, after several hours of supportive care, the patient remained lethargic with rapid heart rate and continued low BP readings. He was placed back in the ICU for approximately 24 hours, and became more alert but with persistence of rapid heart rate and low BP readings. He was also observed to have a low urine output.

The attending physician transferred the patient out of the ICU to an acute medical unit telemetry bed. There, an EKG technician documented the patient to have had a change to an irregular rhythm but the attending physician was not informed of this development. The next day, the patient was seen by the attending physician who offered no comment as to the continuing abnormal heart rate and rhythm. In fact, the physician described the heart rate as "controlled," even though the same chart entry documents a heart rate that continued to be rapid, at 120 beats/min.

Two days later, the patient's cardiac rhythm deteriorated into a more aggressive, dangerous pattern and he experienced a cardiac arrest. Resuscitative efforts were not in compliance with the American Heart Association's 2010 Advanced Cardiac Life Support guidelines algorithm for the type of arrest the patient experienced, were not successful, and the patient died.

[13] Cardiomyopathy is a disease of the heart muscle often characterized by enlargement and, eventually, weakening.
[14] Calcium and magnesium are electrolytes carried in the blood, which are important for the normal function of many cells in the body.
[15] Sinus rhythm is the normal, regular conducting rhythm of the heart.
[16] 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.

No cardiology consultation was documented during the hospital course to advise and assist in managing this patient's unstable condition that was likely caused, or aggravated, by his underlying cardiomyopathy.

Summary of Case Reviews

In each patient's circumstances, there is evidence of a lack of consistently sound clinical judgment, intuitive reasoning, and/or a lapse in following procedure. The result for the patients is a lesser quality of care, or frankly substandard care, and with possible consequences as to clinical outcomes.

In Case 1, a physician's orders for BP monitoring were not timely followed. Poor clinical judgment allowed BP lowering agents to be administered even though available readings suggested that the drugs were not indicated. Although the patient had become clinically unstable, he was not in a closely monitored care setting.

In Case 2, a patient was being managed with a specialized cardiac drug, sotalol, without guidance by a cardiologist and without due consideration given to the specifics of how the body handles sotalol. A patient taking sotalol should be in a setting for cardiac rate and rhythm monitoring when the drug is initiated or when the dose is increased. When the dosage of sotalol is modified, it takes the body up to several days to reach a "steady-state" concentration in the blood.[17] This is important because it allows for an understanding of what level of effectiveness and/or toxicity a specific dose of the drug will have. Sotalol can also affect various segments of a conducted heartbeat as reflected in an EKG tracing. The managing physician made no comments as to any specific EKG segment changes, or lack of changes, on the basis of sotalol dose adjustments. The patient, having been admitted with a rapid heart rate, was prematurely discharged from the facility (and with a faster heart rate than he had been admitted with) returning to the ED within 2 hours with foreseeable cardiac symptoms.

In Case 3, poor staff communication is evident from a lack of notification as to changes in telemetry rhythm. Also, no formal cardiology consult was requested in this complicated patient with heart failure and unstable arrhythmias and a cardiologist's guidance may have improved the patient's care and, perhaps, final outcome.

The facility quality management program generally met VHA requirements, as reviewed, and had identified quality of care concerns. Cases had been referred to peer review and data was sorted by provider, service, and level of review. The three cases summarized in this report have all been peer reviewed, with disclosures completed in the case of each patient.

Issue 2. VANIHCS Leadership

The VANIHCS leadership team for both campuses consists of the Director, COS, and Associate Director for Patient Care Services, and there is an Associate Director for

[17] Steady-state is the concentration of a drug achieved when the rates of drug administration and drug elimination are equal.

Operations at each campus. From 2009–2012, there have been five VANIHCS Directors or Acting Directors and at least five COS or Acting COS. The Associate Director for Patient Care Services was assigned that title in 2003, but had been the Nurse Executive and part of the leadership team since 1998. The Associate Director for Operations at the Marion campus was assigned in 2008 and supervised some services at the facility. There have been seven Associate or Acting Associate Directors for Operations at the facility from 2009–2012. The current COS was assigned in April 2012 and the current VANIHCS Director in December 2012.

Additionally, many key administrative and clinical leadership positions (service chiefs) have been held by individuals on a temporary basis, and we were informed that mid-management decisions were often delayed or frequently changed. Staff reported to us the recurrent leadership changes led to uncertainty and inconsistent administrative and clinical decisions. We were told that there were times when vacancies were not filled in order to balance budget deficits. We were also told that a key clinical service chief resigned due to frustration with ongoing vacancies.

At the time of our review, there were multiple vacancies involving a number of clinical positions. Table 1 indicates the status of key positions as of May 1, 2013.

Table 1. Status of Key VANIHCS Positions

Vacancy:	Offer Date:	Start Date:
Board Certified Cardiologist	April 4, 2013	May 5, 2013
Chief of Extended Care and Rehabilitation Service	Open and Continuous posting	Open
Chief of Medicine	April 19, 2013	June 2, 2013
Chief of Mental Health	Open and Continuous posting	Open
Chief of Primary Care	December 6, 2012	March 24, 2013
Emergency Department (ED) Director (An in-house hospitalist was detailed into the ED physician position effective March 18, 2013)	Open and Continuous posting	Open
ICU Director (Selectee also filled the Board Certified Pulmonologist position)	April 30, 2013	June 2, 2013

Overall, staff expressed confidence in the new VANIHCS Director and COS and are hopeful that, as a management team, they will provide stability in facility leadership.

Issue 3. Factors Leading to the Pause

Ultimately, the VISN Director, after conferring with facility leaders, made the final decision to pause inpatient services, regarding the measure as necessary for proactive risk management. ICU and telemetry beds were paused on October 11, 2012, and all inpatient beds were paused on October 22.

During routine VISN reviews in October 2012, VISN staff found opportunities for improvement in areas of communication, patient care, policies and procedures, and staff training in the inpatient clinical areas. These were planned reviews as part of system redesign and the implementation of the Patient Aligned Care Team initiative.[18] VISN staff, to include the VISN Chief Medical Officer (CMO), completed patient tracers[19] and reviewed patients' records finding structural issues with clinical care, especially within the ICU.

On October 11, admissions to the ICU and telemetry were paused after the CMO discovered qualitative care issues with two specific patients. The first patient had been transferred from another facility to rule out a heart attack and the necessary clinical labs to confirm the diagnosis were not completed for the patient. The second patient, cited as Case 2 in the Quality of Care section above, had a cardiac issue and was discharged from the facility and, less than 2 hours later, was readmitted.

After the ICU and telemetry pause, the Acting VANIHCS Director requested that VISN staff complete a review of selected admissions from the 3 months prior to the pause and look for any trends. The VISN clinical staff obtained a patient admission list from the facility and selected 29 patients for review. They had concerns about care and/or documentation of care for 14 of the 29 patients. It was unclear how these particular 29 patients were selected. During this time, patients were still admitted to the acute medical unit.

On October 22, the VISN made the decision that all admissions to the acute medical unit be paused. Although not determined by a single case, facility leadership described one particular patient event that serves to summarize the reason for the pause. A patient was admitted for alcoholism and had decreasing hemoglobin levels. The VISN CMO was concerned about potential bleeding but the facility's clinical staff did not consider this risk. The patient was eventually transferred to a local community facility.

VISN leaders cited other reasons for pausing all inpatient care. Since 2007, there have been several external reviews with resulting quality of care concerns that led to services being paused at the facility. In 2007, surgery services were paused and in 2009, reusable medical equipment services were paused. The VISN provided a list of previous reviews with subsequent findings, including the lack of documented staff competencies and poor communication among physicians and nurses, as reasons to pause inpatient services. Although the facility implemented changes in response to the external review findings, they did not sustain the corrective actions.

Workload during the Pause

During the pause, outpatient services at the facility remained unaffected and veterans who required inpatient medical or surgical care were referred for community-based care

[18] Patient Aligned Care Team (PACT) is a new VHA initiative to implement a patient-centered medical home model that is a patient-driven, team-based approach to providing total health care.
[19] A patient tracer is a technique used to assess specific care processes by observing and talking to staff in areas where the patient received care.

or to one of three tertiary care VHA facilities within 3 hours drive from the facility. From October 11, 2012, through May 1, 2013, there were 544 veterans who received community-based care. At any given time before the pause, it was normal to have 8–10 patients receiving community-based inpatient care. Facility staff reported to us that in FY 2012, inpatient services constituted 2.64 percent of the facility's total workload. FY 2012 average daily census for the acute medical unit was 15.7 and 1.9 for the ICU. VISN 11 has provided budget support for the non-VA care since the pause.

Issue 4. Measures Needed to Return to Normal Operations

Action Plan

With the goal of resuming inpatient services, the facility has undertaken a detailed four-step, phased plan:

Phase 1. Admission of patients to the acute medical unit for chemotherapy.
Phase 2. Admission of patients to the acute medical unit for general medical and surgical care in six bed increments.
Phase 3. Admission of patients to the acute medical unit for telemetry.
Phase 4. Reopening of the ICU.

On December 3, 2012, the facility started Phase 1 with the resumption of inpatient services by admitting patients to the acute medical unit for chemotherapy infusions. When we made our initial site visit, there was one patient admitted to the acute medical unit for an infusion, and the facility leadership made scheduled visits to the unit during the patient's stay to monitor clinical care.

On February 27, 2013, the facility began Phase 2 with the admission of patients to the acute medical unit with the capacity of six total medical and chemotherapy patients. On March 27, the facility increased the number of patients that could be admitted to the acute medical unit from 6 to 12. There have been 23 observation admissions and 34 full admissions since limited inpatient services were resumed, with an average daily census of 1.6. To support 12 inpatient beds and infusion patients in the acute medical unit, staffing levels are currently set to a skill mix of 51 percent registered nurses (RN), 22 percent licensed practical nurses (LPN) and 21 percent nursing assistants (NA). This level of services (12 acute medical beds) requires total direct care staffing of: 14 RNs, 7 LPNs, and 8 NAs. The plan for Phase 2 includes referring the highest complexity patients to local community partners.

During the pause, some of the inpatient staff were detailed to other clinical areas within the facility. Additionally, staff took the opportunity to complete continuing education requirements and training necessary for maintaining competency. Staff updated policies and procedures and worked with mentors from other VA medical facilities to improve patient care when beds were reopened.

Each phase toward resumption of inpatient services has specific indicators and milestones to complete. Some of these include communication, environment of care,

policies and procedures, psychological safety,[20] staff competencies and training, and staffing.

Organizational Improvement

Facility staff have been involved with multiple Rapid Process Improvement Workgroups (RPIWs).[21] The RPIWs are composed of frontline staff and supervisors from the clinical and operational areas. They assess the current state of a process and may redesign the current processes or systems to meet specific objectives and timelines. These RPIWs have reviewed facility practices and processes, developed new guidelines and policies, implemented changes, and provided training to staff. In April 2013, a RPIW was initiated for telemetry. This workgroup is formulating policies, standard operating procedures, and educational needs for implementation of Phase 3 telemetry.

In February 2013, the VISN CMO joined the facility staff to lead organizational performance at the facility, relinquishing the VISN CMO position. He reports to the VANIHCS Director and has been reviewing both clinical and administrative processes. He is involved in RPIWs and mentoring facility staff in the key measures required to prepare the facility for the resumption of inpatient admissions.

Additionally, the facility has an agreement with the VHA National Center for Organization Development (NCOD) to provide monthly training for frontline staff, supervisors, service chiefs, and the executive leadership team, with a focus on team building and improving psychological safety. NCOD offers organizational assessment and consultation services to VA organizations nationwide. These services may include assessment of the work environment, team building at executive and work group levels, and facilitation of work and process redesign. Monthly NCOD training started in January 2013 and has continued through May.

Clinical staff from other VA medical facilities have been involved with staff training and development, policy evaluation and development, and clinical mentoring during the pause.

Environment of Care

We inspected the acute medical unit and ICU; the mental health (MH), primary care, and specialty care outpatient clinics; the ED; and public areas (bathrooms, hallways, and patient waiting areas). We focused on selected elements in environmental safety, fire safety, infection prevention, and privacy.

Overall, the facility maintained a generally clean and safe environment, and confidential patient information was protected. During the pause from inpatient care, the facility took the opportunity to improve the aesthetics of clinical areas (paint, basic repairs).

[20] Psychological safety refers to an employee feeling safe to discuss errors by openly seeking input from others whose involvement is necessary to make desired changes.
[21] RPIW is a team that utilizes a series of tools to examine clinical and operational processes with the intent of improving a process or system.

Nurse Competencies

The facility had a nurse competency policy that outlined the assessment process and required that competencies be assessed and evaluated annually.[22] Competency assessment and validation documentation processes should include the dates of assessments, the methods used to determine competency, the names and signatures of the individuals performing assessments (validators), and the signatures of the employees being assessed.

We reviewed competency assessment and validation documentation for staff to determine whether validation forms included these key elements. We reviewed 12 nurse competency folders for nursing staff (RN, LPN, NA) assigned to the acute medical unit, ICU, and primary care clinics. A VISN requested VHA review team was onsite during our January inspection to evaluate the nurse competency process for FY 2012. For that reason, we reviewed competency assessment documentation for FY 2010 and FY 2011. All the nursing staff we selected were employed prior to FY 2010. For FY 2010, 5 of 12 assessments had missing documentation. For FY 2011, 10 of 12 assessments had a combination of missing or incomplete documentation. Two of the 12 folders had competency assessment documentation for a combined 2-year period, which was not in accordance with the facility policy of annual assessments. All of the records we reviewed were missing data elements and did not meet facility requirements.

The Associate Director for Patient Care Services told us that there were competency assessments in place and there had been for a number of years. However, we determined the competency assessment process was inconsistent and there were variations in the validation responsibilities, methods, and documentation. It was difficult to determine validation practices since the documentation for each individual skill, dates and methods of assessment, validator signatures, and evidence of employee involvement, was missing or incomplete.

Issue 5. EAR Survey Concerns

Human Resource Operations

Employees reported concerns with the Human Resource (HR) department that included lack of effective leadership, lack of specialized experience, favoritism in hiring, illegal hiring practices, and non-compliance with regulations.

We were not provided specific case information so were unable to review employee concerns. We suggest that VISN staff review HR operations to ensure that HR staff are appropriately trained and aware of HR regulations.

[22] Veterans Affairs Northern Indiana Health Care System Nursing Department Policy ND-2, *Competency Evaluation-Nursing*, March 6, 2009.

Mental Health Staffing

Employees reported a shortage of MH staff, creating concerns of timely service to new patients and rescheduling appointments timely for returning patients.

MH clinic staff stated that veterans' requesting access to MH services experienced a delay of approximately 3-4 weeks prior to being seen. The MH clinic appointment time allotted for Licensed Clinical Social Workers is 1 hour per patient; for psychiatrists 1 hour for new patients and 30 minutes for established patients; and for psychologists, 1 hour per patient. The average patient workload is 5 clinical hours per day. These numbers are consistent with other VHA facilities.

Facility MH clinic staff are currently reviewing MH panel sizes, workload, and missed opportunities for appointments. The facility leadership told us that additional MH providers are being hired, including a Chief of MH.

Nurse Staffing Methodology

Employees reported that the nurse staffing methodology was not implemented in accordance with VHA Directives.

VHA Directive 2010-034 provides a nationally standardized method of determining appropriate direct care staffing for VA nursing personnel.[23] It defines the steps that all facilities must follow to determine appropriate levels of nursing staff (numbers and types) at all points of care. Staffing requirements determined through this methodology support and maintain a standardized approach in ensuring there are adequate nursing staff across the organization.

VHA facilities were required to implement the nurse staffing methodology by September 30, 2011, and apply the nationally standardized methodology process to determine VA staffing for all inpatient points of care.

The facility did not complete the required steps to develop a nurse staffing methodology until September 2012.

Issue 6. Other Issues

ICU Level of Care

Employees reported the ICU was categorized by VA program officials as a level 3 but considered by employees at the facility to be a level 4, and functionally operated as a level 4. A level 4 ICU is expected to provide basic ICU services, such as continuous electrocardiogram, central venous pressure monitoring[24], and complex airway management to include ventilator controlled respiration. A level 3 ICU provides moderate services, such as dialysis, arterial and pulmonary artery wedge pressure

[23] VHA Directive 2010-034, *Staffing Methodology for VHA Nursing Personnel*, July 19, 2010.
[24] Central venous pressure monitoring involves the insertion of a plastic tube into a large blood vessel near the heart; it is a technique used to help guide fluid therapy in hospitalized patients.

monitoring[25], and continuous antiarrythmic drug administration. In a level 4 ICU, primary care physicians can provide ICU care without an intensivist or consultant. The expected length of stay in a level 4 ICU is less than 72 hours; patients requiring longer stays should be transferred to another facility. In a level 3 ICU, more intensive services are provided, multiple consultants must be available, and the average length of stay is expected to be less than 5 days.

Employees reported that the ICU lacked the capability of even a level 4 ICU in the period leading up to the pause. Staff told us they do not know how, or why, the ICU level increased to a level 3 from a level 4, stating that facility leaders had not requested this upgrade, and that it was unknown how the change occurred.

Communication of the Pause

Employees reported that communication about the pause was lacking. From the time of the initial pause in October 2012 until January 2013, there was no official, direct VA communication sent to veterans enrolled at the facility explaining the reasons for the pause and whether there was a plan to eventually resume inpatient services. The first publicity for the pause that veterans would have had access to was a local newspaper article.

On October 15, 2012, the Public Affairs Officer (PAO) prepared a communication action plan to include a media release on the ICU and telemetry pause for review and approval through the VA Office of Public and Intergovernmental Affairs (OPIA)[26] and VISN 11. On this day, the PAO also contacted the local Congressional staff and the County Veteran Service Officers (CVSOs) to inform them of the pause. On October 16, the PAO was advised by OPIA to continue moving forward with planned actions but to hold the press release until further notification.

On October 22, after admissions were paused to the acute medical unit, the PAO was given approval to release a media statement. On this same day, the PAO also contacted the local Congressional staff and the CVSOs to inform them of the pause on admissions to the acute medical unit.

Veterans and facility staff were concerned about the lack of information regarding the pause and there were suspicions in the community that the facility may be closed permanently. On January 4, 2013, a telephone hotline was established to answer questions pertaining to the pause, and it was open to the general public and staff via the facility's website and VA Facebook. On January 11 and 12, nearly 3 months after the pause was implemented, a letter was mailed to 41,173 veterans enrolled at the facility explaining the background and details of the pause and a timeline to resume inpatient services. This letter also provided the telephone hotline number and its hours of operation.

[25] Pulmonary artery wedge pressure monitoring requires a plastic tube to be placed into a blood vessel in the lung to indirectly measure a type of heart pressure.
[26] OPIA is the VA division responsible for communication with veterans, media, and stakeholders.

On February 14, the VANIHCS Director and Acting VISN Director met in Washington, DC, with Congressional delegates to provide a face-to-face update on the pause.

On March 8, the facility hosted a media roundtable with eight local media outlets. The media roundtable panel consisted of the facility's Executive Leadership team and the PAO as the moderator. The focus of the questions was on three areas: the pause, phased re-start, and the path toward opening all beds.

Additionally, the VANIHCS Director has provided updates on the pause to staff in town hall meetings, the facility daily newsletter, and via email. Veterans have been informed through regular meetings with CVSOs and local media.

VHA Policies for Changes in Clinical Programs

VHA has policies and processes for implementing the restructuring of, addition to, or decrease in, major clinical programs that may change or impact the delivery of care provided to veterans.[27]

While VHA has policies with guidance on restructuring of clinical programs, such as when expanding or deleting services, we could not find clear guidance for pausing major clinical services. In interviews, we found that general rules for implementing a facility pause were unclear to VISN staff.

Conclusions

The pause was part of a VISN proactive risk management decision to prevent patient safety issues before actual patient harm occurred. We believe this was a warranted decision based on the entirety of clinical and administrative circumstances affecting the facility at the time. A number of vacancies continue to exist for key positions and it has been difficult to recruit qualified staff.

Our review of competencies only extended to nursing and we did not review competencies for other support services. Competency assessments were identified by the facility as areas for RPIW reviews. Nurse managers had not implemented all required components of the nurse staffing methodology. Completion of all components will provide necessary information to leadership regarding required nurse staffing.

We do not believe the facility, as currently constituted, is prepared to support a level 3 ICU. The facility has formulated a detailed plan to incrementally resume inpatient care. We believe the VISN must maintain an active oversight role in this implementation and continue ongoing reviews to ensure high quality inpatient care is being reliably and consistently delivered.

[27] VHA Handbook 1000.01, *Inpatient Bed Change Program and Procedures*, December 22, 2010. VHA Directive 2009-001, *Restructuring Of VHA Clinical Programs*, January 5, 2009.

The pause was not communicated well to veterans, facility staff, the community, Congressional leaders, or external stakeholders. In interviews, we found that general rules for implementing a facility pause were unclear to VISN staff.

We believe the current VANIHCS Director and COS bring a positive outlook to a beleaguered facility. All employees we spoke with voiced trust in their ethics and managerial skills and appreciated their openness in dealing with the substantive issues facing the facility and the circumstances affecting staff on the basis of the pause itself. Numerous employees independently expressed the hope that the new Director and COS will bring greater leadership stability and effectiveness to the mission of VANIHCS.

Recommendations

1. We recommended that VHA develop policy for guidance when major clinical services are paused at a VA facility.

2. We recommended that the VISN Director ensure that a review of the facility ICU level of care and support services is completed to determine the appropriate designation.

3. We recommended that the VISN Director ensure that qualified clinical staff are available to provide care.

4. We recommended that the VANIHCS Director ensure that efforts continue to recruit qualified staff for vacant leadership positions.

5. We recommended that the VANIHCS Director ensure that nurse competencies are consistently completed and validated annually.

6. We recommended that the VANIHCS Director ensure that the facility fully implement the nurse staffing methodology and complete all required steps.

Appendix A

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: July 17, 2013

From: Under Secretary for Health (10)

Subject: **Healthcare Inspection – Review of Circumstances Leading to a Pause in Providing Inpatient Care, VA Northern Indiana Healthcare System, Fort Wayne, IN**

To: Assistant Inspector General for Healthcare Inspections (54)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I have reviewed the draft report and concur with the report's recommendations. I agree that guidance for implementing Veteran Health Administration (VHA) current policies for temporary reduction in patient services or temporary bed closures is not as clear as it could be.

2. The OIG's report pointed out that VISN staff are unclear about rules and policies for implementing temporary reductions in major services. Importantly, VHA policies on Restructuring of Clinical Programs and Inpatient Bed Change Program and Procedures do apply to both permanent reductions and temporary reductions (or pauses) of major clinical programs or services and bed closures at a facility.

3. Should you have additional questions, please contact Karen Rasmussen, M.D., Acting Director, Management Review Service, at (202) 461-6643, or by e-mail at karen.rasmussen@va.gov.

Robert A. Petzel, M.D.

Appendix A

Comments to OIG's Report

The following Under Secretary for Health comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that VHA develop policy for guidance when major clinical services are paused at a VA facility.

Concur

Target date for completion: September 30, 2013

Under Secretary response:

VHA Directive 2009-001 and VHA Handbook 1000.01 are VHA's current policies on reductions or changes in major clinical services at a facility. Because these policies can be construed to apply only to permanent changes, VHA will reinforce that they apply to both temporary (paused) as well as permanent changes and will clarify how to implement them. The Deputy Under Secretary for Health for Operations and Management and the Assistant Deputy Under Secretary for Health for Clinical Operations will provide policy guidance to key leadership during the Network Directors meeting and the Chief Medical Officers/Quality Management Officers meeting.

Appendix B

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: July 11, 2013

From: Director, Veterans in Partnership (10N11)

Subject: **Healthcare Inspection – Review of Circumstances Leading to a Pause in Providing Inpatient Care, VA Northern Indiana Healthcare System, Fort Wayne, IN**

To: Director, Kansas City Office of Healthcare Inspections (54KC)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. Attached is the Healthcare Inspection – Review of Circumstances Leading to a Pause in Providing Inpatient Care, VA Northern Indiana Healthcare System, Fort Wayne, IN action plan developed by the staff at the Northern Indiana Healthcare System.

2. I have reviewed their plan and agree with the actions that will be implemented to correct the identified deficiencies.

3. Should you have questions about this plan, please contact Cynthia Paterson, Ph.D., at (734) 222-4300.

Paul Bockelman

Paul Bockelman, FACHE
Network Director, VISN 11

Appendix B

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 2. We recommended that the VISN Director ensure that a review of the facility Intensive Care Unit level of care and support services is completed to determine the appropriate designation.

Concur

Target date for completion: December 1, 2013

Facility response:

VANIHCS will complete a review of the facility Intensive Care Unit level of care and support services to determine what level of care should be provided in collaboration with VISN and VHA input. A communication plan will be devised to share the decision with Veterans, staff and stakeholders.

Recommendation 3. We recommended that the VISN Director ensure qualified clinical staff are available to provide care.

Concur

Target date for completion: October 1, 2013 (ongoing)

Facility response:

VANIHCS has worked to aggressively recruit qualified clinical staff to point of contact for physician recruitment; engagement with the assigned national recruiter to increase candidate pool and increased marketing strategies to increase candidate pool. VANIHCS has recently employed the following clinical staff: Cardiologist entered on duty (EOD) May 5, 2013; Intensivist/Pulmonologist (EOD June 2, 2013), three Psychiatrists (estimated start dates ranging between August and September 2013), and five Nurse Practitioners (estimated start dates range from June 30, 2013, to October 6, 2013). Two Hospitalists (EOD June 30, 2013) were hired; however, one has resigned effective July 5,2013, after accepting a different position. Recruitment for the vacant hospitalist position has begun. Professional staff recruitment will be an ongoing process.

Appendix C

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: July 11, 2013

From: Director, VA Northern Indiana Healthcare System, Fort Wayne, IN

Subject: **Healthcare Inspection – Review of Circumstances Leading to a Pause in Providing Inpatient Care, VA Northern Indiana Healthcare System, Fort Wayne, IN**

To: Director, VISN 11, Veterans in Partnership (10N11)

I have reviewed the report and concur with the findings and recommendations.

Denise M. Deitzen
Director
Northern Indiana Health Care System

Appendix C

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 4. We recommended that the VANIHCS Director ensure that efforts continue to recruit qualified staff for vacant leadership positions.

Concur

Target date for completion: October 1, 2013

Facility response:

VANIHCS has aggressively recruited and filled the following positions: Associate Chief of Staff, (ACOS) Primary Care (EOD March 24, 2013), ACOS Acute Care (EOD June 2, 2013, – ACOS is a cardiologoist as well and will be able to provide back up cardiology coverage if needed), and ICU Director (EOD June 2, 2013, – ICU Director is an intensivist and pulmonologist and will provide back up on the medical floor and pulmonary clinic during the time of the ICU pause). VANIHCS is continuing to recruit an ER Director (a hospitalist was detailed to cover this position March 18, 2013). The Chief of Mental Health position remains vacant and VANIHCS has expanded recruitment to include use of relocation, recruitment, and permanent change in station incentives, and authorized the pay-table exception to offer higher salary. Six applicants have been considered in the third quarter of 2013 with no appropriate candidates at this point. An Assistant Chief, Mental Health position has been added to the leadership team. Five candidates were considered for this position and a strong candidate has been identified with a tentative start date of August 11, 2013. The Chief of Geriatrics and Extended Care (GEC) position remains vacant yet moving forward. Recruitment incentives shall be increased to maximize efforts. Four candidates have been considered in the third quarter of 2013 with no appropriate candidates at this point. Recruitment expansion has included utilization of VA and VHA resources, utilization of national trade journals and publications, utilization of commercial recruitment web sites, and direct contact with eleven medical schools to search for potential candidates.

VANIHCS is at the interview stage for an Associate Chief Nurse (ACNS) for Operations (interviews conducted June 28, 2013) and an ACNS, Primary Care (interviews conducted July 1, 2013). The previous ACNS for Mental Health and Ambulatory Care has been divided into two separate positions (ACNS, Mental Health and ACNS, Primary Care) to allow increased nursing leadership in each area.

VANIHCS has been actively recruiting a GS-15 Associate Director since January 2013 through Workforce Management and Recruiting Office, VA Central Office and has a current recruitment closing July 10, 2013.

Recommendation 5. We recommended that the VANIHCS Director ensure that nurse competencies are consistently completed and validated annually.

Concur

Target date for completion: September 13, 2013

Facility response:

VANIHCS Nursing Department Policy ND-2, Competency Evaluation-Nursing is in the review process. The policy has three major changes: annual nurse executive review of competencies; change in competency approval process and change in competency completion timeline.

The policy requires the Nurse Executive to perform a 100 percent review of all nursing staff competency folders prior to the end of the fiscal year for certification and approval of the Director. The policy requires all competency forms be routed and approved through the Nurse Executive Advisory Board for consistency in formatting and appropriate validation methods. Completion of competency review is being changed for all nursing staff from the annual proficiency date to the fiscal year. This will assist in the timely completion of the annual competency review by having all nursing staff on the same review cycle. Each unit will recommend their competencies to the Nursing Executive Advisory Board for review and approval. Education will assist with the training verification and validation of competencies.

Recommendation 6. We recommended that the VANIHCS Director ensure that the facility fully implements the nurse staffing methodology and complete all required steps.

Concur

Target date for completion: August 30, 2013

Facility response:

VANIHCS will ensure the facility implements all requirements of the nurse staffing methodology and ensure the numbers, types, and assignments of nursing personnel are consistent with VHA directive and facility strategic plans.

Appendix D

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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