Department of Veterans Affairs
Office of Inspector General

Health Care Inspection

Quality of Care in Cranial Implant Surgeries at James A. Haley VA Medical Center Tampa, Florida

Report No. 06-01642-126

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VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
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Contents

Introduction

Purpose

The purpose of this inspection was to provide an external review of two incidents involving patient safety at the James A. Haley VA Medical Center (JAHVAMC) and the alleged delay in reporting the incidents to higher levels of VA management.

Background

On March 14, 2006, the U. S. House of Representatives Committee on Veterans' Affairs requested that the Office of Inspector General (OIG) conduct an investigation of two incidents involving the use of non-sterile Stryker® custom cranial implant products. Stryker® custom cranial implants are derived from patient computerized tomography (CT) data. The CT data is converted into 3-D computer generated images, which are subsequently used to create precise anatomical models in order to build the custom cranial implants.

During an attempted cranioplasty[1] on February 28, 2006, operating room (OR) staff were concerned that a non-sterile Stryker® cranial host-bone model was opened onto the intraoperative sterile field. The host-bone model for a patient is provided by the manufacturer as a pre-operative guide to demonstrate orientation and fit of the custom cranial implant. During their review of this incident, operating room staff discovered that one week earlier, on February 21, 2006, a non-sterile Stryker® custom cranial implant was implanted in a different patient. In requesting an OIG investigation, Committee members expressed concerns regarding the incidents themselves and the potential health risk to patients, as well as the 10-day delay by the Medical Center and Veterans Integrated Service Network (VISN) management in reporting these incidents to VA Central Office.

In the VA population, cranioplasty procedures are often performed to cover a defect in a patient's skull. In the past, implants were made in the operating room using titanium mesh or by mixing methyl methacrylate powder with liquid, which then hardens and is molded to approximate a cranial defect. In the last few years, manufacturers have developed technologies to build cranial implants that are customized to fit the anatomic specifications of individual patients. Potential advantages of pre-made anatomically customized implants include better cosmesis, precise fit, less chance of vascular exposure to methyl methacrylate (which is cardiotoxic), and decreased operating room time due to less need for drilling and sculpting at the time of surgery.

Patient-specific cranial implants were first used at the JAHVAMC in April 2004. To date, neurosurgeons at the medical center have used the products of three different

[1] A surgical repair of a defect of the skull; involves the resection, remolding and movement the bones of the head.

manufacturers. One of the products is sterilized by the manufacturer. The products from the other two companies need to be sterilized by the Supply Processing and Distribution (SPD) department of the medical center prior to their use in the operating room.

For this review, it is important to understand the role of SPD, which has the following responsibilities:

1. Supplies nursing care areas including the OR and other specialty areas with the medical supplies and instruments that are needed.
2. Cleans equipment and instrumentation in the decontamination area. Equipment and instrumentation are then moved to the prep area where they are wrapped and sterilized for use. Sterilization is achieved through one of three methods:
    a. Ethylene oxide gas – the most commonly used process for sterilizing temperature- and moisture-sensitive medical devices and supplies; it is toxic and requires great caution.
    b. Steam – inexpensive and effective but cannot be used with heat-sensitive items.
    c. Hydrogen peroxide gas/plasma – is a low-temperature oxidative sterilization method for medical devices and surgical instruments; it is a safe alternative to ethylene oxide sterilization. One is marketed under the trade name Sterrad.™
3. Moves processed equipment and instrumentation out to the appropriate areas throughout the medical center.

Another organization integral to the understanding of this incident is the National Center for Patient Safety (NCPS). Veterans Health Administration (VHA), through NCPS, is focused on reducing and preventing adverse medical events while enhancing the care given patients. NCPS was established in 1999 to develop and nurture a culture of safety throughout VHA. Their goal is the nationwide reduction and prevention of inadvertent harm to patients as a result of their care. There are patient safety managers at all VA hospitals and patient safety officers at each VISN. The program is based on a systems approach to problem solving that focuses on prevention not punishment. They use human factors engineering methods and apply ideas from high reliability organizations, such as aviation and nuclear power, to target and eliminate system vulnerabilities.

One of the most important strategies that NCPS uses is the focus on prevention rather than punishments. They stipulate that the way to promote the reduction or elimination of harm to patients is to learn from close calls, which occur at a much higher frequency than actual adverse events. It focuses everyone's efforts on continually identifying potential problems and fixing them. This does not mean that VHA is a "blame free" organization. Only those events that are judged to be an intentionally unsafe act can result in the assignment of blame and punitive action. Intentionally unsafe acts, as they are related to patients, are those that result from a criminal act, a purposefully unsafe act, or an act related to alcohol or substance abuse or patient abuse. They use a multi-disciplinary team

approach, known as root cause analysis (RCA), to study adverse medical events and close calls. The goal of each RCA is to find out what happened, why it happened, and what must be done to prevent it from happening again.

NCPS is a multi-disciplinary team located in Ann Arbor, Michigan; Washington, DC; and White River Junction, VT. Their aim is to learn from and spread information throughout VHA nationwide. Consequently, their Patient Safety Information System (SPOT), external Patient Safety Reporting System (PSRS), and the chain of communication from local facility, to the VISN, and VHA headquarters are essential components in the process. The integration of all these approaches across the organization creates a level of trust and a focus of efforts that helps perpetuate a culture of safety. In fact VHA been recognized as a leader in improving the quality of health care.[2]

Scope and Methodology

We visited the JAHVAMC on March 20-23, 2006. We reviewed patient medical records for the patient who underwent a cranioplasty on February 21, 2006, and for the patient who underwent a cranioplasty on February 28, 2006. Medical record progress notes were reviewed from the day prior to the procedures to the most recent progress note contained in the electronic medical record as of March 28, 2006. We reviewed VHA and local policy and procedures, a preliminary root cause analysis report, incident reports, and implant sterilization records. We interviewed VA Central Office, VISN 8, and JAHVAMC senior managers and staff with knowledge of the alleged incidents. We obtained Stryker product information from the company web site. We asked for an interview with the local Stryker representative with whom the JAHVAMC staff had dealt. This request was declined, but a company representative was willing and did respond to written questions that we submitted. We examined a Stryker® cranial implant and model and inspected the packaging for the cranial implant and model that were opened during the February 28 procedure. We reviewed the process by which implants are received and sterilized by the facility.

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

[2] Asch, S. M., McGlynn, E. A., Hogan, M. M., Hayward, R. A., Shekelle, P., Rubenstein, L., Keesey, J., Adams, J., and Kerr, E. A. "Comparison of Quality of Care for Patients in the Veterans Health Administration and Patients in a National Sample," *Annals of Internal Medicine*, Vol. 141, No. 12, December 21, 2004.

Results of Inspection

Chronology

Tuesday, February 28, 2006:

A 32-year-old Operation Iraqi Freedom (OIF) veteran underwent a cranioplasty at the JAHVAMC for repair of a skull defect. The patient had sustained a penetrating head injury due to shrapnel fragment from an improvised explosive device (IED) blast. During the procedure, the neurosurgeon encountered difficulties in attempting to place the implant. The neurosurgeon reported that he considered possible etiologies for the difficulty with fit, including the possibility that the implant was not made to specifications; the implant somehow warped during storage at the hospital; or that since his prior hospitalization, the patient had developed bulging, hydrocephalus, edema, or some other change in brain/skull configuration. After re-checking his exposure of the bone edges around the defect, the surgeon used the host-bone model to check for one of the first two considerations. The surgeon requested the model in order to determine if the prosthesis had undergone deformity since leaving the manufacturer. The model, which was packaged in a peel pack, was opened and passed onto the sterile field by the relief nurse circulator.[3] The implant and model fit together nicely and there did not appear to be any defect in manufacturer or subsequent warping. The neurosurgeon tried to modify and fit the implant but felt that its placement was causing unacceptable pressure on the brain, as the patient's brain appeared to protrude out slightly from the normal contour of the skull. After considering alternatives to the prefabricated implant, the neurosurgeon stated that he felt that the best course of action was to terminate the procedure, clinically re-assess the patient, and attempt a repeat cranioplasty at a later date.

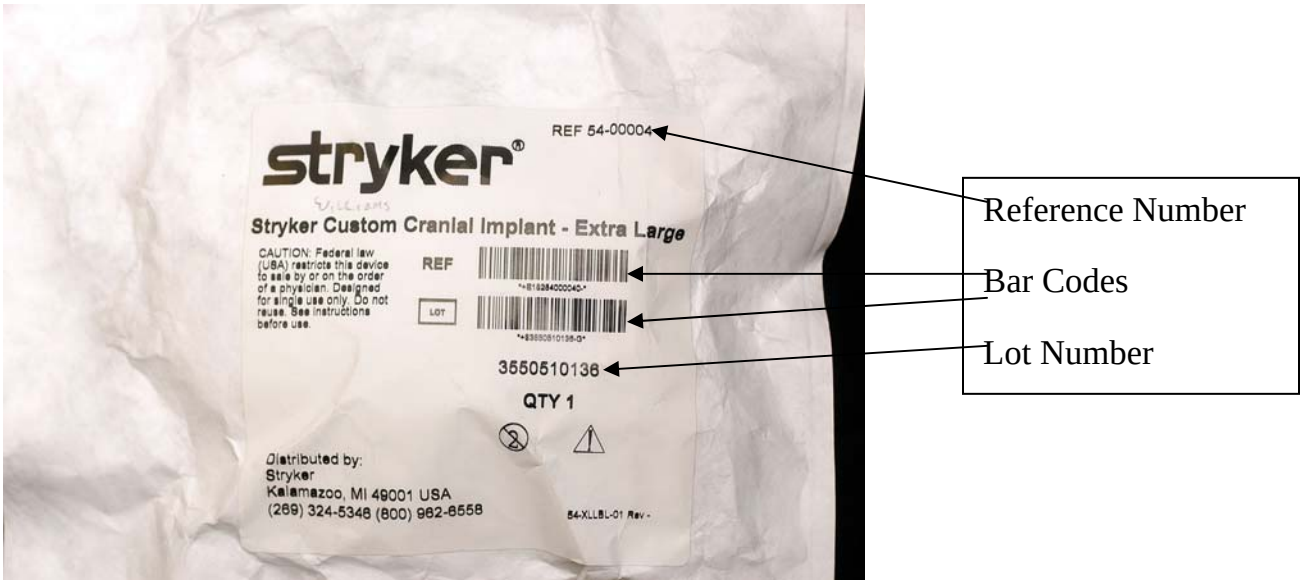
As the surgeon was closing the skin, the assigned nurse circulator, who had just returned from her lunch break, reportedly asked why the cranial model was on the sterile field.

[3] The nurse circulator is a registered nurse who wears clean surgical scrubs, shoe covers, cap, and mask. However, the nurse circulator is not sterile and does not touch items or enter the sterile area of the operating room known as the sterile field. The nurse circulator's main duties include assisting the surgeon, scrub nurse, or surgical assistants into their gowns and gloves, opening the outside wrappings from sterile instrument trays, labeling specimen containers, keeping the sponge count, obtaining unexpected equipment/instruments, keeping the intraoperative nursing documentation records, and helping to escort the patient to the recovery room. Especially in long surgeries, it would not be unusual for a nurse circulator to be relieved at change of shift or for meal break.

Surgeons, scrub nurses, surgical assistants, and surgical technicians wear sterile gowns, shoe covers, caps and masks. The main duties of the scrub nurse or surgical techs include opening all sterile instrument packs, ensuring the right instruments are in the packs, organizing surgical instruments on the sterile field, handing the correct instrument to the surgeon, and doing needle and instrument counts at completion of the procedure.

Both the cranial model and implant had been in peel packages, which can be seen in the following pictures:

The assigned nurse circulator reportedly was concerned because the package label for the model states "Do NOT Implant." This differed from the packaging for the cranial implant itself. The nurse circulator also noted that she erroneously believed that several months earlier someone had told her that the implant was sterile but that the model was not. This also led her to question its sterility. The package had two bar codes, reference number, item number, and other distinctive markings similar to various sterilized prosthetic products that operating room personnel were accustomed to receiving from Stryker and other manufacturers. This can be seen in the following picture:



She stated that she called the local Stryker representative to ascertain whether the model was packaged sterile by the manufacturer. The neurosurgeon reported that at this point, no personnel in the OR suspected that the cranial implant itself had not been sterilized by the manufacturer. The nurse circulator initiated an incident report and left it on the operating room nurse manager's desk. Post-operatively, the patient was started on antibiotic medication.

Wednesday, March 1, 2006:

The OR nurse manager received and reviewed the incident report. After speaking with the nurse circulator and the SPD/Equipment Coordinator for the OR, he questioned whether the cranial implant itself was sterile. He examined a cranial implant in its original packaging and did not see an expiration date or the word sterile on the manufacturer's peel pack. He then notified the Chief of Surgery and directed his staff to contact a Stryker representative for clarification.

The Chief of Surgery notified the Chief of Staff (COS) and the facility Risk Manager (RM). The Chief of Surgery then requested a list of patients who had cranioplasties at JAHVAMC.

The facility RM instructed the facility Patient Safety Officer (PSO) to enter the event into the SPOT database, which is the patient safety information tool for NCPS. The facility RM contacted the VISN 8 PSO to report that a surgical field had been contaminated by the non-sterile model that came with the custom cranial implant.

The VISN PSO contacted the VISN Quality Management Officer (QMO). The VISN PSO and QMO then contacted the VISN Network Director and also emailed the VISN Chief Medical Officer (CMO). The VISN Chief Medical Officer (CMO) e-mailed the VISN PSO requesting additional information about the case. She also reminded the VISN PSO to report the event to the NCPS in the event that patients at other medical centers were inadvertently exposed to non-sterile product.

The OR staff retrieved and read the implant package insert that indicated that the implant was "supplied non-sterile" and required sterilization by 100 percent ethylene oxide. The OR nurse manager stated that he then informed the Chief of Surgery and he showed the package insert to the neurosurgeon. The nurse circulator noted that she spoke with a Stryker representative and reportedly learned that although the implant is not sterilized (and needs to be sterilized at the medical center), the manufacturer does clean each implant before packaging. A Stryker representative told her and later told OIG inspectors that it is cleaned using the following process:

a. Using a clean scrub brush, scrub the implant in a 70/30 mixture of alcohol/distilled water solution.
b. Vigorously rinse, by moving the implant into a separate vessel of 70/30 mixture of alcohol/distilled water solution.
c. Transport implant in a covered container to the designated drying area and allow to air dry for one hour.
d. Place implant in a sealable Tyvek pouch and seal with impulse sealer.

The neurosurgeon discussed the difficulty with placement of the implant and disclosed the adverse event to the patient. That afternoon the patient had developed a 101.6 degree

temperature. The patient's white blood cell count was within normal limits. An infectious disease consult was requested. The patient was evaluated, a chest x-ray and cultures were ordered, and one of two antibiotic medications was changed.

On learning that Stryker® custom fit cranial implants are not fully sterilized by the manufacturer, the OR nurse manager and the neurosurgeon became concerned that one week earlier, on February 21, 2006, a non-sterile Stryker® custom cranial implant may have been used for the cranioplasty of another patient. In the February 21, 2006, procedure the implant readily fit the defect in the patient's skull, and the host-bone model was not needed or used. The neurosurgeon reported that he had been following this patient post-operatively on the rehabilitation unit at JAHVAMC and the patient was doing well clinically, without evidence of complications.

Thursday, March 2, 2006:

The Chief of Surgery obtained the list of patients thought to have had cranioplasties with Stryker/Leibinger implants[4] and provided the list to the COS. The Chief of Surgery spoke with neurosurgical staff to determine the clinical status of the patients who were thought to have undergone cranioplasties at JAHVAMC using Styker/Leibinger implants. This included the patient who had been exposed (Patient G) and the patient who had received the implant (Patient F), as shown in the following patient identification chart.

Date of Procedure	Patient	Procedure	Manufacturer/ Product Used	Sterilization
April 29, 2004	A	Right-sided Cranioplasty	Porex	Manufacturer
August 5, 2004	A	Left-sided Cranioplasty	Porex	Manufacturer
September 30, 2004	B	Right-sided Cranioplasty	Autologous Bone Graft	N/A
February 1, 2005	C	Craniotomy	Bone Paste	N/A
March 16, 2005	D	Right-sided Cranioplasty	Osteoplastix	Facility SPD
March 17, 2005	E	Left-sided Cranioplasty	Osteoplastix	Facility SPD
February 21, 2006	F	Left-sided Cranioplasty	Stryker	None
February 28, 2006	G	Attempted Right-sided Cranioplasty	Stryker	None

[4] Leibinger Micro Implants is a division of Stryker; it develops and produces fixation systems and other materials for neurosurgery and other surgical specialties.

The COS received and reviewed the implant package insert, which did state that the implant required sterilization. The list of patients thought to have cranioplasties using Stryker® custom cranial implants was initially misconstrued as consisting of eight patients rather than seven. This was because one patient (Patient A) had undergone two separate procedures, a right-sided and a left-sided cranioplasty, which had been performed on separate dates. The COS checked to see if any upcoming cranioplasty procedures were scheduled for the imminent horizon. He reviewed the medical records of the patients on the list to see if any of the patients had complications. He reported that his primary concern in this first chart review was to establish the clinical status and well being of the patients. During his review, he noted that several nursing intraoperative notes indicated the use of various Stryker products. In addition to cranial implants, Stryker also makes screws, bone plates, and other hardware used to secure implants, regardless of the cranial implant's manufacturer.

The COS notified the Medical Center Director (MCD) of the incident. The COS began looking into proper procedures for when and how to disclose the adverse event. The COS and RM called the Regional Counsel to seek guidance regarding disclosure of the adverse event. He notified a Stryker representative that the facility planned to submit an adverse event report to the Food and Drug Administration (FDA).

The MCD, COS, and Associate Director called the VISN Network Director and informed him of the situation. At this point, they notified the VISN Network Director that, after having collected some preliminary data, there may have been up to eight patients who had cranioplasties using Stryker® custom implants—but reported that they were unsure. It was unclear how many of the cranial implants were supplied sterile or had been sterilized. They also informed him that they were in the process of trying to determine the number who had received non-sterile implants, and they planned to charter a root cause analysis team. The VISN Director requested further information in writing, which led to the development of a white paper.[5] The VISN director reported to us that in his judgment the facility appeared to be handling the situation appropriately and that it seemed prudent to wait for further data that would clarify how many patients were actually affected. The VISN PSO called NCPS.

Friday, March 3, 2006:

The JAHVAMC RM began to draft the FDA adverse event report. The MCD chartered a RCA team to evaluate for potential root causes underlying the adverse events. The infectious disease consultant noted that the patient was doing very well clinically, had a normal white blood cell count, and negative urine and blood cultures. The plan was to discontinue the intravenous antibiotics after a total of 5 days if the blood cultures continued to remain negative and the patient remained without fever.

[5] A white paper is a brief report on a specific issue or topic.

Monday, March 6, 2006:

The COS asked the Chief of SPD to examine SPD records to see if any of the seven patients on the list had Stryker® cranial implants that had been sterilized by SPD.

Tuesday, March 7, 2006:

The facility Quality Management staff submitted the Medical Device Report (MDR) to the FDA, and the RCA team had its first meeting. The Chief of SPD at JAHVAMC notified the Executive Director of SPD Programs in VA Central Office in Washington, DC, of the incident and told him that the facility had submitted notification to the FDA.

Wednesday, March 8, 2006:

At this point in time, the COS was still under the belief that there may have been seven patients that had received a Stryker® cranial implant. He had previously established that the patients on the list were reportedly doing well. The Chief of SPD informed him that the only Stryker® implant that they could confirm was sterilized by SPD was for a patient whose cranioplasty had been scheduled for March 15, 2006, and had not yet been performed. The COS again called Regional Counsel for guidance on disclosure.

The COS, MCD, and the Associate Director called the VISN Network Director seeking further guidance regarding disclosure. The VISN Network Director was not available at the time. The VISN CMO reported that the COS, MCD, and Associate Director told her that it now seemed that seven or eight patients may have received a non-sterile implant but they were further investigating the situation in order to verify whether these actually were Stryker® implants.

Subsequently, the VISN CMO discussed the situation with the VISN Network Director, who asked his CMO to contact the Clinical/Quality Assurance (QA) Liaison in VA Central Office (VACO) to communicate the seemingly clearer information. At this point it was late in the day. The VISN CMO spoke with the VACO Clinical/QA Liaison about the situation and told her that a white paper would be sent to VACO the following morning. The VACO Clinical/QA Liaison, who was not in Washington, alerted a secretary at VACO to look for the issues brief that would be arriving the next morning. The Health Systems Specialist for VISN 8, who works in the Office of the Deputy Under Secretary for Health for Operations and Management (the Network office in VACO), became aware that an issues brief from VISN 8 was supposed to arrive the next morning.

Thursday, March 9, 2006:

That morning, around 9:00-9:30 a.m., a Special Agent in Charge (SAC) at the Office of Inspector General St. Petersburg Regional Office, contacted the MCD to discuss OIG open cases/issues at JAHVAMC. The SAC was tasked to put together a comprehensive document that listed every issue under investigation by the OIG at the JAHVAMC. After

a comprehensive review of the issues, the SAC asked the MCD if there was anything that the OIG should be aware of that could potentially become an issue. The MCD told the SAC about the issue involving cranial implants and reportedly mentioned that the medical center had prepared a white paper. The SAC stated that he needed the MCD to send him a copy of the white paper.

The MCD called the VISN Network Director and informed him of his conversation with the SAC. He also relayed that the patients thought to be affected were mostly Operation Enduring Freedom/Operation Iraqi Freedom active duty personnel.

That same morning, the COS submitted a memorandum to the MCD detailing the events and actions taken thus far. The MCD incorporated that information into a white paper, which he e-mailed to the VISN Network Director. The white paper was also sent to the VISN 8 Health System Specialist in the Network office in VACO, who recalled receiving it at approximately 11:45 a.m. The Health System Specialist then forwarded the white paper to his supervisor, the Director for Network Support. The facility Chief of Staff later returned a phone call from the Health System Specialist to VISN 8 regarding whether the facility planned a clinical or institutional disclosure. The Network office in VACO worked with the VISN to include pertinent information and complete the issue brief.

The Executive Director of SPD sent a group e-mail asking other VAMCs if they had used Stryker® custom cranial implants. San Diego VAMC initially responded affirmative.[6]

At approximately 5 p.m., the Clinical Executive to the Principal Deputy Under Secretary of Health (PDUSH) was notified and provided an issue brief. The Chief of Patient Care Services and the Deputy Chief of Patient Care Services were consulted in person at VACO. The PDUSH was then notified and provided with incident details and available information. The Director of the National Center for Patient Safety was contacted and reported that NCPS was already addressing the issue. The Under Secretary for Health was then notified about 9:30 p.m.

Friday, March 10, 2006:

The COS met with a neurosurgeon who had performed earlier custom implant cranioplasties at the JAHVAMC. This neurosurgeon normally works at the facility only on Thursdays. The COS reported that the neurosurgeon reviewed the list of potential Stryker® implant recipients and recalled that two of the patients on the list did not have cranial implants (B and C). The COS now questioned the accuracy of the list. Further conversation with the neurosurgeon and a second review of patient medical records

[6] The VISN QMO reported that it was later determined that the university hospital in San Diego contracts with the VAMC to sterilize certain products. The VAMC had sterilized a cranial implant that was used at the university hospital, not at the VAMC.

confirmed that one of the patients (B) had an autologous[7] bone graft (skull flap previously inserted into his abdominal cavity for later re-implantation); the skull defect of a second patient (C) had been repaired with bone paste and not with an implant. The neurosurgeon also remarked that he did not believe that Stryker® cranial implants were commercially available in 2004 when one of the other surgeries (A) was performed. From the nursing intraoperative note, the neurosurgeon and COS were able to identify Porex as the manufacturer for this patient's cranial implant. The COS reported that contact with the company confirmed that Porex cranial implants were shipped sterile.

Including the patient who had received the Stryker® implant on February 21, 2006 (F), and the patient who had been exposed to but had not received the Stryker® implant on February 28, 2006 (G), the facility was now able to account for five of seven patients on the list of potential implant recipients. A repeat review of the nursing intraoperative notes indicated that both of the implants used in the two remaining cranioplasty surgeries (D and E) were sterilized by SPD. However, the intraoperative notes listed the manufacturer as unknown.

Later that day, the COS called the Chief of SPD and requested that she pull SPD records for the two remaining patients on the list. She found the product labels from the implants for the two patients; these indicated that both patients (D and E) had received Osteoplastix™ cranial implants. The COS reported that the company was called and reported that Osteoplastix™ cranial implants are shipped non-sterile. Although labels for the implants for the two patients would logically not have been kept in SPD if the implants had not gone through SPD for sterilization, the COS asked the Chief of SPD to pull sterilization records for the days preceding the two surgeries, in order to cross reference and get further confirmation that the implants were sterilized. The COS reported that these records were kept in the basement, which would make the search more time-consuming.

The COS reported that, in consultation with Regional Counsel, JAHVAMC management decided that it would be prudent to over-disclose, even though at this point they were unable to verify whether these two patients belonged on the list. They were also concerned that if they waited to disclose pending further efforts at verification, families might first learn about the potential adverse event from the media rather than from clinical staff, which would be more appropriate. The COS reported that they spoke to the two families of the Osteoplastix™ implants (D and E).

On the same day, the National Director of Surgery in VACO reportedly called the COS and requested a picture of the peel pack for the Stryker® cranial implant and a copy of the white paper. In addition, the COS, Chief of Physical Medicine and Rehabilitation, and the attending physician for the patient who received the implant on February 21 (F),

[7] Autologous means derived or transferred from the same individual's body.

called this patient and his family. They reviewed and discussed his clinical status and disclosed issues related to implant sterility.

The neurosurgeon reported that on March 1 or 2, he was under the impression that management was in the process of arranging a meeting with the family of the patient who had received the cranial implant on February 21 (F). When he returned to the medical center on March 6, he inaccurately heard from someone that the meeting had taken place. The COS, who had only begun serving in that role in late February, reported that during a March 2 meeting that included the Chief of Surgery, they had planned to call the family; however, the Chief of Surgery felt that it would be most appropriate clinically for the patient's neurosurgeon, who knew the patient, to call the family. The COS reported that he subsequently recalled someone mentioning that the neurosurgeon had spoken with the patient's family. However, several days later, during repeat review of the chart progress notes, the COS did not notice documentation of a discussion between the neurosurgeon and the family. He stated that although he was under the impression that the neurosurgeon had spoken with the family, he called them on March 10 in order to ensure that they had been notified. He reported that he recently has learned, from a conversation with the neurosurgeon, that the neurosurgeon had assumed that the Chief of Staff and Chief of Surgery had already disclosed to the patient's family during their meeting on March 2.

Monday, March 13, 2006:

SPD staff went through the sterilization records over the weekend. The COS reported that he retrieved a voice mail message at 7:00 a.m. informing him that the sterilization records indicated that the Osteoplastix™ implants for the remaining two patients (D and E) had been sterilized by the facility SPD. He called the VISN Network Director and MCD who were in Washington, meeting with the Under Secretary for Health and the Principal Deputy Under Secretary for Health. He spoke with the MCD and informed him that the Osteoplastix™ implants were sterilized by SPD, which meant that one patient (F) had received a non-sterile implant and that one patient (G) was exposed.

The Principal Deputy Undersecretary for Health briefed staff members of the Senate and House Veterans' Affairs Committees.

Friday, March 17:

The COS sent letters to the two patients (D and E) who had received the Osteoplastix™ implants, explaining that the implants had been "properly and thoroughly sterilized" and that "all steps of the sterilization process were completed, including the last step." The letter also discussed the rationale for the previous over-disclosure.

Issue 1: Alleged Post-Operative Complications

We could not find evidence of patient harm directly related to the non-sterile implantation or exposure to the custom cranial implant. A non-sterilized Stryker® custom cranial implant and host-bone mold were placed on the sterile field during a cranioplasty on February 28, 2006. The patient (G) was exposed to the non-sterilized implant and mold but the implant was not ultimately placed. On February 21, 2006, a non-sterile implant was placed during a cranioplasty (F) and utilized to repair the patient's skull defect. The patient exposed to the non-sterile implant on February 28 had a transient temperature of 101.6 degrees on the afternoon following surgery, which resolved. In the medical record progress notes, the infectious disease consultant indicated a routine post operative inflammatory response as the likely cause of the temperature. No signs of infection were noted, and cultures were negative. Antibiotics were discontinued on March 5. A March 6, 2006, follow-up CT scan of the head showed no evidence of recent hemorrhage, and the ventricular size was unchanged. The patient went on an overnight pass with his wife the same day. He experienced no difficulties and was discharged home on March 8.

The patient who received the implant on February 21 (F) is a 22-year-old, who sustained a traumatic brain injury due to a motor vehicle accident in March 2005 in a neighboring state. He subsequently underwent a left parietal/temporal craniotomy with flap due to severe edema. He was transferred to the JAHVAMC in May 2005 for rehabilitation. He was then transferred to the nursing home care unit (NHCU) in June 2005, for continuation of his rehabilitation, with goal of eventual discharge home with his parents. He was readmitted to a rehabilitation unit at JAHVAMC in January 2006, after making progress since transfer to the NHCU. He was able to ambulate 200 feet while using a hand rail, and his following of commands improved, but his verbal communication remained limited.

Following receipt of the custom cranial implant on February 21, we could not find evidence that the patient has experienced complications. A follow-up CT scan 1 day after surgery showed a small left subdural hematoma, which was noted by the neurosurgery service to be non-surgical, and was not felt to be of concern. On February 23, he was cleared by neurosurgery to return to the rehabilitation unit in order to resume treatment with the head injury team. The head nurse on the unit and the patient's neurosurgeon reported that the patient continues to do well clinically and has actually shown some functional improvement, in that he is talking and/or verbally repeating more than he had been prior to surgery.

Issue 2: Process/System Deficiencies

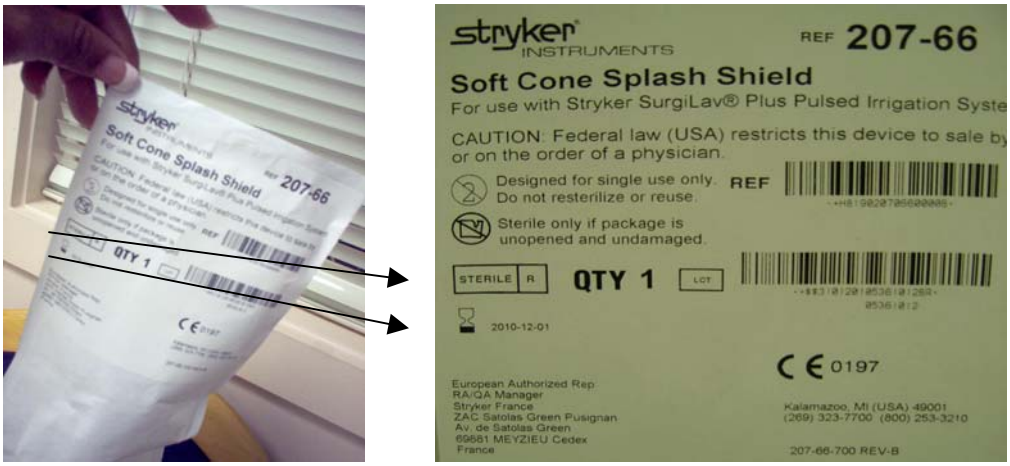
JAHVAMC first used custom cranial implants in April 2004. The facility has purchased custom cranial implants from three separate companies. The facility neurosurgeons used a Porex product in the 2004 surgeries, Osteoplastix products in the 2005 surgeries, and Stryker products in the two recent surgeries. JAHVAMC neurosurgeons also repaired skull defects using an autologous bone graft in one patient and bone paste in another patient.

A. Verification of Sterility by Intraoperative Personnel

As with the previous cranioplasty procedures using custom fit implants, after the neurosurgeon determined that patients were good candidates for the procedure, CT scans were obtained from which the manufacturer constructed a cranial implant designed to fit the individual patient. The neurosurgeon entered a prosthetics request/consult into the computer, which initiated the prosthetic acquisition process. In the two recent surgeries, the Stryker® custom fit cranial implants were then mailed to a local Stryker representative, who reportedly delivered the implants to the prosthetics department. The prosthetic supply technician stated that he informed the SPD/Equipment Coordinator for the OR that the implants had arrived. The implants were stored in the prosthetics department until called for by the OR SPD/Equipment Coordinator. The OR SPD/Equipment Coordinator stated that he received patient F's Stryker® custom cranial implant and then gave the implant to the nurse circulator. In preparing the room for surgery, the nurse circulator reportedly took the implant into the operating room. A Stryker product representative reportedly had arrived in the operating room after patient F's cranioplasty procedure had begun.[8]

At approximately 2:30 p.m., the nurse circulator was permanently relieved by the on-coming nurse circulator. The off-going nurse circulator performed surgical counts, and showed the on-coming nurse circulator the cranial implant. When the surgeon was ready for the custom cranial implant, the on-coming nurse circulator opened the peel-pack containing the Stryker® implant and passed it to the scrub technician, who ultimately passed it to the neurosurgeon. A similar process occurred for patient G, with the exception that a Stryker representative was not in the operating room and the neurosurgeon was having difficulty with implantation fit and therefore requested the model.

[8] Surgical cases involving prosthetic devices often require that prostheses of different sizes are available in the OR, as best fit can often not be determined prior to surgery. Some prosthetic devices are accompanied by kits which contain the hardware and tools used with a prosthetic device. These kits are sterilized in SPD and essentially leased or borrowed by medical centers. It is not unusual for representatives of companies that manufacturer prosthetic devices to be present in the operating room, in case there is a question regarding company tools, changes in product design, sizing, and so forth. In accordance with privacy concerns, surgical staff will routinely obtain a separate consent from a patient in order to allow a company representative to be present in the operating room during that patient's procedure.



As shown in the pictures above, pre-packaged sterile products have sterilization or expiration dates, an hour glass, and the word "Sterile" printed on the package. On the day following the February 28 procedure, while investigating the placement of a non-sterile model on the sterile field, OR staff became aware that the Stryker® custom cranial implant itself also required sterilization by the facility.

Several OR staff reported that the packaging of the Stryker® custom cranial implants appeared similar to them to other Stryker products (see picture above) that are sterilized by the manufacturer. In addition, OR nurses and the SPD Equipment Coordinator for the OR reported that from their experience, regardless of manufacturer, they could not recall other prosthetics that they had seen in the OR which were contained in a manufacturer's peel package that had not been sterilized by the manufacturer. OR staff stated that these were two reasons that they incorrectly assumed that the implants had been sterilized.

Staff also reported that because the implant had been used from the package during the procedure on February 21, they assumed during the February 28 procedure that the implant had been sterilized. Furthermore, OR staff reported having made the assumption that the implants would not have been placed in the OR if they had not already been sterilized.

JAHVAMC Operating Room Policy/Procedure – Principles of Aseptic Technique, July 2001 states, that "Sterility must be assured by the person dispensing the items to the sterile field. The expiration date as well as the integrity of the package and the sterilizer indicating tape must be checked."

Although the Stryker® implant was in a peel package, in the final analysis, the package did not have the word sterile or an hour glass printed on it (see the following picture). OR nursing staff and scrub techs did not verify sterility indicators, the surgeon did not question the sterility of product, and all JAHVAMC staff present in the OR incorrectly assumed that the implant and model were sterilized by the manufacturer. We concluded

that ultimately this policy was not followed during the procedures on February 21 and February 28.

B. Verification of Sterility by OR SPD/Equipment Coordinator

The prosthetics supply technician is responsible for in-processing the implant for billing purposes and notifying the OR SPD/Equipment Coordinator of the arrival of the prosthesis. Once received by the OR SPD/Equipment Coordinator, if deemed non-sterile, the implant is sent to SPD for sterilization. The previous OR SPD/Equipment Coordinator routinely would verify the sterilization for special order items sent to the OR suite. The previous OR SPD/Equipment Coordinator retired on February 21, after several years of working at the VAMC. The OR Equipment Technician, who replaced her and became the OR SPD/Equipment Coordinator, had only been in that role for less than a month. The coordinator reported that he inspected the package for integrity and verified that it was the correct product for the correct scheduled procedure, but he did not check for sterility indicators on the package. In similarity to the OR nursing and surgical staff, he also assumed—based on his experience with other surgical prosthetic products—that because the implant and model were in peel packs, they had been sterilized by the manufacturer.

C. Verification of Sterility at the Point of Entry into the Facility

We found that special order implants can arrive in the operating suite via various routes. It is not unusual in procedures such as orthopedic prosthetic surgery, for surgeons to need prostheses of several sizes to be available in the operating room. Some devices, such as those contained in metal hardware kits, are sterilized and stored in SPD and come to the operating room suite from SPD. Some implants are stored in prosthetics and are carried from there to the OR suite the day before or on the day of surgery. Some prosthetics are brought to the facility a few days before surgery by patient representatives for companies making prosthetic devices. This may be especially true for operations that require a kit with multiple sizes of an item. We found that there is no uniform process through which special order prosthetics arrive at the OR suite. In addition, there is no uniform process

for determining sterilization needs of special order prosthetic products at the point of entry into the facility.

During our review we found that there had been earlier concerns regarding the need for a system of accountability to track implants and equipment from receipt to return. This was the subject of an October 7, 2005, memo from the OR SPD/Equipment Coordinator to the Chief of Acquisition and Material Management, the Chief of Prosthetics, and other specialists in SPD and purchasing. The major points of this memo included the variety of pathways through which implants and equipment destined for the OR can come into the facility, and the need for appropriate receipt, return, and billing. The memo also recognized the difficulty in ensuring proper labeling and handling of sterile and non-sterile materials.

D. Identification of Material Left with Patient

In the intraoperative nursing note, nurse circulators log the lot number, manufacturer, size, and type of hardware and implants placed in patients. In addition, they log whether or not SPD is responsible for sterilization. Metal instrument trays that are sterilized in SPD may not have individual lot numbers and other information on them, but they do have a reference number on them from which SPD can ascertain more detailed information. After sterilization in SPD, custom cranial implants come to the OR with the SPD sterility labeling and packaging but without manufacturer labels, lot numbers, or a reference number on the package. As a result, in the patients who received implants sterilized by SPD, the intraoperative notes listed the use of other Stryker/Leibinger hardware or fixation products but read unknown in the space for cranial implant manufacturer. This is one factor that delayed the facility's ability to confirm whether the two Osteoplastix patients had Stryker or Osteoplastix implants, and to confirm that they had in fact been sterilized. The Chief of SPD reported that SPD now has an informal policy for custom cranial implants to place the manufacturer's label onto the SPD packaging prior to sterilization in SPD. As a result, nurse circulators in the OR should have the manufacturer and lot number available to them for documentation.

Conclusions

1. We concluded that there were two patients who were exposed to or received a non-sterilized Stryker® implant. At this time, there is no indication that either patient has been harmed.
2. The redundancy built into the system, for verification that products taken into the OR are sterile, failed in these two cases.
3. Accurate reporting up the chain of command was impeded by difficulty in retrieving information regarding what custom implants were utilized in which patients.

Recommendations

We recommend that the VISN Director ensure that:

1. The Medical Center Director ensure that medical center staff review and modify policy and procedures on sterilization, and make appropriate changes to ensure that products from all sources are sterilized before delivery to the operating room.
2. The Medical Center Director ensure that medical center staff review and modify policy and procedures that identify non-autologous products that remain with the patient after a surgical procedure.

Under Secretary for Health Comments

The Under Secretary for Health concurred with the findings and submitted an appropriate implementation plan for revised policy and procedures at JAHVAMC. In addition the Under Secretary for Health committed that: (a) the Deputy Under Secretary of Health for Operations and Management will monitor facility progress involving surgical equipment inventory management and oversight of vendor negotiations and (b) the National Center for Patient Safety will also work in coordination with the Food and Drug Administration and other agencies to determine whether more universal safety checks should be applied.

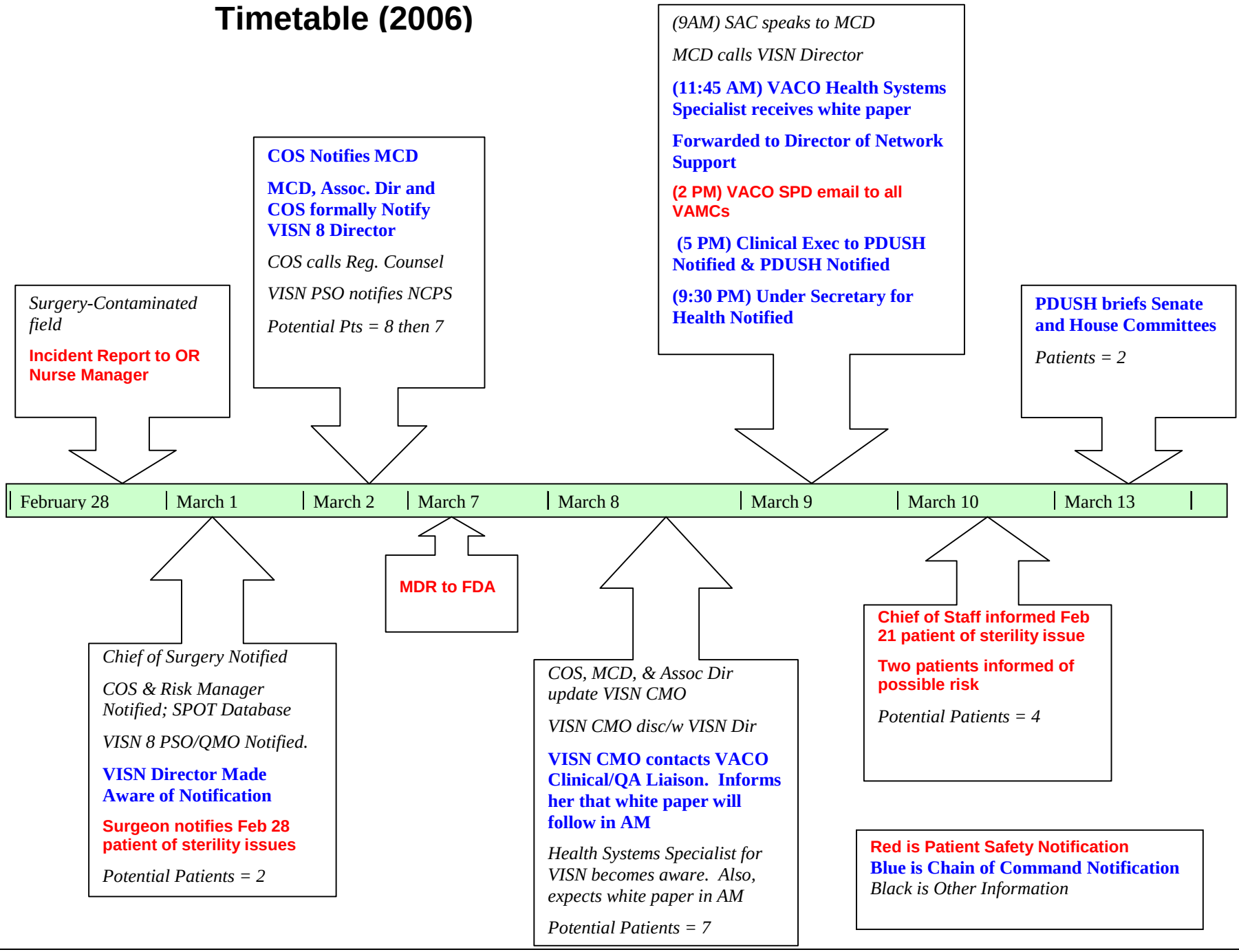
Assistant Inspector General for Healthcare Inspections Comments

The Under Secretary for Health agreed with the findings and recommendations and provided acceptable implementation plans. We will follow up on planned actions until they are completed.

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

Appendix A

Tampa Implant Issue Notification Timetable (2006)



Appendix B

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: April 5, 2006

From: Under Secretary for Health

Subject: OIG Draft Report: **Patient Safety at the James A. Haley VAMC Involving the Use of Cranial Implants**

To: Assistant Inspector General for Healthcare Inspections

1. I have reviewed this draft report and commend you on your balanced investigation of identified cranial implant safety incidents at this facility. Your observations pinpoint how procedural weaknesses and opportunities for unintentional human error can contribute to such potentially adverse situations. I concur in your findings and recommendations, and am confident that facility managers are applying strong corrective measures to assure that such incidents do not recur. Our plan of corrective action is attached.

2. The October 7, 2005, memorandum from the medical center's Surgery Supply Coordinator that you provided as an attachment to your report reflects issues that will be addressed in procedures that the facility is currently revising. The identified concerns support your own, as well as the VISN findings, and raise more far-reaching details involving surgical equipment inventory management and oversight of vendor negotiations. You have my assurance that medical facility management will conduct a careful review of these issues, and implement corrective actions as necessary. The Deputy Under Secretary for Health for Operations and Management will monitor facility progress in these areas.

3. It is apparent to me that as a system, there are many lessons that VHA can learn from the incidents at Tampa. Your report points out that many individuals at that facility

acted in good faith, and that once the problems were identified, all involved made concerted efforts to rectify the situation and to pursue required channels of reporting. The safety and confidence of our patients were at the forefront of all actions, as is appropriate. Your findings underline a basic premise of VA's national patient safety initiative, namely, that system vulnerabilities rather than individual human error are frequently at the core of adverse incidents. Therefore, I am directing VHA's Chief Patient Safety Officer to address your report findings from a national perspective, and take appropriate action to communicate needed information throughout the system. Because identified issues involving packaged equipment sterilization inconsistencies among manufacturers obviously impact national health care in general, the National Center for Patient Safety will also continue to work with the Food and Drug Administration and other involved government agencies to determine whether more universal safety checks should be applied in this regard.

4. Thank you for the opportunity to respond to this report. Your findings are very beneficial to VHA, and we are committed to assuring that every effort will be made to minimize the possibility of such future events. If additional information is required, please contact Margaret M. Seleski, Director, Management Review Service (10B5), at 565-7638.

(original signed by:)

Jonathan B. Perlin, MD, PhD, MSHA, FACP

Attachment

Under Secretary for Health's Comments to Office of Inspector General's Report

VETERANS HEALTH ADMINISTRATION
Action Plan Response
OIG Draft Report: Patient Safety at the James A. Haley VAMC Involving the Use of Cranial Implants

Recommendations/ Actions	Status	Completion Date

OIG Recommendations

We recommend that the VISN Director ensure that:

1. The Medical Center Director ensure that medial center staff review and modify policy and procedures on sterilization, and make appropriate changes to ensure that products from all sources are sterilized before delivery to the operating room.

Concur

The James A. Haley Veterans Hospital is revising its existing policy and procedures to provide greater specificity and to ensure that products from all sources are sterilized through the Supply, Processing, and Distribution (SPD) center before delivery to the operating room. The policy is expected to be completed by May 15, 2006. Appropriate monitors will be established to assure that the policy is being effectively implemented.

In Process May 15, 2006

2. The Medical Center Director ensure that medical center staff review and modify policy and procedures that identify non-autologous products that remain with the patient after a surgical procedure.

Concur

Included in the policy revision will be the addition of strengthened procedures for identifying non-autologous products that remain with the patient following a surgical procedure. As noted, the policy revisions should be completed by May 15, 2006, and monitors will be established to assure that the policy is being effectively implemented.

In Process May 15, 2006

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contacts	Michael L. Shepherd, M.D. (202) 565-4846 Marisa Casado

Appendix D

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U.S. Senators: Bill Nelson and Melquiades R. "Mel" Martinez

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