Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Mismanagement of Resources and Patient Safety Issues
VA Northern Indiana Health Care System
Fort Wayne and Marion, Indiana

Report No. 09-02346-90 **March 2, 2010**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:
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Contents

Executive Summary

The VA Office of Inspector General, Office of Healthcare Inspections received allegations regarding mismanagement of resources and patient safety issues at the VA Northern Indiana Health Care System (the system) in Fort Wayne and Marion, Indiana. The purpose of the review was to determine whether the allegations had merit.

The complainant made the following allegations pertaining to: persistent instrumentation problems with Operating Room (OR) sets and peel packages; ongoing reusable medical equipment issues; Supply, Processing, and Distribution (SPD) stocking and dating of supplies; pharmacy stocking of Operating Room, Post Anesthesia Care Unit, Endoscopy Unit (OR, PACU, EU) medications; and management issues.

We substantiated the allegation that OR sets and peel packages continue returning from the Marion campus' SPD incorrectly as previously noted by a number of external reviewers. We substantiated the allegation that SPD technicians were unable to identify instruments, and pictures of instruments to assemble instrument sets, as previously recommended, would have been helpful.

We did not substantiate that two new HQ180AL model endoscopes were damaged by improper handling. We were unable to substantiate or refute the allegation that leak testing was not consistently done on the B-K 8800 rectal probe. We did not substantiate that endoscopic procedures must be conducted in the small OR because the air handling system in the larger ORs cannot pass inspections.

We did not substantiate the allegation that assigned OR, PACU, EU supply technician was reassigned numerous times to cover the entire hospital so no one administered Integrated Funds Control Point Activity, Accounting and Procurement labels and routinely monitored for outdated supplies.

We substantiated the allegation that an ankle fusion procedure, which required an implant, was canceled and rescheduled three times, however we did not find that cancellations were all related to the system's inability to provide the implant and instrumentation sets.

We were unable to substantiate or refute the allegation that pharmacy technicians remove expired medications and don't always replace them. We substantiated the allegation that specific medication was ordered but not present 7 days later so pharmacy borrowed the medication from a local hospital. We were unable to substantiate or refute the allegation that outdated medication was found on an anesthesia medication cart because we could not rule out that expired medications were found during the system's internal inspections. We did not substantiate the allegation that Sodasorb® for the anesthesia machine was expired, resulting in the delay of a surgical case.

We substantiated the allegation that the OR, PACU, EU nurse manager is responsible for providing coverage in other areas of the hospital and is unavailable to guide staff.

We found other quality of care issues with the Fort Wayne Campus' environment and maintenance that needed to be addressed.

We recommended that the Veterans Integrated Service Network Director ensure that the Acting System Director correct OR and SPD instrumentation problems, take action to ensure that all SPD supplies and equipment are properly managed and ready for patient care as required by Veterans Health Administration policy, review the OR, PACU, EU nurse manager supervisory roles and responsibilities to ensure they are appropriate, and require that identified environmental and maintenance concerns be addressed.

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

TO: Director, Veterans In Partnership (10N11)

SUBJECT: Healthcare Inspection – Alleged Mismanagement of Resources and Patient Safety Issues, VA Northern Indiana Health Care System, Fort Wayne and Marion, Indiana

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections received allegations regarding mismanagement of resources and patient safety issues at the VA Northern Indiana Health Care System (the system) in Fort Wayne and Marion, IN. The purpose of the inspection was to determine the validity of the allegations.

Background

Located in Fort Wayne and Marion, IN, the system is part of Veterans Integrated Service Network (VISN) 11. The Fort Wayne facility provides inpatient medical and surgical care and has an Intensive Care Unit (ICU). The Marion facility provides chronic and acute psychiatric care and long term 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. The system has 22 medical/surgical and 4 ICU beds, 75 acute psychiatry beds, and 150 community living center beds. Outpatient care is provided at three community based outpatient clinics in South Bend, Muncie, and Goshen, Indiana. The system serves a veteran population of about 85,000 throughout 26 counties in Indiana and 3 counties in Ohio.

The complainant made the following allegations:

1. Instrumentation problems persist with operating room (OR) sets and peel packages.

   (a) Sterile sets and peel packages are returning from the Marion Supply, Processing, and Distribution (SPD) incorrectly in the following manner: damaged, single packed instruments when a set is required, two of the same size items when different sizes are required, and sets contain multiple instruments that have been identified as needing replacement or repair.

(b) Staff are unable to identify instruments.

2. Ongoing reusable medical equipment (RME) issues.

   (a) Two new HQ180AL[1] endoscopes were damaged by improper handling.

   (b) Leak testing[2] was not consistently done on the B-K 8800 rectal probe[3] prior to being placed in the STERIS SYSTEM 1®.[4]

   (c) Endoscopic procedures are conducted in the small OR because air handling systems in the larger ORs cannot pass inspections.

3. SPD stocking and dating of supplies.

   (a) Assigned OR, Post Anesthesia Care Unit (PACU), Endoscopy Unit (EU) supply technician was reassigned numerous times to cover the entire hospital so no one administered Integrated Funds Control Point Activity, Accounting and Procurement[5] (IFCAP) labels and routinely monitored for outdated supplies.

   (b) An ankle fusion procedure, which required an implant, was canceled and rescheduled three times.

4. Pharmacy stocking of OR, PACU, EU medications.

   (a) Pharmacy technicians removed expired medications and don't always return them.

   (b) Specific medication was ordered but not present 7 days later so Pharmacy borrowed the medication from a local hospital.

   (c) Outdated medication was found on an anesthesia medication cart.

   (d) Sodasorb®[6] for the anesthesia machine was expired, resulting in the delay of a surgical case.

5. Management issues. The OR, PACU, EU nurse manager is responsible for providing coverage in other areas of the hospital and is unavailable to guide staff.

[1] Scope model number identified by the complainant to describe a specific endoscope.
[2] The determination of any openings in the external surfaces and internal channels that would permit fluid to enter the internal body of the endoscope.
[3] Device used to perform prostate biopsies.
[4] A brand name for a low temperature sterile processing system for immersible surgical and diagnostic devices.
[5] VA database system used to manage the receipt, distribution, and stock maintenance of items received from the supply warehouse and/or outside vendor.
[6] An absorbent that removes carbon dioxide safely from anesthesia systems during surgery.

Instrumentation problems, sterilization issues, and SPD process issues have been noted by a number of external reviewers over the last 3 years. On September 4–6, 2007, Veterans Health Administration's (VHA) SPD Executive Manager conducted a site visit at the system. They identified problems with instrument sets, the transportation of supplies and instruments between the two campuses, sterilization records, outdated supplies, and staff competencies.

A General Surgery Service external site visit was conducted by a physician and registered nurse (RN) October 11–12, 2007. The report cited numerous issues including a lack of surgery-specific instruments and sutures, and incorrect instruments within sets. In mid-October 2007, the System Director "halted" complex abdominal and major surgeries, including colon and gall bladder surgeries, pending review of their surgical program and to allow time for rebuilding the surgery program.

VHA's Office of the Medical Inspector conducted a quality of care review at the system on December 5–7, 2007. They also noted problems with instrument sets and challenges in sterilization due to the transporting of instruments between the two campuses.

A National Surgical Quality Improvement Program (NSQIP) site visit was conducted March 4–5, 2008. The review team noted that sterile packs received in the OR varied daily and often did not include the required instruments. Additionally, the team noted challenges in having surgical activities at one campus and the main SPD sterilization activities located at the other. On May 27, 2008, an external review team recommended that managers develop Standard Operating Procedures (SOPs) regarding outdated supplies; establish quality management tools to track instrument set accuracy, supply availability, and sterilization; and develop plans for routine instrument set maintenance.

On June 3–4, 2009, another site visit was conducted by a VISN 11 team as part of an ongoing initiative to ensure the safety of veteran patients. The purpose of the visit was to review how the system processed and cleaned all types and models of scopes. During the Marion campus visit, the team noted inadequate measuring of solution used for cleaning scopes, a lack of preventive maintenance (PM) labels on equipment, and a lack of training/competency records for a new employee who conducted sterilization. During the Fort Wayne campus visit, the team noted that some equipment lacked PM labels, there was a lack of training/competency records for employees, and that there were no biomedical engineering safety stickers on equipment.

October 5–9, 2009, VISN 11 Director initiated a training enhancement period for system staff. In preparation, 86 patients with scheduled surgical procedures were notified of rescheduling, or in cases where the procedures were urgent, referrals to fee basis providers were made. Focus for the training included assessment of compliance with previously established action plans, developing and teaching OR supply procedures and practices, and assessing training for specific surgical supply management.

November 3, 2009, the System Director retired, and effective November 9, an Acting System Director was appointed.

Scope and Methodology

We conducted an onsite visit July 28–31, 2009, which included both Fort Wayne and Marion campuses, and interviewed the complainant, system senior managers, and other clinical and administrative staff who were knowledgeable about the allegations. We reviewed pertinent documents to include VHA and system policies and procedures, The Joint Commission (JC) standards, and selected administrative and management documents related to the allegations. We requested and reviewed SPD reprocessing methods used throughout VHA's medical facilities. We monitored and followed up on the most recent system and VISN 11 changes and developments involving management actions to improve the quality of care for patients from the onsite visit through December 2, 2009.

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

Inspection Results

Issue 1: Instrumentation Problems Persist with OR Sets and Peel Packages.

Complaint (a): ***Sets and peel packages are still returning from the Marion SPD incorrectly.***

We substantiated the allegation. The system has a history of instrumentation problems that have been noted by a number of external reviewers. Our inspection revealed that these problems have not been resolved. OR staff provided us with a log of instrument count sheets used to document problems for calendar years (CY) 2008 and 2009–July 9. The table below summarizes the types of problems and number of occurrences.

	Instrument damaged and needs to be replaced	Instrument needs to be sharpened or repaired	Improper sterilization (i.e., metal to metal, tape or tags not removed)	Wrong instrument in case/set	Instrument missing from set	Set contaminated by compromised wrapping or debris on instrument(s)
CY 2008	**13**	**10**	**6**	**7**	**4**	**21**
CY 2009 – July 9	**14**	**5**	**3**	**9**	**16**	**4**

Managers had not taken appropriate actions to address ongoing instrument problems. Some of these issues caused patient surgical delays, cancellations, and other problems.

Complaint (b): ***Staff are unable to identify instruments.***

We substantiated the allegation. During the September 4–6, 2007, site visit, VHA's SPD Executive Manager recommended staff training on instrument identification and that pictures be taken of each instrument and instrument set to aid SPD staff in putting the sets together. This need was also cited during the March 2008 NSQIP site visit. SPD technicians reported that instrument training was completed. However, pictures had not been taken, and SPD technicians acknowledged that this would be helpful in recognition of instruments and assembly of instrument sets.

Issue 2: Ongoing Reusable Medical Equipment Issues.

Complaint (a): ***Two new HQ180AL scopes were damaged by improper handling.***

We did not substantiate the allegation. The complainant alleged that two HQ180AL (model number) endoscopes were damaged. However, the system does not have any endoscopes of that model. The system has in inventory eight CF H180AL colonoscopes, five PCF H180AL colonoscopes, and eight GIF H180AL gastroscopes. We requested repair records and associated costs for all scopes sent for repair during the 12 months prior to our inspection. Four of the colonoscopes were sent for repair. Of these, one colonoscope required two separate repairs, and three colonoscopes required one repair each. None of the gastroscopes required repair during that timeframe.

Providers told us that the system's scopes were of high quality. They also stated that scope repairs are to be expected, proportionate to high-volume usage and the rigorous cleaning process. None of the providers or nursing staff interviewed had concerns or were aware of any complaints regarding improper handling of scopes.

We inspected the room where scopes are stored prior to use, and noted that employees followed manufacturer recommendations for scope storage. Employees properly demonstrated scope handling, and they correctly articulated how scopes are managed during the cleaning process. On March 9, 2009, the endoscope manufacturer representative was onsite to conduct in-service training including pre-cleaning, leak testing, manual cleaning, automated endoscope reprocessor high-level disinfection, manual high-level disinfection, rinsing, alcohol flush, and endoscope storage. Staff competency was assessed and verified for employees responsible for endoscope reprocessing.

Complaint (b): ***Leak testing was not consistently done on the B-K 8800 rectal probe prior to being placed in the STERIS SYSTEM 1.***

We were unable to substantiate or refute the allegation because we could not be certain that leak testing was always done before placement in the STERIS SYSTEM 1.

Like other endoscopes, the B-K 8800 rectal probe is categorized as RME. All RME must be checked regularly to maintain a high level of safety, and proper pre-cleaning is essential for the success of any disinfection or sterilization process. Providers told us that once a biopsy is completed in the OR, the rectal probe is wiped down with a disinfectant and then sent to SPD for further reprocessing. We inspected the SPD department and reviewed competency records for staff responsible for RME cleaning and disinfection. Leak testing supplies were available in the department, and competency records indicated that staff had been appropriately trained on reprocessing RME, which includes leak testing.

Complaint (c): ***Endoscopic procedures must be conducted in the small OR because the air handling system in the larger ORs cannot pass inspections.***

We did not substantiate the allegation. We inspected the EU and ORs at the Fort Wayne campus. Staff were conducting endoscopic procedures in the small OR, room 307, because one of the two endoscopy procedure rooms, room 368, was under construction. The nurse manager did not report air handling concerns with the EU or the OR. In addition, we reviewed OR air handling records and found conditions to be within normal ranges for air conditioning and ventilation. Unlike ORs, endoscopy procedure rooms do not require a dedicated air handling unit. Heating, ventilation, and air conditioning in endoscopy procedure rooms can be maintained similar to examination rooms.[7]

During our July 30 inspection, an endoscopic procedure was in progress in room 366, while the second endoscopy procedure room, room 368, remained unused. The OR staff reported that room 368 was not ready for use because construction had not been completed. Engineering staff told us that construction for room 368 began on July 26, 2008, and was completed on July 9, 2009. OR staff requested installation of a different lighting system for room 368, and, therefore, elected to continue to perform endoscopic procedures in room 366 until the new lighting system was installed.

Issue 3: SPD Stocking and Dating of Supplies.

Complaint (a): ***Assigned OR, PACU, EU Supply Technician was reassigned numerous times to cover the entire hospital so no one administered IFCAP labels and routinely monitored for outdated supplies.***

[7] Department of Veterans Affairs, Office of Facilities Management, Strategic Management Office, Facilities Quality Service.

We did not substantiate the allegation. While the SPD staff assigned to the OR, PACU, and EU covered additional clinical areas, we did not find missing IFCAP labels during our inspection of those clinical areas. In addition, we did not find any expired disposable supplies.

However, at the Fort Wayne SPD, we found sterile gloves without expiration dates on the packages. The SPD supervisor and technicians told us that there was a coded "expiration date sheet" which would show the date of expiration for each item; however, the supervisor could not provide us with this document. Staff in all clinical areas must ensure the integrity of products and that items are not used beyond the expiration dates.

Complaint (b): ***An ankle fusion procedure, which required an implant, was canceled and rescheduled three times.***

We substantiated the allegation. However, we did not find that cancellations were all related to the system's inability to provide the implant and instrumentation sets.

A patient was scheduled for an ankle fusion in Same Day Surgery (SDS) on January 23, 2009. This surgery was canceled and rescheduled for February 13 because the patient developed acute left hand and wrist gout.

On February 6, the patient was seen in SDS nursing pre-operative instructions clinic; and on February 11, he was seen by his podiatrist to obtain consent for surgery. The podiatrist informed the patient that the screw set that had been ordered had not yet arrived and that the patient would be notified whether the surgery would take place as scheduled. After seeing his podiatrist, the patient went to walk-in triage clinic and complained of pain in his left wrist. An RN documented that the patient's left wrist and hand were reddened, swollen, and painful to touch. The patient was treated in the Emergency Department and the surgery that was rescheduled for February 13 was canceled and rescheduled again for February 20.

On February 19, the podiatrist documented that the February 20 surgery was canceled "because SPD failed to process the implants in a timely manner despite repeated notifications." Documentation notes that the podiatrist "declined to set up another surgery time" and that the patient would be referred to fee basis.[8] A fee basis consult was written the following day.

On April 9, the podiatrist documented that the patient called and stated that the fee basis physician "declined to do surgery" and said that he needed a leg brace. That same day the podiatrist entered a consult for a "brace double upright for left shoe" as recommended by the fee basis physician. On June 30, the patient was seen by his primary care provider

[8]Program designed to assist veterans who cannot easily receive care at a VA Medical Center.

who documented: "Has had problems with left ankle, now wearing steel ankle brace which seems to be helping. Able to walk much better."

Issue 4: Pharmacy Stocking of OR, PACU, EU Medications.

Complaint (a): ***Pharmacy Technicians remove expired medications and don't always replace them.***

We were unable to substantiate or refute the allegation. The complainant explained that expired medications are removed from service and not replaced. The complainant reported an incident where eye ointment was required for a surgical case and none was available. Four expired eye ointments were removed and not replenished, leaving none for patient surgeries. Staff we interviewed could not identify any specific expired medications or instances where medications were not replenished. We reviewed the Surgical and Anesthesia Care Committee minutes, and this issue was not identified as being problematic.

Complaint (b): ***Specific medication was ordered but not present 7 days later so Pharmacy borrowed the medication from a local hospital.***

We substantiated the allegation. The Chief of Pharmacy indicated that it is a common practice to borrow or purchase medications from the community hospital if a medication is placed on backorder. We were told this process is supported by system policy but the Chief of Pharmacy could not recall the name or specific details of the policy.

Complaint (c): ***Outdated medication was found on an anesthesia medication cart.***

We were unable to substantiate or refute the allegation because we could not rule out that expired medications were found during the system's internal inspections. During our inspection of the OR and anesthesia carts, we did not find expired medications. Managers were not aware of any problems with expired medications. We reviewed the Employee and Patient Safety Committee/Environment of Care Board meeting minutes from October 2008–June 2009, and this issue was not identified as being problematic.

Complaint (d): ***Sodasorb for the anesthesia machine was expired, resulting in the delay of a surgical case.***

We did not substantiate the allegation. We did not find expired Sodasorb during our inspection. Managers were unaware of any surgical case that was delayed due to problems with this product. We reviewed the surgical delay schedule and did not find documentation to support this allegation.

Issue 5: Management Issues.

Complaint: ***OR, PACU, EU Nurse Manager is responsible for providing coverage in other areas of the hospital and is unavailable to guide staff.***

We substantiated the allegation. The complainant stated that the former nurse manager during the 2007 external review was covering SDS; OR; PACU; EU; eye clinic; ear, nose, and throat clinic; and surgery clinic. In a subsequent General Surgery Service site visit, it was also noted that the nurse manager continued managing multiple tasks and responsibilities outside of the OR and was unable to provide appropriate support to the OR activities. Both teams recommended a review of the nurse manager's roles and responsibilities. On May 27, 2008, during a follow-up General Surgery Service review, the team noted that a new OR manager had been hired and this led to "significant improvement." Additional external reviews conducted after the May 27 review, have not cited nurse manager coverage issues in their reports.

We interviewed the nurse manager and the Associate Director for Patient Care Services who described the OR nurse manager duties to include coverage of the OR, PACU, SDS, EU, and podiatry. The OR nurse manager reported having 18 employees under her direction. The OR nurse manager was required to cover "once in awhile" for other inpatient areas such as the ICU and the medicine unit. The Fort Wayne campus filled a nurse manager vacancy; therefore, assignment to cover other areas has been minimal "during the last couple months."

Staff interviewed had differing opinions regarding the nurse manager's availability. All of them acknowledged that the manager has multiple units to cover and is also unavailable at times due to other administrative assignments and meetings.

Issue 6: Other Quality of Care Concerns Identified.

Environmental and Maintenance Concerns Identified at the Fort Wayne Campus.

We inspected the OR, PACU, EU, and SPD areas at both campuses. We also inspected the truck used to transport sterile and soiled instruments between the campuses.

VHA and the JC have established guidelines regarding maintenance of the environment in VA medical facilities, particularly related to infection control, safety, and sanitation. Additionally, medical centers must take action to ensure that areas requiring high levels of sanitation, such as the OR and SPD, are appropriately maintained. During inspections at the Fort Wayne campus, we noted stained or damaged ceiling tiles in the anesthesia area (room 314), in the endoscopy procedure room (room 368), and in the EU storage area (room 369).

In the Fort Wayne SPD, we found holes, penetrations, and cracks in the ceiling and walls in the clean room. There were holes in the wall surrounding the area where pipes

inserted in both the upper and lower areas of the cement wall. There was peeling paint over the field where endoscopes were reprocessed. A water leak was found under the cabinet for the STERIS SYSTEM 1, and the STERIS SYSTEM 1 filters were in standing water. The SPD supervisor and technician had been aware of the water leak but thought the issue was resolved. The leak had been fixed 2 days prior to our inspection, but water remained. The light banks were not flush with the ceiling, and visible cracks and peeling paint were noted. Air vents in the SPD were stained and unclean. There was an open drain in the floor with a grate ajar that appeared dirty and rusty.

Instruments and flexible endoscopes that require sterilization are processed at the Marion campus. Surgery and endoscopic procedures are performed on the Fort Wayne campus. An enclosed truck is used to transport sterile and non-sterile items in case carts between the two campuses. An inspection of the truck was conducted at the Fort Wayne location. We noted an accumulation of debris on the grooved floor surface of the truck. The truck's interior compartment door had oil and dirt on its surfaces.

The truck was refrigerated; however, the driver was unable to articulate how temperature and humidity controls were maintained. The driver stated that the truck is cleaned weekly on Fridays and is spot cleaned as needed. The truck was not cleaned between trips from one campus to the other. This included the transport of non-sterile items, followed by the transport of sterile items. Sterile instrument pans inside the case carts did not have any additional dust or moisture protection such as plastic wrap.

Conclusions

There are continued surgical program issues related to the overall lack of an appropriately managed and safe infrastructure relative to the delivery of patient care in the OR. Extensive reviews conducted by VHA's own independent reviewers show that ongoing issues that negatively affected the quality of care for patients have not been corrected. The numerous recommendations, action plans, and staff efforts to ensure a safe environment were not fully implemented or followed up as required. Attempts to resolve SPD issues to support operative services and provisions for safe patient care are lacking. Management's oversight and abilities to recognize and to follow up on issues were not effective. Substandard environmental conditions and system maintenance problems must be corrected in order to provide safe patient care.

The VISN Director effected several personnel changes as a result of the concerns regarding surgical services at the system and reported that personnel actions would be accomplished in accordance with Federal requirements. Management continues to follow up and correct prior recommendations from external reviews as well as their own most recent internal reviews.

Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Acting System Director correct OR and SPD instrumentation problems.

Recommendation 2. We recommended that the VISN Director ensure that the Acting System Director takes action to ensure that all SPD supplies and equipment are properly managed and ready for patient care as required by VHA policy.

Recommendation 3. We recommended that the VISN Director require the Acting System Director to review the OR, PACU, EU nurse manager supervisory roles and responsibilities to ensure they are appropriate.

Recommendation 4. We recommended that the VISN Director ensure that the Acting System Director requires that identified environmental and maintenance concerns be addressed.

Comments

The VISN and Acting System Directors concurred with the findings and recommendations of this inspection and provided acceptable improvement plans (see Appendixes A and B, pages 12–17, for the full text of the Directors' comments). We will follow up on the planned actions until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: February 10, 2010

From: Director, Veterans In Partnership Network (10N11)

Subject: **Response to Draft Report – Healthcare Inspection – Alleged Mismanagement of Resources and Patient Safety Issues, VA Northern Indiana Health Care System, Fort Wayne and Marion, Indiana**

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

Thru: Director, Management Review Service (10B5)

Per your request, attached is the response from VA Northern Indiana Health Care System. If you have any questions, please contact James Rice, VISN 11 QMO, at (734) 222-4314.

Michael S. Finegan

Attachment

Appendix B

Acting System Director Comments

Department of Veterans Affairs **Memorandum**

Date: February 10, 2010

From: Acting Director, VA Northern Indiana Health Care System (610A4/00)

Subject: **Response to Draft Report – Healthcare Inspection – Alleged Mismanagement of Resources and Patient Safety Issues, VA Northern Indiana Health Care System, Fort Wayne and Marion, Indiana**

To: Director, Veterans In Partnership Network (10N11)

Per your request, attached is the response from VA Northern Indiana Health Care System. If you have any questions, please contact Kimberly L. Radant at 260-426-5431, extension 71504.

Kimberly L. Radant

Kimberly L. Radant, MS, RN

Attachment

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

The following Acting 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 VISN Director ensure that the Acting System Director correct OR and SPD instrumentation problems.

Concur **Target Completion Date: Closed**
Exception: Instrument Picture Target – April 1, 2010

VISN and VA Northern Indiana Health Care System (VANIHCS) staff has reviewed numerous instrument sets on a recurring basis since issues were identified. OR and SPD staff have collaborated to determine the appropriate contents in sets and basins, cups have been removed, and count sheets are being updated. Staff education has been completed regarding the proper assembly of instrument sets. A "just-in-time" communication system has been set up to identify and correct any issues that occur with instrument sets.

Multiple instrument sets have been processed through "test" runs. An interdisciplinary review of instruments sets indicates they are looking clean, and instances of minor water spotting are rare. No linen, debris, or other particulate matter has been observed.

Staff in SPD has begun to send all instrumentation that is damaged or in need of repair to Bio-Medical Engineering. Bio-Medical Engineering repairs or recommends replacement of the instrumentation as needed. Bio-Medical Engineering is also a full participant in the newly developed communication processes.

Staff has removed all known tape from instrumentation. Any remaining sterilized sets in remote areas that may contain tape will be immediately returned to SPD for tape removal and reprocessing.

SPD is in the process of obtaining pictures of the instrument sets to assist staff in assembly of surgical sets. Education is ongoing to help staff identify instrumentation. Approximately 40 percent of the instrument sets

have pictures associated with them. This portion of the recommendation will be completed by April 1, 2010.

SPD is in the process of developing a written Instrument Set Count Sheet procedure. This procedure will require all clinical areas receiving instrumentation from SPD to mandatorily fill out the count sheet and return it to SPD with any concerns or issues noted. This, in conjunction with the "just-in-time" communication chain, should provide improved communication and tracking of issues. The count sheet program will be incorporated in the SPD Performance Improvement Program and trends discussed at the SPD Interdisciplinary Committee.

While actions have been taken to correct OR/SPD issues, monitoring for compliance and sustainability of corrective actions must continue.

Recommendation 2. We recommended that the VISN Director ensure that the Acting System Director takes action to ensure that all SPD supplies and equipment are properly managed and ready for patient care as required by VHA policy.

Concur **Target Completion Date: March 15, 2010**

SPD and Logistics has worked diligently to re-initiate proper generic inventory package (GIP) and revamp the IFCAP labeling system at both campuses. The goal is to have GIP fully implemented March 1, 2010. Reset of primaries at both campuses is complete. Bar code labels and data cleanup is in progress. Levels in Fort Wayne primary have been set. Work is progressing to secondary closets. Purchasing and posting of stock processes have been reviewed and improvement initiated.

Facility outdate policy is complete and signed. The facility is still finding occasional outdated items, and this information is shared with staff and addressed on a "just-in-time" basis. This has improved since last fall. We continue to conduct regular outdate rounds, and we anticipate the rebuild of GIP will assist in the effort of reducing and removal of outdated items. An education module in Learning Management System has been assigned to all identified staff requiring knowledge to complete outdates of supplies. Over 59 percent of the staff has completed this module, with an expected completion of remaining staff by March 15, 2010.

VANIHCS SPD has posted the expiration data sheet for gloves and catheters in all areas where these items are stocked to assist with outdating. These specifically are items that do not have a clear expiration date on the packaging but rather have a shelf life determined by manufacturer

guidance. During Environment of Care (EOC) rounds, staff members completing rounds are required to assess supplies and check for outdated items.

It is anticipated that OR morning report and OR/SPD communication chain will prevent any episodes where a procedure is cancelled because the instruments for the procedure were not sterilized or available in advance of the procedure.

Recommendation 3. We recommended that the VISN Director require the Acting System Director to review the OR, PACU, EU nurse manager supervisory roles and responsibilities to ensure they are appropriate.

Concur **Target Completion Date: Closed**

The Associate Director for Patient Care Services has determined the OR nurse manager will not be responsible to routinely cover other units in the absence of the nurse manager. This ensures the OR nurse manager is able to assist OR staff members as issues arise. The OR nurse manager is the direct supervisor for 20 staff members. The Acting Director has noted that the OR staff is acutely aware of and concerned any time anyone is detailed from the OR or when other duties are assigned to staff within the OR. Efforts will be made to utilize the communication chain to discuss such concerns and promote understanding and flexibility as workload demands fluctuate and require the adjusting of assignments, not just of the OR supervisor, but of the OR nursing staff as well.

Recommendation 4. We recommended that the VISN Director ensure that the Acting System Director requires that identified environmental and maintenance concerns be addressed.

Concur **Target Completion Date: Closed**

On July 31, 2009, all stained and damaged ceiling tiles were replaced. All holes and cracks in walls and ceilings of the clean room in SPD were repaired, and all signs of peeling paint were removed. Engineering repaired the leak below the STERIS SYSTEM 1, and there is no further evidence of water. These repairs and replacements in the SPD area were validated by the VISN during a visit August 5, 2009, and during subsequent EOC rounds by the VANIHCS staff. Environmental Management Service cleans this area on a daily basis. Cleaning schedules for SPD staff have been developed for both campuses.

VANIHCS developed an SPD Transport Truck SOP for the decontamination of the vehicle. This SOP was developed with the assistance of Infection Control and Safety. The SPD transport truck is decontaminated by wiping the inside walls, ceiling, and floor with enzymatic cleaner after each trip. Weekly, the truck is taken off post to be power washed. This is in compliance with the SPD Transport Truck SOP. Appropriate staff members have been educated, and their competency has been validated.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Verena Briley-Hudson, MN, RN Director, Chicago Office of Healthcare Inspections (708) 202-2672
Acknowledgments	Lisa Barnes, MSW, Team Leader Judy Brown, Program Assistant Paula Chapman, CTRS Reba Ransom, RN, MSN Roberta Thompson, MSW Ann Ver Linden, RN

Appendix D

Report Distribution

VA Distribution

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Director, VA Northern Indiana Health Care System (610A4/00)

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