



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Infusion Clinic Closure and Patient Notification VA Southern Nevada Healthcare System Las Vegas, Nevada

**To Report Suspected Wrongdoing in VA Programs and Operations
Call the OIG Hotline – (800) 488-8244**

Executive Summary

The purpose of this inspection was to determine the validity of allegations made by an anonymous complainant that: (a) the infusion clinic was closed because managers failed to complete the necessary paperwork authorizing physicians to administer chemotherapy, (b) managers did not notify patients of the clinic's closure, (c) some patients were denied care or turned away when they reported for their prescribed treatments, and (d) infusion clinic nurses were reassigned to other departments during the closure.

We did not substantiate the allegations that the infusion clinic was closed because of incomplete paperwork, patients were denied care, or that nurses were reassigned to other areas during the closure. We did substantiate the allegation that managers did not notify patients of the clinic closure in a timely manner. Consequently, some patients were confused and upset when they arrived for their appointments and found the clinic closed. We concluded that managers could have better anticipated the needs of patients for information and should have planned a more effective communication process.

We recommended that the VISN Director ensure that the Healthcare System Director develops a more comprehensive action plan with accurate implementation status, informs affected employees of the plan, and monitors compliance to ensure that improvements are achieved and sustained. We also recommended that managers employ a similar review process in other clinics to determine if the patient safety issues identified in the infusion clinic exist elsewhere and if so, address any issues accordingly. Managers submitted appropriate action plans, and we will follow up on all actions not yet completed.



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

TO: Director, Veterans Integrated Service Network 22

SUBJECT: Healthcare Inspection – Infusion Clinic Closure and Patient Notification, VA Southern Nevada Healthcare System, Las Vegas, Nevada

Purpose

The Department of Veteran Affairs, Office of Inspector General (OIG), Office of Healthcare Inspections reviewed the validity of allegations made by an anonymous complainant pertaining to the closure of the infusion clinic at the VA Southern Nevada Healthcare System (the healthcare system) in Las Vegas, NV.

Background

The healthcare system provides inpatient and outpatient health care services in Las Vegas, NV, and provides additional outpatient care at community based outpatient clinics located in Henderson and Pahrump, NV. Outpatient care in the Las Vegas metropolitan area is distributed among seven clinic sites. The healthcare system is affiliated with the University of Nevada's School of Medicine. It is part of Veterans Integrated Service Network (VISN) 22 and serves a veteran population of about 240,000 in a primary service area that includes Clark, Lincoln, and Nye counties in Nevada.

The infusion clinic was closed September 4–7, 2007, (4 days) and was reopened on Monday, September 10. On September 6, an anonymous complainant contacted the OIG Hotline and alleged that:

- a. The infusion clinic was closed because managers failed to complete necessary paperwork authorizing physicians to administer chemotherapy.
- b. Managers did not notify patients of the clinic's closure in a timely manner.
- c. Some patients were denied care or turned away when they reported for their prescribed treatments.
- d. Infusion clinic nurses were reassigned to other departments during the closure.

Scope and Methodology

We examined patients' medical records, reviewed pertinent documents, and conducted interviews with managers and staff. We conducted a site visit October 3–4, 2007.

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

Inspection Results

Issue 1: Incomplete Paperwork Caused Clinic Closure.

We did not substantiate this allegation.

The decision to close the infusion clinic was made by the healthcare system Director based on patient safety concerns identified by an internal interdisciplinary review team and input from other clinical and administrative managers. We determined that infection control practices, medical record maintenance, medication management, and other clinical issues influenced the Director's decision to take immediate action to ensure patient safety.

We found no evidence that the infusion clinic closure was caused by management's failure to complete paperwork involving any of the physicians authorized to administer chemotherapy.

We reviewed the team's findings and recommendations and the subsequent corrective action plan developed by managers. The plan included action items with assigned responsibilities and corresponding completion dates. However, not all of the issues identified were incorporated into the action plan. For example, the plan did not include corrective actions to address concerns about consent form documentation or knowledge deficits of staff regarding medical equipment. We also learned that the implementation status for some action items was not accurate. For example, the plan reflected that the action to develop "quick set orders" had been completed; however, we were told that not all aspects of this electronic order set template had been developed. We determined that this item, and possibly others, needed to remain open until managers are assured that action items are fully completed and implemented. In addition, not all affected employees were aware of the identified concerns and corrective actions. The infusion clinic nurses told us that the findings were not discussed with them and that they were not aware of all the corrective actions or the implementation status of the actions.

We concluded that managers needed to develop a more comprehensive action plan with accurate implementation status, communicate the plan with all involved employees, and conduct ongoing monitoring to ensure that improvements are achieved and sustained.

We also learned that the issues identified by the review team were not unique to the infusion clinic. For example, we were told that other clinics within the healthcare system are not compliant with policies related to duplicative (shadow) charts, medication reconciliation, and use of electronic patient consent forms. Managers acknowledged this possibility.

We concluded that managers needed to employ a similar review process to determine if these issues exist in other clinics and address any issues accordingly.

Issue 2: Managers Did Not Notify Patients in a Timely Manner.

We substantiated this allegation.

The decision to close the clinic was made late in the afternoon of Friday, August 31, 2007, before an extended holiday weekend. We learned that managers and staff worked diligently over the weekend to address many of the logistics associated with the clinic closure. For example, contracts with community cancer centers were established, temporary medical records were assembled, and patient transportation arrangements were negotiated. Managers chose not to notify patients over the weekend and neglected to establish an alternative plan for communicating information to patients when they arrived on Tuesday morning for their scheduled appointments. Consequently, patients were confused and upset because no one with full knowledge of the logistics was present to provide instructions and alleviate their concerns.

We concluded that managers could have better anticipated the needs of patients for information and should have planned a more effective communication process. Managers acknowledged this oversight. We made no recommendation because patient care was not compromised, and all other logistics were well executed.

Issue 3: Patients Were Denied Care or Turned Away.

We did not substantiate this allegation.

We found no evidence that patients scheduled for chemotherapy were turned away or denied care when they reported to the infusion clinic. One patient elected to wait and resume his chemotherapy when the clinic reopened rather than receive his scheduled treatment at a community cancer care center.

We concluded that managers adequately provided alternative arrangements for chemotherapy and that no patients were denied care or experienced negative outcomes.

Issue 4: Staff Were Reassigned During Clinic Closure.

We did not substantiate this allegation.

We learned that the Associate Director for Patient Care Services issued a memorandum notifying all infusion clinic nurses of the clinic closure. The memorandum included a description of activities that would take place during the closure and potential reassignments. However, all of the infusion clinic nurses told us that they were not reassigned. Managers arranged for them to remain in the clinic where they received training, reviewed policies, and implemented clinic changes associated with the closure. They continued to fulfill other patient care responsibilities within their assigned areas.

Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Healthcare System Director develops a more comprehensive action plan with accurate implementation status, informs affected employees of the plan, and monitors compliance to ensure that improvements are achieved and sustained.

Recommendation 2. We recommended that the VISN Director ensure that the Healthcare System Director employs a similar review process to determine if the patient safety issues identified in the infusion clinic exist in other clinics and addresses any issues accordingly.

Comments

The VISN and Healthcare System Directors agreed with all findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 5–12 for the full text of their comments.) We will follow upon on all planned actions until they are completed.

(original signed by:)

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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: November 14, 2007

From: Network Director, VA Desert Pacific Healthcare Network (10N22)

Subject: Healthcare Inspection – Infusion Clinic Closure and Patient Notification, VA Southern Nevada Healthcare System, Las Vegas, Nevada, Project No.: 2007-03298-HI-0383

To: Director, Los Angeles Regional Office of Health Care Inspections (54LA)

Thru: Director, VHA Management Review Services (10B5)

1. I have read the OIG Draft Report – Infusion Clinic Closure and Patient Notification, VA Southern Nevada Healthcare System, Las Vegas, Nevada, Project Number: 2007-03298-HI-0383, and I concur with the recommendations in this report.

2. Please direct any questions that you may have to Mr. John Bright, Director of the VA Southern Nevada Healthcare System, at (702) 636-3010.

(original signed by:)

Kenneth J. Clark, FACHE

Attachments

Healthcare System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: November 14, 2007

From: Director, VA Southern Nevada Healthcare System (593/00)

Subject: Healthcare Inspection – Infusion Clinic Closure and Patient Notification, VA Southern Nevada Healthcare System, Las Vegas, Nevada, Project No.: 2007-03298-HI-0383

To: Director, Los Angeles Regional Office of Health Care Inspections (54LA)

Thru: VISN 22 Director (10N/22)

1. I have read the OIG Draft Report – Infusion Clinic Closure and Patient Notification, VA Southern Nevada Healthcare System, Las Vegas, Nevada, Project Number: 2007-03298-HI-0383, and I concur with the recommendations in this report.

2. Please contact me at (702) 636-3010 if you have any questions.

(original signed by:)

Anne Marie Feistman for

John B. Bright

Attachments

Healthcare System Director Comments

The plan below was submitted in response to the recommendations in the Office of Inspector General’s report.

Location	Findings	Recommendation	Action
Infusion Clinic	Staff is unable to verbalize if infusion pumps and other medical equipment are maintained according to organization guidelines. Staff is not certain about biomedical maintenance and provided inconsistent responses about cleaning IV pumps post-infusion.	<ul style="list-style-type: none"> • Staff education. 	<ul style="list-style-type: none"> • In-service scheduled with Bio-Med on November 13th to provide staff approved guidelines in regards to the maintenance of the infusion pumps and other medical equipment.
Infusion Clinic	<p>“Ghost” charts are currently being maintained by staff (<i>original documents, ex: consents remain in these charts up to six months after treatment before they are submitted to medical records for receipt/record entry. Staff utilizes these because they find using the CPRS system is not convenient.</i>)</p> <p>Working charts for nurses have a sequential documentation of vital signs, laboratory results, and previous medication dose administrations that are entered into CPRS when time permits. (<i>This is a duplicate process. The record is retained for an extended period of time, resulting in a lack of timely entry into CPRS. There is no staff signature/initial identification on this flow to determine who made these entries. This record is destroyed once the patient is discharged from care.</i>)</p>	<ul style="list-style-type: none"> • Scan forms into CPRS and attach to appropriate visit. • Proper destruction of documents that are duplicate entry. • Eliminate use of “ghost” charts as the information is in the CPRS note (per staff). • Utilize parent/child progress note function (progressive documentation) instead of chemo flow sheet. • Educate staff on proper tools within the CPRS window. • Eliminate nursing work sheets (to avoid duplicate entry, risk for transcription error, and loss of record and other issues). • Consider bedside computer charting. 	<ul style="list-style-type: none"> • Information from duplicate charts has been scanned into CPRS. Completed 9/22/07. • All duplicate “shadow” charts have been turned into medical records to be destroyed. Completed 9/22/07. • Nursing flow chart to be revised and approved by medical records (target 12/1/07). Once the flow chart has been approved, information will be scanned into CPRS daily. Establishing process/protocol to support this initiative. HIMS will assist in the process (target 1/31/08).

Location	Findings	Recommendation	Action
Infusion Clinic	Medication orders are handwritten and submitted to Pharmacy staff for CPRS entry (<i>additional shadow records are maintained in pharmacy</i>). Providers are not using Provider Order Entry in CPRS. Nursing/Pharmacy are completing electronic order entry,	<ul style="list-style-type: none"> • Pharmacy to stop electronic order entry effective immediately. • Complete POE (Provider Order Entry) according to facility MCM and discontinue nursing order entry. • Implementation of Intellidose program currently available at VISN facility – issues may require additional server to implement. • Elimination of shadow records (triplicate documents), and any new documents need to be scanned into CPRS. 	<ul style="list-style-type: none"> • Pharmacy discontinued electronic entry on 9/5/07. • 9/11-9/12/07 – APN educated on provider order entry. • Initial meeting with Intellidose on 10/11/07. Estimated timeline for program to be initiated on site is 6–9 months (target 5/30/08). • Pharmacy maintains a secured working copy (compounding chart) until completion of patient’s cycle. Will be scanned into CPRS once complete. Working copy will be destroyed within facilities guidelines and policies.
Infusion Clinic	Medication Reconciliation not occurring. (<i>Staff state they are “too busy” to complete this documentation.</i>)	<ul style="list-style-type: none"> • Re-educate Oncology staff, pharmacy, and administrative staff on process. • Evaluate staffing and scheduling patterns to determine proper utilization of appointment slots and effective staffing patterns. 	<ul style="list-style-type: none"> • Pharmacy staff assigned to Medication Reconciliation the week of 9/11/07. Will migrate back to providers at a later date.
Infusion Clinic	Provider privileges not readily accessible through N Drive folder to Oncology staff.	<ul style="list-style-type: none"> • Provide immediate access to folders for appropriate staff involved in procedures. 	<ul style="list-style-type: none"> • Provider credentials/ privileges available through supervisor upon request effective 11/7/07.

Location	Findings	Recommendation	Action
Infusion Clinic	Inconsistent on-site availability of providers during infusions.	<ul style="list-style-type: none"> Provider to be available during infusions (on site). 	<ul style="list-style-type: none"> Recruitment for one additional oncologist is in progress. Providers are available during infusion process. Providers make daily rounds on infusion patients. (effective 9/17/07)
Infusion Clinic	Multiple procedures in close proximity to each other increase risk to immune compromised patients – lack of space. <i>(For example: IV antibiotics – wound patients; BCG – active bacteria in same area as immune compromised patients.)</i>	<ul style="list-style-type: none"> Infectious Disease MD recommends the removal of BCG and Infectious patients from the infusion clinic. 	<ul style="list-style-type: none"> Antibiotic infusions to have initial dose in Infectious Disease clinic, and then the patients will be referred to home health infusion service (effective 9/15/07). Other non-infectious patients to receive IV medicines (ex: Prolastin) (effective 10/15/07).
Infusion Clinic	Lack of patient privacy during interview and treatment process.	<ul style="list-style-type: none"> Evaluate need for privacy barriers, other privacy options. 	<ul style="list-style-type: none"> Privacy curtains in use (effective 9/10/07). Extensions ordered the week of 9/4/07 and will be installed once they arrive on site (pending). Utilize other exam rooms for intake (effective 9/7/07).
Infusion Clinic	Potential competency issues for RN's assisting with multiple procedures (bone marrow, thyroid biopsy as an example).	<ul style="list-style-type: none"> Nurse Managers to review competency, establish standards if not in place, and document proficiencies on an annual basis. 	<ul style="list-style-type: none"> Competencies for all staff on up to date and on file. Reviewed by Pat Hess 9/7/07.

Location	Findings	Recommendation	Action
Infusion Clinic	Lack of consent form documentation in CPRS or Consolidated Record. <i>(Multiple consents related to procedures and other protocols are maintained in the research department. They are not part of the record, none are available in CPRS. It is not clear to staff where these should be kept or if these should be part of the infusion record. They cannot consistently speak to infusion and research consent requirements.)</i>	<ul style="list-style-type: none"> • Review research protocol requirements; provide a copy of the consent into CPRS. • Scan other consent form into initial CPRS infusion note for future reference. • Re-educate providers/nursing on the use of electronic IMED consent; placement of IMED consent forms at all infusion clinic CPUs. • Scan Research protocol consents into the CPRS for reference/trial participation. 	<ul style="list-style-type: none"> • 9/7/07 all IMED consent devices in place, providers and staff trained; additional CPU's added to infusion space with IMED consent capability available on at least one CPU. • 9/14/07 – request CAC to provide development and implementation of quick set orders. CBC quick set in place effective the week of 9/17/07.
Infusion Clinic	Unclear terminal cleaning protocol for BCG administration patients.	<ul style="list-style-type: none"> • Develop protocol to provide appropriate management of post-BCG administration. 	<ul style="list-style-type: none"> • BCG removed from infusion clinic – to Fee Basis.
Infusion Clinic	Medication management prone to errors due to nursing and pharmacy transcribing hand-written orders.	<ul style="list-style-type: none"> • POE entry of orders and elimination of hard-copy orders. 	<ul style="list-style-type: none"> • Under daily review for improvement. Currently considering protocol sheet.
Infusion Clinic	IV administration order verification process uncertain. <i>(Nursing is currently accepting IV infusions with the IV Bag "label" as confirmation that pharmacy has reviewed/checked order.)</i>	<ul style="list-style-type: none"> • Nursing staff to review pharmacy verification in CPRS medication order according to facility MCM. 	<ul style="list-style-type: none"> • Week of 9/11/07 established new consult process which provides electronic order validation to confirm medication doses to be administered.

Location	Findings	Recommendation	Action
Infusion Clinic	Staff cannot verbalize the process for patients taking their routine scheduled medications during their stay at the infusion clinic. Pharmacy states they have not been requested to participate in any self-medication issues.	<ul style="list-style-type: none"> • Implementation and adherence to facility MCM. • Improved coordination between nursing and pharmacy. 	<ul style="list-style-type: none"> • MCM – 11-05-22. Staff will be given a copy. Expected completion date: 11/29/07. Documentation will be on record indicating staff has received and reviewed policy.
Infusion Clinic	Blood transfusion issues include: <ul style="list-style-type: none"> • Provider is not always available during transfusion, per staff. • Cannot always contact on-call staff. • Time interval from ordering of blood products to administration time can occur in the same day, increasing the potential for errors. Staffs (both lab and nursing) feel rushed with this process. 	<ul style="list-style-type: none"> • Re-evaluate process, improved planning/scheduling of patients to allow adequate preparation time. • Initiate transfusions during morning clinic, with provider coverage always available. • Lab staff and MOFH pathologist to meet regarding use of blood product infusions in the outpatient setting. 	<ul style="list-style-type: none"> • Two meetings have taken place to re-evaluate the process (9/17 & 10/12/07) with Air Force. • Air Force currently implementing new policy – time line uncertain as of 11/7/7. • Nursing SOP completed and published in July 2007.
Infusion Clinic	Blood transfusion process issues: <ul style="list-style-type: none"> • Transfusion reaction management needs further review. • Staff not consistently reporting transfusion reactions to patient safety. 	<ul style="list-style-type: none"> • Review and revision of Blood Product Transfusion MCM. • Timely reporting of transfusion reactions according to facility MCM. 	<ul style="list-style-type: none"> • Air Force pathologist/ service reviewing administration protocol.
Infusion Clinic	Unapproved abbreviations identified in handwritten orders.	<ul style="list-style-type: none"> • Compliance with facility MCM. 	<ul style="list-style-type: none"> • Electronic consult in use, providers will be educated on appropriate abbreviation use.
Infusion Clinic	Verbal orders accepted by infusion clinic staff.	<ul style="list-style-type: none"> • No verbal orders are to be accepted, in accordance with facility MCM. 	<ul style="list-style-type: none"> • Practice stopped immediately on 9/4/7.

Location	Findings	Recommendation	Action
Infusion Clinic	BCG infusion orders not consistently provided <i>(some orders lacking components such as dose, route, or other required information).</i>	<ul style="list-style-type: none"> • Clarification on BCG protocol required. • Orders need ordered in accordance with facility MCM. 	<ul style="list-style-type: none"> • 9/11/07 – BCG was temporarily Fee Basis in local community. Evaluating other facility policies. Surgical Svs. currently handling BCG Fee-Basis consults.
Infusion Clinic	Lack of active MOA/MOU with community to deal with contingency episodes such as staffing shortages.	<ul style="list-style-type: none"> • Development of ongoing agreement with community oncology groups to manage urgent/continual contingencies related to unavailability of staff, facility closure (fire, damage) or other unforeseen circumstance. 	<ul style="list-style-type: none"> • AO for Medicine to develop MOA/MOU to provide action plan for unanticipated contingencies. (Dec–Feb estimated completion date)
Infusion Clinic	Pharmacy expressed concerns about scheduling practices that result in high census periods. This requires high-volume production of IV Infusion add-mixtures that can result in compressed time lines, increased potential for error, and waste when patients fail to show. <i>(Pharmacy prepares some infusions in advance of patient appointments, resulting in product lost if the patient does not show.)</i>	<ul style="list-style-type: none"> • Evaluation of scheduling practices and consideration of more equitable distribution of appointments to avoid “peaks” and “troughs” in demands. • Scheduling of “one-time” IV antibiotics in the afternoon infusion clinic and Chemotherapy infusion during AM clinic <i>(when provider access is provided)</i>. This allows advanced preparation of IV add-mix (other than Chemo) that can be retained for future use if patients cancel. 	<ul style="list-style-type: none"> • Fee Basis to local community continues as an “as needed” service. • One-time Antibiotics are now administered in the Infectious Disease Clinic then continue in outpt Fee Basis infusion clinics.

OIG Contact and Staff Acknowledgments

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

Daisy Arugay
John Tryboski, RN

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, Desert Pacific Healthcare Network (10N22)
Director, Southern Nevada VA Healthcare System (593/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate: John Ensign, Harry Reid
U.S. House of Representatives: Shelley Berkley, Dean Heller, Jon Porter

This report is available at <http://www.va.gov/oig/publications/reports-list.asp>.