United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

January 14, 2010

Via Electronic Transmission

The Honorable Eric K. Shinseki
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary Shinseki:

As the senior Senator from Iowa and Ranking Member of the United States Senate Committee on Finance (Committee), it is my Constitutional duty to conduct oversight into the actions of the Executive Branch, including the activities of the Department of Veterans Affairs (VA).

I recently received the enclosed memorandum, which documents that the wrong filter was used in dialysis machines at the VA Palo Alto Health Care System last year, putting 83 patients and possibly more who were treated using the contaminated machines at risk of being infected with hepatitis, HIV, or other infectious diseases. I understand that as of the date of the memorandum, all of these patients had not been informed of the incident.

What is as troubling is that this is not the first incident of contaminated equipment in the VA health system. The *Associated Press* reported that in February 2009 the VA started notifying more than 11,000 patients treated at three VA medical centers to get their blood checked because they may have been exposed to infectious body fluids. It was discovered two months earlier that equipment used for colonoscopies at these three hospitals was not properly cleaned or sterilized. Similarly, in April 2006, the VA issued an alert that a biopsy device used to take tissue samples from the prostate, to test for cancer in VA facilities had not been cleaned adequately, thus potentially exposing patients to infectious agents.

These incidents raise serious questions about the VA's infection control processes and practices. Accordingly, I request that the VA respond to the following questions by no later than January 28, 2010. In responding to this letter, please repeat the enumerated question and follow with the appropriate response and documentation.

1) In light of these recent health care-associated exposures within the VA health care system, what measures does the VA plan to put in place to prevent similar incidents from occurring in the future?

2) What infection control policies, guidelines and practices are currently in place to prevent the development and transmission of disease and infection in VA health care facilities throughout the country?

    a. Please specify changes, if any, to the policies, guidelines, procedures and practices that were implemented by the VA in response to the earlier incidents.

    b. Please also describe any structural changes that were implemented.

3) What office within the VA's Veterans Health Administration (VHA) has primary responsibility for the infection control program?

4) What system does VHA currently have in place to track rates of health care-associated infections in VA health care facilities?

    a. How is the data collected? Please describe in detail.

    b. Is the data made available to VA health care providers?

5) What is VHA's budget for its health care-associated infection control program and how is it allocated among the VHA offices?

    a. Does VHA have specific guidelines for infection control staffing levels? Please describe.

    b. What specific products, resources, or training over the last five years has been made available to VHA health care providers to minimize and prevent health care-associated infections?

6) Has the VA, VHA and/or other government entities or third parties reviewed VA's infection control program in the last five years? If so, please provide a copy of the review(s) and specify whether or not the VA implemented changes to its infection control program in response to any recommendations.

7) If the patients who were treated using the contaminated dialysis machines have not been informed of the potential risk of infection, please explain why they have not yet been notified. If all the patients have since been notified, please specify when they were contacted.

Thank you in advance for your attention to this important matter. Should you have any questions regarding this matter, please do not hesitate to contact Angela Choy of my Committee staff at (202) 224-4515. All documents responsive to this request should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov.

Sincerely,

Charles E. Grassley
Ranking Member

Enclosure

Department of Veterans Affairs

Memorandum

Date: November 16, 2009

From: Deputy Under Secretary for Health for Operations and Management (10N)

Subj: Appointment of CRAAB

To: Associate DUSH for Quality and Safety (10NG)
Chair, Clinical Risk Assessment Advisory Board (CRAAB)

1. Please be advised that I am requesting that the CRAAB be convened as soon as possible to review issues related to the use of an incorrect type of primary transducer protector on 17 dialysis machines at VA Palo Alto Healthcare System. These primary transducer protectors were initially purchased between January and February of 2009 and were used in the 17 machines. Due to the use of incorrect primary transducer protectors, blood was able to pass through the transducer protector to the secondary transducer protector of the pressure monitor line. A pre-CRAAB was held on November 10, 2009 and the decision was made to convene the full CRAAB.

2. Please convene the appropriate experts in this area as well as those representatives from key program offices as identified in VHA Directive 2008-002, Disclosure of Adverse Events to Patients dated January 18, 2008. The group should review the issue of using the incorrect primary transducer protector, the risk to patients, and determine the number of patients who may have been affected by this process.

3. Should you require further information, please contact Odette Levesque via email.

for William Schoenhard, FACHE

CC: Principal Deputy Under Secretary for Health

Attachment:

VHA Issue Brief

ISSUE TITLE:
Dialysis Filter Issue at the VA Palo Alto Health Care System (VAPAHCS)

DATE OF REPORT:
November 3, 2009

BRIEF STATEMENT OF ISSUE AND STATUS:
On October 26, 2009, it was discovered that the incorrect type of primary transducer protector was being purchased and used in 17 dialysis machines at VAPAHCS. These primary transducer protectors were initially purchased between January and February of 2009 and were used in the 17 machines. These primary transducer protectors are at the end of the pressure line monitor and do not have a primary function in the dialysis process. Due to the use of incorrect primary transducer protectors, blood was able to pass through the transducer protector to the secondary transducer protector of the pressure monitor line. The tubing and the primary transducer protector are changed between patients, but the secondary transducer protector, which is inside the machine, is not changed. Contamination of the secondary transducer protector could theoretically allow cross-contamination during dialysis treatments.

Background
October 2008: The VAPAHCS dialysis team, including the manufacturer's representative, completes the decision to purchase the Braun Dialog Plus Dialysis System.[1]

January 2009: 20 dialysis machines arrive at VAPAHCS.

January 12-13, 2009: VAPAHCS dialysis staff receive training on the Dialog Plus Dialysis System and competency is obtained. During this training, there is no discussion of what type of transducer protector is to be used with these machines.

February 17, 2009: The first order for replacement transducer protectors was made. The VAPAHCS Chief Dialysis Technician ordered 5 micron, 2-way disc filters[2] instead of the 0.2 micron 1-way threaded transducer protector[3]. The technician stated he ordered these filters based on advice from the manufacturer, but this cannot be verified. It was not realized that these filters could not function as transducer protectors. A total of 1600 filters were ordered over the course of the next six months.

June/July 2009: During an in-service provided by the vendor to the biomedical technicians responsible for the maintenance of these machines, no contamination was observed in the three machines randomly tested. The vendor did not notice the wrong filters were being used.

July 2009: VAPAHCS transferred three of the 20 machines to the San Francisco VA Medical Center (SFVAMC).

October 21, 2009: Contamination of the transducer protectors was originally discovered during VAPAHCS annual maintenance inspection of its dialysis machines. During this evaluation, it was discovered that 13 of 17 dialysis machines had evidence of blood contamination in the secondary transducer protectors[4]. The contamination was presumed to be a manufacturer defect in the transducer protector.

October 26, 2009: VAPAHCS staff contacted the manufacturer to discuss the issue of the contamination and the possible defect in the transducer protector. At this time, it was discovered that the replacement part ordered by VAPAHCS was not an approved transducer protector, but was in fact an aspiration/injection disc filter. The transducer protectors are designed to be impermeable while the filters are designed to be permeable[5]. As a result, a filter used in place of a transducer protector would allow the contamination of the secondary transducer protector.

ACTION and PROGRESS:
A formal review of each machine was completed by VAPAHCS Nursing Service, Biomedical Engineering Section, the vendor representative and the Chief Dialysis Technician to install the correct transducer protectors and clear each machine for patient use. All incorrect filters have been removed to prevent a reoccurrence.

Inspection of the secondary transducer protectors will be completed by dialysis staff after each procedure and all staff involved were re-educated on proper procedure.

SFVAMC has confirmed that their three machines were not contaminated and that their Biomedical Engineering and Nursing Sections have re-inspected and cleared them for patient use.

As a result of the October 26, 2009 findings, VAPAHCS Infection Control has been contacted to evaluate the risk of possible cross-contamination. The final recommendation was that the risk to patient was very low. No patients have been contacted to date. VAPAHCS will await direction from the VAPAHCS Chief ID, VISN 21 and VACO regarding next steps regarding potential patient notifications.

A total of eighty-three patients, 18 transient and 65 chronic, have been treated using these 17 machines. Their latest test results for Hepatitis B (Antigen and Antibody), Hepatitis C and HIV are shown in the attached list of patients. For those patients who have tested positive for any of these tests, VAPAHCS staff are examining their test results prior to January 2009 to determine if there has been a status change. Further details regarding the look-back and look-ahead processes will be provided.

A Root Cause Analysis regarding VAPAHCS equipment orientation processes will be chartered.

UPDATE
On November 2, 2009: VAPAHCS was contacted by then National Center for Patient Safety to verify reported information. The October 26, 2009 version of this report was provided, along with photographs of the pieces involved, and the number of patients possible affected.

VAPAHCS also received a final recommendation from the Chief of Infectious Disease, which was that the risk for the patients involved is very low, but not zero.

CONTACT FOR FURTHER INFORMATION:
Elizabeth Joyce Freeman, Director, at [redacted]