



Interim Summary Report

April 12, 2017

On March 21, 2017, a confidential complainant forwarded to the Office of Inspector General (OIG) documents describing equipment and supply issues at the Washington D.C. VA Medical Center (the Medical Center) sufficient to potentially compromise patient safety. OIG promptly reviewed the documentation.

On March 29, 2017, OIG deployed a Rapid Response Team to assess the allegations. OIG's team conducted interviews, collected documents, and conducted a physical inspection of the Medical Center's satellite storage areas on March 29–30, 2017. The team returned for an additional site visit on April 4–6, 2017, and is on-site for a third inspection at the time of this report's publication.

OIG has preliminarily identified a number of serious and troubling deficiencies at the Medical Center that place patients at unnecessary risk. Although we have not identified at this time any adverse patient outcomes, we found that:

- there was no effective inventory system for managing the availability of medical equipment and supplies used for patient care;
- there was no effective system to ensure that supplies and equipment that were subject to patient safety recalls were not used on patients;
- 18 of the 25 sterile satellite storage areas for supplies were dirty;
- over \$150 million in equipment or supplies had not been inventoried in the past year and therefore had not been accounted for;
- a large warehouse stocked full of non-inventoried equipment, materials and supplies has a lease expiring on April 30, 2017, with no effective plan to move the contents of the warehouse by that date; and
- there are numerous and critical open senior staff positions that will make prompt remediation of these issues very challenging.

At least some of these issues have been known to the Veterans Health Administration (VHA) senior management for some time without effective remediation.

Although our work is continuing, we believed it appropriate to publish this Interim Summary Report given the exigent nature of the issues we have preliminarily identified and the lack of confidence in VHA adequately and timely fixing the root causes of these issues. We are also including recommendations for immediate implementation.

The Medical Center Placed Patients at Unnecessary Risk

The Medical Center placed patients at unnecessary risk by failing to ensure that appropriate medical supplies and equipment were available to providers when needed; that recalled supplies or equipment were not used on patients; and that sterile supplies were stored appropriately.

Supply Shortages and Inventory Management Practices

The Generic Inventory Package (GIP) is the authorized software program used by VA medical facilities to manage the receipt, distribution, and maintenance of supplies. On May 6, 2015, the Medical Center became one of several pilot sites for a new type of inventory system called Catamaran that was implemented by a vendor under contract. Medical Center staff informed the OIG that the Catamaran system was never relied upon at the DC Medical Center. This is corroborated by May 25, 2015 project implementation meeting minutes from the VA Central Office indicating that just a few weeks after initial installation the system was not working in DC. Meeting minutes from the January 13, 2016 Catamaran Project Governance Meeting indicate that the DC Medical Center “appeared to be making no effort to use the [Catamaran] system. . . .” Ultimately, VA did not renew the contract with Catamaran.

From January 24 through January 26, 2017, and prior to OIG receiving these allegations, the VHA Procurement and Logistics Office, Policy, Assistance, and Quality (PAQ) branch, conducted a review of inventory management at the Medical Center. PAQ determined that there was “no VA approved Inventory Management System in place.” At that time, PAQ identified stock outages and infection control issues in multiple clinical supply areas.

Then, on March 21, 2017, the Deputy Under Secretary for Health for Operations and Management directed the Director of the Veterans Integrated Service Network (VISN) 5 and the Medical Center Director to provide a corrective action plan addressing these concerns. When OIG staff arrived at the Medical Center on March 29, 2017, the VISN Chief Logistics Officer and a Chief of Logistics from another facility had been temporarily assigned to the Medical Center to assist in correcting the deficiencies.

However, the OIG received documentation of, or directly observed, the following recent events:

- At the time of our site visit, the Medical Center was in the process of conducting a patient safety review because sterile processing ran out of supplies to test the insulation of scopes used in laparoscopic or endoscopic procedures. This testing is used to detect holes in the insulation surrounding the scopes that may result in the transmission of electrical current into surrounding tissues. If this occurs, patients may develop burns or latent infections. The Medical Center could not verify whether this testing had been done on scopes used in approximately 20 procedures since February 28, 2017-March 16, 2017.

- As recently as March 15, 2017, the Medical Center ran out of bloodlines for dialysis patients on the second shift—they were able to provide dialysis services to those patients only because staff borrowed bloodlines from a private hospital.
- On March 29, a nurse emailed the patient safety manager, reporting that during an acute episode, she needed to provide oxygen to a patient. The floor was out of oxygen nasal cannulas (tubing that fits into a patient’s nose and provides oxygen). The nurse was able to use one found on the crash cart, but reported the shortage as a risk to patient safety.
- On March 29, a vendor loaned bone cements to cover two total knee replacements for surgeries scheduled that week. Operating room staff requested that prosthetics purchase the bone cement, but was told the company could not deliver it until the next week.
- On March 30, the dialysis unit ran out of dialyzer bloodlines and 15 gauge fistula needles, both of which are essential for dialysis treatments.
- On April 4, OIG staff inspected the storeroom on the floor that had run out of the oxygen nasal cannulas. Between 11 a.m. and noon, OIG staff determined the storeroom was out of alcohol pads; slipper socks/aqua shoes; denture cups (plastic containers used to store patients’ dentures); and large tegaderms, a type of wound dressing. OIG was informed that nursing staff inventoried the rooms three times a day, and sent requests to logistics to replenish stock as needed. However, when OIG staff returned after 6 p.m. on the same day, only the alcohol pads had been replenished.
- On April 5, the lead sterile processing technician had been tasked with finding a clip applier for use in a procedure scheduled to occur the next day. A clip applier is a device that deploys surgical clips that may be used to close off blood vessels or other tubular structures. OIG staff accompanied the technician as she searched for the device in the sterile processing department and in the central supply room. Despite having the purchase order number for the device, she was unable to find it.
- On April 11, OIG received an email stating that the operating room (OR) ran out of vascular patches, despite having requested the assistance of the Deputy Chief Medical Officer of VISN 5 in obtaining them two weeks ago. The OR also ran out of Doppler probes. Nursing staff stated that the ORs could not form emergent or elective open vascular surgery without those in stock.
- On April 11, OIG received an email stating that the OR ran out of sequential compression devices (SCDs). These are devices placed on patients’ legs to prevent blood clots during surgery. Surgery proceeded without the devices.

The OIG further determined that supply issues had persisted for some time. The following are examples of situations in which patient care was compromised as a result of the failure to maintain appropriate equipment or supplies within the Medical Center:

- Since January 1, 2014, the Medical Center has recorded 194 patient safety reports relating to the unavailability of equipment or supplies.

- In February 2016, a Stryker bone tray used in surgeries to repair mandibular (jaw) fractures had been removed from the facility due to outstanding invoices from the vendor. Surgical staff informed us that a procedure had to be delayed as a result.
- Four prostate biopsy surgical procedures were canceled on April 25, 2016 because prostate biopsy guns were out of stock. A nurse wrote an email to the medical center director on April 26, 2016 recommending an OR “stand down” until the operating room’s inventory situation could be remedied.
- In June 2016, the Medical Center discovered that one of its surgeons used expired surgical equipment on a patient during a surgical procedure. The Medical Center determined that the lack of an inventory management program caused the error. Rather than undertake measures to implement an appropriate inventory program, the Medical Center elected to require its nursing staff to conduct monthly rounds to identify and remove any expired supplies.
- On March 16, 2017, the facility found Sterrad chemical indicator strips that expired on February 28, 2017 in sterile processing. The indicators are placed with equipment and change colors when exposed to hydrogen peroxide. This allows a visual verification that sterilization occurred. The Medical Center could not determine whether the expired indicators had been used on some of the 396 items sterilized in the Medical Center between the date of the strips’ expiration and the date staff discovered the expired strips and removed them from the facility.

Assurance that Recalled Equipment and Supplies are Not Used on Patients

OIG further determined that the Medical Center’s action plan to remediate deficiencies in inventory practices did not include a means of determining whether current stock had been recalled. A medical device recall occurs when a manufacturer takes a corrective or removal action to address defective devices or devices that are a risk to public health.

In a VA facility with an approved inventory management system, reliable controls exist that can be used to determine whether the facility’s stock includes any recalled items and where such items are located. The DC Medical Center has no such system.

Instead, staff responsible for confirming the removal of supplies and equipment subject to patient safety recalls explained to the OIG that their practice was to use email to communicate with the various hospital units to determine whether any of the units had supplies or equipment subject to the recall. Logistics staff reported to the OIG that supply purchase records would also be consulted to determine whether the Logistics Services Department had purchased items subject to the recall.

The Medical Center’s approach to removing recalled items is prone to human error and may have resulted in recalled items being missed. Moreover, several staff members reported to the OIG that significant volumes of medical equipment and supplies have been acquired for the

Medical Center by employees outside of the Logistics Services Department through the use of Government-issued employee purchase cards. These improper purchasing practices render inadequate the Logistics Services Department's practice of reviewing logistics' purchase records because its records may not reflect all purchases made within the facility.

Detecting recalled items is not part of the current action plan for restoring the Medical Center's inventory management. Based on our preliminary review, the OIG is identifying a need for further action to ensure that recalled supplies or equipment are not used on patients.

Storage of Sterile Supplies

OIG also identified deficiencies in the storage of sterile supplies. Sterile supplies must be stored in a safe manner to ensure that sterilization is maintained. Environmental factors can contribute to the contamination of an item, including dust in the environment, air movement, traffic, location, humidity, temperature, and open or closed shelving. OIG staff inspected 25 sterile satellite storage areas and identified numerous ongoing deficiencies. Specifically, OIG found that:

- Eighteen sterile storage areas were dirty.
- Five sterile storage areas mixed clean with dirty equipment or supplies.
- Eight sterile storage areas contained supply racks lacking solid bottom shelves as required to reduce cross-contamination from the floor.
- Seventeen sterile storage areas lacked a method to monitor pressure, temperature, and humidity.
- Five sterile storage areas were cluttered.
- Five sterile storage areas improperly served multiple purposes including office and patient care space. These areas also lacked security and appropriate environmental controls.

Under these conditions, the VAMC lacks assurance that sterile supplies maintained their integrity.

The ongoing inventory practices at the Medical Center are placing patients at unnecessary risk. We are particularly concerned that the VAMC, VISN, and VACO have been slow to remediate these serious deficiencies. The OIG's work is continuing and will include an assessment of whether patient harm has resulted from any of these inventory practices in its final report on the Medical Center.

The Medical Center's Capital Asset Management Practices

Moreover, the Medical Center's failure to maintain an adequate inventory management system is placing a significant amount of assets of the Federal government at unnecessary risk. Accountability over supplies and equipment is not adequate.

VHA policy requires that facilities conduct an annual physical inventory of all nonexpendable, accountable personal property with an acquisition value of greater than \$5,000 (Accountable Property). Accountable Property must be included on the facility's equipment inventory lists (EILs) and inventoried no less frequent than every 12 months. A custodial officer (section chief or other official) signs the EIL, certifying that the equipment listed is present and accounted for as of that date.

VHA policy also requires EIL inventories be conducted using barcode / hand scanner technology compatible with automated equipment inventory systems. In this system, staff scans barcodes on equipment or supplies using a handheld scanner, which automatically imports information about the item scanned into an electronic inventory system. Through documents provided by the Medical Center, we determined as of 2012, the facility did not have barcode scanners needed to conduct the inventories. The VISN purchased 50 scanners for the facility in January 2013. However, the OIG obtained documentation that showed 27,494 items worth a total of \$154,876,092 were unaccounted for during the past 12 months on the facility's EIL (as of March 2017). In addition, the VAMC was not performing Reports of Survey to identify and account for missing inventory. This does not mean that the equipment is necessarily missing—rather, this is just the total amount of equipment that has not been inventoried. In interviews, staff from logistics, clinical services, and leadership at the facility informed the OIG that the Medical Center Logistics Service had not been using a formal method of inventorying equipment.

In the January 2017 PAQ site visit report, VA Central Office staff referenced an approximately 100,000 square-foot warehouse facility full of non-inventoried materials and supplies. Documents provided to OIG estimated the value of these supplies to be in excess of \$15 million, although this amount has not been confirmed.

At the time of the OIG's site visit in early April, the warehouse remained full of supplies and equipment. The facility Assistant Warehouse Chief stated that until recently, several warehouse staff had keys and access to the offsite warehouse but could not provide an exact number. OIG staff was told during our site visit that the warehouse locks have been changed recently, and only two individuals have keys.

OIG is concerned about additional losses to the Federal Government because, according to the Acting Chief of Logistics present at the facility on April 5, 2017, the offsite warehouse lease is expiring on April 30, 2017. Logistics staff expressed concerns that the warehouse could not be emptied before April 30, 2017 without additional resources devoted to moving the equipment and supplies from that location. Reinforcing our concern, on April 10, 2017, OIG learned from VA personnel that potentially usable medical supplies that had been identified in the warehouse were discarded during the weekend. This disposition was performed in an uncontrolled manner that caused it to be impossible to determine precisely what was discarded and whether these materials were truly useable or otherwise salvageable.

Resource Challenges May Jeopardize Remediation Efforts

Finally, multiple critical staff, hospital management, and human resource vacancies may jeopardize efforts to address promptly deficiencies at the Medical Center.

Medical Center Leadership Vacancies

The Medical Center has operated without a permanent Associate Medical Center Director since at least December 2015. The Medical Center has operated without a permanent Associate Director for Patient Care Services since August 2016. Other critical management vacancies include the Chief of Human Resources, Chief of the Business Office, Chief of Mental Health, Chief of Voluntary Service, Chief of Integrated Health and Wellness, Chief of Police, and Chief of Radiology.

In the absence of a full complement of leadership, the Medical Center management team faces significant challenges in coordinating staff in various departments (Information Technology, Human Resources, Facilities, Nursing, and others) whose support will be essential to rapidly transform the Logistics Services Department, as well as address any other patient safety issues that may be discovered.

Logistics Department Vacancies

Key leadership vacancies exist in the positions of Chief Logistics Officer and Deputy Chief Logistics Officer. Equally urgent, the Logistics Services Department is authorized for 42 full time equivalent (FTE) employees to perform daily inventory management tasks, but currently employs only 33.

Staffing vacancies have persisted for some time. In October 2014, an external consultant identified staffing deficiencies in logistics throughout VISN 5. VISN 5 conducted an internal staffing review in the third and fourth quarters of FY 2015. This review disclosed that the Medical Center had at that time a 33 percent vacancy rate in expendable supply positions and a 50 percent vacancy rate in non-expendable equipment/supply positions. Recommendations of the review included increasing the existing ceiling of 36 FTEs to 42 FTEs. According to this report, comparable facilities averaged 64.8 FTEs devoted to logistics staffing.

Since January 2017, the Medical Center relied on the emergency assistance of experienced chief logistics officers from two other facilities to provide temporary support. After Thursday, April 13, 2017, the Medical Center will be entirely reliant upon the temporary assistance of VISN 5 personnel until another Chief Logistics Officer from another facility can be identified to serve in this role. OIG staff has been told that plans are in place to seek logistics candidates from within VISN 5 to accept temporary assignment to the DC Medical Center until permanent staff can be hired. In our review, limiting the temporary assignment request to VISN 5 personnel may

unduly limit the potential pool of candidates and restrict the Medical Center's ability to obtain adequate support for its transformation.

Human Resources Department Vacancies

On February 27, 2017, the Network Director for VISN 5 issued a notice to the Medical Center Director that effective March 5, 2017, all new hiring for the DC Medical Center will be handled by Human Resources staff of the VA Maryland Health Care System for a period of 120 days (Notice).

The Memorandum of Understanding (MOU) accompanying the Notice indicated that in the VISN's determination the Medical Center "has been unable to sustain and maintain a sufficient HR program." The MOU recited a frustrated history of repeated site visits from the VISN and VHA starting in September 2015 and continuing until October 2016. During that same 12 month period, various teams of supplemental personnel were dispatched to the Medical Center to assist with the provision of fundamental HR services. Notwithstanding such support, the Medical Center has been unable to establish an effective Human Resources (HR) program. As a result, the Medical Center does not have direct authority over its recruitment and hiring functions.

VA and OIG's Response

The OIG determined that a site visit team from VA Central Office knew of the Medical Center's deficiencies in medical supply and equipment management since at least January 2017. While Logistics personnel from the Veterans Integrated Service Network (VISN) and another facility were onsite when the OIG arrived at the facility on March 29, significant equipment and supply shortages continued, placing patients at risk.

After the OIG notified VHA of its preliminary observations and findings on March 30, VHA took additional actions, which included establishing an incident command center¹ (now deactivated) and temporarily assigning an additional logistics chief, technicians, and VISN staff to the facility on a temporary basis. These actions are short term and potentially insufficient to guarantee the implementation of an effective inventory management system and address the other issues identified. Further, shortages of medical equipment and supplies continued to occur while the OIG was onsite, confirming that problems persisted despite these measures.

The OIG is conducting a comprehensive review that will include an assessment of the circumstances that contributed to the conditions found at the Medical Center during March and April 2017. This review will also include concerns raised by Medical Center staff during the course of our inspection.

¹ An incident command center is an emergency operations procedure that engages leadership and establishes certain processes for communicating and responding to significant events affecting basic medical center operations.

To ensure all veterans receive appropriate care, and that financial losses to the Federal Government are minimized, we submit to the VA Under Secretary for Health the following recommendations for immediate implementation. We will address the sufficiency of the VA Under Secretary for Health's actions to implement the following recommendations in our final report.

1. We recommended the Under Secretary for Health take immediate action to ensure that necessary supplies and equipment are available in patient care areas at the Washington DC, VA Medical Center.
2. We recommended the Under Secretary for Health take immediate action to implement an effective inventory management system throughout the Washington DC, VA Medical Center.
3. We recommended the Under Secretary for Health take immediate action to ensure that current stock at the Washington DC, VA Medical Center does not include recalled equipment or supplies.
4. We recommended the Under Secretary for Health take all appropriate steps to ensure that the environmental integrity of the sterile satellite storage areas complies with VA policy.
5. We recommended the Under Secretary for Health take immediate action to create an inventory and establish accountability over the equipment and supplies in the off-site warehouse.
6. We recommended the Under Secretary for Health take all appropriate steps to ensure that the Washington DC, VA Medical Center and Veterans Integrated Service Network arrange the orderly movement of goods and supplies from the warehouse that minimizes losses to the Government.
7. We recommended the Under Secretary for Health deploy additional logistics staff with in-depth Generic Inventory Package experience to the Washington DC, VA Medical Center until reasonable assurances can be provided that existing logistics staff can maintain an effective inventory management system.
8. We recommended the Under Secretary for Health expedite hiring of permanent positions at the Washington DC, VA Medical Center, to include the Associate VA Medical Center Director, the Nurse Executive, the Chief of Logistics, Assistant Chief of Logistics, and supply technicians.

Our inspection is continuing and we will publish a final report with any additional recommendations when our work is completed.



MICHAEL J. MISSAL

Inspector General

April 12, 2017

Appendix A Background, Scope and Methodology

Background

The Washington DC VA Medical Center (Medical Center) is a Complexity Level 1a facility that supports four community based outpatient clinics located in Ft. Belvoir, VA; Southeast Washington, DC; Charlotte Hall, MD; and Camp Springs, MD. It serves more than 98,311 enrolled veterans in the Washington, DC metropolitan area.

The Medical Center is part of the Veterans Integrated Service Network (VISN) 5, a regional network of VA hospitals, clinics, and other facilities located in Maryland, the District of Columbia, and portions of Virginia, West Virginia, and Pennsylvania.

Scope and Methodology

We initiated this review in response to a confidential complainant's allegations submitted to OIG on March 21, 2017, describing equipment and supply issues at the Medical Center sufficient to compromise patient safety. The OIG conducted site visits on March 29–30, and April 4–6, 2017. The OIG interviewed Medical Center leadership, including the Medical Center Director, Chief of Staff, Chief of Prosthetics, Chief of Fiscal Management Services, Acting Associate Medical Center Director for Patient Care Services, Chief of Quality Management, and former and Acting Chiefs of Logistics. OIG interviewed VISN leadership, including the Deputy Chief Medical Officer, the Chief Quality Management Officer, the Chief Logistics Officer, and the Network Material Manager. Finally, the OIG conducted numerous additional interviews with medical center staff, including physicians, nurses, supply technicians, sterile processing technicians, and administrative officers.

The OIG reviewed documents relevant to the allegations, including emails; meeting minutes; former VISN and facility reports regarding the logistics service; patient safety reports; root causes analyses; facility, VISN, and VHA policies; equipment and supply purchase orders; exhibits and sworn testimony obtained during an administrative investigative board, as well as the findings of the board.

OIG conducted inspections of the sterile processing areas, outpatient clinics, sterile supply storage areas, onsite and offsite warehouse supply, and equipment storage areas.

We conducted this review in accordance with Quality Standards for Inspection and Evaluation published by the Council of the Inspectors General on Integrity and Efficiency. We only complied with the evidence, timeliness, and reporting standards.