

**STATEMENT OF
JOHN D. DAIGH, JR., M.D.
ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS
OFFICE OF INSPECTOR GENERAL
DEPARTMENT OF VETERANS AFFAIRS
BEFORE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
HEARING ON
"A CONTINUED ASSESSMENT OF DELAYS IN VA MEDICAL CARE AND
PREVENTABLE VETERAN DEATHS"
APRIL 9, 2014**

Chairman Miller and Members of the Committee, thank you for the opportunity to testify today to discuss preventable medical errors at Department of Veterans Affairs (VA) medical facilities. The VA Office of Inspector General (OIG) has issued many reports that have addressed circumstances that led to patient harm, including death at VA medical centers (VAMC). I am deeply concerned that these reports portray events which, had the VA medical center staff followed VA policy, may have never occurred. For the purposes of this statement, I will focus on seven recent reports that I believe are indicative of issues facing VA in providing quality health care.¹

BACKGROUND

The VA provides medical care to 6.5 million veterans through a system of medical facilities including 151 Medical Centers, 300 Vet Centers, and 820 Community Based Outpatient Clinics (CBOC). The Veterans Health Administration (VHA) Central Office provides leadership and policy guidance to the nationwide system of care. Hospitals, clinics, and related medical facilities are grouped into 21 Veterans Integrated Service Networks (VISN). VISNs and their related hospitals' organization and business practices have evolved at different paces and have been significantly influenced by local preferences since their creation, resulting in 21 different VISN organizations, each charged with the same mission.

¹ *Healthcare Inspection – Gastroenterology Consult Delays, William Jennings Bryan Dorn VA Medical Center, Columbia, South Carolina (9/6/2013); Healthcare Inspection – Mismanagement of Inpatient Mental Health Care, Atlanta VA Medical Center, Decatur, Georgia (4/17/2013); Healthcare Inspection – Unexpected Patient Death in a Substance Abuse Residential Rehabilitation Treatment Program, Miami VA Healthcare System, Miami, Florida (3/27/2014); Healthcare Inspection – Patient Care Issues and Contract Mental Health Program Mismanagement, Atlanta VA Medical Center, Decatur, Georgia (4/17/2013); Healthcare Inspection – Emergency Department Patient Deaths Memphis VAMC, Memphis, Tennessee (10/23/2013); Healthcare Inspection – Inappropriate Use of Insulin Pens, VA Western New York Healthcare System, Buffalo, New York (5/9/2013); Healthcare Inspection - Review of VHA Follow-Up on Inappropriate Use of Insulin Pens at Medical Facilities (8/1/2013).*

COLON CANCER SCREENING

Colon cancer has long been recognized as a silent killer in that the cancer is often able to grow within the intestine to significant size before being discovered. Patients may be screened for this cancer by a variety of tests, some of which focus upon the presence of blood within stool or the physical presence of a mass within the intestine. Examinations that test stool for the presence of blood or other chemicals or visualize the intestine are common diagnostic tests used to discover the presence of this silent killer.

In 2006, the OIG published a review, *Colorectal Cancer Detection and Management in Veterans Health Administration Facilities* (February 2, 2006), of aspects of VHA's performance in the delivery of colon cancer screening and management of positive screening tests. This review found that the time between having a positive screening test for colon cancer and the provision of the next test to diagnose a tumor took several months. VA agreed that this delay in action was not acceptable. When colon cancer was diagnosed, surgeons and oncologists responded quickly with treatment, yet the lag between the identification of a specific risk and the determination that there was or was not colon cancer was not timely.

In that report, the Under Secretary for Health concurred with the findings and recommendations we made to more efficiently and more timely address the lag between the positive screening test and the diagnostic test for colon cancer. The Under Secretary for Health indicated in the response to this report that timelines would be established to monitor the timeliness of colon rectal cancer diagnosis after a positive screening test and that a directive would be issued to establish national standards for the management of this process. This was accomplished with the issuance of VHA Directive 2007-004, "Colorectal Cancer Screening," in January 2007.

In September 2013, the OIG reported a disturbing set of events at the William Jennings Bryan Dorn VAMC in Columbia, South Carolina, that led to thousands of delayed gastroenterology (GI) consults for colon cancer screening and the determination that over 50 veterans had a delayed diagnosis of colon cancer, some of whom died from colon cancer.² After patients are screened positive for possible colon cancer or require a GI procedure, a consult to GI is usually sent by the primary care provider. Network and facility leaders became aware of the GI consult backlog at Columbia in July 2011 involving 2,500 delayed consults, 700 of them deemed "critical" by VA physicians. Additional funds were requested by the facility upon determining the need for a large number of GI procedures, and the VISN awarded the facility \$1.02M for Fee-Basis colonoscopies in September 2011.³ However, facility leaders did not ensure that a structure for tracking and accounting was in place and by December 2011, the backlog stood at 3,800 delayed GI consults. The facility developed an action plan in January 2012 but had difficulty making progress in reducing the backlog. The delayed diagnosis

² *Healthcare Inspection – Gastroenterology Consult Delays, William Jennings Bryan Dorn VA Medical Center, Columbia, South Carolina (9/6/2013).*

³ Fee basis care is non-VA/private sector care paid for by VA when the service is not available in a timely manner within VHA due to capability, capacity, or accessibility.

of a patient with colon cancer in May 2012 prompted facility leaders to re-evaluate the GI situation, and facility, network, and VHA leaders aggressively pursued elimination of the backlog. This was essentially accomplished by late October 2012. However, during the review “look-back” period, 280 patients were diagnosed with GI malignancies, 52 of whom were associated with a delay in diagnosis and treatment. The facility completed at least 19 institutional disclosures providing patients and their family members with specific details of the adverse event or delay of care and their right to file a claim.

A confluence of factors contributed to the GI delays and hampered efforts to improve the condition. Specifically, the facility’s Planning Council did not have a supportive structure; Nursing Service did not hire GI nurses timely; the availability of Fee Basis care had been reduced; low-risk patients were being referred for screening colonoscopies, thus increasing demand; staff members did not consistently and correctly use the consult management reporting and tracking systems; critical network and facility leadership positions were filled by a series of managers who often had collateral duties and differing priorities; and Quality Management staff was not included in discussions about the GI backlogs.

In its response to the report, VHA indicated that national VHA leadership considered delays in consult responsiveness to be of significant concern. VHA Central Office leadership took specific steps to address these issues in Columbia as well as system-wide. In January 2013, VHA undertook a national review of open consults to gain a better perspective on nationwide demand for consultative services. In May 2013, VHA launched an initiative to standardize use of the clinical consultation software package in the electronic health record.

The appropriate management of patients who are at risk for colon cancer is standard medical practice. This issue has been discussed by VHA for years, and yet veterans were not timely diagnosed with colon cancer at this academic VA medical center.

MENTAL HEALTH POLICIES AND PROCEDURES

The OIG has issued two reports recently on veterans who died of narcotic drug overdoses while in VA facilities for mental health care.⁴ In both cases, the hospital staff failed to ensure that veterans, who by their prior behavior were known to be at risk of abusing narcotic medication, were placed in environments that were secure from those drugs.

At the Miami VA Healthcare System, in Miami, Florida, we found that a patient died in his room in the substance abuse residential rehabilitation treatment program (SARRTP), and autopsy results indicated the patient died from cocaine and heroin toxicity. This veteran had a history of multiple positive urine drug screens while in the SARRTP. We found that the SARRTP security surveillance camera was not working at the time of the

⁴ *Healthcare Inspection – Mismanagement of Inpatient Mental Health Care, Atlanta VA Medical Center, Decatur, Georgia (4/17/2013); Healthcare Inspection – Unexpected Patient Death in a Substance Abuse Residential Rehabilitation Treatment Program, Miami VA Healthcare System, Miami, Florida (3/27/2014).*

patient's death, was still not working at the time of our site visit, and no alternative arrangements were made to monitor patients in the absence of an operational camera. Moreover, we found that evening, night, and weekend SARRTP staff often sat in a backroom where they had an extremely limited view of the unit and no view of the unit's entrance and exits. We also found that staff were not consistent in their methods of contraband searches and did not monitor patient whereabouts or unit visitors as required.

In our report on the Atlanta VA Medical Center in Decatur, Georgia, we received allegations that the VA did not protect a veteran from illicit drugs while an inpatient on the locked mental health unit and that he died of an overdose. We substantiated that the facility did not have adequate policies or practices for patient monitoring, contraband, visitation, and urine drug screening. We found inadequate program oversight including a lack of timely follow up actions by leadership in response to patient incidents.

At both Miami and Atlanta, as the reports indicate, standard steps to ensure veterans were kept safe while under VA control were not taken and two veterans died. In each instance, VA managers did not ensure that hospital staff performed their jobs.

The OIG reported on poor management of contracted mental health care at the Atlanta VAMC, where between 4,000 – 5,000 veterans who were referred for non-VA mental health care at a public non-profit Community Service Board (CSB), were not followed or managed.⁵ In a sample of 85 cases, 21 percent of the referred veterans did not receive mental health care and, outside of the sample, several veterans were found to have died with a history of inadequate mental health care support from VA or non-VA sources. Mental Health Service Line managers did not adequately oversee or monitor contracted patient care services to ensure safe and effective treatment. This lack of effective patient care management and program oversight by the facility contributed to problems with access to mental health care and as a VA employee told the OIG “may have contributed to patients falling through the cracks.” The facility's contract program lacked an integrated and effective Quality Assurance (QA) program and did not have a CSB QA process. For example, VA facility program managers did not track and trend patient complaints or conduct oversight visits to the CSB sites, as required by VA directives and the contract.

Our review also confirmed that facility managers did not provide adequate staff, training, resources, support, or guidance for effective oversight of the contracted mental health program. Managers and staff voiced numerous concerns including challenges in program oversight, inadequate clinical monitoring, staff burnout, and compromised patient safety. Furthermore, other administrative issues contributed to the delay because the facility managers did not pay invoices promptly. These delays affected the CSBs' ability to accept new patients and plan their patient census.

⁵ *Healthcare Inspection – Patient Care Issues and Contract Mental Health Program Mismanagement, Atlanta VA Medical Center, Decatur, Georgia (4/17/2013).*

The Atlanta VAMC was overwhelmed by the demand for mental health services over a multiyear period. VA leadership's response to this crisis was fragmented, ineffective, and resulted in poor care, and may have contributed to the death of some of the veterans among the 4,000 to 5,000 patients referred for non-VA care.

EMERGENCY DEPARTMENT ISSUES

In October 2013, we issued a report detailing three deaths in the Emergency Department (ED) at the Memphis VAMC in Memphis, Tennessee.⁶ We received allegations that three patients died subsequent to care they received in the Memphis VAMC ED. We found the following:

- A patient was administered a medication in spite of a documented drug allergy and had a fatal reaction. Handwritten orders for this patient did not comply with the facility's requirement that all provider orders and patient care be documented in the electronic medical record. Since the orders were not entered into the electronic medical record, systems in place to notify the provider of a drug allergy conflict with ordered medications were bypassed. The patient died of a reaction to a medication allergy that was identified in the electronic medical record.
- Another patient was found unresponsive after being administered multiple sedating medications without being properly observed.
- A third patient had a critically high blood pressure that was not aggressively monitored and experienced bleeding in the brain.

The facility did complete protected peer reviews of the care for all three patients. Two of the deaths were also evaluated through root cause analyses (RCA), which are quality reviews designed to identify and correct systemic factors and conditions that may pose a threat to patient safety. However, we found that the implementation of the RCA action plan was delayed and incomplete. Additionally, the RCA documentation we reviewed contained several errors of fact, such as how long Patient 1 was monitored in the emergency room before discharge and the number of intravenous medications given to Patient 2.

Decisions were made which permitted the electronic medical record and its safeguards to be bypassed and to have patients on multiple sedating medications to be located in places difficult to monitor. Furthermore, when issues were identified through the RCA process, actions to prevent a recurrence were not taken seriously.

INTRODUCTION OF NEW TECHNOLOGY

Several VAMCs including the medical centers in Buffalo, New York, and Salisbury, North Carolina, failed to introduce new technology properly into the hospital

⁶ *Healthcare Inspection – Emergency Department Patient Deaths Memphis VAMC, Memphis, Tennessee (10/23/2013).*

environment.⁷ This resulted in 700 patients at Buffalo and 260 patients at Salisbury being exposed to the risk of blood borne viral infections when insulin pens, designed to be used with one pen per patient, were instead used improperly such that one pen was used on multiple patients.

In late October 2012, the Buffalo Chief of Pharmacy discovered three insulin pens, which were designed for single-patient use only, with no patient labels in a supply drawer of a medication cart. Facility officials subsequently found three more pens without patient labels in medication carts on three other inpatient units, and, when queried, several nurses reportedly acknowledged using the pens on multiple patients. Inappropriately using single-patient use insulin pens on multiple patients may potentially expose patients to blood borne pathogens.

We identified six factors that contributed to the misuse of insulin pens at Buffalo. We also found that misuse of the insulin pens went undetected for 2 years because even though facility staff often observed pens with no patient labels on the medication carts, they did not report it because they either did not fully comprehend the clinical risks of sharing pens, or they accepted the unlabeled pens as standard practice believing they were both multi-dose and multi-patient devices. We found that VHA did not notify Members of Congress or at-risk patients until January 2013 because of the time required for multiple levels of coordination between VA and VHA and inefficiencies in VHA's internal review process for large-scale adverse event disclosures.

In addition to the Buffalo incident, nurses at two other facilities were found to have inappropriately used insulin pens on multiple patients. In January 2013, the Salisbury VAMC reported that two nurses had inappropriately used insulin pens on multiple patients. VHA instituted a large-scale adverse event disclosure to notify 266 at-risk patients. At another facility, a nurse acknowledged using a pen on two patients on one occasion. We identified two contributing factors to explain why some nurses misused the insulin pens:

- Facilities did not fully evaluate the risks of using insulin pens on inpatient units, specifically in regards to the impact on nursing procedures.
- Facilities did not provide comprehensive nurse education on the pens.

We found that VHA has processes in place to identify important patient safety alerts, including product recalls, and disseminate this information to facility managers. VHA's National Center for Patient Safety and Pharmacy Benefits Management Service lead VHA's efforts to collect patient safety information and share this information with facilities. At the facility level, patient safety managers are responsible for disseminating alerts to appropriate administrative and clinical staff and tracking the facility's response through a national database. VHA has followed up and tested for evidence of infection in the patients identified in this report.

⁷ *Healthcare Inspection – Inappropriate Use of Insulin Pens, VA Western New York Healthcare System, Buffalo, New York (5/9/2013); Healthcare Inspection - Review of VHA Follow-Up on Inappropriate Use of Insulin Pens at Medical Facilities (8/1/2013).*

The use of these insulin pens in this fashion violates the core principles of infection control. Multiple personnel in several hospitals over an extended period of time failed to comprehend the impact of the decision to introduce pens of this nature onto inpatient wards. The decision to introduce new technology into hospital use is one that occurs routinely and to be done safely requires facility leaders to coordinate their actions and understand the implications of their decisions. Facilities with a singular focus on delivering high quality medical care should have recognized the risk these devices bring to the inpatient environment and taken appropriate actions to mitigate that risk.

OBSERVATIONS

OIG work routinely reports on clinical outcomes or performance that did not meet expectations. We routinely determine that there were opportunities by people and systems to prevent untoward outcomes. In addition to local issues at the facility, there are several organizational issues that impede the efficient and effective operation of VHA and place patients at risk of unexpected outcomes.

Although health care delivery may be the first priority of many within the system, others are focused on research, training the next generation of health care providers, disaster preparedness, homelessness, support for compensation evaluation requirements, and other related missions. This lack of focus on health care delivery as priority one can be seen by the process commonly used at hospitals to fill vacant positions. A resource board reviews open positions and then determines which should be filled. Thus the position recently occupied by a nurse in the GI clinic, who is essential to the delivery of required care, may not be filled while a position that is important to the research or teaching community is filled. The decision by this board, to not fill a clinic position, may have far reaching consequences. The clinic that does not have the nurse may not function properly. The leadership of the clinic is left believing that hospital “leadership” does not understand or does not care about the care provided in that clinic. All a provider can do is ask for clinical positions to be filled, and if they are not filled, either leave VA or agree to work in an environment that provides less than satisfactory care. There is no national process to establish a set of positions that are deemed “essential” to the delivery of health care and thus are priority one for the hospital administration to resource.⁸ The establishment of “essential positions” in the context of a standard hospital structure would enhance the delivery of quality patient care.

VA hospitals and clinics do not have a standard organizational chart. Some hospitals have a chief of surgery and a chief of anesthesia; others have a chief of the surgical care line. The lack of a common organizational chart for medical facilities results in confusion in assigning local responsibility for actions required by national directives. Variation in staff organization also creates difficulty in comparing the performance of clinical groups between hospitals and clinics.

⁸ *Healthcare Inspection – Delayed Cancer Diagnosis, VA Greater Los Angeles Healthcare System, Los Angeles, California (7/24/2007).*

Leadership, teamwork, communication, and technical competence are among the most important factors in providing quality health care. However, organization, assignment of clear responsibility, and efficiency of operation all make important contributions to the process of improving the quality of health care delivered.

CONCLUSION

The unexpected deaths that the OIG continues to report on at VA facilities could be avoided if VA would focus first on its core mission to deliver quality health care. Its efforts would also be aided by discussion of the best organizational structure to consistently provide quality care. The network system of organization and the accompanying motto, 'all health care is local,' served the VA well over the last several decades but does not standardize the organization of medical centers. It is difficult to implement national directives when there are no standard position descriptions or areas of responsibility across the system. VA has embraced the "aircraft checklist" approach to improve the chances that preventable medical errors will not occur in the operating room, but has taken the opposite approach to the assignment of duties and responsibilities in medical centers, where no two hospitals are alike. I believe that it is appropriate to review the organizational structure and business rules of VHA to determine if there are changes that would make the delivery of care less prone to error and reinforce the priority that the delivery of health care should receive.

Mr. Chairman, that concludes my statement and I would be pleased to answer any questions that you or other Members of the Committee may have.