Federal Health Matters

VA Report Says Endoscope Problems Continue

The VA's Office of the Inspector General (OIG) reported on June 16 that, as of the previous month, most VA facilities were not in compliance with department policies on endoscope reprocessing. This finding came after months of scrutiny on the VA's endoscope safety policies by media, Congress, and the VA itself, beginning with the department's finding in December 2008 and January 2009 that improperly reprocessed endoscopes at three of its facilities had exposed 10,617 veterans to the risk of infection.

The OIG based its report on surprise inspections it made at 42 VA facilities on May 13 and 14. The inspections' results, the office said, suggested that only 43% of all VA facilities were in compliance with two requirements of a February VA directive: that facilities make standard operating procedures for endoscope reprocessing readily available and that they document staff members' training on endoscope reprocessing. The OIG report concluded that widespread noncompliance with the VA directive was resulting "in a risk of infectious disease to veterans."

Several members of Congress responded to the report by criticizing the VA harshly. Rep. Tim Walz (D-MN) said the report has "catastrophic" implications, and Rep. Bart Gordon (D-TN) commented that "veterans' confidence in the VA is shaken." Rep. Phil Roe (R-TN) said he sterilized endoscopes routinely during his 31-year practice as a physician and that doing so is "not a complicated procedure."

In addition, both the OIG report and Sen. Daniel K. Akaka (D-HI), chairman of the Senate VA Committee, suggested that the VA may need to make structural changes in order to ensure that its facilities comply with its directives. The report recommended that Gerald M. Cross, the department's acting under secretary for health, "review the VHA organizational structure and make the necessary changes" in order to ensure compliance with VA directives and implement quality controls regarding endoscope reprocessing. Akaka said at a June 24 hearing of the Senate VA Committee that the VA's endoscope problems and other issues indicate the department "has become too decentralized" and has ceded oversight "to individual VA hospitals, with little or no direct oversight by VA's central office." He added that he would work with the Obama administration to make changes in this regard.

On the day of the Senate hearing, the VA announced that it would make a more immediate change by spending $26 million from its reserve funds on new sterilizing equipment for endoscopes and other reusable medical equipment (RME). In addition, Cross testified at the hearing that the VA's national staff would visit every VA facility by July 14 to ensure that the facilities document staff training on endoscope reprocessing. Furthermore, the VHA issued a directive on June 26 that called on its VISNs and facilities to standardize organizational structure and reprocessing requirements in regard to endoscopes and other RME. The directive ordered that "each VHA facility must have a systematic standardization and oversight plan for reprocessing RME according to current manufacturers' instructions and systematically retire and replace older equipment in place" and that "each VISN must have a Supply, Processing, and Distribution Management Board established and functioning no later than September 1, 2009."

As of June, the VA said it had followed up on 96% of the veterans exposed to infection risks by improper endoscope reprocessing at the VA Tennessee Valley Healthcare System in Murfreesboro, TN; the Miami VA Medical Center in Miami, FL; and the Charlie Norwood VA Medical Center in Augusta, GA. The department said that 34 of these veterans had tested positive for hepatitis C, 13 had tested positive for hepatitis B, and six had tested positive for HIV. It is impossible, however, to prove whether the veterans contracted their infections from the VA's endoscopes.

Brachytherapy Controversy Erupts at Philadelphia VA Medical Center

In late June, national attention focused for the first time on reports that the prostate brachytherapy program of the Philadelphia VA Medical Center (PVAMC), Philadelphia, PA gave incorrect doses of radiation to 92 patients between 2002 and 2008. Questions also arose as to why these incorrect doses went undetected for nearly six years.

The *New York Times* reported on June 21 that the PVAMC program, which began in 2002 and was suspended on June 11, 2008, was the subject of ongoing investigations by the VA and the United States Nuclear Regulatory Commission (NRC), which oversees the medical use of radioactive material. These investigations were described in further detail during a field hearing of the

Senate VA committee held June 29 at the PVAMC. The hearing included testimony by Gerald M. Cross, the VA's acting under secretary for health; Steven Reynolds, who oversees materials safety at the NRC; and Gary D. Kao, MD, PhD, a radiation oncologist who performed most of the PVAMC's problematic brachytherapy procedures. Kao had contracted for the PVAMC program but no longer works at the facility. He is on staff at the University of Pennsylvania School of Medicine, Philadelphia, PA, which granted him a leave of absence on June 25.

The VA and NRC investigations were prompted by a PVAMC staff member's discovery on May 15, 2008 that a brachytherapy procedure performed at the facility ten days earlier had dosed the patient's prostate with less radiation than intended. The investigations eventually determined that 92 of the 112 brachytherapy procedures performed at the facility met the NRC's definition of problematic "medical events" because they underdosed the prostate or dosed organs or tissues other than the prostate. Cross emphasized that "the definition of 'medical event' does not necessarily mean veterans were harmed," however, and Kao testified that NRC guidelines do "not constitute a clinical standard of care for brachytherapy treatment."

The findings of problematic procedures at the PVAMC, in turn, prompted the facility to suspend its brachytherapy program and contact all veterans treated through the program, according to Cross. These findings also prompted the NRC to begin inspecting all other VA brachytherapy programs in September 2008. Since then, Cross said, the VA has suspended such programs at facilities in Washington, DC; Cincinnati, OH; and Jackson, MS. He added that while "the Cincinnati program was found satisfactory," reviews of the other programs are continuing.

At the committee hearing, Rep. John Adler (D-NJ) said he was "very troubled that the [VA] could not offer a better explanation of how this pattern of substandard care occurred over the course of six years" at the PVAMC. Cross said that while the VA National Director of Radiation Oncology is continuing to investigate this question, many of the VA's internal and external quality-control measures appear to have failed. Reynolds said that the NRC was contacted about potential problems with the PVAMC's program in 2003 and 2005 but, after investigating both times, determined that the facility had not violated any NRC regulations. He added that the NRC investigation started in May 2008, however, has found six apparent violations of NRC regulations.

The *Times* reported that peer review did not exist in the PVAMC program, and it quoted a NRC report as saying that the program lacked a "safety culture." Kao disputed the *Times* account sharply, however, saying that the PVAMC's brachytherapy team "was minutely supervised every step of the way by the radiation oncology department, the radiation safety office, and, ultimately, by the administration of the PVAMC." He added that there "were a number of systematic failures at the PVAMC that affected the brachytherapy program," though. For example, he said, there was no standard definition of a reportable medical event when the program started, and there was no system to train program members on that definition after it developed.

Despite defending his work overall, Kao apologized at the hearing to Reverend Ricardo Flippin, on whom he performed a brachytherapy procedure in May 2005. According to the *Times*, Flippin's procedure caused his rectum to be dosed with radiation, but the VA did not inform Flippin of this fact until August 2008. In the meantime, Flippin experienced pain, bleeding, and digestive problems that incapacitated him for five months; was diagnosed by a physician outside the VA with radiation injury to the anal canal; and underwent surgery to repair the radiation damage. Despite the latter procedure, he still suffers from lack of bowel control.

Kao hugged Flippin and said, "Reverend Flippin, we should have, we can do better. I hope we have a chance to do better for you and your colleagues in the future." ●

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