



# Department of Veterans Affairs Office of Inspector General

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## Healthcare Inspection

### Quality of Care Issues VA Medical Center, Marion, Illinois

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## **Executive Summary**

### **Introduction**

The Veterans Health Administration's (VHA's) National Surgical Quality Improvement Program (NSQIP) identified the VA Medical Center (VAMC) at Marion, Illinois, as having a mortality rate that was over four times the expected rate as calculated by VHA during the first 2 quarters of fiscal year (FY) 2007 (October 1, 2006, through March 31, 2007). In response, a NSQIP review team was sent to the Marion VAMC on August 29, 2007. By the end of its 2-day visit this team had identified concerns with the quality of surgical care provided patients and deficiencies related to medical center leadership and the Surgery Service, including quality management (QM) processes, such as peer reviews and credentialing and privileging of physicians. As a result of this review, inpatient surgery was suspended at the Marion VAMC, and the Under Secretary for Health and Congress asked the Office of Inspector General (OIG) to perform a comprehensive review of these concerns.

The OIG Office of Healthcare Inspections (OHI) immediately initiated a review making numerous site visits to Marion VAMC and the Veterans Integrated Service Network (VISN) 15 in Kansas City, MO. OHI reviewed all Marion VAMC NSQIP surgical mortality cases for FY 2007 and selected morbidity cases and ancillary services, such as respiratory therapy and intensive care unit capabilities, necessary to permit the safe performance of inpatient surgery. OHI retained distinguished surgeons and an anesthesiologist not employed by the Federal government to further review cases in question. OHI also conducted a comprehensive review of the credentials and privileges of the Marion VAMC surgical staff and a review of NSQIP processes and data.

OHI staff interviewed physicians; other clinical and administrative staff; veterans and family members; and VHA leadership at Marion VAMC, VISN 15, and VA Central Office in Washington, DC. OHI also interviewed staff at the NSQIP Denver Data Analysis Center (DDAC), the NSQIP Boston Coordinating Center, and the Information Service Center at Birmingham, AL. Records were subpoenaed from state medical licensing boards and other institutions. The Federation of State Medical Boards (FSMB) was contacted to determine the extent of information provided VHA, as was the Department of Health and Human Services concerning VHA inquiries regarding the National Practitioner Database (NPDB).

### **Inspection Findings**

#### **Quality of Care in Selected Cases**

Overall, OHI concluded that the Surgical Specialty Care Line at Marion VAMC was in disarray. Based on a review of 29 deaths that occurred among veteran patients who

underwent surgery at the Marion VAMC in FY 2007, OHI concluded that there were specific problems with actual quality of care provided to veteran patients. These problems included pre-operative, intra-operative, and post-operative quality of care issues. OHI discusses three mortality cases as examples of those which did not meet the standard of care. A veteran suffered a traumatic rupture of his spleen requiring urgent surgery. Sufficient blood transfusions were prepared for this patient, but they were administered too late to be effective. The second example involved the care provided for a patient whose heart disease placed him at increased risk for surgery. This patient, who died 1 day after surgery, received inadequate intra- and post-operative care. The third case involved a death following elective gallbladder surgery, with clear evidence of inadequate management of the patient's ventilation and post-operative instability.

OHI also identified examples of non-fatal complications resulting from poor care involving other patients treated by surgeons at Marion VAMC. In one case, OHI found that Marion VAMC failed to appropriately diagnose and treat a young Operation Iraqi Freedom Marine veteran following the onset of severe abdominal pain. Areas of deficiency related to this case included availability and use of consultants and the transfer of his care to his home state. He also faced substantial barriers to ongoing specialty care in the private-sector due to the lack of specialty surgeons participating in TRICARE. Other cases discussed in this report include a veteran who received substandard care by an orthopedic surgeon managing a knee infection following total knee replacement surgery, and a urologist who perforated both the bladder and the sigmoid colon of another veteran patient while attempting to incise a urethral stricture.

OHI also substantiated allegations of poor medical care involving two patients treated by non-surgical providers. One case involved allegations relating to the follow-up of a patient with a thoracic aortic aneurysm, and the other the medical management of a patient with hypotension.

## **Quality Management**

Quality Management is designed to monitor quality and performance improvement activities, compliance with selected VHA directives and appropriate accreditation standards, as well as Federal and local regulations. The ability of Marion VAMC to effectively respond to quality of care concerns was hampered by an ineffective QM Program. OHI found that failure to comply with VHA QM policies resulted in deficiencies in the peer review process, tracking and collecting service line or medical provider performance data, reporting adverse events and occurrences, and mortality assessments, among others.

OHI concluded that the oversight reporting structure for QM reviews at Marion VAMC was fragmented and inconsistent, making it extremely difficult to determine the extent of oversight of patient quality or corrective actions taken to improve patient care. This occurred partially because QM responsibilities were split between multiple groups at the

facility with little or no management oversight. Likewise, Surgery Service leadership was ineffective, including communication between the NSQIP nurse, surgical providers, and the Chief of Surgery, allowing multiple QM processes within the care line to fail.

An important component of the QM Program is the peer review process. VHA defines peer review as a protected, non-punitive, medical center process to evaluate the care at the medical provider level. The peer review process includes an initial review by an individual peer to determine if the most experienced practitioners would have managed the case in a similar fashion (Level I), might have managed one or more aspects of the care differently (Level II), or would have managed the case differently (Level III) in one or more prescribed categories. At Marion VAMC, surgical peer review results from February 2007 through August 2007 resulted in 131 Level I findings, 4 level II findings, and no Level III findings. These results appear inconsistent with OHI review findings of the mortality and morbidity cases discussed in this report. Also, it was not clear how cases at Marion VAMC were identified for peer review, and cases were not presented in a timely manner. Local policy states that reviews should be completed in 30 days, although some cases took as long as 5 months.

VHA policy requires that standardized trending of patient deaths occur at each medical facility. The results are required to be presented in a regular forum in order to identify unusual patterns or trends. Although VHA policy does not designate the frequency for presentation of death reviews, standard practice is to aggregate and report results quarterly. OHI found that Marion VAMC reviews are compiled annually. If there were a trend in mortality, an annual review would not address issues in a timely manner. For example, the latest review at Marion VAMC was presented in April 2007, but it was limited to deaths that occurred during FY 2006. As such, the spike in deaths reported by NSQIP that occurred during the 1st and 2nd quarters of FY 2007 would not have been compiled and assessed for unusual patterns or trends until almost a year later.

OHI also found that Marion VAMC had inadequate quality management measures in place for tracking, trending, and evaluation of data relating to patients undergoing cardiac catheterization. The facility also failed to adequately document nursing staff and provider competencies to perform services in the cardiac catheterization laboratory.

## **Credentialing**

Credentialing refers to the process by which health care organizations screen and evaluate medical providers in terms of licensure, education, training, experience, competence, and health status. The credentialing process is done for a medical provider's initial appointment in VHA and every 2 years following. Credentialing occurs at the VISN 15 level in a centralized credentialing office. VISN 15 also queries the FSMB and the NPDB to obtain information regarding any disciplinary actions taken against a provider's medical license and any paid malpractice claims. Even though credentialing is centralized to

VISN 15, credentialing decisions must still be approved at the medical center by the Professional Standards Session of the Clinical Executive Board (Marion VAMC's term for the Professional Standards Board or PSB). Credentialing is done through VetPro, VA's credentialing and privileging system.

OHI found deficiencies in the credentialing of physicians. For example, the PSB at Marion VAMC failed to document consideration of important credentialing information such as malpractice claims identified through the NPDB, the health status of a surgeon who recently had a visual problem, and information on previous performance problems contained in provider references. OHI also found discrepancies in the number of malpractice claims reflected in primary source documents from malpractice carriers and the initial application of a medical provider without evidence that this discrepancy was addressed by the PSB, the Chief of Staff, or the Chief of Surgery Service. Other examples include not completing documentation related to verification of licensure, registration, and board certification requirements in a complete and timely manner. In one instance, a physician was granted privileges on May 3, 2007, even though the Chief of Staff did not complete reporting requirements until August 27, 2007.

VHA does not require physicians to have a medical license in the state in which they are employed with VA. As a result, a surgeon at Marion VAMC can hold a medical license issued by a state other than Illinois. It is also common for VA physicians to simultaneously hold licenses from more than one state, and to let licenses lapse and apply for new ones throughout their career. Being able to identify which state or states a physician is or has been licensed in is critical in obtaining information regarding any disciplinary actions taken against a physician's medical license for credentialing purposes. VHA currently has no means of identifying all states in which a physician holds a license to practice medicine if that physician does not disclose those licenses on his or her initial application.

OHI found the existence of undisclosed medical licenses in both surgical and non-surgical providers. For example, OHI reviewed credentialing and privileging files for 14 non-surgical providers and found that 2 providers held licenses not listed on the initial application. In one of these examples, the medical provider had not disclosed a license in a state where disciplinary action was ultimately taken against that license. OHI also discovered an instance where VHA received a disciplinary alert from the FSMB concerning a Marion VAMC medical provider's license, but they failed to fully evaluate the alert for more than 9 months after receiving it.

### **Privileging**

OHI found significant deficiencies in the privileging of physicians, which is the process by which physicians are granted permissions by the medical center to perform various diagnostic and therapeutic procedures. For example, multiple instances were discovered in

which physicians were privileged to perform procedures without any documentation of current competence to perform those procedures. In one instance, a surgeon received privileges to perform colonoscopies at the Marion VAMC. His privileges from his previous institution did not include colonoscopies. On February 22, 2006, a report of contact written by the Operating Room (OR) nurse manager described an incident in which a technologist reported to her that this surgeon had difficulty identifying colon anatomy and in maneuvering the colonoscope. OHI was informed that the surgeon was asked not to perform colonoscopies at the Marion VAMC. Although no documentation was identified of any action taken against his privileges, there were no records indicating that the surgeon performed colonoscopies after that date.

In another example, OHI could not find documentation that the PSB considered current competence of a surgeon to place a central line. On November 1, 2007, the Acting Medical Center Director at Marion requested an administrative board of investigation (ABI) to examine the surgeon's treatment of a complication arising from central line placement. The physician placed a central line, and the patient, who was receiving mechanical ventilation at the time, developed a tension pneumothorax. The ABI found that, while both the surgeon and another physician involved in the care of the patient were privileged to perform needle decompression of a tension pneumothorax, neither could articulate the proper procedure to the ABI. The ABI recommended that the facility evaluate processes in place for requesting and approving provider privileges.

Not only did the facility fail to document consideration of the current competence of a physician to perform certain procedures, the PSB also failed to consider professional performance data in its decision to re-privilege physicians at the institution. For example, as early as May 19, 2006, the Medical Center Director was notified of serious problems with documentation of patient encounters. Multiple e-mails document that this problem was ongoing. On November 20, 2006, the Quality Assurance Session of the Clinical Executive Board identified that a specific physician had an increased number of post-operative infections. On April 24, 2007, the OIG referred a complaint against this physician to Marion VAMC for review of allegations of inappropriate conduct and tardiness. On June 20, 2007, Marion VAMC notified the OIG that an ABI substantiated multiple reports of vulgar language and prolonged waiting times for patients resulting from numerous factors, including physician tardiness. The ABI recommended appropriate progressive disciplinary or other administrative actions related to the physician's behavior. On May 10, 2007, his service chief received peer reviews conducted on this physician's cases which identified clinical care issues in 8 of 12 cases reviewed. Nevertheless, the physician was re-privileged without reference to aggregated data from the peer reviews, the results of the ABI, or the physician's problems with documentation.

In part, privileging is facility specific because, regardless of the expertise of the physician involved, the availability of services at a facility may limit the appropriateness of performing those procedures at that facility. OHI found that facility leadership did not



limit provider privileges based upon medical center capabilities. For example, the Marion VAMC Surgical Specialty Care Line Operational Planning Guide reflected interest in establishing a specialty surgery program in part to decrease fee basis costs. As a result, in January 2006, Marion VAMC hired a general surgeon to perform surgery in that specialty, even though he was not board certified in general surgery or the specialty surgery at the time he was hired. He also received special pay based on the facility's recruitment and retention difficulties related to hiring surgeons in that specialty. Also, Marion VAMC did not have in house 24-hour coverage in respiratory therapy, pharmacy, and radiology. Because of that, OR staff expressed concern about performing such complex procedures at Marion VAMC. Clinical staff at the facility acknowledged that they felt pressured to perform more complex procedures in order to reduce fee basis costs.

### **Facility Leadership**

Problems identified in the areas of quality management and credentialing and privileging, as well as the quality of care issues identified in specific cases, are a reflection of facility leadership. The Marion Medical Center Director, Chief of Staff, Chief of Surgery, Associate Chief Nurse, and Associate Director for Patient Care/Nursing Services have specific responsibilities for the performance of quality management activities in the surgical specialty care line. OHI found that there were significant warnings of many of these very problems that were available to medical center senior management well before the NSQIP site visit and the subsequent suspension of inpatient surgery. These took the form of a detailed external review of the Surgery Service by a consultant nurse occurring in October 2006, and a similar review performed by the Chief of Surgery Service of a large midwestern VAMC. Likewise, we found internal reports of contact and e-mails detailing frontline nursing surgical staff problems with many aspects of the Surgery Service. It appears that most of this information, with the possible exception of the aforementioned Chief of Surgery Service's report, was not disseminated to other VHA managerial entities such as VISN 15 or VA headquarters in Washington, DC.

### **National Surgical Quality Improvement Program**

NSQIP data are collected locally at each VAMC and analyzed centrally in the DDAC. The Marion VAMC NSQIP data were abstracted and entered by the same NSQIP Surgical Clinical Nurse Reviewer (SCNR) for the 1st and 2nd quarters of FY 2007, during which the Marion VAMC had elevated Observed-to-Expected mortality ratios which triggered the NSQIP team site visit. During her tenure as the Marion SCNR from September 1998 until her retirement in April 2007, there is no evidence to question her technical competence as the NSQIP SCNR.

OHI concluded that NSQIP offers an opportunity of providing evidence-based monitoring and improvement in VA quality of surgical care. NSQIP could improve by developing an operations manual for the DDAC, reviewing and adopting the state-of-the-art statistical

methodologies, detailing its risk-adjustment methodology in a technical report, taking more advantage of the VA computerized medical records system in its data collection and edits, and evaluating evidence of its tangible improvement in VA quality of surgical care. NSQIP would enhance the utility of its risk-adjusted and unadjusted surgical outcome measures by taking its sampling scheme into account in their estimation to reflect the actual outcome experience of the VA surgical patient population.

## Recommendations

The following recommendations are based on the findings of this report.

**Recommendation 1:** The Under Secretary for Health develop and implement a national quality management directive that ensures a standardized structure and mechanism throughout VHA for collecting and reporting quality management data.

**Recommendation 2:** The Under Secretary for Health develop and implement a mechanism to ensure that VHA's diagnostic and therapeutic interventions are appropriate to the capabilities of the medical facility.

**Recommendation 3:** The Under Secretary for Health explore the feasibility of implementing a process to independently identify all state licenses for VA physicians.

**Recommendation 4:** The Under Secretary for Health develop and implement formal policies and procedures to ensure that Federation of State Medical Boards' Disciplinary Alerts are timely addressed by medical facilities, VISNs, and VHA headquarters.

**Recommendation 5:** The Under Secretary for Health conduct reviews to determine appropriate administrative actions against Marion VAMC leadership and other staff responsible for the problems cited in this report, to include the Medical Center Director, the Chief of Staff, the Chief of Surgery, the Associate Director for Patient Care/Nursing Services, and the Associate Chief Nurse of the Surgical Service.

**Recommendation 6:** The Under Secretary for Health issue guidance that clearly defines what constitutes evidence of current competence for use in the privileging process.

**Recommendation 7:** The Under Secretary for Health consider the issues which are identified in this report for modifications to NSQIP and other related programs.

**Recommendation 8:** The Under Secretary for Health confer with the Office of General Counsel regarding the advisability of informing families of patients discussed in this report about their right to file tort and benefit claims.

**Recommendation 9:** The Under Secretary for Health ensure that Marion VAMC complies with VHA policies regarding peer review, mortality assessments, adverse event reporting, and the performance of root cause analyses.

**Recommendation 10:** The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider National Practitioner Database results and document consideration of those results.

**Recommendation 11:** The Under Secretary for Health ensure that Marion VAMC appropriately credentials providers with references executed in accordance with VHA Handbook 1100.19 and documents consideration of discrepancies in provider disclosures and information obtained from references.

**Recommendation 12:** The Under Secretary for Health require the Marion VAMC Chief of Surgery, Chief of Staff, and Professional Standards Session of the Clinical Executive Board to consider the health status of practitioners for credentialing and privileging purposes in accordance with VHA Handbook 1100.19.

**Recommendation 13:** The Under Secretary for Health require the Marion VAMC Chief of Staff to sign and complete the certification correctly on VA Form 10-2850, *Application for Physicians, Dentists, Podiatrists and Optometrists*.

**Recommendation 14:** The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider and resolve discrepancies in the number of malpractice claims disclosed by a practitioner and the number obtained through primary source verification.

**Recommendation 15:** The Under Secretary for Health require that the Marion VAMC Chief of Surgery Service and the Professional Standards Session of the Clinical Executive Board record the documents reviewed and rationale for the conclusions reached with respect to privileging process.

**Recommendation 16:** The Under Secretary for Health require that the Marion VAMC Chief of Surgery, Chief of Staff, and Professional Standards Session of the Clinical Executive Board document consideration of quality assurance data in accordance with VHA Handbook 1100.19 in the re-privileging of medical providers.

**Recommendation 17:** The Under Secretary for Health ensure that the new cardiac catheterization laboratory at Marion VAMC fully institutes quality management measures, performs appropriate competency evaluations for staff, and evaluates the privileging of catheterization laboratory providers in according with VHA policy.

## Comments

The Under Secretary for Health concurred with our findings and stated that he was committed to ensuring that the recommendations were implemented as swiftly as possible. The action plans submitted outline steps to strengthen surgical programs and service to veterans. In addition, VHA is revising its peer review policies, as well as its credentialing and privileging policies and training.

We find the improvement plans acceptable and will follow up until all recommendations are implemented.

*(original signed by:)*

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## Part I. Introduction

### Purpose

On August 29–30, 2007 a three-person site visit team constituted by the Veterans Health Administration's (VHA's) National Surgical Quality Improvement Program (NSQIP) visited the Marion, Illinois VA Medical Center (VAMC). This 2-day site visit was prompted by a higher than expected "observed to expected" (O/E) ratio, that is to say, the observed to predicted mortality ratio for a sample of surgical cases performed at the Marion VAMC during the first 2 quarters of fiscal year (FY) 2007. Among numerous concerns, the NSQIP site visit team reported that there were deficiencies in the quality of surgical care provided to Marion VAMC's veteran patients; there were Surgery Service and medical center leadership deficiencies; and there were problems with the Surgery Service's quality assurance/quality management (QA/QM) processes. The NSQIP team found that many surgical staff, especially nursing staff, were distraught, particularly in the aftermath of several recent unexpected surgical deaths. Notably, these deaths were not a contributor to the elevated O/E mortality ratio that engendered the NSQIP site visit in the first place. Staff also reported two deaths to the OIG; among these were a man who allegedly bled to death after a splenectomy (removal of the spleen) and a middle-aged male patient who allegedly bled to death after a laparoscopic cholecystectomy (gallbladder removal).

Based upon these and other concerns, the NSQIP team recommended that inpatient surgery at the Marion VAMC be halted. Furthermore, upon dissemination of its opinions to Veterans Integrated Service Network (VISN) 15 (the VA Heartland Network) and VA Central Office (VACO) senior officials, key staff at the Marion VAMC were shortly thereafter placed on administrative leave, including its Director, Chief of Staff (COS), Chief of Surgery Service, and a staff anesthesiologist.

As well as VISN 15 and VACO senior officials being made immediately aware of the NSQIP site visit team's preliminary impressions, so, too, were the United States Congress, VA Secretary, and VA Office of Inspector General (OIG). At the request of the Under Secretary for Health and Congress, VA OIG's Office of Healthcare Inspections (OHI) began a comprehensive review of the Marion VAMC Surgery Service. The purpose of this review was to further examine the issues described by the NSQIP team, to examine additional issues and concerns promulgated by members of the United States Congress, to further study the elevated O/E mortality ratio, and to review selected aspects of the NSQIP program itself, given its central role in its case.

In September 2007, early in the course of OHI's review onsite at the Marion VAMC, numerous additional allegations concerning both the Marion VAMC Surgery Service in general and specific surgical cases in particular alleging poor surgical care, were made. Concerns about the credentialing (the verification of a practitioner's background and

training) and privileging (the process whereby practitioners are granted permissions at a VA medical center to engage in specific diagnostic and therapeutic activities) soon came forth. These “credentialing and privileging” or “C&P” concerns initially centered around one Marion VAMC surgeon but soon allegations were made regarding C&P processes concerning several medical center surgeons.

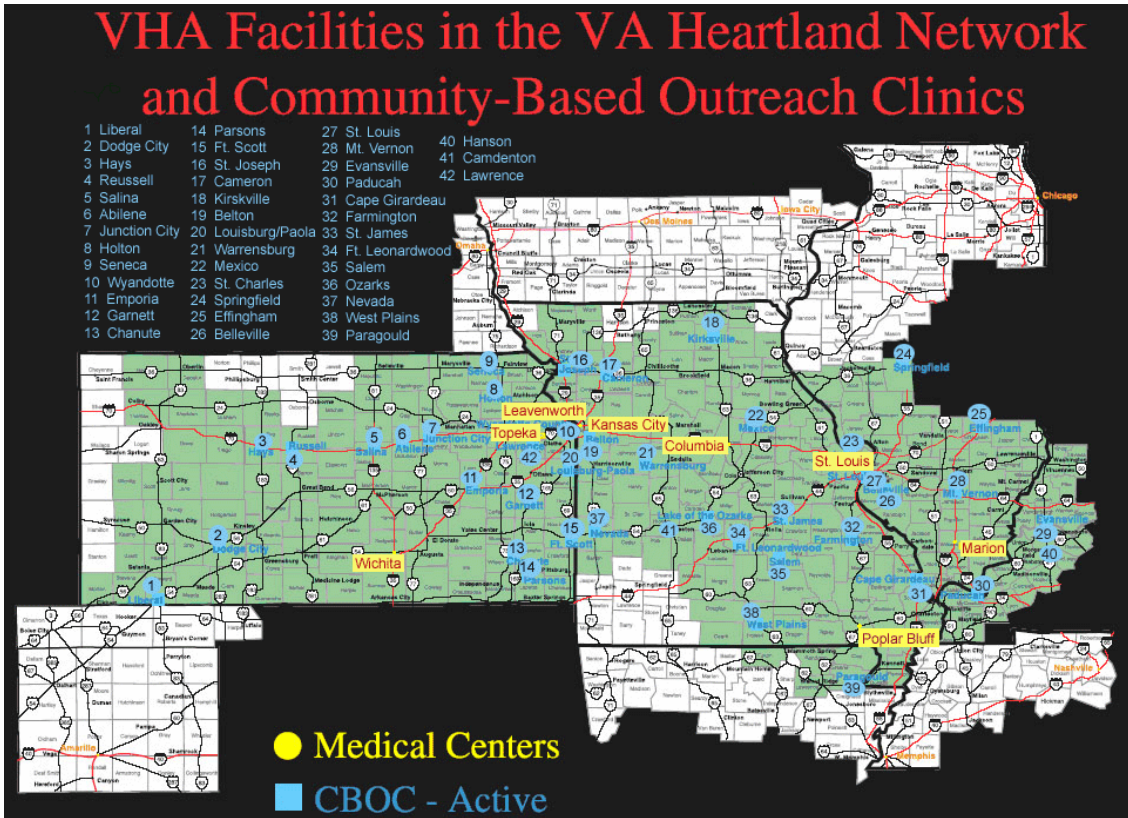
In most OIG hotlines, the complainant is typically an individual, such as a patient, family member, friend, employee; or group of individuals, such as a veterans service organization, union, family, or group of employees. However, the effective complainant in this case was one of the VHA’s quality assurance programs, NSQIP. While there had been previous external reviews of the Marion VAMC’s Surgery Service which raised concerns, it was not until the late August 2007 site visit by a NSQIP team that these concerns became significantly elevated to higher levels within VHA and externally to Congress.

The purpose of this review is, thus, also to review specific cases in which poor quality of surgical care was alleged; to review all of the NSQIP surgical mortality cases occurring in FY 2007, both those that contributed to the elevated NSQIP O/E ratio and those not sampled by NSQIP, and to address the C&P allegations. A still larger purpose of this review is to conduct a comprehensive review of Marion VAMC’s Surgery Service, addressing issues of leadership; C&P; QA/QM; individual cases; and medical center support services for the performance of surgery, such as support and back-up in anesthesiology, laboratory services, radiology, respiratory therapy; pharmacy support; and ICU physician coverage; and in-hospital physician coverage during off hours so that the Department’s management may make informed decisions as to if, when, and how to resume inpatient surgery at the facility, and to assess proactively whether similar vulnerabilities exist elsewhere in the VHA system. Finally, the purpose of this report is to be responsive to specific questions put forth to the OIG by the U.S. Congress.

## **Background**

### **A. Overview**

The Marion, Illinois, VAMC is one of eight VAMCs located in the VA Heartland Network (VISN 15). These are the Columbia, Missouri, VAMC; the Leavenworth, Kansas, VAMC and the Topeka, Kansas, VAMC—which together comprise the Eastern Kansas Health Care System; the Kansas City, Missouri VAMC; the Marion, Illinois, VAMC; the Poplar Bluff, Missouri, VAMC; and the St. Louis, Missouri, VAMC—which includes the John Cochran and Jefferson Barracks Divisions; and the Wichita, Kansas, VAMC. VISN 15 is headquartered in Kansas City, Missouri, and spreads across a broad swath of the middle United States from southwestern Kentucky, southwestern Indiana, and southern Illinois, across to Missouri and northern Arkansas, and westward across Kansas. This is illustrated by the following map.



From: [http://www.visn15.med.va.gov/v15/sites\\_cboc\\_map.asp](http://www.visn15.med.va.gov/v15/sites_cboc_map.asp)

The Marion VAMC is located in Marion, Illinois, a city with a population of approximately 17,000. Its catchment area includes 52 counties located in southern Illinois, southwestern Indiana, and southwestern Kentucky. It serves as the home hospital for five of VISN 15's 42 VA community based outpatient clinics (CBOCs). These CBOCs are located in Evansville, Indiana; Effingham and Mt. Vernon, Illinois; and Paducah and Hanson, Kentucky. Despite the largely rural area of the Midwest in which the medical center is located and from which it draws its patients, it has the second highest number of veterans in VISN 15 on its rolls, exceeded only by the St. Louis VAMC.

The Marion VAMC's programs include primary, specialty, and long term care services. It employs approximately 1,000 persons and operates 115 beds. This includes 55 acute inpatient beds, made up of 8 intensive care unit (ICU) beds, 41 internal medicine beds, and 6 Surgery Service beds. The medical center also operates 60 nursing home care unit (NHCU) beds. In FY 2007 the medical center treated 43,550 unique patients, with an inpatient care workload totaling 3,359 patients. Outpatient workload was 389,424 visits. Average daily census was 37.2 on the inpatient units, 3.4 in the ICU, and 59.4 in the NHCU.

The medical center's medical care budget was \$110,526,000 in FY 2006 and \$125,602,000 in FY 2007. FY 2006 staffing was 973, including 58 physicians and 192 nurses, which increased to 1,039 in FY 2007, with 65 physicians and 211 nurses.

## **B. Leadership Structure**

Senior leadership at the facility consists of a Medical Center Director (MCD), Associate Director (AD), Nurse Executive, and Chief of Staff (COS). This team has been stable, with all members of the team having been in place for over 5 years, with the exception of the AD, who left the Marion VAMC in February 2007 for a promotion. The Director has been in his position since August 2000, the Nurse Executive has been in her role since November 2000, and the Chief of Staff since December 2001.

In December 2004, the medical center initiated a reorganization of its staff and processes. In December 2005, the VISN signed a new organizational chart that aligned the Nursing Service under the Nurse Executive instead of the COS, created "Care Lines" which consolidated services into functional groups, and positioned Associate Chief Nurses with Physician Chiefs of Service Directors for individual Care Line leadership.

In order to assist in providing effective management and oversight, a medical center Clinical Executive Board (CEB) advises the MCD on issues concerning patient care, medical staff appointments, credentialing and privileging, and quality assurance, and utilization review issues. This board, also referred to as the Executive Committee of the Medical Staff, includes the Chief of Staff (Chairperson); and a membership of the Director of Primary Care; Director of Surgical Service; Director of Medical Specialty; Director of Behavioral Medicine; Director of Inpatient/Acute Care; Extended Care Senior Licensed Independent Provider (LIP); Medical Officer–Evansville CBOC; Radiology Program Physician; Laboratory Program Physician; Dental Program DDS Lead; Secretary, Medical Staff; and numerous *ex-officio* members, including the MCD or designee, who may exercise the right to vote or attend meetings.

Also integral to medical center management and the delivery of quality patient care is the presence of a facility-based Quality Management System (QMS). VHA has no national directive describing how a facility's QMS should be organized. Thus, the Marion VAMC's Medical Center Memorandum QM-00Q-06-57, *Quality Management System (QMS) Performance Improvement Plan*, March 16, 2006, serves to describe the operation of its particular QMS program. It delegates responsibility for monitoring and coordinating the QMS program to a Performance Management Clinical Manager. However, it also notes that "[t]he Director, Chief of Staff (COS), Associate Director for Patient Care/Nursing Services, and Associate Director are responsible for assuring that all Care Lines under their supervision consistently support and participate in the QMS program." This policy also indicates that all Care Line Directors, Program Managers, and Nurse Managers are responsible for developing service level QMS activities and ensuring their



effectiveness and ensuring the implementation of appropriate follow-up and corrective actions as needed.

## **C. Surgery Service Overview**

There are three operating rooms (ORs) in the Marion VAMC. The OR staff utilize two ORs concurrently for surgical procedures. The OR nurse manager provided a report from the computerized surgical package, documenting that during FY 2007, Marion VAMC performed 4,863 total procedures in otorhinolaryngology, endoscopy, urology, ophthalmology, oral, orthopedic, podiatry, thoracic, vascular, and general surgery. The Surgery Service consists of a Chief of Surgery (1.0 full-time employee equivalent or FTE), an Associate Chief Nurse (0.5 FTE), 3 General Surgeons (3.0 FTE), 2 anesthesiologists (2.0 FTE), 2 urologists, 1 ophthalmologist, 1 orthopedic surgeon, 1 vascular surgeon (0.5 FTE) and 1 podiatrist. During FY 2007, the Surgery Service also employed 2 physician assistants and 1 nurse practitioner, as well as 3 surgery technicians, 4.5 RNs (FTE), and 1 nurse manager. Nursing staff work 8-hour shifts, either 7:30 a.m.–4:00 p.m. or 8:00 a.m.–4:30 p.m., Monday through Friday. The nurse manager uses a rotational schedule to assign weekly on-call coverage from 3:00 p.m.–7:30 a.m. daily.

Marion VAMC surgical workload data indicates that the predominance of its cases are outpatient cases. Additionally, from FY 2003 to FY 2006, the medical center performed between 350–500 inpatient surgeries yearly. In FY 2007 there was a drop in inpatient surgeries, most probably attributable to the resignation of a general surgeon in August 2007 and the stand-down ordered at the end of August 2007.

Perhaps more revealing, is a NSQIP analysis that demonstrates a substantial increase in the percentage of complex surgeries at the Marion VAMC over time, particularly for FYs 2006 and 2007. As an illustration, in FYs 2003–2005, approximately 7.5–8.5 percent of Marion VAMC's surgeries were highly complex; that is, they were among the types of surgery in the top 20 percent of VHA's surgeries ranked for complexity. This number rises to 10.5 percent for FY 2006 and 17 percent in FY 2007.

## **D. National Surgical Quality Improvement Program**

### **1. NSQIP Background**

In December 1985, Congress mandated that VA report risk-adjusted (for patient's illnesses) mortality and morbidity rates for surgical procedures it performs and compare these data to a national average (Public Law 99-166, Section 204). In response, VA launched surgical quality programs, including the Continuous Improvement in Cardiac Surgery Program (CICSP) for open heart surgery and the National Surgical Quality Improvement Program (NSQIP) for all non-cardiac major surgery. The National Surgical Program in VHA's Office of Patient Care Services currently administers these programs.

NSQIP has its origins in CICSP. Since 1987, the Center for CICSP at the Denver VAMC has reported risk-adjusted morbidity and mortality semi-annually. In 1991, a parallel effort in all major non-cardiac surgery was piloted at the 44 academically affiliated VAMCs that performed cardiac surgery as of October 1, 1991, through the National Veterans Affairs Surgical Risk Study (NVASRS). NVASRS was conducted between October 1, 1991, and December 31, 1993, and was retrospectively designated Phase I of NSQIP. NVASRS demonstrated the feasibility of collecting patient risk and surgical outcome data nationally in VAMCs. In 1994, NSQIP was initiated to extend the methods and reporting of comparative risk-adjusted mortality and morbidity to all VAMCs that perform major surgery. These VAMCs fell administratively into 22 (now 21) VISNs. Phase II of NSQIP represented the 20-month period between January 1, 1994, and August 31, 1995, during which all VAMCs performing major surgery participated. Phase III of NSQIP began September 1, 1995, with revised data collection protocols and definitions. Those data collection protocols and definitions have been used similarly since October 1, 1995, except for some major modifications for NSQIP eligibility in 2006. NSQIP is unique in the magnitude of data collection and analysis of surgical practice across all VAMCs. It is by far the most ambitious effort to date to provide risk-adjusted surgical mortality and morbidity outcomes. A parallel program, modeled on VA NSQIP and known as the American College of Surgeons NSQIP (ACS NSQIP), has existed in the private sector since October 2004.

NSQIP has been recognized as an outcomes reporting system for major non-cardiac surgery. It provides risk-adjusted surgical mortality and morbidity to chiefs of surgery, chiefs of staff, facility directors, and the managers of VISNs and VHA. However, the NSQIP Executive Committee is also charged with assessing and reviewing all major non-cardiac surgical outcomes and programs (VHA Directive 2007-008<sup>1</sup>), through which the NSQIP Board makes recommendations to VHA operations and to field entities for site visits and for enhanced monitoring of specific surgical programs. In addition, the Board responds to quality issues raised by the field or VA Central Office entities.

## **2. NSQIP and the Marion VAMC**

In the first quarter of FY 2007, risk-adjusted data reported from the Marion, Illinois, VAMC suggested an operative mortality rate of more than four times the expected rate. Seven surgical deaths appeared on the NSQIP quarterly report for Marion VAMC out of a total number of 180 cases reported to NSQIP from Marion VAMC during that time interval. If seven deaths were expected for those cases, then the O/E ratio would be 1. However, the O/E ratio was reported as 4.3, indicating that seven surgical deaths for these cases was over four times the expected (predicted) number of deaths. An additional two deaths were reported in the second quarter of FY 2007. Because the ratio is cumulative, the O/E ratio remained over 4.0 despite a decline in the absolute number and percentage of deaths. In other words, because the NSQIP O/E ratio is a running ratio throughout all 4

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<sup>1</sup> VHA Directive 2007-008, *Quality Reviews of Surgical Programs and Outcomes*, February 08, 2007.

quarters of a fiscal year, the Quarter 1 (Q1) ratio is created by dividing an expected mortality number into observed deaths for Q1; the Q2 ratio is obtained by dividing an expected mortality number into the sum of Q1 + Q2 deaths, the Q3 ratio is obtained by dividing an expected mortality number into the sum of Q1 + Q2 + Q3 deaths, and so on, for the 4 quarters of each fiscal year. One implication of this methodology is that a high number of deaths early in a fiscal year, especially in Q1, may create an elevated O/E ratio throughout the fiscal year. Yet despite an elevated O/E throughout the fiscal year, the actual data creating that elevation may apply to 1 quarter only.

Thus, as a result of 2 consecutive quarters reflecting an elevated O/E ratio above 2.0, in accordance with its general practice, NSQIP conducted a site visit in August 2007. Among the observations of the NSQIP reviewers were that, “[s]erious deficiencies in the credentialing and privileging process [are present],” “[c]omplex surgical procedures or simple procedures on seriously ill patients were attempted despite the lack of personnel skilled and handling such cases,” and “quality oversight appeared inadequate.”

## **E. Additional Allegations**

During the course of our review, we received additional allegations from both staff interviewed and congressional sources. These included:

- Serious deficiencies existed in the credentialing and privileging processes.
- Complex surgical procedures were performed without the availability of trained personnel and appropriate ancillary services.
- Providers were pressured to perform complex procedures because of fee basis concerns.
- The NSQIP nurse was not able to properly perform her job because of significant case management responsibilities.
- Quality management processes appeared inadequate to monitor service-specific or provider-specific outcomes.
- The Chief of Surgery was not qualified for his position.
- The Associate Chief Nurse for the Specialty Care Line and the Chief of Surgery failed to insure the quality of services rendered.
- The facility had an increased postoperative infection rate following orthopedic procedures.
- There was an increased rate of bladder perforations.

- A veteran’s mother alleged that the Marion VAMC failed to appropriately diagnose and treat her son’s ulcerative colitis; failed to arrange for necessary specialty consultation; and perforated her son’s colon following an exploratory laparoscopy and appendectomy.
- A veteran alleged that he contracted an infection following a total knee replacement performed at the Marion VAMC and that the infection was not properly treated.
- A veteran’s spouse alleged that the Marion VAMC failed to provide adequate follow up of the veteran’s heart and circulatory problems resulting in deterioration of the veteran’s health status.
- Allegations of falsification of certain documents.
- Allegations that the newly constituted cardiac catheterization laboratory is “going to be the next OR.”

## **Scope and Methodology**

In this review we endeavored to review the Marion VAMC’s Surgery Service in its entirety, particularly as it pertained to FY 2007. We examined FY 2007 mortality cases, both those counted by the NSQIP program and those not counted. We reviewed Surgery Services processes, such as quality assurance and credentialing privileging; structure such as ancillary services; and their outcomes, as exemplified through case reviews.

In addition to reviewing the Marion VAMC’s Surgery Service, we also reviewed the newly instituted cardiac catheterization laboratory.

We reviewed credentialing and privileging folders from services other than the Surgery Service in order to ascertain how those processes were performed in other sections of the medical center.

Because the NSQIP program was essential to this entire case, we performed an overview of that program.

We reviewed corrective actions taken in response to surgical deaths by the facility and the VISN 15. We looked at oversight processes at the VISN level and VACO level, particularly as they pertained to the credentialing and privileging processes.

Despite the detail and complexity of this review, it is not a review of the Marion VAMC in its entirety. Most particularly, this review does not cover its internal medicine, long term care programs, or the day-to-day operations of the Marion VAMC’s five CBOCs.

OHI inspectors visited the Marion VAMC on September 18–21, 2007, September 24–28, 2007, October 1–5, 2007, December 3–7, 2007, and interviewed a since-resigned Marion

VAMC surgeon near his home on November 30, 2007. On October 9–12, 2007, we visited VISN 15 headquarters in Kansas City, MO. We also made repeated visits to VACO to interview staff, such as VA's National Director of Surgery and National Director of Credentialing.

To perform a review of the credentialing and privileging processes at the Marion VAMC, we first identified all physicians actively privileged to provide surgical services at the Marion VAMC. The facility supplied us with a list of 22 physicians providing services in surgery and anesthesia between October 1, 2005, and September 30, 2007. We examined each physician's credentialing and privileging files for deficiencies in the initial application; consistency between primary source documents and applications or VetPro entries; Professional Standards Board (PSB, termed the Professional Standards Session of the Clinical Executive Board at Marion VAMC) approval for credentialing, privileging, reappraisal or reprivileging; previous and current specific privileges; and documentation of current competency to perform those procedures. We also compared the PSB minutes and provider-specific quality assurance data and administrative reviews to determine whether documentation existed that these materials were considered in the decision to reprivilege or grant each provider additional privileges. We further reviewed documents pertaining to the strategic planning of the facility for performing certain procedures and for ancillary services available to support those procedures as it related to the granting of privileges to perform those procedures.

We conducted multiple interviews, including interviews with the facility credentialing and privileging liaison, the VISN 15 Credentialing Manager, VHA's Director of Credentialing and Privileging, and quality assurance individuals at the facility and VISN level. With the assistance of the OIG Office of Investigations, we obtained and reviewed e-mails from VHA officials involved in the credentialing and privileging processes and evaluated an allegation that in one instance, privileges were altered without request of the provider or appropriate approval of the PSB.

We then sought primary source verification of information contained within credentialing and privileging files and obtained through interviews from several external agencies. We contacted the Federation of State Medical Boards to determine the parameters of information supplied to VHA during the credentialing and privileging process. We obtained from the Department of Health and Human Services OIG a list of all NPDB queries performed on every physician at the Marion VAMC; we then compared this list against the dates of initial credentialing and privileging, reappraisal, and reprivileging or addition of privileges. We issued subpoenas to 5 state medical boards and to an institution at which one of the providers had previously worked. By the date of this writing, four of the five state medical boards complied with our subpoenas in whole or in part.

Because of the findings described within this report, we chose to review a sample of non-surgical providers, to determine whether the problems identified were limited to the surgical service at the Marion VAMC. We reviewed a random sample of 14 non-surgical

providers: 3 primary care physicians, 3 cardiologists, 2 psychiatrists, 1 psychologist, 1 hospitalist, 2 emergency room physicians, and 2 optometrists. We reviewed PSB minutes from FYs 2006 and 2007 in their entirety, as well as selected entries related to the credentialing or privileging of these providers prior to October 1, 2005.

We visited NSQIP's Boston Coordinating Center on October 19, 2007, and the NSQIP Denver Data Analysis Center (DDAC) on November 1, 2007.

In order to address individual hotline cases, we interviewed a surgeon who cared for a veteran at a large VAMC near his home after the veteran had been discharged from the Marion VAMC. We also interviewed the veteran at his attorney's office in his home state.

At the Marion VAMC we interviewed clinical, quality assurance, clerical, and administrative staff, interviewing virtually everyone associated with the Surgery Service and with responsibility for managing the service. We inspected the OR, ICU, and Post Anesthesia Care Unit (PACU) areas. We obtained extensive paper documentation including but not limited to medical records, incident reports, meeting minutes, e-mails, policies, medical center census information, bed and program occupancy data, and the full range of QA documents.

Employing data from NSQIP's DDAC, we identified and reviewed all surgical deaths occurring in the first 3 quarters of FY 2007, that is, for the period October 1, 2006–June 30, 2007. In this report, we define surgical or operative mortality as death from any cause inside or outside of the VAMC within 30 days after the index surgical procedure. Additionally, we identified and reviewed all NSQIP surgical deaths for the 4th quarter of FY 2007 (July 1, 2007–September 30, 2007) and reviewed those cases. A NSQIP surgical death is a surgical death that met programmatically defined inclusion criteria that engendered its inclusion in the NSQIP analysis data file. We retained distinguished surgeons and an anesthesiologist not employed by the Federal government to assist us in our case reviews. In all but one case we completed reviews. This last case is still undergoing analysis by OHI and its consultants. We followed a similar process for morbidly cases, which were reviewed by both OHI medical staff and non-VA external reviewers.

Numerous reviews were conducted concurrently with and prior to this OIG review. These included a detailed external review of the Surgery Service by a consultant nurse (October 27, 2006); an external review of the Surgery Service performed by the Chief of Surgery Service of a large midwestern VAMC (December 19–20, 2006); external case reviews of surgery mortality cases conducted by surgeons from the Kansas City VAMC and St. Louis VAMC staff; a Joint Commission triennial survey (August 27–31, 2007); the NSQIP site visit (August 29–30, 2007); an Office of Medical Inspector site visit (September 4–5, 2007); an unannounced for-cause Joint Commission 1-day survey (September 14, 2007); a site visit by a team from the VHA Inpatient Evaluation Center (September 20–21, 2007); a VISN 15 review of the Marion VAMC's Quality Management

program (October 16–17, 2007); an unannounced site visit regarding environment of care issues conducted by the VISN 15 Capital Assets Manager and the VISN 15 Safety Manager (November 6, 2007); a site visit by a team of approximately 30 VA/VHA staff, consisting of subgroups addressing human resources, labor relations, EEO, leadership, clinical privileging, environment of care, and quality management (November 13–16, 2007); and another Joint Commission unannounced for-cause survey (December 3, 2007).

We obtained and studied these reviews, often interviewing team members from each of these review groups.

In order to address allegations of record falsification, we utilized the OIG's Office of Investigations. This office interviewed numerous Marion VAMC staff and assisted us with document analysis.

We sent a team of inspectors with expertise in cardiac catheterization programs to review the Marion VAMC's nascent program in this area.

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

## **PART II. RESULTS AND CONCLUSIONS**

### **A. Quality of Care — Review of Surgical Cases**

#### **Review of NSQIP Mortality Cases for FY 2007**

Twenty-nine deaths occurred among patients who underwent recent surgery at the Marion VAMC in FY 2007; 17 of these were reported to VHA's National Surgical Quality Improvement Program. We reviewed all 17 of the cases reported to NSQIP. We discuss three mortality cases as examples of those which did not meet standard of care in detail below.

Among the 12 cases not reported to NSQIP, 9 involved patients who had undergone minor procedures and died at least 14 days after the procedure (cataract extraction, GI procedures, and cystoscopy).

#### **Patient 1: Case Review**

The patient was a man in his early 60's with a 100 percent service-connected disability rating for post-traumatic stress disorder related to military service in Vietnam. He had a history of myocardial infarctions in 1994 and 1998, and had undergone placement of coronary stents. He was also treated for major depression, hypothyroidism, diabetes mellitus, hypertension, and hyperlipidemia. At a primary clinic visit in June 2007, he described having had no recent angina.

In late June 2007, he presented to the Marion VAMC emergency room complaining of left chest and abdominal pain after having fallen on his left side. At that time his vital signs were normal and he was admitted to the ICU for observation. A chest computed tomography (CT) revealed "evidence of a subcapsular hematoma and rupture of the superior aspect of the spleen." Admission blood tests (collected at 1922) revealed a hematocrit of 42.4 percent (normal range, 39–54).

At 2313, the blood pressure (BP) was recorded to be 102/75 mm Hg, down from 132/95 on admission. At 0100 on June 25 the blood pressure was 82/53, and at 0245 a nurse noted that the patient was having more severe pain. This pain persisted despite the administration of intravenous morphine. At 0630 the hematocrit was 35.7. He was taken to the radiology suite for an abdominal CT scan. The CT scan, performed at 0726, showed a large volume of intraperitoneal fluid felt to be most consistent with hemorrhage.

The patient was taken to the operating room at approximately 0900. Just prior to surgery his BP was 97/68. During the operation, which lasted from 0930 to 1031, 2 units of packed red blood cells were administered. A blood specimen sent just as surgery ended showed a hematocrit of 25.3 percent. Vital signs recorded every 1–5 minutes in the post-anesthesia care unit (PACU) from 1044 to 1124 indicate that the patient's mean heart rate was 124



and never less than 108 (17 measurements). The final four PACU systolic BP readings were 73–91, with corresponding heart rates  $\geq$ 116.

At 1140 the patient was transferred from the PACU to the ICU. At 1143 the surgeon entered an order for transfusion of 2 units of packed red blood cells. By 1145 the patient was noted to be “desatting 80’s, tachypneic, tachycardic...difficult to arouse” (oxygen saturation 80–90 percent, rapid respiratory rate, rapid heart rate). At 1150 a Code Blue was called. Blood transfusions were started at 1221 and 1230. Despite intensive and prolonged resuscitative efforts, including additional blood transfusions, the patient remained hypotensive. At 1258 the hematocrit was 18.3; subsequent results were 15.4 percent (1443) and 13.3 (1452). With the patient’s family at his bedside, resuscitative efforts were discontinued and he expired at 1515.

### **Patient 1: Findings**

This patient suffered traumatic rupture of his spleen requiring urgent surgery. Prior to surgery he was initially stable and was appropriately admitted for observation. When his pain worsened and his blood pressure and hematocrit fell, he was taken to the operating room. During the operation he received two blood transfusions and was stable as the operation ended. However, in the PACU, his heart rate remained elevated and his blood pressure again fell. His last recorded vital signs prior to his transfer from the PACU to the ICU showed persistent and profound hypotension. Taken together with his falling hematocrit (25.3 percent at the end of surgery), his deterioration was probably due to intra-abdominal bleeding. In this patient with significant coronary artery disease, persistent tachycardia and hypotension undoubtedly contributed to cardiac arrest soon after his arrival in the ICU. Extensive resuscitative efforts were insufficient following the stress of protracted cardiac ischemia. Sufficient blood transfusions were prepared for this patient, but they were administered too late to be effective.

### **Patient 2: Case Review**

The patient was a man in his late 70’s with a history of Crohn’s disease and coronary artery disease. In 2001 he had undergone abdominal hernia repair with insertion of mesh, and subsequently developed chronic drainage from the surgical incision site. In April 2007, because of worsening chronic angina, he underwent cardiac catheterization at the St. Louis VAMC. He was found to have three-vessel coronary artery disease and moderate-severe aortic stenosis (calculated valve area 0.76 cm<sup>2</sup>), but surgery was not thought to be urgent and he was discharged home with plans to schedule elective coronary artery bypass graft (CABG) surgery at the Harry S. Truman Memorial VAMC in Columbia, Missouri. The patient was scheduled for CABG surgery with possible aortic valve replacement at the Columbia VAMC in July 2007. However, prior to the surgery cultures of his abdominal drainage grew *Staphylococcus aureus* and *Serratia marcescens* and surgery was canceled.

The patient's cardiothoracic (CT) surgeon contacted the Marion VAMC Surgery Service and requested surgical intervention to control the patient's infection. The patient was seen by a Marion surgeon and scheduled for surgery to remove the infected mesh in August 2007. Cardiac evaluation was obtained prior to surgery. The cardiologist noted that the patient had major predictors of cardiac morbidity and mortality, was at high risk for surgery, and advised that the patient's risk factors be managed aggressively. An anesthesiologist also noted that the patient was at high risk for surgery. The anesthesiologist recommended that the team discuss with the CT surgeon at the Columbia VAMC the alternatives to and risks and benefits of doing the surgery at Marion prior to his CABG surgery in Columbia. There is no indication in the medical record that any such discussion occurred.

The patient was taken to the operating room. Shortly after induction of anesthesia, his heart rate increased and his blood pressure dropped, but these soon stabilized. Surgery lasted 42 minutes, after which the patient was extubated in the OR and taken to the recovery room. However, approximately 10 minutes after being extubated, the patient desaturated and required reintubation. He was seen by a cardiologist and transferred to the ICU. The cardiologist felt that the patient had pulmonary edema and recommended transfer to a nearby hospital so that a ventricular assist device could be employed if necessary. Later that day he was transferred by ambulance to the other hospital and died there the next day.

### **Patient 2: Findings**

This patient was scheduled for an operation that was well within the capabilities of the operating surgeon. However, the VAMC did not provide adequate anesthesia and post-operative support for the surgery. Appropriate management of this patient should have included more aggressive monitoring of his cardiac status, including the placement of an arterial line.

### **Patient 3: Case Review**

A man in his fifties presented in February 2007 to the Paducah, Kentucky, CBOC to establish VA primary medical care. He had a 65 pack-year history of smoking. His body mass index was 34.<sup>2</sup> He was taking medication for diabetes, diabetic neuropathy, hypertension, and hyperlipidemia, and had a past medical history of peptic ulcer disease.

In June 2007 he was evaluated by his primary care provider for new right upper quadrant abdominal pain. Five days later abdominal ultrasonography revealed "multiple echodensities in the gallbladder" and he was referred to the Marion General Surgery Clinic. He was evaluated by a surgeon on in early August and scheduled to be admitted a week later for elective laparoscopic cholecystectomy.

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<sup>2</sup> A body mass index  $\geq 30$  indicates obesity.

The operation note and report describe the operation as being uneventful, but the discharge summary states “that the patient in the middle of the procedure had an episode of hypotension.” The anesthesia record documents a blood pressure drop, but no readings indicative of frank hypotension (the patient’s minimum systolic BP was 100 mm Hg). Tachycardia was treated with esmolol. The operation note states:

The anesthesiologist after the dressings were placed attempted to extubate, but the breathing of the patient was not satisfactory and the anesthesiologist retained the patient for more than 45 minutes in the operating room trying to get him awake. Finally the anesthesiologist came out and he said that the patient was not breathing and he would take him to the Intensive Care Unit for continuity of care, connected to a mechanical ventilator which was carried out in the ICU.

In the ICU, the patient was hypothermic and remained hypotensive despite the administration of intravenous fluids and blood products. Ninety minutes after completion of surgery, the hematocrit was 31.8 percent, a marked decrease from the most recent previous value of 47.9 1 week prior to surgery (normal range, 39–54). One hour later the hematocrit was 15.3. Arterial blood gases showed the pCO<sub>2</sub> to be 99 mm Hg (normal range, 35–45), indicative of hypoventilation, and the pCO<sub>2</sub> was 104 mm Hg 2 hours later. Approximately 4 hours after leaving the operating room, he was taken back for exploratory surgery, and a large amount of bloody fluid was found in the abdomen. No definite source of bleeding was identified. He was noted to be coagulopathic and acidotic. He remained unresponsive and was hypotensive despite vasopressor infusions. After discussion with the family, he was disconnected from the ventilator and vasopressors were discontinued. He died shortly thereafter, less than 24 hours after the start of the original surgery.

### **Patient 3: Findings**

This patient never recovered following elective laparoscopic surgery. He failed to awaken from anesthesia and was in hemorrhagic shock. The precipitous drop in his hematocrit accompanied by hypotension should have prompted a return to the operating room for exploratory surgery sooner.

Although intra-operative anesthesia care is difficult to assess, it is clear that the patient’s blood pressure did fall during surgery. He also had an elevated heart rate and decreased blood oxygen saturation. These events were not explained, and we could not determine whether they were preventable or had untoward effects. However, there is clear evidence of inadequate management of the patient’s ventilation.

## **Review of Other Surgical Complications**

We identified non-fatal complications resulting from poor care involving three patients treated by surgeons at the Marion VAMC. We further identified excessive complication rates for patients undergoing orthopedic and urologic operations.

### **1. Allegation: A veteran's mother alleged that surgeons at the Marion VAMC failed to appropriately diagnose and treat her son and perforated his colon.**

The mother of a veteran of Operation Iraqi Freedom contacted a U. S. Senator to complain of poor quality health care provided for her son at VAMC Marion, Illinois, in June 2007.

Following a discussion with the complainant, the following specific allegations were delineated:

- Abdominal surgery was unnecessary. The surgeon was determined to operate, without regard for appropriate attention to details of the patient's history.
- Surgery was not performed correctly, causing bowel perforation.
- No gastroenterology consultant was available, and the opinions of consulting and collaborating physicians were given inadequate attention.
- Diagnostic testing was insufficient both before and after surgery. Specifically, endoscopic examination of the patient's lower gastrointestinal tract should have been done.
- After surgery, the surgeon failed to attend to the fact that the patient was not getting better, persisting on a course appropriate for a recovering post-appendectomy patient.
- Discharge processes were inadequate with respect to transportation and handoff of information.
- Antibiotics were underused post-operatively and mismanaged at discharge.
- TRICARE is not accepted by many healthcare providers, greatly limiting access to needed specialty care.

## **Case Review**

The patient is a man in his mid-twenties serving as a member of a United States Marine Corps Reserves. After being called to active duty for training, he served as a truck driver in Iraq for 7 months in 2006–2007. While in Iraq in early 2007, he began to have blood in

his stools intermittently. He sought the advice of his corpsman, but he declined referral for medical evaluation so that he could remain with his unit.

After returning home in the spring of 2007 he continued to have intermittent symptoms. However, he felt generally well and did not seek medical attention until symptoms gradually worsened over the ensuing 2 months. In the early summer of 2007, he was released from active duty. Shortly thereafter he began to have worsening abdominal pain, diarrhea, and then nausea and vomiting. Approximately two weeks after discharge, he and his parents were visiting family in Indiana when his symptoms became severe, so the family contacted the Evansville, Indiana, Community Based Outpatient Clinic; he presented to the Marion, Illinois, VAMC Emergency Room the next day

In the Emergency Room he was found to have a temperature of 100.7° F, with a heart rate of 124 per minute and a blood pressure of 168/81 mm Hg. He was evaluated by a physician who noted his abdomen to be soft and slightly tender, but with “no guarding or rebound.” The physician ordered blood tests and an abdominal computed tomography (CT) scan. The patient was also evaluated by a general surgeon, who felt he most likely had “Colitis of undetermined cause. Possibly infected or parasite origin. No definite evidence of any acute appendicitis.” He was admitted for observation under the care of the general surgeon. Results of initial blood testing revealed an elevated white blood cell (WBC) count (19,430 per mm<sup>3</sup>; normal range, 4,800–10,800) with 83.1 percent neutrophils (normal range, 44–74 percent). The hematocrit was 42 percent (normal range, 39–54). Urinalysis showed a specific gravity of  $\geq 1.030$ , and fecal examination for ova and parasites was negative. The CT scan was interpreted as revealing “fluid filled loops in the right lower quadrant of the abdomen” indicative of “nonspecific ileus.” Initial management included nothing by mouth except medications, intravenous fluids and antibiotics (ampicillin/sulbactam), and an oral antibiotic (metronidazole).

On the morning of the second hospital day the patient continued to have pain, with intensity rated as 3–6 on a 10-point scale, but his vital signs were improved (temperature 99.9°, pulse 98, blood pressure 138/80) and he was able to tolerate a full liquid diet. On the morning of the third hospital day, nursing staff recorded that he had vomited three times and passed seven liquid stools in the prior 24 hours. During that time he had also had a temperature elevation to 101.4° and blood cultures were obtained. His surgeon noted that his abdomen was now somewhat distended and that there was rebound tenderness. However, the surgeon also noted that the patient’s “condition and presentation appears to be not fitting into any one std [standard] pathological process.” He therefore requested an Internal Medicine consultation as well as a second surgical opinion, and described to the patient and his family the possibility and details of surgical exploration. Laboratory testing showed the WBC count to be little changed (18,110) and the hematocrit 35.4.

The second surgeon evaluated the patient late on the morning of the third hospital day. He noted that the patient had been given morphine prior to his examination, but still “grimaces the face while palpating in the RLQ [right lower quadrant of the abdomen] and finger point

tenderness is strongly positive.” His assessment was that the patient had “Regional peritoneal signs in RLQ. Highly suggestive of A.[acute] Appendicitis.” He advised that the patient undergo laparoscopic exploration.

The Internal Medicine consultant, recording additional historical details, noted that the patient had had recent weight loss and had also had tenesmus. Her abdominal exam revealed pain in the lower abdomen, worse in the left lower quadrant, not associated with guarding. She suggested additional laboratory testing (erythrocyte sedimentation rate and fecal leukocytes) and noted the “possible need to have flex sig/colonoscopy [to] r/o [rule-out] inflammatory bowel disease.” The consultant entered orders for the suggested laboratory tests, but there is no documentation of any acknowledgement of the consultation results by or discussion with either surgeon. There is also no documentation that this consultant saw the patient again.

The patient was taken to the Operating Room in the late afternoon of the third hospital day. Laparoscopic surgery was performed by the second surgeon, with the first surgeon serving as first assistant. Anesthesia records indicate that the operation lasted 33 minutes. The note entered immediately after the surgery by the second surgeon described the post-operative diagnosis to be “Viral enteritis, Periappendicitis.” Neither the brief post-operative note nor the dictated Operation Report mentions systematic diagnostic exploration of the abdomen. After surgery the second surgeon assumed responsibility for the patient’s treatment; he entered an “MD Discharge Instruction Team Note” and a prescription for the antibiotic doxycycline. Antibiotics for inpatient administration were not continued after surgery.

On the fourth hospital day, one day after surgery, the patient continued to have loose bowel movements, but his status was described by the surgeon who had admitted him as “feeling better, trocar wounds healthy, will start on liquid diet, if continues to do well plan discharge in am.” That evening his pain was recorded to be of intensity 8/10, his temperature was 101.7 F°, and a nurse described his abdominal exam as “soft, distended, tender with bowel sounds x 4 quad. c/o abdominal pain and nausea.”

On the fifth hospital day another nurse noted that the patient’s abdomen was “slightly distended, soft, tender @ post-op sites, no rebound tenderness, hypoactive BS” and that he “continues to have diarrhea, tolerating clear liquids fairly well but...had an emesis this morning after breakfast.” That morning his temperature was 100 F° and his pulse 126. The physician who saw him that day, a Sunday, wrote, “in light of pt still having pain and seeing blood in his stool, will recommend GI Consult. Request submitted.” The request for GI consultation was received by the general surgeons who were already familiar with the patient.

The surgeon who had admitted the patient evaluated him later that day, writing, “will continue same treatment with pain med and iv and po antibiotics.” However, no antibiotics

had been ordered or given on this or the previous day. That evening the surgeon entered new orders to resume the antibiotics which had been given prior to surgery.

On the sixth hospital day, the patient had vomiting and diarrhea and was able to eat little of the liquid diet which had been ordered. He received four doses of acetaminophen/hydrocodone for pain and five doses of promethazine for nausea and vomiting. His pulse was 110-124 and his maximal temperature was 100.4 F°. A nurse wrote that his abdomen was “soft, distended, tender LLQ-pt grimaced when touch LLQ....” The surgeon who had performed laparoscopy advanced the patient’s diet from liquids to a soft diet. In his final note for this patient’s hospitalization, he wrote, “Doing well, C/o Diarrhoea...Stool bacteriology negative... Possible Viral Entero Colitis.” He prescribed diphenoxylate/atropine for diarrhea.

On the fourth day after surgery, the seventh hospital day, the patient continued to have pain and diarrhea, but was reported to be feeling a little better. On this day he received three doses of acetaminophen/hydrocodone and three doses of promethazine. His pulse was 123-130 and his maximal temperature was 101.1 F°. His mother made inquiries regarding his return to Texas. An Infectious Diseases consultant noted that stool collected on the day prior showed 4+ leukocytes and wrote that the “presentation is consistent with a dysentery-like illness. Prolonged duration of symptoms is worrisome for parasitic illness such as Entamoeba. Bacterial infection remains a possibility. Stool culture was negative but this was collected after antibiotics were started.” In addition to further diagnostic tests, he recommended discontinuing ampicillin/sulbactam, increasing the dose of metronidazole, and adding a different antibiotic (ciprofloxacin). He also recommended that diphenoxylate/atropine be discontinued and antidiarrheal agents avoided, and suggested that the patient should continue to be treated as an “inpatient until fever resolves.”

On the patient’s final day of hospitalization at the VAMC (the eighth hospital day), he received two doses of acetaminophen/hydrocodone and two doses of promethazine. He was afebrile, but his pulse was 120-130. A physician assistant entered an “MD Discharge Instruction Team Note” and a “Medication Reconciliation” note, both of which specified that the patient would be discharged with the prescription for doxycycline entered 5 days earlier by the operating surgeon. That prescription, along with pain medication, was given to the patient when he was discharged. Prior to discharge, a social worker arranged for funds to be provided to pay for transportation of the patient to St. Louis. The social worker also provided “the names POC [point of contact] and Case Managers in [a large] VA Medical System [near his home] for follow up care upon his return home.” The patient and his parents spent that evening in a hotel and the next morning traveled to the St. Louis airport. On that same morning, the Infectious Diseases consultant (who had been off-duty the prior day) discovered that the patient had been discharged without the antibiotics he had recommended and prescribed. At the consultant’s direction, a nurse contacted the patient by phone and informed him that the correct antibiotics could be obtained from the large VAMC near his home.

The following day (one day after discharge from Marion VAMC), the patient and his mother arrived in his home state and presented to his local VAMC. They were unable to reach the individuals whose names were provided in Marion and found no medications waiting for them at the pharmacy. At that point, they learned from a member of the patient's military unit that the patient was eligible to receive private-sector treatment through TRICARE. They then left the local VAMC. The patient wished to stay at home that evening, but presented the next morning to a private hospital closer to his home.

At the private hospital Emergency Room an abdominal CT scan revealed extensive free air in the abdominal cavity, indicative of bowel perforation requiring immediate surgery. In the operating room that afternoon, the surgeon found perforations of the sigmoid colon and of the cecum, along with extensive abscess formation between loops of the small intestine. He removed segments of the right and left colon, and created an ileostomy and a mucous fistula.<sup>3</sup> Because of fecal contamination, he carried out extensive irrigation and left the surgical wound open to heal by secondary intention. Pathologic examination of resected colon revealed "significant transmural inflammation," with negative cultures.

Following this operation, the patient's recovery was slow. After 2 weeks he was still having abdominal pain and fever. A Gastroenterology consultant performed an endoscopic examination of the rectum, and biopsy revealed diffuse colitis. With little response to antibiotics and negative tests for infectious causes, ulcerative colitis was considered likely. Antibiotics were discontinued and corticosteroid therapy instituted. Over the following week, the patient's symptoms gradually improved and he was discharged home in mid summer.

Because the gastroenterologists who treated the patient while he was hospitalized did not accept TRICARE reimbursement for outpatient care, he established follow-up care with a gastroenterologist in Fort Worth. That specialist performed endoscopic examinations of the terminal ileum, mucous fistula, and rectum. He found the ileum to be normal, but observed significant inflammation of the colon and rectum and intensified the patient's anti-inflammatory regimen. Current medications include prednisone and azathioprine. Plans were made for re-examination in early 2008 and consultation with a surgeon for possible re-anastomosis of the remaining colon. The private hospital surgeon recommended follow-up evaluation with a colo-rectal surgery specialist, but the patient had difficulty locating any specialist of this type who would accept TRICARE.

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<sup>3</sup> Following removal of all or part of the colon, a mucous fistula is created when the end of a non-functional segment of bowel is exteriorized.



## Findings

### 1. Appropriateness of surgery

This patient was admitted to the Marion VAMC with abdominal pain and chronic bowel symptoms, and was initially felt to have a possible infectious colitis. However, after a period of observation during which he did not improve, exploratory surgery was undertaken.

The two surgeons and the internist who examined the patient prior to surgery recorded disparate descriptions of his abdominal examination. Only the first surgeon described rebound tenderness or other evidence of peritoneal inflammation, and the two providers who mentioned localized tenderness differed with respect to its location (RLQ vs LLQ). Further, the internist indicated that there was no guarding.

Taken together, the patient's overall history and the observations documented by his providers suggest that surgery might best have been deferred until specialty consultation and diagnostic testing were obtained. In particular, consultations with Infectious Diseases and/or Gastroenterology specialists probably should have been obtained prior to surgery.

### 2. Adequacy of surgery that was performed

Prior to the operation, surgeons indicated that exploratory surgery was planned. However, our review of the operative note, operation report, and anesthesia record, and our interviews with both of the surgeons involved, revealed that in fact only minimal if any exploration occurred. Once the decision was made to perform exploratory surgery, conscientious exploration should have been carried out. The operating surgeon asserted that the scope of surgery was limited because appendicitis was obvious, but this was refuted by the other surgeon (who was also in the operating room) and by pathologic examination of the excised appendix.

We interviewed the surgeon who operated on the patient in his home state and reviewed records from that hospitalization. We were unable to substantiate or refute the allegation that the patient's bowel perforations were caused during his initial operation in Marion.

### 3. Availability of gastroenterology consultation and use of consultants and collaborating physicians

Gastroenterologists are employed on a part-time basis at the Marion VAMC. They work exclusively in the outpatient area. We confirmed that inpatient Gastroenterology consultation was not available.

We confirmed poor communication among treating physicians. On the third hospital day, approximately 6 hours prior to surgery, an Internal Medicine consultant evaluated the patient. The consultant recommended additional diagnostic tests, but these were not

performed until after surgery. There is no documentation of any acknowledgement of the consultation results by or discussion with either surgeon. There is also no documentation that this consultant saw the patient again.

On the seventh hospital day, an Infectious Diseases consultant made several specific recommendations and entered orders to effect the changes. However, despite the consultant's intervention, the operating surgeon and a physician assistant discharged the patient without prescriptions for either of the recommended antibiotics. There is no documentation of any acknowledgement of the consultation results by or discussion with the surgeon or physician assistant.

4. Use of diagnostic tests and responsiveness of surgeon to the patient's condition

We confirmed that diagnostic testing was probably insufficient both before and after surgery. The period of time during which the patient was hospitalized prior to surgery was sufficient to obtain adequate testing of stool specimens, consultation with specialists, and possible endoscopic examination of the lower gastrointestinal tract. We also confirmed that the surgeon failed to attend to the fact that the patient was not getting better, continuing to ascribe the patient's symptoms and signs to a viral illness.

5. Adequacy of discharge processes

We confirmed that the patient's discharge was mishandled in several respects. At the time of discharge the patient was on broad-spectrum antibiotic coverage, but continued to have a markedly rapid heart rate and was requiring narcotics for pain control. When the patient and his family requested that treatment be continued near their home in another state, Marion providers should have established direct contact with physicians at the large VAMC near his home to facilitate expeditious care transition. Though a Marion social worker provided contact information for her counterparts in at the large VAMC near his home, the patient was unable to reach the identified individuals on the day of his arrival.

When the patient was discharged, he was given a prescription for an ineffective antibiotic rather than the two antibiotics initiated by the Infectious Diseases specialist.

6. Use of antibiotics post-operatively and at discharge

The surgeons who managed the care of this patient used antibiotics erratically and ineffectively. The admitting surgeon documented no rationale for his initial selection of two antibiotics, and there is no evident rationale for these antibiotics being discontinued after surgery by the operating surgeon. When the patient remained ill after surgery, the same antibiotics were re-instituted, again with no suggestion of a rationale. In fact, the stated reason for the patient's continued symptoms – a viral illness – would argue against the use of antibiotics.

Apparently anticipating that discharge would occur soon after surgery, the operating surgeon entered an outpatient antibiotic prescription immediately after the operation was completed. The basis for the use of that antibiotic (doxycycline) was not stated. Apparently unaware of the Infectious Diseases consultation, the surgical physician assistant continued with the plan for that antibiotic at the time of discharge.

7. Adequacy of insurance coverage for private-sector specialty care

Providers in his home state confirmed that many physicians and surgeons in the area of the patient's residence do not accept TRICARE. At the time of this review, the patient had yet to establish care with a colo-rectal surgeon.

## **Conclusions**

Although we were unable to substantiate every allegation, it is clear that this veteran received sub-standard care at the Marion VAMC. The decision to perform laparoscopic surgery could be questioned, but is probably within the range of acceptable clinical practice. Likewise, we could neither substantiate nor refute the allegation that surgeons caused bowel perforations. In many other respects, however, care provided by individuals and by the medical center was poor. Areas of deficiency include the availability and use of consultants, attention to clinical signs and symptoms, consideration of relevant diagnostic possibilities, use of antibiotics, and conscientious transfer of care at discharge. In addition, we identified substantial barriers to ongoing specialty care attributed to insufficient insurance payments for private-sector care.

2. Allegation: The facility had an increased postoperative infection rate following knee arthroplasty.

We performed our own review of infections following total knee arthroplasty and also assessed the care of a patient with a knee infection which was brought to our attention. It should be noted that we did not use NSQIP criteria for infection in our review. We considered the record to reflect evidence of an infection if there was documented reference in post-surgical notes to an infection at the surgical site and treatment with antibiotics. In contrast, NSQIP criteria require purulent drainage from the incision, organisms isolated from culture, the incision deliberately reopened by the surgeon, or the diagnosis of superficial incisional surgical site infection made by the surgeon or attending physician. In our review, we did not exclude documentation of infection by a physician assistant.

Of 29 total knee arthroplasties performed at the facility between January of 2006 and September of 2007, we found 3 cases with notes describing an infection significant enough to require a second operative procedure. These three cases alone would yield an infection rate in excess of 10 percent for total knee arthroplasties. There were three additional patients who informed this orthopedist at follow-up clinic visits that they had a postoperative infection requiring treatment by a private physician. We could find no

documentation that this second set of three cases were reviewed by the Chief of Surgery or the peer reviewer. Finally, there was a third set of three additional patients who had hospital or clinic notes referring to infection at the operative site and which were subsequently placed on antibiotics.

We found that of the remaining 20 patients, discharge summaries reflect that 2 were discharged on antibiotics for reasons unrelated to the total knee arthroplasty and 9 were discharged on antibiotics without reference to any infection or reason for the antibiotics.

### **Case Review**

A veteran in his mid-50's with rheumatoid arthritis underwent total knee arthroplasty at the Marion VAMC on the fall of 2006. Two weeks later, the patient was seen in orthopedic clinic and noted to have drainage to the tip of the incision. The orthopedic surgeon scheduled a follow-up appointment 2 weeks later for re-evaluation. At the time of that follow-up, the orthopedic surgeon observed that 2 centimeters of the incision had dehisced. He submitted a specimen from the fluid drainage for culture and started the patient on ciprofloxacin 750 mg twice daily, an oral antibiotic.

The orthopedic surgeon next evaluated the patient 4 days later. At that time, he observed that "the wound is nearly healed." He continued the ciprofloxacin and scheduled the patient for a follow-up visit in 1 month. However, the patient was next seen 2 weeks later, complaining of continued drainage at the incision site. The attending surgeon diagnosed a draining sinus, continued the antibiotics and treated the drainage site with cautery and wound care instructions.

Because the drainage persisted, the orthopedic surgeon performed an excision of the sinus tract, debridement and closure approximately 1 week later; the patient was readmitted a week later. Cultures grew a coagulase negative *Staphylococcus aureus* and *Peptostreptococcus*. He was placed on intravenous clindamycin. An infectious disease specialist was consulted a few days later and changed the antibiotics to vancomycin and rifampin.

In early 2007, the orthopedic surgeon performed a debridement, wash out, and exchange of the tibial insert. The metallic femoral component of the total knee replacement remained in place. General surgery inserted a catheter for administration of intravenous antibiotics at home. Subsequently, the orthopedic surgeon and infectious disease specialist saw the patient several times, who remained on intravenous antibiotics at home for the next several months. In late summer of 2007, the patient received an irrigation and debridement and right total knee arthroplasty revision involving all three components at an outside facility by a private orthopedic surgeon.

We found deficiencies in the orthopedic surgeon's initial treatment of this patient's postoperative wound infection. Specifically, persistent drainage more than 5 to 7 days

postoperatively is an indication for open debridement. The orthopedic surgeon did not fully debride, wash out and exchange the tibial insert until approximately 10 weeks postoperatively. Further, he initially treated cultures growing a coagulase negative *Staphylococcus aureus* and *Peptostreptococcus* with intravenous clindamycin, which would not provide full antibiotic coverage for this class of organisms. Finally, we note that the orthopedic surgeon did not remove all components of the total knee replacement despite persistent evidence of prosthetic infection.

### 3. Allegation: There was an increased rate of bladder perforations.

We also received an allegation that there was an increase rate of bladder perforations during urological procedures at the Marion VAMC. While calculation of a rate which risk-adjusts for the numerous co-morbidities of these patients is beyond the scope of this report, we do note that there were four bladder perforations by the same urologist. Below is a review of one such case.

A man in his late 50's presented with a urethral stricture resulting in difficulty in urinating. The attending urologist performed a cystoscopy and attempted to incise a urethral stricture in early summer of 2007. During the course of the procedure, the urologist perforated the bladder and lacerated the distal sigmoid colon. While these complications were appropriately recognized and treated, perforation of both the bladder and sigmoid colon during the course of these procedures is not generally an acceptable complication. We thus concluded that there were deficiencies in the intraoperative treatment of this patient's urethral stricture.

## **B. Quality of Care – Review of Non-Surgical Cases**

During our investigations, allegations of poor medical care involving two patients treated by non-surgical providers were brought to our attention.

### 1. Allegation: The Marion VAMC failed to provide adequate follow up of the veteran's heart and circulatory problems resulting in deterioration of the veteran's health status.

A man in his late 60's with a history of coronary artery disease underwent coronary artery bypass surgery and aortic valve replacement in January 2000. Between 2001 and 2006, we found that he was seen by his primary care physician regularly and by a cardiologist at the VA in March 2005. The cardiologist altered medications and ordered a Cardiolite stress test, which estimated the veteran's ejection fraction at 43 percent but was negative for ischemia. He also requested that a biventricular pacemaker implantation be scheduled, but subsequently noted that the patient did not meet criteria. An echocardiogram demonstrated that he did have a dilated aortic root of 5 cm.

The risk of rupture for a 5 cm aneurysm is about 3 percent annually. Because there is substantial variation in aneurysm growth rates, all aneurysms must be followed up with regular surveillance imaging. We do not find that the VA appropriately followed up on

this finding. The last CT of the chest at the VA occurred in 2000. The report of this examination did not comment on the existence of an aneurysm. We could locate no progress notes documenting that the cardiologist followed up on the dilation of the aortic root noted on the echocardiogram. While records obtained from an outside cardiologist document the existence of a thoracic aortic aneurysm, we did not find that notes from the Marion VAMC listed this as one of the patient's medical conditions.

The veteran's wife further alleged that the veteran's low cardiac output, lack of energy, and inability to cross the room without becoming short of breath was the result of inadequate follow-up. While the veteran did not see a cardiologist at the Marion VAMC annually, nor did he receive a CT scan or other evaluation of the aortic root dilation, we could not find evidence that this resulted in any deterioration of the patient's medical condition.

## 2. Allegation: The Marion VAMC failed to admit a veteran when he presented with low blood pressure.

A man in his late 70's with a remote history of colon cancer presented for primary care follow-up in November 2007. He had been living alone at home and self-managing his colostomy until approximately a month earlier, when he had a fall and was admitted from the emergency room with dizziness and hypotension. He had urinary retention and was treated for a urinary tract infection. Hospitalization was prolonged because he became somnolent and medication adjustments were required. Two weeks later he was discharged with an indwelling urinary catheter to an inpatient rehabilitation facility.

At the time of his follow-up appointment in November, he was transported by wheelchair van to his scheduled visits with his primary care provider and his urologist. His daughter accompanied him at the hospital and gave most of the answers to providers' questions. The patient remained in his wheelchair and spoke very little. His blood pressure at 0854 was recorded to be 67/37. The primary care provider recorded "hypotension" as the number one issue in his assessment and discontinued two of the patient's medications (lisinopril and cyclobenzaprine) and reduced the dose of a third (venlafaxine). The patient returned to his rehabilitation facility by wheelchair van.

That evening he was noted to be increasingly weak and to be hypotensive. He was transported by ambulance to a nearby hospital and found to be hypotensive (47/33) and in respiratory distress. He was intubated, mechanically ventilated, and treated with the antibiotic levofloxacin. A chest x-ray and echocardiography were unremarkable. The white blood cell count was mildly elevated initially, but was normal by the third hospital day. Blood cultures were negative. He was discharged back to his rehabilitation facility on 4 days later. Plans were made for his transfer to an assisted living facility.

We found that further attention should have been given to the patient's low blood pressure when he saw his primary care provider in November 2007. Although medication adjustments were appropriate, they were insufficient.

## Recommendation Related to Quality of Care

**Recommendation 8:** The Under Secretary for Health confer with the Office of General Counsel regarding the advisability of informing families of patients discussed in this report about their right to file tort and benefit claims.

### C. Quality Management

The Leadership of the Marion VAMC did not address many of the quality of care issues identified in the forgoing section. This resulted in part from the facility's ineffective Quality Management Program. We substantiated the allegation that quality management processes at the facility were ineffective and not in compliance with multiple VHA policies.

#### Purpose of Quality Management Program

VHA requires that its facilities operate a quality management (QM) program to monitor quality and performance improvement activities. QM activities also monitor compliance with selected VHA directives and appropriate accreditation standards, as well as Federal and local regulations. Required data management process steps include:

- Identification of problems or potential improvements.
- Data collection and critical analysis.
- Comparison of data analysis results with established goals or benchmarks.
- Determination of specific corrective actions when results do not meet goals.
- Implementation and evaluation of actions until problems are resolved or improvements are achieved.

According to local policy, the medical center-wide Quality Management System (QMS) is an organized, systematic, continuous effort to: (a) monitor the quality and appropriateness of patient care and services provided, (b) identify and resolve problems, (c) evaluate and maintain internal controls, (d) utilize external data for comparison, and (e) implement improvements to achieve excellence in the delivery of health care services. The QMS program is responsible for providing oversight to all aspects of care provided by the medical center. This includes quality of care, medical necessity and appropriateness of care, utilization of resources necessary to provide quality care, the safety of patients, and the clinical performance and conduct of VA employees and others engaged in the provision or support of care to VA beneficiaries.

#### QM Program and Structure

The QMS program is structurally located under the Medical Center Director's supervision. Local policy states that the Medical Center Director is responsible for the operation of the QMS plan and for the overall direction of the internal control systems and must certify

annually that internal controls are in place and working effectively. Areas of QMS responsibility include oversight of all patient care treatment processes and major function reviews. Infection control, utilization review, medical records review, safety, External Peer Review Program (EPRP), the National Surgical Quality Improvement Program (NSQIP), risk management, occurrence screening, and other VHA mandatory activity requirements are included in the QMS program. Continuous monitor reviews include: Medical Records, Surgical Case Reviews, Blood Services, Therapeutic Agents and Pharmacy, Laboratory and Radiology, Restraints and Seclusion Usage, Infection Control, Mortality and Morbidity, and Surgical Complications. Local policy states that surveillance activities will be primarily ongoing with information captured periodically and that in-depth studies are required only when the cause or scope of a suspected problem is not known.

The Director of Performance Management (DPM) is responsible for the QMS program and reports to the Medical Center Director. The current DPM has been in the position for 10 years and is responsible for monitoring and coordinating QMS and internal control systems activities. The DPM evaluates programs to ensure that effective monitors are in place, that reviews are meaningful and purposeful, and that assessment information is used in identifying and solving problems. The DPM also serves as the Risk Manager and coordinates all risk assessment and evaluations.

There are 21.5 FTE assigned to the QM Department as displayed in the table below:

| <b>Title</b>                                     | <b>Number FTE</b>                                 |
|--|---|
| Director, Performance Management                 | 1   |
| Care Coordination and Resource Management (CCRM) | 6 (2 are also assigned NSQIP duties)              |
| Risk Management Specialist                       | 1   |
| Program Support Assistants                       | 1.5   |
| Clerks (CCRM)                                    | 5 (2 in Evansville outpatient clinic)             |
| Infection Control Nurse                          | 1   |
| MRSA <sup>4</sup> Prevention Coordinator         | 1   |
| Program Analyst                                  | 1   |
| Registered Nurses                                | 4 (3 Evansville and 1 Paducah outpatient clinics) |

The Patient Safety Manager was formerly located in the QM Department but is now located under the direct supervision of the Medical Center Director. This change occurred in July 2007, because of a VHA mandate. VHA Handbook 1050.1 *National Patient Safety Improvement Handbook* specifies that adverse events occurring in a medical center must be reported to the Patient Safety Manager or designee.

<sup>4</sup> MRSA is methicillin resistant *Staphylococcus aureus*.



The Risk Management Specialist position was approved and a selection had been made; however, that person was the program analyst and had not started in the new role as of October 2007. The CCRMs are registered nurses responsible for admission and continued stay appropriateness reviews. They follow patients through the continuum of care, ensuring that documentation, consults, and fee basis referrals are appropriate. They also serve as patient transfer coordinators. Along with their utilization review (UR) responsibilities, they assist in QM activities and perform medical record reviews to address surgical quality, peer review, and patient incidents. The position description notes responsibilities of maintaining tracking systems for transfer of patients, inpatient appropriateness of admission, adverse patient occurrences, patient complaints, deaths, operative and invasive quality issues, and peer reviews. They provide the data for provider reprivileging. While they promote reimbursement from third party payers by providing timely and appropriate information, there are UR nurses located in the Business Office who deal specifically with insurers.

The Director, Chief of Staff, Associate Director for Patient Care/Nursing Services, and the Associate Director are responsible for assuring that all Care Lines under their supervision consistently support and participate in the QMS program. Care Line Directors, Program Managers, and Nurse Managers are all responsible for:

- Being familiar with and meeting requirements for their Care Line or Program.
- Developing and implementing a program QMS plan, and evaluating it annually.
- Developing mechanisms for ongoing monitoring and assessment of functions provided by their Care Line, including peer review activities.
- Ensuring that QMS activities are purposeful and meaningful and that appropriate follow-up and evaluation of corrective action is performed.
- Ensuring that QMS records of monitoring activities are maintained.
- Assuring that internal controls exist and are followed.
- Ensuring that results of QMS activities are considered during re-credentialing, re-privileging, and included in performance files as appropriate.
- Submitting QMS activity reports within established timeframes.
- Informing the DPM of external reviews within their areas.
- Providing education and training based on identified need.

### **QM Oversight**

Based on the local QMS Performance Improvement Plan, dated March 16, 2006, the Clinical Executive Board (CEB) and Executive Leadership Council (ELC) are responsible for reviewing and acting upon results of studies or recommendations referred to them, and for facilitating implementation of any approved QMS corrective actions. The DPM is responsible for scheduling biannual reports from Care Lines and Programs to the ELC. The Chief of Staff schedules CEB reviews of reports from Care Lines and monitoring committees; this includes Blood Usage, Infection Control, Medical Records, Pharmacy and

Therapeutics, Medication Safety, Ethics, Women Veterans, Functional Groups, and Surgical Case Review. The CEB is also responsible for reviewing risk management reports relating to patient safety, tort claim litigation activities, and results of occurrence screens. Specific program reports will be discussed later in this section.

A more recent medical center policy dated March 16, 2007, states that the Quality and Performance Improvement Council is responsible for “the promotion of systematic evaluation processes such as performance improvement, and effective oversight for programmatic and systematic health care delivery design enhancements.” This committee was never organized and had not met as of October 2007. Performance improvement activities were reported through either ELC or CEB. There are three different sessions of CEB: (a) PSB, (b) quality assurance (QA) or peer review, and (c) general or administrative. Membership differs for each session. The former quality assurance session was renamed peer review in May 2007.

The local QMS Performance Improvement Plan states that the QM program is integrated into the re-credentialing of licensed independent providers (LIPs) through patient care monitoring, utilization review, staff growth and development, Care Lines, and program evaluation. According to local policy, the DPM is responsible for providing physician quality assurance folder reviews on request for renewal of privileges. The CCRMs collect the majority of information placed in the folders during their medical record reviews. Members of the Professional Standards session of CEB make recommendations to the Medical Center Director on medical staff appointments, promotion requests, and clinical privilege applications. The local policy on appointments and clinical privileges states that Care Line Directors are responsible for continuing surveillance and evaluation of professional performance of all individuals who have delineated clinical privileges in the department. Care Line Directors are also responsible for recommending to the medical staff the criteria for clinical privileges in the department through use of aggregate, relevant provider-specific information on performance improvement activities, and for assuring that quality and appropriateness of patient care provided within the department are monitored and evaluated. The Medical Staff Bylaws, Rules, and Regulations note that recommendations for reprivileging will be based on professional performance, judgment, and clinical and/or technical skills and quality of care including results of monitoring and evaluation activities where applicable. Examples of these are listed as surgical case review, mortality assessments, drug usage evaluation, infection rates, medical record review, blood usage review, pharmacy and therapeutics review, monitoring and evaluation of quality and appropriateness of clinical aspects of patient treatment and risk management activities.

Findings: The oversight reporting structure for QM reviews was fragmented and inconsistent. It is extremely difficult to determine oversight of patient quality or corrective actions taken to improve patient care, based on minutes that the medical center provided for our review. The CEB and ELC committee minutes that we reviewed did not address all

required program reporting functions. Documentation of discussion of areas that were reviewed was limited. Patient satisfaction surveys and performance measures were reviewed consistently. Care Lines, including surgery, did report to ELC but monitors did not cover key elements that would provide management meaningful information regarding quality of care. Because QM responsibilities were split between multiple groups, fragmentation of processes resulted.

## **Peer Review**

VHA defines peer review as a protected, non-punitive, medical center process to evaluate the quality of care at the provider level. VHA Directive 2004-054, *Peer Review for Quality Management*, specifies that the facility director or designee “has ultimate responsibility for peer reviews for quality improvement that are protected and performed within the facility.” This process differs from most other QM reviews that are designed to identify system issues. A peer is defined as an individual of similar education, training, licensure, and clinical privileges. The peer review process includes an initial review by an individual peer to determine if most experienced, competent practitioners would have managed the case in a similar fashion (Level I), might have managed one or more aspects of the care differently (Level II), or would have managed the case differently (Level III) in one or more of the following aspects:

- Choice of diagnostic tests and timely ordering of diagnostic tests.
- Performance of a procedure and/or treatment.
- Addressing abnormal results of diagnostic tests.
- Timeliness of diagnosis and appropriateness of diagnosis.
- Timing of treatment initiation and appropriateness of treatment.
- Adequacy of technique during procedures.
- Recognition and communication of critical clues to patient’s condition during period of clinical deterioration.
- Timely initiation of appropriate actions during periods of clinical deterioration.
- Other relevant aspects of care.

All deaths must be screened against VHA death review criteria and exceptions to the *criteria*. VHA Directive 2005-056, *Mortality Assessment* specifies that all mortalities and major morbidities associated with a surgical procedure or occurring during the same hospitalization must be peer reviewed within 30 days of the original procedure. Any cases with negative or unexpected outcomes, any concerns regarding QM issues, tort claims, or concerns within facility groups require peer review.

VHA Directive 2004-054 also requires completion of the initial peer reviews within 45 days. Completed reviews are then forwarded to a multidisciplinary peer review committee for validation or changes of the initial findings. The peer review committee’s evaluation must occur within 120 days from the date of determination that a peer review is necessary.

The results are then shared with the involved provider in order to provide feedback about their practice. The Peer Review Committee must meet at least quarterly and report quarterly to the Executive Committee of the Medical Staff. This quarterly aggregate tracking report includes the number of reviews completed, the outcome of the reviews by level, the number of changes from one level to another during the review process, follow-up on action items, and recommendations that result from completed peer reviews. When conducted systematically and credibly, peer review can result in both immediate and long-term improvements in patient care by impacting individual provider's practices.

Findings: This report is limited to the Marion VAMC surgical peer review process. There were several deficiencies in the process. The process was not in compliance with VHA Directives and did not ensure the review of practitioner practice. VHA requires that peer review include all practitioners (such as registered nurses) and be multidisciplinary. The local policy only addresses LIPs.

VHA Directive 2004-054 requires that facility policy state criteria for those circumstances requiring peer review. However, we found that it was not clear how cases were identified for peer review. The DPM and CCRMs told us that they did not use the VHA Occurrence Screening computerized system because it was not accurate, but we did find printouts of those forms in supporting raw data. CCRMs identify negative or unexpected patient outcomes associated with care or services during their medical record reviews. (The NSQIP nurses are included as CCRMs). They refer those cases to physicians for peer review. Surgical service also has a Total Quality Improvement (TQI) Committee where LIP peer reviews are discussed. The Chief of Surgery then reports findings from that committee to the Peer Review session of CEB. However, cases were not presented in a timely manner. For example, the March 2007 minutes include discussions of patients hospitalized in October and November 2006. This violates time limitations for peer review found in both VHA Directive 2004-054 and VHA Directive 2005-056.

CCRMs reported that their reviews are frequently done retrospectively, rather than concurrently, because of the priority to perform the fee basis review functions of their jobs. The former NSQIP nurse told us that her reviews fell behind for several months because of personal leave and coverage for other CCRMs. She had reported her concerns to her supervisor, noting the potential impact on patient care. Surgical service had requested that she be transferred to their service so that she could perform full-time surgical review but the Medical Center Director refused that request. The DPM told us that surgical TQI minutes were not completed for several months because the recording secretary left the position. The DPM told us that she reported the lack of information to her supervisor, the Medical Center Director.

VHA Directive 2004-054 also requires that the peer review committee track on a quarterly basis the number of reviews performed, outcomes, the number of changes from one level to another, follow-up on action items and recommendations that result from peer reviews. Local policy, however, states only that an aggregate review of findings will be part of the

annual performance improvement plan with establishment of goals based on trends or significant findings. As a result, there was no quarterly summary analysis of actions taken from the peer review process to improve patient care. The DPM told us that the medical center had not implemented all the requirements of the VHA Directive. VHA requires that facilities send quarterly peer review aggregate reports to the VISN. The VISN Quality Management Officer (QMO) did not recall if they had received reports from Marion.

The following are surgical peer review aggregate results that we compiled from discussion in surgical TQI and CEB committee minutes from January–August 2007.

| <b>Initial Individual Review Findings</b> |     | <b>Changes After Committee Review</b> |
|---|-----|---------------------------------------|
| Level I                                   | 132 | 1 to a Level II                       |
| Level II                                  | 3   | 0                                     |
| Level III                                 | 0   | 0                                     |

### **Mortality Assessment**

VHA recognizes that meaningful mortality assessment remains a challenge in any healthcare system because of the lack of validity of risk adjustment in clinically complex patients. It is VHA policy that standardized trending of deaths that occur in VA inpatient or procedure units be implemented at each medical facility. Deaths are to be trended by facility, ward, service line, shift time, and provider. Results are required to be presented graphically in a regular forum in order to identify unusual patterns or trends. If there are unusual patterns, there must be a formal peer review. All mortalities and major morbidities associated with any surgical procedure are required to be peer reviewed within 30 days of the original procedure.

According to local policy, the DPM is required to present mortality analysis twice a year to the CEB. The DPM told us that her reviews are compiled annually for this presentation. The latest review was presented at the April 2007 CEB. This graphic presentation covered deaths that occurred during FY 2006.

Findings: We found that VHA Directive 2005-056 does not designate the frequency for presentation of death reviews. However, the Directive does state that the facility Director is responsible for ensuring that “[t]rending of mortality data to identify suspicious events and trends is implemented. Deaths are to be trended by facility, ward, service line, shift time and provider when a specific provider can be linked to the care of specific patients....”

While VHA policy does not specify the frequency for mortality review, we note that the Joint Commission (previously the Joint Commission on Accreditation of Healthcare Organizations or JCAHO) considers quarterly reviews minimal. Local policy requires semiannual reports. We noted that the graphic presentation of deaths by unit is confusing and when there was an increase in ICU deaths during one month, no action was taken to

assess that pattern. When we asked for names of patients who were included in the November 2006 increase, the QMS data analyst was unable to provide the raw data. We consistently experienced difficulty obtaining names of patients who died at the facility during specified time periods. Another graphic display compared deaths to deaths with Do Not Resuscitate (DNR) orders or terminal illness. However, there was no analysis to determine when patients were made DNR. This could have occurred immediately before death, creating the appearance that death was expected.

Mortality assessment is a component of the annual performance improvement program evaluation but the DPM only included a brief summary stating no trends were identified, with only one graph of deaths stratified by shift.

### **Patient Safety**

The Patient Safety Manager (PSM) had been under the direct supervision of the DPM until July 2007 when that position was moved under the Medical Center Director, per VHA mandate. This person is responsible for the incident reporting program and root cause analysis (RCA). The RCA process is used to identify contributing causes of variations in care associated with adverse events.

The Patient Safety Council is the medical center's committee for oversight of the patient safety program. The committee reviews falls, medication errors, and other patient safety related issues. We interviewed the PSM regarding the roles and responsibilities of the position and the safety culture of the medical center. The VA National Center for Patient Safety (NCPS) has devoted time and resources to develop a culture that is free from blame and one in which employees feel comfortable reporting incidents through the safety program. The PSM told us that a culture free from blame did not exist at the medical center. Employees do not file incident reports on all adverse events or near misses. The PSM was not aware of any problems in the surgical service and only had one incident report on the recent surgery deaths. We were presented, however, with over 30 reports of contact completed between February 21, 2006 and October 24, 2007 which detailed problems in the surgical service. Although many of these include notations that they were forwarded to the Chief of Surgery, Chief of Staff, and/or the Associate Chief Nurse, we do not find any evidence that they were forwarded to the PSM. The PSM did receive at least 18 incident reports describing relatively minor deficiencies in the surgical service. We found that only one of these concerned the surgical deaths described in the first part of this report.

The medical center process for filing incident reports requires that a form (either paper or electronic) be completed at the time of the event. This is the only acceptable method of filing a report. Other VA medical centers have implemented telephone message lines, e-mails, and even anonymous reporting in order to capture events. The DPM also reported that services did not participate in RCAs, making it difficult to meet the 45-day time requirement for completion. VHA policy requires that RCAs be completed and forwarded

to the National Center for Patient Safety (NCPS) within 45 days of the team charter. NCPS must approve any requests to extend the time requirement. The DPM stated that RCAs were not a priority and team members frequently missed meetings. To meet time requirements, she often completed them by herself.

### **NSQIP Nurse**

The NSQIP nurse reviewer in Marion was structurally located in the Quality Management office and supervised by the DPM. She had been in her position as a full-time employee for 7.5 years until she retired in May 2007. During interviews, we were told that the surgical care line did not receive NSQIP data for months because the nurse reviewer was assigned 25 percent to NSQIP and 75 percent for case management reviews. To remedy the problem, the surgical care line asked the Medical Center Director to reassign the nurse reviewer to their direct supervision but the request was denied. This nurse provided documentation that she informed the DPM she was unable to perform her assigned duties because of increased surgical workload, workload in the fee basis area, and family leave. Along with her NSQIP duties, she also reviewed cases for clinical appropriateness and provided medical record review and quality indicator data for the Surgical Total Quality Improvement Committee. She also informed us that the Chief of Surgery and former Acting Chief did not review cases with her. She input the required data without their feedback.

We believe this had the potential to adversely impact the integrity of data entry at the facility. Since the former nurse's retirement, the DPM assigned two CCRMs the NSQIP review responsibility so there would be backup. They each have 50 percent responsibility for NSQIP and 50 percent for fee basis; thus there is now 1 FTE devoted to NSQIP duties. They attended national training in September 2007. They reported to us that they did not have sufficient time to spend on NSQIP and surgical reviews because of fee basis responsibilities.

### **Conclusions**

In general, the QMS program collected large amounts of data. Performance measures and patient satisfaction scores were the focus of the program. Because the medical center performed well in these areas, the VISN told us there was no reason to expect any unusual events. The medical center received a good review from the Joint Commission. On the surface, the program appears to be meeting requirements. However, several key processes were not functioning adequately. When evaluating actual raw data, the validation process could not be explained. VISN involvement was present but could be improved.

The CCRMs spent at least 50 percent of their time on utilization review/case manager activities rather than on QM review activities. The NSQIP review nurses also performed utilization review activities. Because of time constraints and priorities, data was collected retrospectively rather than concurrently. This resulted in delayed peer reviews, RCAs, and

mortality reviews. QM activities were disjointed and fragmented in several committees and the balance between services versus QMS responsibilities was not clear. QM data presented for practitioner competence during reappraisal and reprivileging was not meaningful and would not demonstrate competency.

It is difficult to determine if any of these factors resulted in increased mortality among surgical patients but the medical center could have had stronger programs in place to monitor the quality and appropriateness of the provision of patient care and services. Meaningful data would provide information regarding opportunities for improvement.

### **Recommendations Related to Quality Management:**

**Recommendation 1:** The Under Secretary for Health develop and implement a national quality management directive that ensures a standardized structure and mechanism throughout VHA for collecting and reporting quality management data.

**Recommendation 9:** The Under Secretary for Health ensure that Marion VAMC complies with VHA policies regarding peer review, mortality assessments, adverse event reporting, and the performance of root cause analyses.

## **D. Credentialing and Privileging**

### **Overview of Credentialing and Privileging**

One very important component to quality management is the proper credentialing and privileging of providers. Credentialing generally refers to the process by which health care organizations screen and evaluate providers in terms of licensure, education, relevant training and experience, current competence and health status. Privileging refers to the process by which a specific facility determines what procedures or services an individual provider may offer at that facility based on specific clinical competence as well as the needs and capabilities of the institution. Privileges are facility specific and are only granted for activities actually performed at a given facility.

VHA Handbook 1100.19, *Credentialing and Privileging*, March 6, 2001, describes VHA's policies and procedures for the initial credentialing and privileging of health care providers. It applies to individuals permitted by law and the facility to provide patient care services independently. It also outlines the processes under which credentials (the reappraisal process) and privileges (the reprivileging process) are reviewed every two years. This handbook was revised on October 2, 2007; however in this report we apply the 2001 version of the handbook as this version was in effect at the time the providers discussed in this inspection were credentialed, privileged, reappraised, and repriviledged by the Marion VAMC and VISN 15. The actual credentialing and privileging process is conducted through VetPro, VA's electronic credentialing and privileging system.



## **Credentialing**

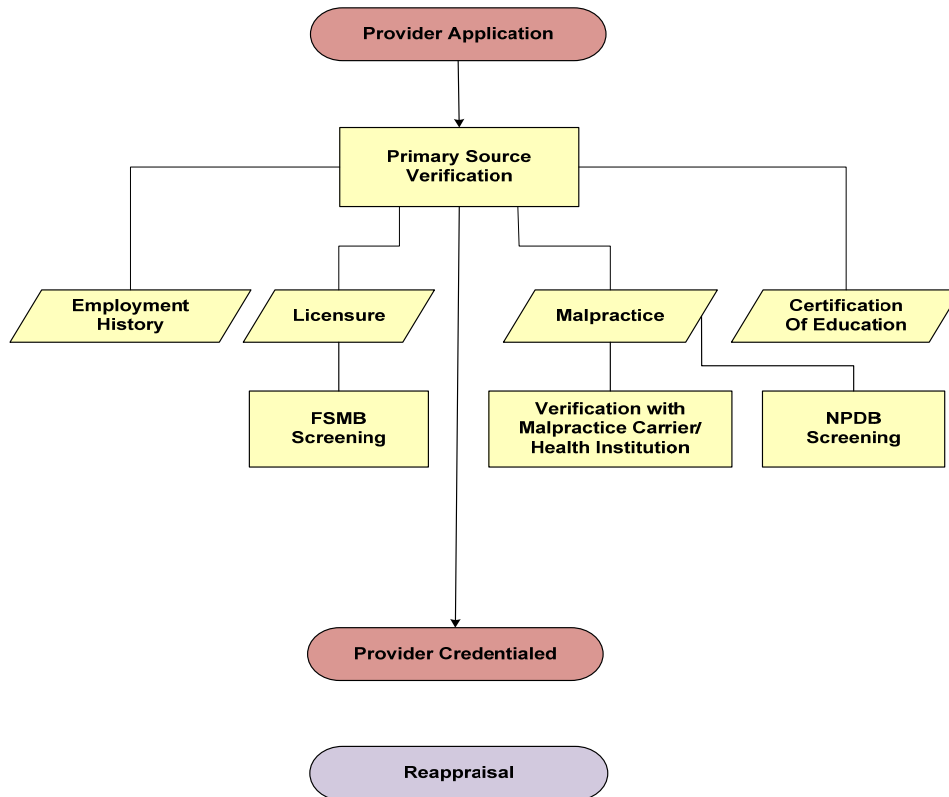
In VISN 15, credentialing occurs at the VISN level in a centralized credentialing office in Leavenworth, Kansas. This office has seven employees: five GS-6 program support clerks, one GS-7 lead program support clerk, and one supervisor at the GS-9 level. This office verifies licensure, education, and references. It also queries both the Federation of State Medical Boards (FSMB) and the National Practitioner Data Bank (NPDB) to obtain information regarding any disciplinary actions taken against a provider's license and any paid malpractice claims. We do note that prior to January 2007, Eastern Kansas Health Care System–Leavenworth supervised centralized credentialing processes rather than the VISN directly.

### **Failure to Appropriately Address a Federation of State Medical Boards Disciplinary Alert**

When a provider initially applies for a position within VHA, facilities must query the FSMB to determine if disciplinary action has been taken against an applicant's license. FSMB operates the Federation Physician Data Center, which maintains records of disciplinary actions taken against licensees by the boards and other governmental authorities. The FSMB provides information only regarding disciplinary actions taken against a provider's license. It neither maintains nor provides VHA with information on all states in which a provider holds a license if there are no final disciplinary actions against those licenses. VHA facilities are required to document that a query was made, the date of the query, and the query batch number on the VetPro Licensure screen during the reapproval process. In addition to the initial inquiry, providers are placed in VHA's FSMB Disciplinary Alerts Service. This allows continuous monitoring of VA providers, triggering an electronic alert notifying VHA's Director of Credentialing and Privileging when a disciplinary action occurs against a provider's license.

During the credentialing process, facilities must also obtain written verification of all education, residencies, medical licenses, and board certification. If a provider has had any adverse action taken against a license, including a voluntary surrender pending action, the officials included in the appointment process must review all state licensing board documentation and the applicant's subsequent conduct before determining that the provider can serve as a health care practitioner in the VA. VHA's credentialing process is illustrated in the diagram on the following page.

**VETERANS HEALTH ADMINISTRATION  
CREDENTIALING PROCESS**



We found that a Marion VAMC surgeon completed his application for employment at the Marion VAMC in the fall of 2005. Correspondence from the state in which he was licensed, from the early winter of 2005, stated there were no closed complaints or final board disciplinary actions against the provider and he was appointed effective early in 2006. Later that month, the medical center COS certified that he (the surgeon) had verified licensure and registration with State boards, and cited evidence of citizenship. The surgeon possessed one active medical license in one state with former licenses held in two other states at the time of his employment. His background investigation was completed in May 2006.

On July 12, 2006, this surgeon entered into a voluntary agreement not to practice medicine in the state of licensure. In August 2006, the Director of Credentialing and Privileging in VHA’s Office of Quality and Performance (OQP) e-mailed the VISN 15 Centralized Credentialing Supervisor to inform her that her office was scanning an FSMB alert that needed to be reviewed because it appeared that it was against the only active license the

surgeon had at the time of employment. The VISN 15 Centralized Credentialing Supervisor contacted the state board on the next day and indicated to the facility that there was a pending investigation but the board would not release any further information. She also sent a letter to the surgeon asking for the reason why he entered into the agreement with the state board. She further noted that the surgeon had a license in another state reinstated in mid-summer 2006.

On August 10, 2006, the VISN Chief Medical Officer informed the VISN 15 Centralized Credentialing Supervisor and the facility COS that based upon a review of unspecified documents, he did not find any information indicating that the voluntary agreement resulted from a clinical competency issue so there was no need to restrict the surgeon's practice. On August 17, 2006, OQP asked the Credentialing Supervisor whether there had been a response from the surgeon. The Credentialing Supervisor responded on August 21, 2006 stating that she believed "this had been settled."

On August 21, 2006, the VISN 15 Centralized Credentialing Supervisor received a letter from the surgeon which included a copy of the voluntary agreement not to practice medicine as well as a letter to the state board from the surgeon addressing the issues raised by the state board. The letter to the state board, dated February 15, 2006, references two malpractice actions in 2003, monitoring by the surgeon's previous institution as a result of poor documentation practices, and failure to disclose a paid malpractice claim. We were provided with no documentation that this information was shared with the VISN CMO. Minutes from the facility PSB do not document that these facts were ever evaluated by the facility. On September 19, 2006, OQP e-mailed the Credentialing Supervisor again stating that the file had not been reopened for the surgeon to update the information contained within that file.

On Monday, October 30, 2006, OQP again requested that the VISN Credentialing Supervisor follow up with the surgeon because no update had been placed in VetPro at that time. On November 14, 2006, the Credentialing Supervisor responded that she sent him another letter on November 13, 2006, requesting that he update his information. On December 8, 2006, the credentialing liaison at the facility notified the Chief of Surgery, the Associate Chief Nurse, and the surgeon that the surgeon's response still was not in VetPro. The credentialing liaison indicated that the surgeon had entered the information but it apparently was not saved in the VetPro system.

We were provided with no further correspondence regarding the FSMB alert or the surgeon's need to respond to it until May 1, 2007, at which time OQP sent another e-mail to the VISN 15 Credentialing Supervisor stating that the matter should have been closed within 30 days of the alert and the file was still open without information submitted from the surgeon. The Director of Credentialing and Privileging in OQP responded on the same date that "we need to get this closed or we will have to escalate it." On May 2, 2007, the Marion COS wrote the surgeon a letter of reference, stating that he "has displayed exemplary skills as a surgeon for the past sixteen months," also reporting that his infection

and complication rates were below the national average. On May 16, 2007, the COS gave the surgeon a generic statement indicating that, between January 23, 2006, and April 30, 2007, the surgeon “performed 289 surgical procedures with no complications.” PSB minutes do not document that the facts and circumstances surrounding the FSMB alert were addressed prior to the surgeon’s resignation on August 13, 2007, more than 1 calendar year after the date of the FSMB alert.

**Recommendation 4:** The Under Secretary for Health develop and implement formal policies and procedures to ensure that Federation of State Medical Boards’ Disciplinary Alerts are timely addressed by medical facilities, VISNs, and VHA headquarters.

### **Failure to Properly Address NPDB Results As Required in VHA Policy**

The National Practitioner Data Bank (NPDB) is a national database containing information on disciplinary actions taken against a provider’s license as well as malpractice payments made on behalf of a practitioner. VA facilities are required to query the NPDB at the time of initial hiring, every 2 years following reappraisal, and any time a provider requests additional clinical privileges. VHA Handbook 1100.19 indicates that “[w]hen any initial, biennial or other NPDB report calls into question the professional competence or conduct of an individual appointed or utilized by VA, the facts and circumstances are to be reviewed to determine what action would be appropriate, including such actions as revision of clinical privileges, removal, etc.” However, when queried on August 2, 2006 because a surgeon requested additional privileges, a new match revealing an additional malpractice action not previously disclosed appeared in the NPDB. We found no evidence that the PSB considered this additional malpractice action in granting this surgeon’s request for additional privileges.

**Recommendation 10:** The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider National Practitioner Database results and document consideration of those results.

### **Failure to Address Inconsistencies in Provider References**

On initial application for privileges, a provider must give at least three references. VHA Handbook 1100.19 specifies that “references should contain specific information about the individual’s scope of practice and level of performance. For example, information on: (a) the number and type of procedures performed, range of cases managed, appropriateness of care offered, outcomes of care provided, etc.” We note that none of the reference letters we examined for this review contained information on the number and type of procedures performed.

Further, we found an example in which references disclosed a previous problem with a surgeon’s performance, but the PSB did not document consideration of that information. A surgeon gave five references, all of whom rated his professional knowledge and skills as

satisfactory. Three of the five referred to a period of monitoring used on poor documentation, while two indicated that his participation in medical staff affairs, including the timeliness, clarity and completion of medical records, was excellent.

**Recommendation 11:** The Under Secretary for Health will ensure that Marion VAMC credentials providers with references executed in accordance with VHA Handbook 1100.19 and documents consideration of discrepancies in provider disclosures and information obtained from references.

### **Failure to Evaluate the Health Status of Practitioner**

In early 2007, a surgeon was out on sick leave for approximately 3 weeks. The surgeon initially requested annual leave for that time, but subsequently it was changed to sick leave with a note indicating a visual problem. This change in leave was approved by the Chief of Surgery Service. In an interview, the Chief of Surgery informed us that he spoke informally with the surgeon's ophthalmologist regarding the surgeon's visual problems and determined that there were no significant residual effects that would compromise the surgeon's ability to operate. Although the Chief of Surgery was aware of the problem, PSB minutes from January through April do not reflect that the PSB ever considered the surgeon's visual problems as they related to his privileges to perform surgery at the facility.

**Recommendation 12:** The Under Secretary for Health require the Marion VAMC Chief of Surgery, Chief of Staff, and Professional Standards Session of the Clinical Executive Board to consider the health status of practitioners for credentialing and privileging purposes in accordance with VHA Handbook 1100.19.

### **Failure to Address Deficiencies in Providers' Initial Applications for Employment**

We found that there were discrepancies in the number of malpractice claims reflected in primary source documents from malpractice carriers and the initial application for at least one other provider without evidence that this discrepancy was addressed by the Chief of Surgery, COS, or PSB.

In another instance, a physician initially completed VA Form 10-2850 on February 26, 2007, and it is stamped received as of March 1, 2007. The physician's privileges were approved on May 3, 2007, by the PSB. He began providing services at the Marion VAMC in May 2007. We found that the medical center COS did not sign VA Form 10-2850 verifying licensure, registration, and board certification until August 27, 2007. Additionally, in two other C&P files reviewed, we found that the COS's signature was missing altogether, and in two additional cases, the COS did not check that he had verified licensure and board certification.

**Recommendation 13:** The Under Secretary for Health require the Marion VAMC Chief of Staff to sign and complete the certification correctly on VA Form 10-2850, *Application for Physicians, Dentists, Podiatrists and Optometrists*.

**Recommendation 14:** The Under Secretary for Health will require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider and resolve discrepancies in the number of malpractice claims disclosed by a practitioner and the number obtained through primary source verification.

### **Inability to Determine All States in Which a Provider Maintains Medical Licensure**

We also note that the VHA currently has no means of determining all states in which a provider holds a medical license if that provider does not disclose that information on his or her initial application. FSMB notifies VHA of disciplinary actions taken against licensure, but does not maintain a list of all states in which a provider holds licensure.

We noted the existence of undisclosed medical licenses in both surgical and non-surgical providers. We reviewed the credentialing and privileging files of 14 non-surgical providers. In summary, we found that two providers held licenses not listed on the initial application although they were issued prior to the date of the providers' initial applications. We present the following example from the surgical service of an undisclosed license.

Provider 2's privileges at the facility lapsed when he did not re-enter his information in VetPro during the reappraisal process prior to October 5, 2007. The facility queried the NPDB as required during this process, which returned a new entry. The query revealed that Provider 2 also had a license in a second state which was not disclosed on his initial application. This second license appeared in the NPDB because of disciplinary action taken against the license.

On October 20, 2006, the medical licensure board from this state received a report from the NPDB showing a malpractice payment made on behalf of Provider 2. A letter was sent to Provider 2 notifying him of the board's decision to consider action based on that NPDB report on the same day. Provider 2 entered into an agreement with the board which stipulated that Provider 2 "provided health care which fails to meet the standard of health care provided by other qualified physicians in the same or similar communities." It further required a period of monitoring should he resume practice in that state. This agreement was signed by Provider 2 on October 1, 2007. Provider 2, who was then Acting Chief of Surgery, was placed on Authorized Absence effective October 17, 2007, pending review of his failure to disclose on his initial VA application a second state in which he held a medical license.

**Recommendation 3:** The Under Secretary for Health explore the feasibility of implementing a process to independently identify all state licenses for VA physicians.

## **Privileging**

Each facility grants privileges to its own providers based on the needs of the facility and the individual qualifications of the practitioner. VHA Handbook 1100.19 requires that the process of delineating those privileges be documented in local VA facility policy. Medical Center Memorandum 11-11 06 195 *Medical Staff Appointments and Clinical Privileges*, dated March 6, 2006, describes the Marion VAMC's privileging policy. This policy specifies that the "ultimate responsibility for credentialing and privileging resides with the Medical Center Director." The VISN 15 Centralized Credentialing Center is responsible for completing and maintaining credentialing folders. The Credentialing Liaison at the Marion VAMC is responsible only for tracking folders through the Workforce Development Department.

Credentialing folders are provided only to the Chief of Staff for use in medical staff appointments or clinical privileging review. "The Chief of Staff has delegated responsibility for the Credentialing and Privileging Program and acts as Chair of the Professional Standards Board." Clinical Directors such as the Chief of Surgery are responsible for "continuing surveillance and evaluation of the professional performance of all individuals who have delineated clinical privileges in the department." The Clinical Executive Board, Professional Standards Sessions, makes recommendations directly to the Medical Center Director for approval of medical staff appointments and privileges. The policy states that procedures for credentialing and privileging are found in the medical staff by-laws. Every provider signs a written statement at the time of initial appointment that they have received a copy of the by-laws.

According to Medical Center Memorandum 11-11 06 475, *Medical Staff Bylaws, Rules, and Regulations*, the decision to re-privilege a provider will be based on multiple factors, including quality of care with monitoring and evaluation of activities where applicable, giving specific examples such as mortality assessments, infection rates, medical record review, and "monitoring and evaluation of quality and appropriateness of clinical aspects of patient treatment and risk management activities." The Clinical Executive Board may recommend a change in privileges or require that practitioners requesting additional privileges be subject to proctoring for a period of time to verify competence.

### **Failure to Privilege Surgical Providers in Accordance With Facility Strategic Planning and the Availability of Ancillary Support Services**

In part, privileging is facility-specific because, regardless of the expertise of the physician involved, the availability of services at a facility may limit the appropriateness of performing those procedures at that facility. Provider 1 was not board certified, but practiced in general and a specialty surgery. He was hired to perform specialty procedures, receiving special pay based on the facility's recruitment and retention difficulties related to the hiring of surgeons in that specialty, not as a general surgeon. The facility's FY 2007 Surgical Specialty Care Line Operational Planning Guide reflected the facility's interest in

establishing that specialty surgery program as part of a focus on decreasing fee basis costs. A planned strategic action summary sheet indicated that the facility's goal was to "establish [specialty] surgery program," and it acknowledged the need for additional staff and training. Surgeon Staffing Reports, however, record that Provider 1 began to perform specialty procedures in April of 2006, 6 months before the beginning of FY 2007.

The facility's FY 2007 Surgical Specialty Care Line Operational Planning Guide also listed as a goal establishing another specialty surgery program and acknowledging the need for additional staff and training. Provider 2 received special pay based on the facility's recruitment and retention difficulties for surgeons in the second specialty, not as a general surgeon. He received performance pay on December 15, 2006, as a result of his making the second specialty service operational and doubling the number of laparoscopic procedures. He was board-certified in general surgery, but not the second specialty surgery. According to Surgeon Staffing Reports, Provider 2 performed his first major specialty procedure at Marion on June 16, 2006.

Further, the Operational Planning Guide made no reference to provisions for ancillary services such as respiratory therapy, intensive care unit facilities, or after hours pharmacy availability. In FY 2007, the Marion VAMC had limited support services available after hours in all of these areas. Respiratory Therapy Services, for example, provides diagnostic non-invasive and invasive respiratory testing and treatment to inpatients and outpatients. To perform these services, the medical center has four FTE respiratory therapists who work from 8:00 a.m.–4:30 p.m. There is no respiratory therapist onsite or on call for the medical center after 4:30 p.m. daily. After that time, registered nurses perform respiratory therapy duties, including ventilator management. Respiratory therapists are responsible for weaning patients from the ventilator. The Respiratory Therapy Services manager submitted proposals requesting additional staff for off-shifts, weekends, and holidays. The director approved the proposal in September 2007.

The medical center pharmacy is responsible for medication dispensing and distributions to all inpatients and outpatients. Additional responsibilities include: providing consultation to physicians, clinical staff, and patients; interviewing and evaluating patients for appropriateness of pharmacological therapy; designing and participating in research or outcomes research involving drug therapy or clinical pharmacy functions; reporting adverse drug reactions; and managing the medical center formulary and ensuring its appropriate utilization by health care providers.

The Pharmacy Service has 16 FTE pharmacists, 1 part-time pharmacist, and several technicians on staff. The pharmacists work 8-hour shifts beginning at 8:00 a.m., 9:30 a.m., or 11:30 a.m. daily. The medical center has no in-house pharmacist after 8:00 p.m. However, one pharmacist is scheduled on-call each night from 8:00 p.m.–8:00 a.m. The Pharmacy Service stocks an oversupply of emergency and routine medications in the Pyxis machines to ensure 24-hour access to certain medications.



The ICU provides primary nursing care with 18 registered nurses scheduled to work 12-hour shifts from 7:45 a.m.–8:15 p.m., or from 8:00 p.m.–8:00 a.m. There are four nurses assigned to each shift when there is maximum bed occupancy. While the Marion VA Medical Center Intensive Care Unit (ICU) has 24-hour staffing, we found that capabilities to care for extremely ill patients are limited. The unit has an eight-bed capacity and maintained an average daily census (ADC) of 3.8 in FY 2006 and 3.4 for FY 2007. The top five ICU diagnoses in FY 2007 were Unspecified Essential Hypertension, Unspecified Congestive Heart Failure, Atrial Fibrillation, Type II or Unspecified Diabetes Mellitus without Mention of Complication, and Organism Unspecified Pneumonia.

From September 20–21, 2007, VHA’s Inpatient Evaluation Center (IPEC) performed an assessment of the ICU. In October 2004, IPEC began as a pilot project in certain VISNs, including VISN 15, which measures intensive care unit outcomes and processes. The relatively small number of admissions to the ICU at the Marion VAMC limits the validity of certain statistical analyses relative to mortality measurements in the ICU. Nevertheless, IPEC made many recommendations as a result of both document review and their site visit. These recommendations included reviewing credentials for physicians providing services in the ICU; reviewing the approach to physician coverage for the ICU; contracting for radiologist services during non-administrative hours; the need to meet staffing and leadership expectations for a Level 3 ICU as well as to provide 24-hour respiratory therapy; increasing intensive care unit staff expertise; creating a system to review patient outcomes and an infrastructure to support nursing and respiratory therapy; and developing a policy concerning a list of patient conditions requiring transport to another facility.

Marion OR staff expressed concern about performing complex procedures in patients without the availability of 24-hour ancillary support services on more than one occasion. In a report of contact dated April 5, 2007, the OR nurse manager indicated that a patient was scheduled for a thoracoscopy, distal esophagectomy, fundoplication, and an open Heller myotomy on a Friday afternoon. Concerned about the availability of weekend support services, the report of contact indicates that the OR nurse manager spoke to the Chief of Surgery regarding her concerns. This included that Provider 2 had previously suggested that the person receive services at St. Louis VAMC, where the case could be performed laparoscopically with full support services available 24 hours a day. The report of contact indicates that the Chief of Surgery spoke to the Chief of Staff and the procedure was scheduled. The Leapfrog Group,<sup>5</sup> an advisory group making evidence-based recommendations to improve the quality of health care, recommends that a facility perform a minimum of 13 esophagectomies per year with a minimum of 2 such procedures performed by each surgeon per year. We could find documentation that only one such procedure was performed at the Marion VAMC during FY 2007.

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<sup>5</sup> The Leapfrog Group is an initiative driven by member organizations that buy health care who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans.

On July 28, 2007, the Associate Chief Nurse e-mailed the Associate Director for Patient Care/Nursing Services stating that she had received information that Provider 3 did not want to perform a procedure because of limited post-operative care. She states in the e-mail: “This is part of our problem that physicians feel they are forced to do things that they would not normally do but if they say that they can’t do it, they hear from [Chief of Staff] and he gets on them.”

While multiple reasons could exist as to why such procedures were performed at this facility, we include a couple of examples of reasons given to us by facility personnel. One provider recounted a conversation with the Chief of Staff following an incident in which the provider recommended sending a patient with carotid stenosis to another facility to undergo carotid stent placement rather than performing a carotid endarterectomy at the Marion VAMC. The provider stated that the Chief of Staff told him:

Well, as I’ve told you before, I get a certain amount of money in the beginning of every fiscal year. And if I keep sending more patients out because of reasons like that, it will end with me having no money left by the end of the year to take care of my veterans.

We note that Marion’s FY 2006 expenditures for services provided to veterans outside the VA were elevated compared to VISN and VHA expenditures in the same areas. This provider also stated, however, that certain surgeons were pushing to do more complex procedures of their own volition. Other reasons could exist as well. However, regardless of the reason, we found that the facility inappropriately privileged providers to perform procedures without a showing of provider, staff, or facility competence to perform them.

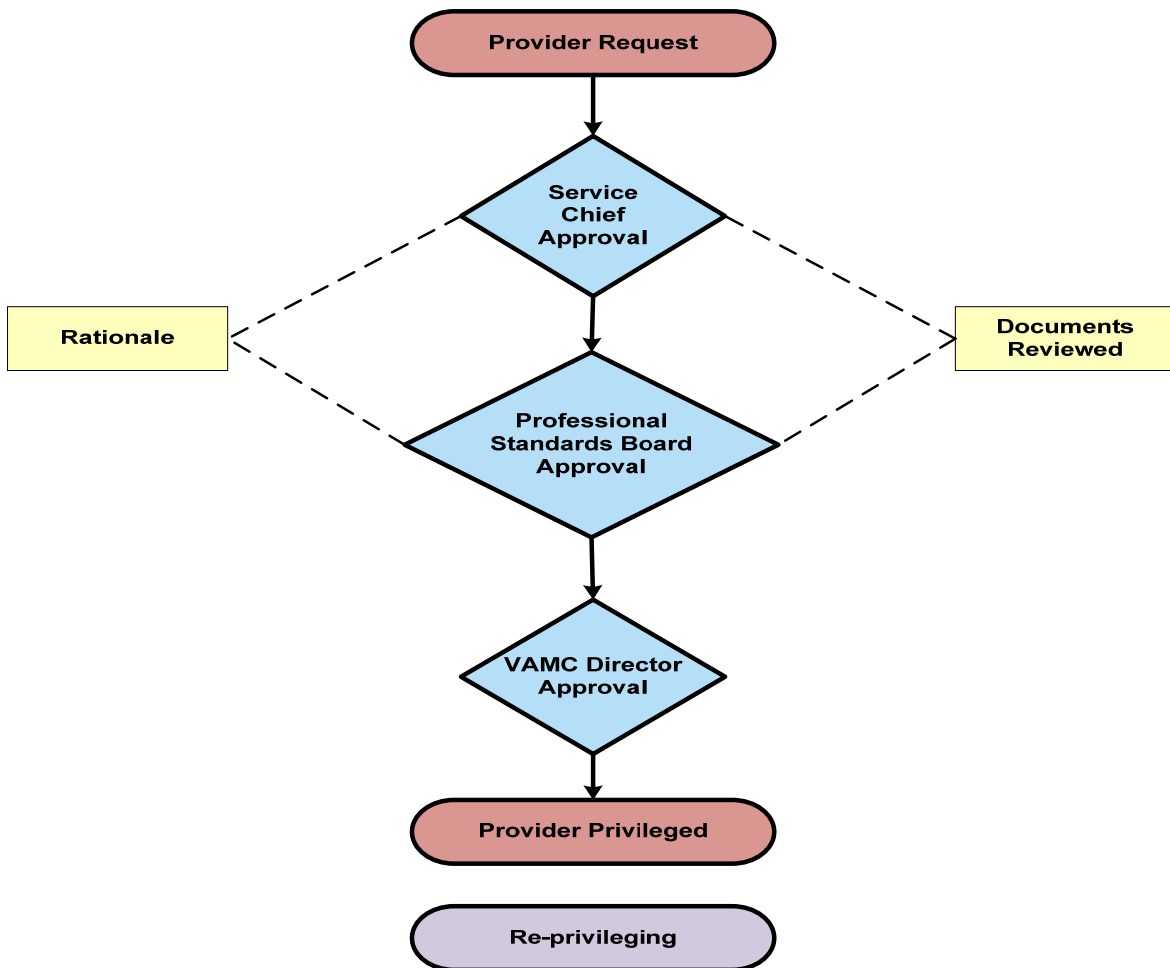
**Recommendation 2:** The Under Secretary for Health develop and implement a mechanism to ensure that VHA’s diagnostic and therapeutic interventions are appropriate to the capabilities of the medical facility.

### **Failure to Document Current Competence of Providers Requesting Privileges for Specific Surgical Procedures**

VHA Handbook 1100.19 indicates that “[t]he VA medical facility must delineate the process for granting privileges by level of training and experience, and/or patient risk categories, and/or using lists of procedures or treatments established by the Executive Committee of the Medical Staff.” At Marion VAMC, the PSB reviews and makes recommendations regarding the credentialing and privileging of specific providers. The Chief of Staff chairs the PSB, and PSB recommendations are forwarded to the Medical Center Director for approval. Copies of current privileges must be available to hospital staff in areas where it is necessary for them to be aware of provider privileges, such as in the ORs and ICUs.

VHA policy requires the service chief to review credentialing and privileging information including clinical and technical skills, conclusions from performance improvement activities, and references. Documentation of this review “must include, at least, a list of the documents reviewed and the rationale for the conclusions.” The following diagram illustrates VHA’s privileging process.

### VETERANS HEALTH ADMINISTRATION PRIVILEGING PROCESS



In addition, high risk privileges as defined by medical center policy may require proctoring or supervision by another privileged practitioner for a certain time period. After review of this information, the service chief then makes a recommendation for or against privileging at the facility. This recommendation is reviewed by the PSB. VHA Handbook 1100.19

indicates that “[m]inutes will reflect the documents reviewed and the rationale for the stated conclusion.” A final recommendation is then submitted to the facility Director.

In this inspection we found that in all cases reviewed there were significant deficiencies in the documentation provided in support of PSB decisions and actions. First, we found that, contrary to VHA policy, the Chief of Surgery did not document the information he reviewed or the rationale for his conclusion recommending specific privileges for a provider in any of the charts we examined. Current competence of providers to perform given procedures was inconsistently documented by the PSB as well, with seven providers requesting and receiving additional privileges without reference to the basis on which the PSB established current competence. We further found that, in reference to the other 15 providers, the Chief of Surgery, COS, and PSB documented only privileges previously held by a provider as evidence of current competence in 13 of 15 providers. Regarding a 14th provider, the PSB documented evidence of attendance at educational sessions. For the 15<sup>th</sup> provider reviewed, there was no previous set of privileges in the file and no documented evidence of current competence other than a reference to approval by an outside PSB.

In PSB minutes dated May 17, 2007, an entry states: “Members would like to further review our process for the renewal of clinical privileges. Should we consider verification of competency based on number of procedures performed?” We found that the medical center facility did not consider verification of competency based on the number of procedures, and did not consistently document the basis for clinical competence findings in specific instances. We present the following examples below:

#### *Provider 1*

Initial privileges granted to Provider 1 in January 2006 included multiple surgical procedures as well as colonoscopy. The copy of former privileges contained within his C&P file did not include colonoscopy. We received no documentation that the provider gave additional evidence of competence in this procedure to the Chief of Surgery or to the Professional Standards Board, nor is it reflected in PSB meeting minutes. On February 22, 2006, a report of contact was written by the OR nurse manager, stating that, on February 17, 2006, an instrument technologist informed her that Provider 1 was experiencing difficulty in identifying colon anatomy and maneuvering the scope. Under observation, he appeared to have difficulty performing colonoscopy. The OR nurse manager contacted the Associate Chief Nurse and informed her of the situation. We noted that, while Provider 1 performed eight colonoscopies at the facility between January 20, 2006, and March 8, 2006, we could find no evidence that he continued to perform the procedure after March 8, 2006. However, no action was taken against his privileges and we could find no evidence that the PSB reviewed or evaluated the information contained within the report of contact.

A provider may request modification of clinical privileges at any time. However, VHA Handbook 1100.19 states that “[r]equests to increase privileges will be accompanied by the

appropriate documentation which supports the practitioner's assertion of competence, i.e., advanced educational or clinical practice program, clinical practice information from other institution(s), references, etc." A query to the NPDB is also performed whenever a provider requests additional privileges. Provider 1 requested and received additional privileges in thoracic surgery, approved January 23, 2006. On February 24, 2006, Provider 1 requested additional privileges for breast biopsy, simple and modified radical mastectomy, sentinel node biopsy, and total abdominal hysterectomy.

A copy of his privileges from the last facility at which he worked prior to his VA service did include these privileges, and the PSB approved the additional privileges on March 2, 2006. There is no documentation of how many such procedures he had performed at his previous institution, or the time period in which such procedures were performed. He applied for no additional privileges until June 18, 2007, at which time he requested privileges to perform esophagectomies, stating in his request for the privilege that he had already performed one at the facility. These additional privileges were approved by the Chief of Surgery, the Chief of Staff, and the Medical Center Director. The copy of Provider 1's privileges prior to coming to the Marion VAMC contained within the credentialing and privileging folder at the facility did include esophagectomy. There was no other documentation in the file that the provider's competence to perform this procedure had been evaluated prior to the granting of his privileges, or that the provider had been disciplined for performing a non-emergent procedure for which he did not have privileges. We could find no evidence that the PSB evaluated his specific competence to perform esophagectomies or the circumstances under which he admitted performing one without privileges at the facility. We were told by at least one of his references, however, that he had performed esophagectomies at his previous institution. We issued a subpoena for the records from his previous institution, but had not obtained such records by the date of this report.

In addition, we located a report of contact dated September 25, 2006, from the OR nurse manager which recorded a conversation between a surgical technologist and Provider 1 alleging that Provider 1 "stated that he has not performed thoracic surgery in over ten years ...." The report of contact further noted that four out of eight thoracoscopic procedures had been converted to thoracotomies. We note there is no documentation that this report of contact was considered by the PSB. A notation on the report of contact indicates that it was sent to the Chief of Surgery. We were told by Provider 1's references, however, that he had performed thoracic surgeries at his previous institution.

### *Provider 2*

Provider 2 was appointed in October 2005. Provider 2 listed four references, one of whom was Provider 7 prior to his employment with the VA. All recommended him without reservation. Provider 2 submitted a request for additional privileges to perform various laparoscopic procedures including Meckel's diverticulectomy, small bowel resections, fundoplication, colectomies, ventral hernia repairs, appendectomy, and diagnostic

laparoscopy as well as “miscellaneous intra-abdominal laparoscopic procedures where indicated.”

This was supported by certificates reflecting attendance at Laparoscopic skills programs on April 10, 1999, and December 3, 2005. The Chief of Staff recommended approval on January 13, 2006, without further delineation of what was meant by “miscellaneous” endoscopic procedures. The Professional Standards Board “recommended approval of additional privileges as delineated on the request form” on January 13, 2006. The copy of the provider’s previous privileges prior to employment with the VA contained within his credentialing and privileging file indicated privileges for laparoscopic surgery. Provider 2 had not specified which laparoscopic surgeries he performed on this privilege list from the prior institution. We could find no documentation in Provider 2’s credentialing and privileging folders or in PSB minutes that the provider gave evidence of current competence to perform the specific laparoscopic procedures requested.

On March 10, 2006, Provider 2 requested the addition of privileges to perform laparoscopic tubal ligation, open tubal ligation, and simple oophorectomy. These were recommended and approved by the Chief of Surgery, the Chief of Staff, and the Medical Center Director on March 17, 2006. There is no reference to specific competency information.

#### *Provider 3*

Provider 3, a general surgeon, was repriviledged in January 2005, and in December 2006. Although he had not previously requested these privileges, the privilege list he submitted on October 9, 2006, included privileges for tendon repair, closed reduction of fractures, and open suprapubic cystostomy. These were approved by the Chief of Surgery, the Chief of Staff, and the Medical Center Director by December 27, 2006. There was no discussion regarding the addition of these privileges documented in PSB minutes, nor in the credentialing and privileging file. We did not find documentation, however, that he actually performed these procedures at the Marion VAMC.

#### *Provider 4*

Provider 4 was initially privileged at the Marion VAMC in August 2002. He requested and obtained privileges to perform excisions of scrotal tumors and hydroceles. He subsequently was repriviledged in August 2004, at which time he did not request or obtain privileges to perform these procedures. Then, in August 2006, he was repriviledged again at the facility, this time requesting and obtaining privileges to perform excisions of scrotal tumors and hydroceles. We could find no reference in PSB minutes supplied to us by the facility documenting current competence or discussion of the decision to add back these privileges in 2006. Surgical package reports did not reflect that he performed these procedures at the facility between October 1, 2005, and September 30, 2007.

### *Provider 9*

Provider 9 was appointed in the spring of 1996, as a part-time ophthalmologist at the Marion VAMC while concurrently working at the St. Louis VAMC. He received privileges at the Marion VAMC to perform a variety of procedures, including cataract extraction. On September 1998, he again requested similar privileges, including cataract extraction. The then-Chief of Surgery did not recommend that he be granted privileges to perform cataract surgery, with a notation that cataract surgery was not in the scope of needed services at the Marion VAMC. In July 2000 and in June 2002, he again requested privileges for cataract extraction. His request was again not recommended by the Service Chief on either occasion, with the same notation.

In July 2004, Provider 9 once again requested privileges to perform cataract extraction. On this occasion, his privileges were recommended by the Chief of Surgery and approved by the PSB, the Chief of Staff as Chairman of the PSB, and the Medical Center Director. In October 2006, Provider 9 was reprivilaged again at the Marion VAMC, at which time he was also approved for privileges to perform cataract surgery. PSB minutes do not reflect that Provider 9 supplied any documentation of current competence to perform this procedure. There is no record that he performed these procedures, or any operative procedures, at the Marion VAMC until the year 2006. We were informed that prior to that time, he worked in a clinic setting only at the Marion VAMC.

**Recommendation 6:** The Under Secretary for Health issue guidance that clearly defines what constitutes evidence of current competence for use in the privileging process.

**Recommendation 15:** The Under Secretary for Health require that the Marion VAMC Chief of Surgery Service and the Professional Standards Session of the Clinical Executive Board record the documents reviewed and rationale for the conclusions reached.

### **Failure to Consider Provider-Specific Performance Data in the Reprivileging of Surgical Providers**

The medical center requires reappraisal to be conducted at least every 2 years. During this process, facilities are required to review a provider's professional performance, judgment, and clinical or technical competence and skills through the tracking of provider specific performance improvement activities. VHA policy requires that the practitioners' service chiefs conduct these ongoing reviews that include, when applicable, information from surgical case review, infection control reviews, drug usage evaluation, medical record review, blood usage review, pharmacy and therapeutic review, monitoring and evaluation of quality, utilization, risk, and appropriateness of care. The reappraisal process should include consideration of the number of procedures performed or major diagnoses treated, complication rates compared with others doing similar procedures, and adverse results that would indicate patterns or trends in the practitioner's clinical practice.

Reprivileging is also required every 2 years and is normally conducted at the same time as the reappraisal. According to VHA requirements, the service chief must document that the results of quality of care activities have been considered in recommending individual privileges and then makes a recommendation as to the practitioner's request for clinical privileges.

QM department staff (CCRM) collect provider specific information during their clinical reviews. QA provider files are maintained at the service level and in the QM office. The DPM submits a summary analysis of the QA folder information to the PSB when a practitioner goes through the reappraisal and reprivileging processes. This summary analysis includes sections for medical record review, quality indicators, medication use, infection control, patient complaints and satisfaction, and utilization management. The DPM told us that services are responsible for keeping the QA folders and she monitors them annually to ensure that some data is present. However, it was not clear that the service collected any of the information in the folders since the DPM signed off on the summary instead of the service chief. Local policy states that the DPM is responsible for summarization of medical staff data at the time of recredentialing.

We reviewed the QA folders for surgical staff who had been reappraised or repriviledged in the last 12 months. The QM information was not rate-based and was not provider appropriate. (An example is the medical record review related to documentation of anesthesia classification prior to surgery but this assessment is performed by anesthesia and not surgery.) A more appropriate monitor would be operative note and discharge summary completion statistics. Quality indicators were reported as individual incidents, such as the number of deaths or complications, but there was no comparison to total cases performed. Infection rates were compared to facility averages but only for a period of 6 months, rather than the full 2-year cycle. Medication use monitors were not consistent among providers and were not included in all files. These were limited to non-formulary requests, controlled substances, and provider order entry. The raw data provided is difficult to interpret and not clearly identified. There is no information regarding the actual number of surgical procedures performed, complications, or deaths. The summary includes a conclusion stating that, "general review of the clinical performance folder on this provider reveals sufficient evidence to support clinical competence and the recommendation to grant clinical privileges" and signed by the DPM. VHA policy clearly states that service chiefs must make that determination and it is not appropriate for the DPM to make that statement. Since our initial visit, that process has changed and service chiefs are now signing the QM summaries.

Further, we found that the facility failed to appropriately document consideration of provider specific performance data in the PSB minutes. The minutes provided never specified quality factors considered in the reappraisal or reprivileging process of any provider, stating only that each provider's quality assurance folder was reviewed. In the September 29, 2006, minutes, the PSB acknowledged that "[c]redentialing and privileging



of practitioners requires an objective and evidence-based process of monitoring performance including formalized Peer Review aggregate evaluation for renewal consideration.” These minutes subsequently list the provider quality assurance folders as containing indicators on medical records, quality, Provider Order Entry, medication monitoring, infection control, and patient satisfaction. They indicated that specialty-specific measures needed to be incorporated and updated with input from Care Line Directors. The PSB also requested that the Patient Advocate reports be presented in a provider-specific format rather than a clinic-specific format, so that this information could be included in the credentialing and privileging process. PSB minutes reflect a target date for completion of these initiatives as November 30, 2006. There is no reference to the status of these initiatives again in PSB minutes obtained through September 21, 2007.

We present the following example regarding the facility’s failure to consider professional performance data relative to a single physician.

*Provider 5*

While the PSB minutes reference that the quality assurance folders contain information on infection control issues, we found that the copy of the quality assurance folder we obtained for Provider 5 did not contain aggregate information on peer reviews for Provider 5’s cases or on postoperative infections following total knee arthroplasties (replacements). We further found that there is no evidence that the PSB reviewed significant and ongoing issues pertaining to the provider’s documentation habits, professional conduct, and tardiness.

The Chief of Staff approved Provider 5’s application for employment on June 6, 2005. He began to perform total knee replacements at the Marion VAMC in January of 2006. As early as November 20, 2006, Clinical Executive Board QA Session minutes indicated that the Chief of Staff reported that Provider 5 had been identified as “exceeding the threshold for surgical site infections.” Infection control was to provide follow-up, with the Chief of Surgery and the infection control nurse named as the responsible parties. On February 15, 2007, a report to the Chief of Staff from the Chief of Surgery disclosed that the infection control nurse had reported a 20 percent infection rate overall in orthopedic cases. The NSQIP nurse was asked to review total knee arthroplasties in light of criteria used by NSQIP to identify surgical site infections. She identified only three cases potentially meeting NSQIP criteria. The Chief of Surgery stated that, while these three cases alone would result in an infection rate of 6.5 percent sufficient to require monitoring, he recommended “that the 1<sup>st</sup> and 2<sup>nd</sup> cases should be defended as questionable. This would result in a 1.1 % infection rate & within the expected rate.”

On May 10, 2007, the Chief of Surgery received peer reviews on Provider 5’s cases from another orthopedic surgeon. The peer reviews identified operative or management issues in 8 of the 12 cases reviewed. Only three of the cases reviewed were total knee replacements. The peer reviewer identified operative and management issues in one of the

three cases reviewed. The Chief of Staff approved Provider 5's reprivileging on behalf of the PSB on May 31, 2007. In PSB minutes provided to us by the facility, the PSB minutes indicated that Summary Quality Management Analysis of the QA folder for this physician stated only that provider order entry was lower than the facility aggregate; that there were two cases with Level 2 outcomes, one in 2005 and one in 2007; there were some patient complaints but "nothing of significance"; and that two cases of postoperative infections were reviewed but "data did not support provider-specific issues." Another reference to the reprivileging of Provider 5 appears in the June 15, 2007, meeting minutes. These minutes state that Provider 5 had a health problem and his physician wrote a note indicating that he was able "to do clinic work." The Board accepted this as validation of his current health status. There is no other reference to PSB approval for reprivileging of the provider. A copy of the quality assurance folder we obtained that was used in the credentialing and privileging of Provider 5 did not contain aggregated data from this peer reviewer in which 8 of 12 cases were identified as problematic.

E-mails obtained from the facility also document significant and ongoing issues regarding Provider 5's documentation habits and conduct. As early as May 19, 2006, the Medical Center Director was notified that "after multiple interventions" by coding staff, his nurse, the Chief of Surgery, and the Chief of Staff, missing or incomplete documentation remained in the medical record of multiple patients. Despite this notification, on August 7, 2006, another e-mail to the Chief of Surgery, the Chief of Staff, and the Medical Center Director states: "Serious problems remain with [Provider 5] not completing documentation . . . [a VISN official] inquired as to what is going to be done discipline-wise for this physician and his non-compliance with documentation . . . ." No documentation in his credentialing and privileging file indicated that this problem was resolved, or that the PSB addressed it during this provider's reprivileging.

On April 24, 2007, the Office of Inspector General referred a complaint against Provider 5 back to the facility for investigation. This complaint involved the provider's personal conduct, and did not reference his documentation practices or any quality of care issues. The facility performed an Administrative Board of Investigation (ABI) and responded to the Office of Inspector General on June 20, 2007. The ABI substantiated numerous reports of vulgar language and prolonged waiting times for patients occurring because of several factors including provider tardiness. The ABI recommended appropriate progressive disciplinary or other administrative actions related to the subject's inappropriate behavior and repeated tardiness and that he should attend training on professional conduct in the workplace. The ABI further recommended that the Chief of Surgery should attend supervisory training to learn the process related to progressive disciplinary action. We could find no documentation that the PSB addressed these issues during the reappraisal or reprivileging process.

**Recommendation 16:** The Under Secretary for Health will require that the Marion VAMC Chief of Surgery, Chief of Staff, and Professional Standards Session of the Clinical

Executive Board document consideration of quality assurance data in accordance with VHA Handbook 1100.19 in the reprivileging of providers.

## **Conclusions**

Our review revealed a pattern of deficiencies in credentialing and privileging at the Marion VAMC. While multiple deficiencies existed in the credentialing process, the failure of the facility to address provider and institutional competence to perform complex surgical procedures was particularly concerning in light of quality of care deficiencies identified in the forgoing sections of this report.

Further, the FSMB notifies the VA of disciplinary actions against medical licenses, but does not maintain a list of every state in which a provider has a license. As discussed above, if a provider is licensed in more than one state and fails to disclose a medical license on their initial application, and no final disciplinary action has been entered against that license, the VA currently would have no way of knowing that the provider was licensed in that state. They would therefore be unable to query that state directly. Querying each state for every provider credentialed and privileged by the VA would be time-consuming. This issue should be further addressed at the VACO level.

## **E. Role of Medical Center Leadership**

We substantiated the allegation that medical center leadership knew or should have known of issues of quality management in the Surgical Service.

The current Chief of Surgery was appointed February 5, 2006, and the former chief resigned on January 22, 2004. In that 2-year vacancy, two staff surgeons served as acting chief because of difficulty recruiting for the position.

A nurse reviewer, who is also a NSQIP nurse, was asked to review the Marion OR program and performed a site visit on October 27, 2006. The report addressed staffing issues, patient flow through the OR, scheduling, utilization of resources, quality management in surgery, the use of the surgery computer package, and documentation. The nurse noted the importance of collecting information in the preoperative clinic and the role of the facility NSQIP nurse to inform OR staff about ways they can improve patient outcomes. The report also addresses the need for an OR Committee and suggests primary duties and areas of review, again noting the important role of the facility NSQIP nurse and identification of cases requiring peer review. Finally, the report stresses the need for a Medical Director for the ICU, who would follow surgical patients postoperatively.

From November 14–17, 2006, a team from VHA's Systemwide Ongoing Assessment and Review Strategy (SOARS) visited the Marion VAMC and made numerous recommendations. While SOARS believed there was an effective QM structure in place, its findings included the following:

There is an Executive Leadership Committee with oversight and a number of demonstrated significant improvement [sic] and success. In a sample review of committee minutes—when issues were identified the team could not consistently track the actions recommended/taken or the follow up to resolution or completion.

In addition, while noting that peer reviews were conducted, the SOARS team recommended further evaluation to determine whether the process complied with VHA directives. They did not, however, identify deficiencies in the credentialing and privileging of physicians at the facility.

VISN 15 and Marion VAMC leaders also requested a site visit by another VA surgeon to review the inefficiencies in the Operating Room and recommend ways to improve the utilization of resources. That visit occurred on December 19–20, 2006. The brief report summary states that Marion leadership and staff providers were committed to patient care and that the quality of care appeared excellent. The reviewer also commented that the Surgery Chief was functioning well as a leader and communicator, “albeit a surgical specialist (ophthalmologist)”. The report noted the expansion of OR cases from 4,931 in FY 2004 to 6,251 in FY 2006 but that most cases performed in the OR were GI endoscopic procedures (about 3,000 per year). The reviewer stated that it was unclear if the NSQIP nurse met with the Chief of Surgery weekly or on a regular basis, and that she reported to Quality Management. The review noted that it was perceived that OR staffing was less than adequate. The reviewer made nine recommendations for better practices to enhance efficiency of the OR. These included but were not limited to appointing an interdisciplinary OR Committee, filling vacant positions, starting cases promptly, and ensuring that the NSQIP nurse meet regularly with the Chief of Surgery to validate NSQIP data entry and review potential process of care issues.

While noting that the primary purpose of both the nurse and physician reviews was not to evaluate quality management, both reports contained findings sufficient to notify leadership that problems existed in that care line. The SOARS report also suggested that at least some QM processes required additional evaluation. We do not find that problems identified in these reports were adequately addressed prior to the NSQIP site visit in August of 2007. Further, we note that the Marion VAMC leadership was aware of the increased number of mortalities reported by NSQIP months prior to the NSQIP site visit. The Chief of Surgery sent a memorandum addressed to the Medical Center Director dated April 30, 2007, in response to being identified as a high outlier for all operative mortality for the first quarter of 2007. Eight cases were reviewed by the Chief of Surgery who summarized that all cases were consistent with accepted operative standards of care and that the deaths were not directly related to surgical interventions or complications. The Chief of Surgery sent another memorandum through the Chief of Staff on May 17, 2007, after cases were peer reviewed by general surgeons on staff at the Marion VAMC. All cases were assigned Level 1 peer reviews. On August 2, 2007, the Chief of Surgery sent

another memorandum discussing the same cases to the Medical Center Director through the Chief of Staff.

Multiple factors contributed to the failure of facility leadership to respond to early warnings of problems in the surgical service at the Marion VAMC. The Chief of Surgery retired in January 2004 and multiple physicians rotated the position for the next 2 years. According to Human Resources the medical center had difficulty filling the position. In February 2006, an ophthalmologist who worked part-time at Marion was appointed. His background included military leadership but no prior VA administrative experience. The PSB minutes document the approval by the National Program Office for the hiring of the Chief of Surgery. Both Medical Center and VISN leaders told us that they knew he did not have specific VA leadership experience, but with support they felt he could learn the role.

As recorded in the PSB minutes, the appointment of the Chief of Surgery was supported by the National Program Office. While Medical Center Memorandum QM-00Q-06-57 specified that the service line chiefs were responsible for quality assurance activities in their service lines, we found that the Performance Plan for the Chief of Surgery did not include quality management activities. Further, because the Chief of Surgery was not a general surgeon, general surgeons at the Marion VAMC chaired the Surgical TQI meetings on a rotating basis. In a performance appraisal covering the period of February 5, 2006, to September 30, 2006, the Chief of Surgery received an Excellent rating. In the narrative portion of the appraisal, however, the Chief of Staff commented that the Chief of Surgery was “new to VA management. His service skills need improvement in planning programs to improve efficiency.” The narrative did not address quality management activities in any way.

The Chief of Surgery told us in an interview that he did not receive any formal training for his position as a service line director at the time of his appointment. In interviews, the Chief of Surgery indicated that he felt overwhelmed and unprepared for the role. He told us he “floundered for the first 16 months,” prior to getting formalized service chief training. He indicated that he did not know of the existence of data contained within the VA’s computer system that tracked procedures and complications at the time of his hiring. He did attend the Service Chief Senior Line Manager Orientation program, from May 7–10, 2007, more than 15 months after he began functioning as the Chief of Surgery at the Marion VAMC.

While the physicians that we interviewed felt the Chief of Surgery tried to be supportive of surgical issues, they explained as an ophthalmologist his knowledge of general surgical procedures was limited. The Chief of Surgery also stated that the Associate Chief Nurse (ACN) was “very knowledgeable but refused to assist him.” The ACN is a Nurse IV who “[d]evelops strategies, provides recommendations, and coordinates implementation of actions to facilitate quality programs and performance for Specialty Care Line in conjunction with the Director of Surgical Specialty Care Line and the Director of Medical

Specialty Care Line.” The ACN reports to the Associate Director, Patient Care/Nursing Services (ADPCS).

The Chief of Surgery and ACN failed to work together to provide the oversight and leadership inherent in running an increasingly complex surgical program. The Chief of Surgery and the Medical Administrative Officer told us that despite multiple attempts to meet with the ACN as a group to plan and conduct surgical care line business, “of 10 scheduled leadership meetings the ACN showed up at 4.” A nurse told us she was instructed by the ACN not to give access to the OR surgical software package to the Chief of Surgery so he could run quality management reports. The ACN denied saying this.

Beginning on April 18, 2007, attendance at QA meetings of the CEB were limited to providers, the QM Director, the Medical Center Director, and the Associate Director for Patient Care/Nursing Services. The ACN indicated prior to this e-mail that she had attended these meetings in an effort to monitor quality management activities. Further, she provided us with an e-mail dated October 2, 2006, in which she wanted to set up regular meetings with the Chief of Surgery. She states in the e-mail: “I feel that we have not been communicating effectively, which is negatively impacting the Care Line functioning, staff and ultimately the patient, which I cannot let happen.”

Regardless of the reasons, we found that the Chief of Surgery and Associate Chief Nurse did not ensure effective quality management of the surgical specialty care line. Further, findings in the credentialing and privileging section as well as the quality of care section of this report indicate that neither the Chief of Staff nor the Medical Center Director properly discharged their responsibility to ensure quality health care and the proper credentialing and privileging of health care providers. In addition, we found some evidence that reports of contact were created and forwarded to the Associate Chief Nurse, the Chief of Surgery, the Chief of Staff, and the Associate Director for Patient Care/Nursing Services suggesting problems within the surgical care line before the NSQIP reported the data that triggered this review. We made the following recommendation:

**Recommendation 5:** The Under Secretary for Health conduct reviews to determine appropriate administrative actions against Marion VAMC leadership and other staff responsible for the problems cited in this report, to include the Medical Center Director, the Chief of Staff, the Chief of Surgery, the Associate Director for Patient Care/Nursing Services, and the Associate Chief Nurse of the Surgical Service.

## **F. Other Findings**

During the course of our review, we also received allegations regarding falsification of documents and the quality of care in the cardiac catheterization laboratory. We present our findings below.

## **1. Allegation: Dates Were Altered on Certain Privileging and Peer Review Documents.**

We partially substantiated this allegation.

A complainant alleged during our site visits that privileging documents were altered. We substantiated this allegation. In September 2007, the OR nurse manager received copies of a new set of privileges for Provider 11. As required by VHA policy, provider privileges are available to OR personnel, and are maintained at the Marion VAMC in a paper format in a book kept in the OR. When the OR nurse manager placed the new set of privileges in the book, she noted that the new set of privileges was dated October 4, 2005, and added privileges for temporary pacemaker insertion and endotracheal intubation. She e-mailed the Chief of Staff on September 10, 2007, stating that she received a new set of privileges with the addition of these privileges but with the old date. The Chief of Staff responded in an e-mail on September 11, 2007: “A date on the privilege list is unnecessary. The granting of the privileges is kept in the credential file. All you folks need is to know what the doc’s privileges are, not when they were granted.”

Privileges may only be added at the request of a provider, with the approval of the service line chief and PSB. The original set of privileges indicated that the provider had requested privileges for temporary pacemaker insertion and endotracheal intubation, but these had not been approved. In an interview with Provider 11, he indicated he had not applied for these additional privileges in 2007. He believed these privileges had been approved at the time of his initial appointment, and indicated that he had been placing pacemakers during the course of his employment. He further indicated that no one had informed him of this incident prior to our interview.

It was also alleged that other documents were dated incorrectly, including peer reviews. The Associate Chief Nurse alleged that the Chief of Surgery asked physicians to perform peer reviews of surgical procedures in August of 2007 and then included those reviews in the minutes of a meeting held in January of 2007. We were unable to substantiate or refute this allegation because the peer review documents completed were not signed or dated.

## **2. Allegation: The Newly Constituted Cardiac Catheterization Laboratory is “Going To Be the Next OR.”**

This allegation was substantiated.

We found that the medical center has inadequate quality management measures in place for ongoing tracking, trending, and evaluation of data relating to care of patients undergoing cardiac catheterization.

We further found that there is inadequate documentation of competency validation for moderate sedation for nurses working in the cardiac catheterization laboratory (CCL).

We also found poor documentation concerning privileging of a cardiologist to perform invasive procedures such as permanent pacemakers, automatic internal cardiac defibrillators, and biventricular pacemakers. We also found privileges allowing performance of invasive procedures such as permanent pacemakers, automatic internal cardiac defibrillators, and biventricular pacemakers by a cardiologist without supportive documentation of adequate training or competence.

No policies could be identified for admission, discharge, and exclusion criteria for the CCL.

### **Recommendation Related to the Catheterization Laboratory:**

**Recommendation 17:** The Under Secretary for Health ensure that the new cardiac catheterization laboratory at Marion VAMC fully institutes quality management measures, performs appropriate competency evaluations for staff, and evaluates the privileging of catheterization laboratory providers in according with VHA policy.

### **G. Marion VAMC and Other VHA Interventions**

We found that the facility has attempted to address concerns after the NSQIP site visit in August 2007. Following the stand down of surgery on August 31, 2007, the VISN CMO developed guidance on the appropriate scope of surgical services at the Marion VA. On September 11 the Network Director placed the facility director and COS on leave and appointed interim leadership. A town hall meeting was held on September 14 by the VISN leadership to introduce the Acting Director and answer questions regarding the stand down of surgery. The same day, an anesthesiologist was placed on administrative leave pending a meeting of the PSB. Additionally, the Chief of Surgery was also placed on administrative leave. The Acting Director and VISN CMO met with staff, local media, and service organizations. On September 17 an Acting Chief of Surgery was appointed.

The OIG made its first site visit the week of September 18–21, 2007, at the request of the Under Secretary for Health. During that week, the VISN CMO added additional restrictions on the scope of outpatient surgical procedures. On September 27, the Acting Chief of Staff discussed his plan to initiate a NPDB query for all active Marion VAMC physicians. VISN 15 initiated briefings to VISN 15 Directors, COS, and Nurse Executives to summarize areas of concern and recommendations for reviews at each facility.

On October 10 the Deputy Under Secretary of Health for Management and Operations issued a directive regarding credentialing and privileging. Changes include a requirement that OQP forward to the facility any FSMB alert received within 24 hours. Final actions taken by a licensing board will be reviewed by the service chief and Executive Committee of the Medical Staff.



At the request of the VISN CMO and QMO, an external review team from Kansas City VAMC conducted a quality management program review on October 16–17. As a result, the facility took administrative action against the QM coordinator. On October 17, the Acting Chief of Surgery was placed on administrative leave after receipt of a new NPDB alert revealing an undisclosed license. On October 17, the CMO presented “lessons learned” to all Chief Medical Officers regarding issues that should be considered for review at all medical centers. The VISN Director conducted a site visit at Marion on October 18.

On November 1, the VISN Director in collaboration with the CMO and regional counsel imposed additional ICU and OR privilege restrictions on three physicians. At the direction of the VISN, the Capital Assets Manager and VISN Safety Manager reviewed allegations of environment of care and safety issues from a group of current and former environment of care (EOC) employees. The National Center for Organizational Development (NCOD) was contacted to work with EOC employees. On December 10 the VISN Director presented “lessons learned” at the Network Director Retreat.

A Surgical Program Reactivation Business Plan draft was developed to respond to various recommendations of internal and external review groups. A multidisciplinary group of over 100 front line employee volunteers gave input on how to improve the surgery and support programs.

Other actions taken have been a review of the VISN 15 credentialing and privileging process using system redesign principles. All surgery staff had clinical privileges reviewed and adjusted. The facility conducted a nurse locality pay survey to assist with recruiting; it temporarily redesignated the ICU to a Level 4, indicating that it is not equipped to care for the most severely ill patients; and it arranged for additional anesthesia coverage. It further initiated efforts to provide after-hours pharmacy and respiratory therapy services. Telemetry functions are being moved to the Medical/Surgical floor, with appropriate adjustments to staffing, training, and equipment.

Additional site visits have been conducted by the CMO on December 26–28 and the VISN Director on January 2, 2008.

## **H. Review of NSQIP**

NSQIP data are collected locally at each VAMC and analyzed centrally at the Denver Data Analysis Center (DDAC). For the NSQIP review, we searched and reviewed its own and other relevant publications, reports, VHA directives, and its Operations Manual for data collection. We had numerous communications through telephone calls and e-mails with the staff at the NSQIP DDAC; the NSQIP Boston Coordinating Center; the Information Service Center at Birmingham, Alabama; and the VAMC Seattle, Washington. We also visited the VAMC Washington, DC, on October 4, 2007; the Boston Coordinating Center

on October 19, 2007; and the DDAC on November 1, 2007. We also communicated with the OMI on its inter-rater reliability study, which was completed in May 2006.

## **1. NSQIP Organizational Structure**

NSQIP involves several components:

(1) The Executive Board is comprised of the National Director of Surgery, representative Chiefs of Surgery from several VAMCs, the NSQIP Senior Biostatistician, the NSQIP National Nurse Executive, and selected consultants.

(2) The Boston Coordinating Center (physically located at the VAMC in West Roxbury, MA) manages the entire NSQIP data collection process. The data collection activities are performed locally by Surgical Clinical Nurse Reviewers (SCNRs) at all VAMCs that perform surgery in the VHA.

(3) VAMC Birmingham, Alabama, Information Systems Center (ISC) is responsible for computer software enhancement to facilitate NSQIP data entry and downloading the NSQIP data and all surgical operations entered into the Surgery Package by Operating room staff for the Denver Data Analysis Center.

(4) The DDAC is in charge of all aspects of data checks, analyses, and data reporting, as well as coordinating access to the NSQIP database by health researchers.

## **2. NSQIP Data Collection**

The overall process of NSQIP data collection includes:

- Identification of major non-cardiac operations eligible for data collection.
- Collection of pertinent demographic information, preoperative comorbidities and lab test results, intra-operative data, and postoperative outcomes for all eligible operations included in NSQIP.

The Boston Coordinating Center manages all aspects of NSQIP data collection activities. In addition, any issues that are not directly related to the NSQIP data reports are channeled to this office.

As of January 2007, NSQIP collects 200 data elements: 5 related to patient demographics, 3 surgical operation identifiers, 41 preoperative risk factors, 13 preoperative laboratory variables plus their 13 dates, 41 related to the operation/intra-operation, 12 postoperative laboratory variables plus their 12 dates, and 60 related to patient outcome and the corresponding 60 dates.

### **A. Surgical Clinical Nurse Reviewer**

A Surgical Clinical Nurse Reviewer (SCNR) at each VAMC is responsible for collecting the NSQIP data and transmitting all the validated data elements required for the program. As of January 2007, 148 full-time and part-time individuals fulfill the role of SCNR at 121 VAMCs nationally. The nurses receive in-depth training on definition of NSQIP data items (variables) and data collection methods. In addition, the operations manual for data collection (NSQIP Operations Manual) that outlines these definitions and procedures in depth is provided to each nurse.

Based on the geographic location of each VAMC, the SCNRs organized into 10 regional teams. Each of the 10 Regional Coordinators oversees from 10 to 13 SCNRs. Regional Coordinators provide mentoring and support needed to troubleshoot problems from SCNRs in their regions and maintain the communication between the SCNRs in VAMCs and the NSQIP National Nurse Executive in the NSQIP Boston Coordinating Center. They also provide the 3–4 day orientation training about NSQIP for new SCNRs. The Regional Coordinators provide continuing education to the nurses in the field via conference calls twice a month, as well as being available by phone and e-mail to answer questions or offer advice on a daily basis.

The NSQIP SCNR competence exam was developed and given to all SCNRs in January 2000. Since then, each new SCNR is required to take a competency examination between 6 months to 1 year after being hired.

All of the SCNRs attend an annual NSQIP SCNR Conference. The conference usually runs about 3–4 days. It reviews NSQIP in its entirety and presents various topics of interest, such as clinical issues, research issues, and nursing advancement. In addition to training, the annual meetings help novice SCNRs benefit from the more experienced ones through break-out discussions and specialized workshops. The 1st NSQIP SCNR conference was held in Charleston, SC, in 2000. The 6th Conference was held in Orlando, FL, September 25–27, 2007. It focused on the continuing education of the SCNRs about NSQIP, its data variable definitions, Inter-Rater Reliability (IRR) results, and Surgical Package.

In addition, SCNRs undergo annual IRR testing. The first annual IRR exam was given to all SCNRs in February 2000. The scoring results of this IRR testing over the duration of NSQIP have been no less than 98 percent. The OMI also completed an IRR study on 59 NSQIP patient risk and outcome variables to assess the reliability of NSQIP data in 2006. This study was based on the 550 patients who had NSQIP surgery during March 2004 within 15 VAMCs. The selection of participating VAMCs was based on (1) high and low surgical workloads, (2) affiliated and non-affiliated with medical school surgical teaching programs, (3) different geographic location (East, Midwest, South, and West), (4) reporting NSQIP data on-time and slow, and (5) high and low statistical outlier status of mortality and/or morbidity in FY 2004. The overall (unadjusted for chance) agreement is excellent: 96 percent for the 52 categorical variables of the 59 variables studied. The chance-corrected agreement (kappa statistic) was almost perfect for 12 out of the 52 variables,

substantial for 26, moderate for 12, and fair for 2. Under the recommendation of the OMI report, beginning in 2007, NSQIP has been funded for 2 full-time nurses to re-abstract the NSQIP data at 65 VA medical centers per year for inter-rater reliability studies.

The Marion NSQIP data were abstracted and entered by the same NSQIP SCNR for the 1st and 2nd quarters of FY 2007, during which the Marion VAMC had elevated O/E mortality and thus triggered the NSQIP team site visit. During her tenure as the Marion SCNR from September 1998 until her retirement in April 2007, there is no evidence to question that SCNR's technical competence while functioning as a NSQIP SCNR. We decided not to re-abstract the Marion NSQIP data for the first two quarters of FY2007 based on the following assumptions and observations:

- The risk-adjusted mortality uses the NSQIP patient demographic, pre- and intra-operative data that are mostly captured automatically, since the Surgical Risk Assessment module of the VAMC is linked to Surgery Package 3.0 in the Veterans Information System and Technology Architecture (VISTA).
- Marion has a low volume of surgical operations, thus, the risk adjustment results are highly dependent on other VAMC data.
- The same competent SCNR worked on NSQIP data collection for the time period of interest.
- The track record of reliability of NSQIP data.
- The impracticality of training OIG personnel to re-abstract and validate all the data elements required by the NSQIP program from Marion for this period of time.

## **B. NSQIP Procedure Inclusion**

NSQIP collects data on all eligible major non-cardiac surgical operations. Beginning on October 1, 2006, determination of NSQIP eligible surgical procedures is completely based on Current Procedural Terminology, 4<sup>th</sup> edition (CPT-4) codes only. Prior to that, only major procedures that were performed under general, spinal, or epidural anesthesia were eligible to be included in the NSQIP. Selected CPT codes with known low postoperative mortality and morbidity are excluded. These eligible operations are selected to be included in NSQIP. Sampling is accomplished by accruing the first 36 non-concurrent (except for carotid endarterectomies) consecutive eligible surgical procedures in an 8-day cycle. Therefore, all eligible procedures performed at low-volume VAMCs may be included in NSQIP, in contrast to high-volume VAMCs where the eligible operations are sampled. The sampling scheme begins on October 1 of every year to coincide with the Federal fiscal year (October 1 to September 30). The 8-day cycle ensures starting the next cycle on a different day of the week. A concurrent procedure is defined as any procedure that is performed during the same operative procedure, using the same anesthesia, but performed

by another surgical team of a different subspecialty. For example, a urology procedure is a concurrent procedure if it is performed with a general surgery procedure.

Because SCNRs are also responsible for collecting cardiac data for the Continuous Improvement in Cardiac Surgery Program (CICSP), these 36 operations also include all cardiac procedures for CICSP where VAMCs have cardiac surgical services. After the maximum of 36 procedures, all the remaining cardiac, bariatric, and transplant procedures continue to be collected in the VAMCs where performed. The following common operations are limited to the first 5 procedures each in an 8-day cycle: transurethral resections of prostate and bladder tumor, inguinal hernia repairs, and breast lumpectomies. Excluded are all procedures with a score of 6 using American Society of Anesthesiology (ASA) Physical Status classification. An ASA score of 6 defines a declared brain-dead patient whose organs are being removed for donor purses. In addition, the SCNR may exclude 10 percent of workload; this “vacation” exclusion is because there is no backup for the SCNR to collect data when the SCNR is absent.

### **C. NSQIP Data Elements**

NSQIP collects data on preoperative, (intra-)operative, and postoperative variables. These data elements were selected on the basis of clinical relevance, reliability of data collection, and availability and ease of data collection. Preoperative variables include demographics; some lifestyle variables; functional status; ASA Physical Status classification; selected latest laboratory tests within 90 days prior to surgery; and selected pulmonary, cardiac, hepatobiliary, renal, vascular, central nervous system, nutritional, and immunologic comorbidities. Operative data include CPT codes for the principal operation and any secondary operations, emergency case, wound classification, anesthesia method, operative times, and blood loss and blood transfused. Outcome variables include 30-day mortality from any cause inside or outside the hospital, length of hospital stay, return to the operating room, and selected different postoperative complications (morbidity) occurring in the 30-day postoperative period.

Preoperative risk factors, operative information, and postoperative outcome data are collected on all included non-cardiac procedures by SCNRs. NSQIP procedures on which pre-operative, operative, and post-operative data are collected are called "assessed" procedures. Demographic data are automatically captured from the Patient Information Medical System (PIMS) package except the transfer status. Lab variables and some operative data are also automatically captured as the Surgical Risk Assessment module of the VAMC's is linked to Surgery Package 3.0 in the Veterans Information System and Technology Architecture (VISTA). Operative data are also collected by SCNRs from the operative notes and anesthesia records.

Preoperative data can be obtained from a variety of document sources of both local and remote VAMCs, including

- History and Physical
- Anesthesia assessment
- Progress notes
- Prior discharge summaries
- Reports and diagnostic studies
- Prior operative summaries
- Prior Discharge Diagnoses (ICD-9 Codes)

The SCNR follows each assessed procedure for thirty days postoperatively and record any adverse incidents (morbidity) into the proper pre-coded operative outcomes.

Surgical complication outcome data are collected through a variety of means, including:

- Discharge summaries
- Progress notes
- Mortality and Morbidity (M & M) Committee meetings and minutes
- Remote data collection from other VA sites
- Lab (including pathology) reports
- Problem lists
- 30-day patient follow-up letter

The SCNR is expected to complete data collection on each patient and the entry of the collected data into the special risk assessment module within 45 days of the date of operation. With the concurrence of the chief of surgery, the data are submitted electronically to the NSQIP national database.

### **3. NSQIP Data Transmission**

The Birmingham, Alabama, VAMC Information Systems Center (ISC) developed a surgical risk assessment module that facilitates NSQIP data entry by SCNRs at VAMCs. It also maintains and enhances the computer software and coordinates the installation at participating VAMCs to aid in the data collection process.

The assessed data entered by SCNRs at VAMCs are automatically transmitted to the holding database located at the server in Hines, IL. Birmingham ISC periodically downloads data on the NSQIP surgical operations assessed by SCNRs (known as 20-line file). In addition, Birmingham ISC downloads all (non-assessed) operations entered into the Surgery Package by Operating Room staff (known as 1-line file) from the Hines holding database 45 days after each quarter. The 1-line data file is used for surgical workload reports, and serves as well as the universe of NSQIP surgery for checking completeness of NSQIP case inclusion. Birmingham ISC then notifies Denver Data Analysis Center on these available data files.

## **4. NSQIP Data Analysis and Reports**

The NSQIP DDAC is responsible for:

- (1) Editing, cleaning, and managing the ongoing NSQIP database that currently contains nearly 1.3 million records of patients who have undergone major surgery in the VA system from 1991 to the present.
- (2) Performing statistical analysis and producing the quarterly and annual NSQIP reports.
- (3) Responding to questions regarding the NSQIP data, handling special data analyses and data requests, and providing data or performs analyses for researchers interested in asking questions from the NSQIP database.

### **A. NSQIP Data Management**

Both NSQIP-assessed 20-line data and non-assessed 1-line data are downloaded to the DDAC on the 25th of each month from February through November, to allow for data error fixing before the NSQIP quarterly reports are sent out in March, June, and September and the annual report in February.

The downloaded flat file is read into Statistical Analysis System (SAS) datasets. The NSQIP assessed 20-line data are then passed through a CPT code exclusion list to determine if they should have been assessed. If it is determined that the procedure should not have been assessed, it is placed in an exclusion file. The included procedures that are determined to be 1) transurethral resections of prostate (TURPs) and transurethral resections of bladder tumor (TURBTs), 2) inguinal hernias, or 3) breast lumpectomies are each programmatically limited to five procedures in an 8-day cycle. All data (both 1 and 20-line) are then put through a data-editing program to check for missing or out-of-range values and inconsistencies between data fields. Data records with potential errors are put into a suspend file until these are rectified by the SCNR at the VAMC. Query reports are sent to the VAMCs for correction of potential errors. Suspended records are then corrected and retransmitted, if necessary, and passed again through the data-editing program.

As of our site visit to the DDAC on November 1, 2007, the DDAC sent eight types of query reports to the VAMCs for correction of potential errors:

- NSQIP assessed (20-line) data file.
- The 1-line data file from the Surgical package.
- Eligible but not assessed NSQIP operations.
- Excluded list.
- Mortality list.
- Data transmission.
- Vacation exclusion.

- 8-day sampling cycle.

Error-free 20-line assessed procedures are then processed into an analysis file. At the end of each quarter and at the end of the fiscal year, the analysis file is given to the biostatistician for mortality and morbidity modeling to be used in quarterly and annual reports.

## **B. NSQIP Statistical Reports**

In this report, we define the surgical or operative mortality as death from any cause inside or outside of the VAMC within 30 days after the index surgical procedure. Surgical or operative morbidity included NSQIP assessed complications occurred within 30 days of the index surgical procedure.

Only index procedures are included in NSQIP statistical analysis. All NSQIP assessed non-cardiac surgical procedures are eligible for potential inclusion as index procedures. A patient may have multiple index procedures performed in a FY. The first index procedure for a patient is the first assessed operation performed on that patient in a FY. Multiple index procedures from a same patient are at least 31 days apart. For example, John Smith had 3 NSQIP assessed procedures that were operated on October 18, November 12, and November 18, 2007, respectively. The assessed October 18 operation was his first index procedure in FY 2008. The November 18 operation was his second index procedure because it occurred 31 days after his first index procedure. The November 12 operation was not an index procedure as it was within 30 days of his first index procedure occurred on October 18. Thus, this assessed NSQIP procedure on November 12 is excluded from the NSQIP analysis data file for surgical mortality and morbidity analysis. In addition, all transplant procedures are excluded from the NSQIP reports.

Reporting of NSQIP data is timed to coincide with the Federal fiscal year (FY). The quarterly reports are disseminated through the NSQIP restricted intranet web site to VA Central Offices, VISN Directors and Clinical Managers, the Chiefs of Surgery, and the SCNR. The 6-page quarterly report updates VAMC surgical workload, accrual of NSQIP assessed procedures into the database for the current FY, and unadjusted and risk-adjusted surgical mortality and morbidity outcome based on the data accrued so far for that FY. Therefore, the NSQIP second quarter report uses cumulative data (accrued) in the first half FY (October 1 to March 31), and its third quarter report use data for all three quarters (October 1 to June 30).

One of the most important products from the DDAC is the annual NSQIP statistical report that is distributed to all SCNRs, Chiefs of Surgery, Chiefs of Staff, VAMC Directors, VISNs, VA Central Office, and the NSQIP Executive Board. The NSQIP annual reports include: information about the program; trends in annual unadjusted and risk-adjusted surgical mortality and morbidity and length of hospital stay; frequency of top surgical operations in the NSQIP database; surgical workload by VAMC; accrual of NSQIP



assessed cases into the database; each VAMC's risk-adjusted surgical outcomes for each of eight surgeon subspecialties and all operations combined; comparison of each hospital's patient characteristics compared to the national average; risk-adjusted surgical outcomes at the VISN level; data analysis description; best practices for previous FY; and current year articles that used NSQIP data.

## **5. NSQIP Risk-Adjusted Surgical Mortality**

Because patients present with varying levels of disease severity and comorbid conditions, valid outcomes analysis typically requires adjustment of observed outcomes for the preexisting risks of individual patients. Difference in crude (unadjusted) mortality can be the result of differences in patient mix as well as differences in quality of surgical care. The risk-adjusted surgical mortality seeks to account for differences in patient mix (patient pre-operative risks) among the VAMCs through statistical modeling. Thus, differences in risk-adjusted surgical mortality and morbidity may be a potential indicator of differences in quality of care.

The NSQIP analytic file used for statistical analysis is created by including only those data records on index procedures accrued so far for the FY. All transplant procedures are excluded from the analytic data file and thus excluded from NSQIP reports. All multiple index procedures from a same patient are included for analyses. For example, if John Smith had survived both of his two index operations, both of his index procedures would be used in data analysis as if they were from two different patients: John Smith1 and John Smith2. The DDAC does not take into account for intra-correlations between multiple index procedures from a same patient in all its data analyses.

### **A. Imputation of Pre-Operative Lab Values**

NSQIP risk-adjusted surgical mortality analysis starts with imputing missing data on the pre-operative variables that are used for modeling patient risks of surgical mortality (morbidity). The missing data are mainly caused by preoperative laboratory values:

- (1) In circumstances where the laboratory tests were not ordered (such as for emergency operations).
- (2) The out of range lab values confirmed by SCNRs during the data checking process. These confirmed out of range values are set to missing only for risk assessment modeling analyses.

Specifically, for their given measuring unit, the thresholds for setting preoperative lab values to missing lab values for imputation are: Sodium > 180, BUN > 200, BUN < 0, Creatinine > 35, Albumin > 10.29, Bilirubin 1 > 43.93, SGOT > 6000, Alk. Phos > 2500, WBC > 200, HCT > 75, Platelets > 1000, PTT > 120, and PT > 50.

The imputation is done using a regression type analysis that uses the information for the patient from the other variables that are not missing.

## **B. Surgical Mortality Risk Assessment Model**

NSQIP collects few surgery-specific variables because it covers all major non-cardiac operations performed in VAMCs. To account for differences in complexity of the different operations performed in VAMCs, a complexity score for each operation was developed in the early phase of NSQIP. Complexity of operations was judged independent of the risk factors of the typical patient having that operation. Panels of surgical subspecialists reviewed the CPT-4 codes of the operations in their specialty areas and ranked the complexity of each operation on a 1-to-5 scale, with 1 being the least complex operation and 5 being the most complex. The complexity score needs to be updated as CPT codes change and new CPT codes emerge. To avoid reconvening the panels of subspecialists periodically, the DDAC explored the use of CMS work RVU in place of the original NSQIP complexity score. CMS work RVUs are updated annually. It was found that the correlation between the complexity score and the work RVU was about 0.80; that is, over 60 percent variations in NSQIP original complexity score could be explained by variations in the CMS work RVU. NSQIP replaced its original complexity score with the work RVU as a measure of operation complexity in 2002.<sup>6</sup>

After data imputation, (forward) stepwise logistic regression analysis is used to develop 30-day mortality prediction model. In this risk assessment model, the dependent (outcome) variable is vital status at 30 days of the index operation. The independent (predictors) variables are patient demographics, comorbidities, preoperative laboratory values, operative variables, and work RVU that are associated with that index operation. The stepwise logistic regression analysis starts by entering into the model the most statistically significant predictor variable. It then adds to the model at each step the next most significant predictor variable, given that the previous variables have already entered the model. The process stops when no additional predictors can be entered into the model at the 0.05 level of significance. The model of the final step in stepwise logistic regression is then used for estimating individual patient probability of dying within 30 days postoperatively.

The discrimination of the mortality prediction model is measured by the c-index. Discrimination is the model's ability to separate index operations' surgical mortality outcome. The c-index is the probability of concordance between predicted and outcome of the surgical death. The estimated c-index gives the proportion of all possible pairs of index operations with surgical death and index operations without surgical death for which the predicted probability of death for the index operation with surgical death is greater than

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<sup>6</sup> Henderson WG, Khuri SF, Mosca C, Fink AS, Hutter MH, and Neumayer LA. *Comparison of risk-adjusted 30-day postoperative mortality and morbidity in Department of Veterans Affairs hospitals and selected university medical centers: general surgical operations in men.* J Am Coll Surg 2007;204:1103-1114.

that of the index operation without surgical death. The calibration or reliability of the model is checked by the Hosmer-Lemeshow goodness-of-fit test. Calibration is the ability of the model to make unbiased estimate of outcome. The Hosmer-Lemeshow test compares the expected and observed surgical deaths in 10 equal subgroups delineated by the deciles of the estimated probability of death.

### **C. O/E Ratio Statistics**

The O/E ratios are presented in NSQIP annual reports for all surgical procedures combined and for each of surgical subspecialty. NSQIP quarterly update reports give only O/E ratios for all surgical procedures combined because of concerns that the number of surgical deaths is too low to develop a logistic regression model for each of surgical subspecialty, separately.

Based on the logistic regression model, a predicted probability of death is estimated for each index procedure based on preoperative risk factors associated with that index procedure. A patient may contribute multiple index procedures, in which case a predicted probability of death is estimated for each of his/her index procedures as if these index procedures were from different patients. These estimated probabilities are then summed within each VAMC and surgical subspecialty to obtain the expected number of surgical deaths, E. The observed number of surgical deaths, O, divided by the expected number of surgical deaths, E, gives the O/E ratio for that subspecialty at that VAMC. O/E ratios  $> 1$  indicated inferior risk-adjusted outcomes and O/E ratios  $< 1$  indicated superior risk-adjusted outcomes. NSQIP employs a false positive rate of 10 percent for its mortality, which means that one out of ten times the true O/E ratio is in fact 1 when we conclude that the true O/E ratio is greater than or less than 1. In other words, we are 90 percent confident that the true O/E ratio for the VAMC subspecialty is somewhere within that interval.

Assume that the estimation of O/E properly takes into account the NSQIP sampling scheme. An O/E ratio of 1 indicates that the observed number of surgical deaths is equal to the number of surgical deaths predicted (expected) from the logistic model based upon the patient mix in the subspecialty at that VAMC. If the O/E ratio is substantially greater than 1, it indicates that more deaths have occurred than the predicted relative to the patient mix at the VAMC. If the O/E ratio is less than 1, the VAMC has experienced fewer deaths than the predicted from the model given the patient mix.

## **6. Use of O/E Ratios for Monitoring**

NSQIP uses O/E ratios as an instrument for monitoring and improving the quality of surgical care at VAMCs, which rests on two key assumptions:

- (1) Surgical mortality rates are determined by patient-related risk factors and by the VAMC's quality of surgical care.

(2) After adjusting for patient specific risk factors, surgical mortality indicates the quality of surgical care at a particular VAMC.

Assume these two hypotheses are true. If the lower bound of the 90 percent confidence interval is above 1, this indicates that the surgical care within the VAMC is a (statistical) “high-outlier” (bad quality of surgical care). If the upper bound of the confidence interval is below 1, this indicates that its surgical care is a “low-outlier.”

The NSQIP Executive Board reviews annual O/E ratios for each VAMC every January for all operations combined and for each surgical subspecialty for the last 4 fiscal years. A statistically high O/E ratio will prompt the Executive Board to ask for VAMC action plans for improvement or conduct a site visit to alleviate the level of concern (VHA Directive 2007-008). A low-outlier VAMC is often asked to supply the NSQIP with a description of their “best practices” to share with other VAMCs.

One of the triggers for a paper audit or site visit is the reported “level of concern” that accompanies the NSQIP semi- or annual report. The levels of concerns can be 1, 2, or 3 for overall surgery and 0.5 within a subspecialty alone.

The level of concern criteria are as follows:

Level 0.5

There is a high O/E mortality ratio for at least one subspecialty but not all operations in the current fiscal year. Recommend paper audit of all surgical deaths.

Level 1.0

There is a high O/E mortality ratio for all operations and/or all non-cardiac operations in the current fiscal year. Recommend paper audit of all surgical deaths.

Level 2.0

There is a high O/E mortality ratio for all operations and/or all non-cardiac operations in the current fiscal year and one additional period in the past 4 years. Recommend follow-up report and/or site visit.

Level 3.0

There is a high O/E mortality ratio for all operations and/or all non-cardiac operations in the current fiscal year and two or more other periods in the past 4 years. Recommend follow-up report and/or site visit.

In accordance with VHA Directive 2007-008, a NSQIP site visit team has at least 3 members. A NSQIP site visit team usually consists of a surgeon in the specialized area of concern, a VACO representative from Patient Care Services, the NSQIP nurse executive, and/or an anesthesiologist. The site visit team usually reviews the following areas: data collection procedures, service lines and communication, and other process and structure concerns associated with the surgical service.

## Issues and Findings

1. NSQIP should develop an operation manual for the DDAC and develop a technical document/report that details its statistical methodology.

The DDAC does not have its own operation manual. The current NSQIP operations manual is centered on its data collection. It is not transparent how the center carries out its functions. The DDAC also does not have a technical document that details its risk-adjustment methodology. For example, when we asked for the documentation for the NSQIP data imputation method, the center could provide only a reference to a non-NSQIP-related research article published in 1960<sup>7</sup> for the generic statistical methodology and a 1987 article<sup>8</sup> for the SAS program code NSQIP used. The documentation is lacking on how the DDAC adapted this methodology to its imputation model, which makes it difficult to evaluate the specific imputation approach that the DDAC uses.

NSQIP publications in the peer-reviewed non-statistical journals contain general descriptions of some of its methods. They are, however, usually not that accurate or detailed. In addition, these publications do not reflect updates the center made as time and NSQIP evolve, such as the adoption of CMS RVU as replacement for VA surgical complexity scores. NSQIP should document changes and their corresponding effective dates the center made to its operations and methods.

2. The DDAC should take into account the sampling design in its data analyses to reflect the actual mortality and morbidity experience of the VA surgical patient population.

The NSQIP sampling scheme leads to unequal sampling or inclusion probabilities of index surgeries. The issue of unequal sampling probabilities is, however, not accounted for in NSQIP estimation of (both crude and risk-adjusted) mortality and morbidity rates. As a consequence, these measures would not divulge the actual surgical outcome experience of VA or VAMCs surgical population, which impairs the use of these outcomes measures as an instrument for monitoring and improving the quality of surgical care at VA.

3. NSQIP should consider stopping data collection for NSQIP eligible surgical operations that occurred within 30 days of their index surgery, as these data are not used at all for both crude and risk-adjusted surgical mortality and morbidity.

4. NSQIP should study the impact on mortality and morbidity outcomes as a result of its eligibility changes (that is, switching eligibility to based on CPT-4 codes only) in FY 2007. Changes in trends of mortality and morbidity may be confounded with its surgical operation eligibility change.

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<sup>7</sup> Buck SF. *A method of estimation of missing values in multivariate data suitable for use with an electronic computer.* J. R. Stat. Soc. B, 1960;22:302-307.

<sup>8</sup> Roberts JS and Capalbalbo GM. *A SAS macro for estimating missing values in multivariate data.* SAS Users Group International Twelfth Annual Conference Proceedings. Dallas, TX, February 8–11, 1987.

5. NSQIP should update timely its data collection operations manual to keep it current. The manual should record the changes made to its data definitions and surgical operation eligibility and their corresponding effective dates.

6. NSQIP needs to resolve conflicting definition of surgical mortality in its current operations manual with the 30-day mortality used by the DDAC. The current NSQIP Operations Manual (page 3-3) states that “Surgical Mortality is defined as any death occurring within the 30 days following surgery, regardless of cause, in or out of hospital, and any death occurring later than 30 days as a direct result of a peri-operative complication of the surgery and patient remains in the hospital in an acute care setting.” However, the DDAC counts the deaths that occurred only within 30 days of the operation. It does not count “deaths that occur beyond 30 days as a direct result of a peri-operative complication and patient remains in the hospital in an acute care setting”. This represents a discrepancy in the NSQIP data operations manual and what the DDAC has done for years. The NSQIP needs to edit the Manual for accuracy.

7. NSQIP should develop and deploy “Edits Check” software interface for the surgical risk assessment module that is currently used for NSQIP data entry. This would ensure correct case selection and accurate data capture.

We found that some SCNRs collect data for transurethral resections of prostate and bladder, inguinal hernia repairs, and breast lumpectomies that are programmatically limited to the first 5 procedures each in an 8-day cycle. Although these assessed procedures are excluded by the DDAC from its analysis data files, the “Edits Check” software could alert the SCNR before the data collection work is done.

Some data error checking seems to be better performed through “Edits Check” software interface. The interface should capture the potential data entry errors and/or confirm the out of range variable values at the VAMC at the time of data entry, rather than going back and forth between the DDAC and SNCRs. For example, the Edit Check could build in the DDAC error checking program for the NSQIP assessed (20-line) data file that looks at:

- Age is between 16-160 years.
- Operation began before it ended.
- Admission before surgery.
- All risk factors all entered or ns is entered.
- Post graduate year entered.
- Emergency entered.
- Wound class entered.
- Redo entered.
- ASA classification entered.
- # of blood units transfused entered.
- Post-operation ICD-9 code entered.

- Principal CPT-4 code entered.
- Concurrent procedures entered.
- Other procedure CPT-4 codes entered.
- If inpatient, has admission date.
- If outpatient, does not have an admission date.
- All the dates follow in order for admission transfer, pre-operation labs and post operation labs.
- Discharge dates.
- If a date of death is entered it is after the operation.
- Return to the operation room within 30 days after the index procedure has the related CPT-4 code entered.
- All complications are marked yes or not; if yes then date must be entered.
- Other complications have an ICD-9 code; then a date must entered.
- Serum sodium between 110-170; and has a date entered.
- Albumin between 0-50, and has a date entered.
- Bilirubin between 0-1000, and has a date entered.
- BUN between 0-200, and has a date entered.
- Creatinine between 0.1-35.0, and has a date entered.
- SGOT between 0-1000, and has a date entered.
- Alkaline Phosphatase between 0-1000, and has a date entered.
- WBC between 5-50, and has a date entered.
- Hematocrit between 5-65, and has a date entered.
- Platelet count between 10-999, and has a date entered.
- PTT between 18-150, and has a date entered.
- PT between 9-100, and has a date entered.
- Potassium between 1.5-8.0, and has a date entered.
- High CPK between 0-6000, and has a date entered.
- High CPK-MB between 0-50, and has a date entered.

8. NSQIP should consider exploring the use of all (i.e., without sampling) eligible surgical operations for mortality analysis by capturing the preoperative lab values, comorbidities, and operative data electronically to take more advantage of VA computerized Medical Records.

9. NSQIP should explore sampling its index surgery using the available 1-line data file as the sampling frame.

10. NSQIP should review and employ state-of-art statistical methodologies to improve the imputation model (e.g., by considering the multiple imputation method)

11. NSQIP should review and employ state-of-art statistical methodologies to improve risk assessment models. Consideration includes:

- Validate risk assessment models.
- Allow interaction terms between risk factors and surgery complexity, which may potentially improve the model performance.
- Check the assumption of linearity (on logit scale) for continuous variables. For example, it seems that the effect of increasing age from 40 to 45 would be quite different from increasing age from 90 to 95. In addition, it is also likely that the effect of an increase of CMS work RUV from 30 to 40 would be quite different from an increase from 10 to 20.
- Account for risk factors and surgery-specific variables that would be better to be included in the model but data are unavailable for doing so. One approach is to include random effects in the model.
- Take into account for the correlation within multiple index operations performed on a same patient. One approach is to use generalized estimating equation methodology.
- Consider entering or removing all design variables together that are formed from a polychotomous variable in stepwise regression analyses. Whenever a categorical independent variable is included (or excluded) from a model, all of its design variables should be included (or excluded); to do otherwise implies that we have recoded the variable.

12. NSQIP should take into account for the variation of E and the dependence between O and E when calculating confidence limits for O/E ratios.

In NSQIP confidence interval calculations, E is treated as if it is fixed and independent from O. In fact, E is an estimate, and O and E are not independent. One approach is to utilize resampling methods.

13. NSQIP should further study the limitation of its O/E ratio, including consideration of utilizing other outcomes measures.

A tendency is noted for the ACS NSQIP risk-adjustment algorithm to underestimate expected deaths (E = 19.63, actual deaths = 31) in the highest mortality quartiles and to overestimate expected deaths (E = 17.28, actual deaths = 10) in the lowest-risk mortality quartile<sup>9</sup>. This results in generating a higher O/E ratio (“false-positive” flag) for providers with higher-risk patient populations and passing an unfavorable judgment on their

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<sup>9</sup> Hall BL, Hirbe M, Waterman B, Boslaugh S, Dunagan WC. *Comparison of mortality risk adjustment using a clinical data algorithm (American College of Surgeons National Surgical Quality Improvement Program) and an Administrative Data Algorithm (Solucient) at the case level within a single institution.* J Am Coll Surg 2007;205:767–777)



performance. In contrast, this also leads to producing a lower O/E ratio (“false-negative” flag) for providers with low-risk patient populations and passing a favorable judgment on their performance.

14. NSQIP should consider adding a method section to its reports.

15. NSQIP should continue to develop improved reports focusing on issues such as clarity (e.g., state clearly in the 2nd and the 3rd quarterly reports that these quarterly reports use cumulate data) and better visual presentation (e.g., consider plotting O/E on a log scale).

16. NSQIP should continue to evaluate evidences of its tangible improvement in VA quality of surgical care.

It is hypothesized that a high outlier of O/E indicates questionable quality of care at that VAMC. However, based on the NSQIP chart review study, ratings of overall quality of care did not differ significantly between patients from VAMCs with higher and lower than expected mortality and morbidity.<sup>10</sup> In addition, it would also be expected that O/E ratios for NSQIP surgical mortality and morbidity would be highly correlated. However, little or no correlations have been found in a NSQIP study.<sup>11</sup>

## Conclusions

We concluded that NSQIP offers an opportunity of providing evidence-based monitoring and improvement in VA quality of surgical care. NSQIP could improve by developing an operation manual for the Denver Data Analysis Center, reviewing and adopting the state-of-art statistical methodologies, detailing its risk-adjustment methodology in a technical report, taking more advantage of the VA computerized medical records system in its data collection and edits, and evaluating evidences of its tangible improvement in VA quality of surgical care. NSQIP would enhance the utilities of its (both risk-adjusted and unadjusted) surgical outcome measures by taking its sampling scheme into account in their estimation to reflect the actual outcome experience of the VA surgical patient population.

## NSQIP Recommendation:

**Recommendation 7:** The Under Secretary for Health consider the issues which are identified in this report for modifications to NSQIP and other related programs.

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<sup>10</sup> Gibbs J, Clark K, Khuri S, Henderson W, Hur K, and Daley J. *Validating risk-adjusted surgical outcomes: chart review of process of care.* International J for Quality in Health Care 2001;13.,3:187–196.

<sup>11</sup> Daley J, Khuri SF, Henderson W, Hur K, Gibbs JO, Barbour G, et al. *Risk adjustment of the postoperative morbidity rate for the comparative assessment of the quality of surgical care: results of the National Veterans Affairs Surgical Risk Study.* J Am Coll Surg 1997;185:328–340.

## Under Secretary for Health's Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** January 23, 2008

**From:** Under Secretary for Health (10)

**Subject:** OIG Draft Report, *Healthcare Inspection, Quality of Care Issues, VA Medical Center, Marion, Illinois*

**To:** Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with your recommendations. The findings outlined in your review and the lack of appropriate and timely management intervention to address the situation are disturbing. Let me assure you that I am personally committed to ensuring that the recommendations made in this report are implemented as swiftly as possible and that the circumstances that allowed these events to unfold are prevented from recurring at this facility or any other VHA facility.

2. As outlined in the attached action plan, VHA is taking a number of steps to strengthen its surgical programs, monitoring, and oversight, which will allow identification of potential problems much sooner than we can now and will strengthen our surgical programs and service to veterans. VHA is revising its peer review policies with the intention that it will serve as a benchmark for peer review in the United States. VHA is also revising its credentialing and privileging policies and training to ensure that the issues identified at Marion do not occur at any of VHA's facilities. I have directed the review of leadership and other staff responsible for these events and will take appropriate action once the reviews are completed. VHA will also provide assistance and information, in conjunction with VA's General Counsel, to those patients and/or their representatives involved in these adverse events.

3. In summary, VHA takes what has occurred very seriously, and I regret these unfortunate events. Your assistance in helping to identify the issues is appreciated. I assure you that needed improvements are being implemented, with careful monitoring by both Network and VACO program officials, who will keep my office fully apprised of progress.

*(original signed by:)*

Michael J. Kussman, MD, MS, MACP

Attachment

VETERANS HEALTH ADMINISTRATION  
Action Plan Response

**OIG Draft Report, Health Care Inspection, Quality of Care Issues,  
VAMC Marion, IL, Draft Report, Dated January 16, 2007**

| Recommendations/<br>Actions | Status | Completion<br>Date |
|-----------------------------|--------|--------------------|
|-----------------------------|--------|--------------------|

**OIG Recommendations**

**Recommendation 1:** The Under Secretary for Health develop and implement a national quality management directive that ensures a standardized structure and mechanism throughout VHA for collecting and reporting quality management data.

Concur

VHA will form a work group to make recommendations about the structure and processes for the collection, analysis, management and reporting of quality management data into VHA policy. OIG will be invited to brief the workgroup about their findings and their recommendations related to this item.

VHA is in the process of formalizing an Integrated Risk Management Program. Implementation of the Risk Management Program will depend upon the recommendations of the workgroup report.

Although the current peer review policy exceeds national standards, VHA has recently revised its directive on Peer Review for Quality Management. Our intention is that this new policy will serve as the benchmark for peer review in the United States.

In process

May 2008

**Recommendation 2:** The Under Secretary for Health develop and implement a mechanism to ensure that VHA's diagnostic and therapeutic interventions are appropriate to the capabilities of the medical facility.

Concur

As surgical procedures and peri-operative care become more complex, it is increasingly important to understand the nature, and to qualify and quantify the extent, of processes and personnel involved in the pre-operative assessment, the operative intervention, and the post operative care of the surgical patient. It is essential to match the complexity of a procedure, the skills of the surgeon, and the extent of peri-operative support.

To understand and quantify, to the degree possible, those complex systems interactions, the Under Secretary for Health chartered an *Operative Complexity and Infrastructure Standards Workgroup* in December 2007. This workgroup has been tasked with the following key deliverables: (1) Identify a structure with which to define the complexity of surgical procedures/interventions, (2) Identify and categorize the elements (infrastructure) involved in peri-operative care, (3) Develop a matrix model to correlate level of peri-operative services with complexity of procedures to be performed, (3) Identify plan for quality management/monitoring, and (4) Identify strategies and action plans for roll out.

In process

July 2008

**Recommendation 3:** The Under Secretary for Health explore the feasibility of implementing a process to independently identify all state licenses for VA physicians.

Concur

We recognize that this is a national problem for VA, DoD, IHS, PHS and all U.S. healthcare organizations and VHA will explore the feasibility of implementing a process. VA policy requires practitioners to report all current and previously held licenses at the time of initial appointment and keep the agency apprised of anything that would adversely affect or otherwise limit their clinical privileges. Failure to do so may result in administrative action. Additionally, all practitioners are required to account for their personal history from the time of graduation. Staff must look at this personal history and discern if there is potential for the practitioner to have a license that is not declared during the application process. Medical staff credentialers and leadership will have this process reinforced by Office of Quality and Performance staff and VHA will continue to look for solutions to this issue.

In process

March 2008

**Recommendation 4:** The Under Secretary for Health develop and implement formal policies and procedures to ensure that Federation of State

Medical Boards' Disciplinary Alerts are timely addressed by medical facilities, VISNs, and VHA headquarters.

Concur

VHA has already incorporated language into VHA Handbook 1100.19, Credentialing and Privileging (currently in concurrence) requiring VA medical center staff notified of a Disciplinary Alert from the Federation of State Medical Boards as follows: Facility credentialing staff must obtain primary source information from the State licensing board for all actions related to the disciplinary alert. Complete documentation of this action, including the practitioner's statement, is to be scanned into VetPro before filing in the paper credentials file. Medical staff leadership is to review all documentation to determine the impact on the practitioner's continued ability to practice within the scope of privileges granted. This review must be completed within 30 days of the notice to the facility staff of the alert and complete documentation in VetPro prior to filing in the paper file. This process will be coordinated and monitored by staff from the Office of Quality and Performance. Failure to complete these actions within 30 days will be reported to the VISN Chief Medical Officer. Compliance with this policy will be assessed through the System-wide Ongoing Assessment and Review Strategy (SOARS) process.

In process

April 2008

**Recommendation 5:** The Under Secretary for Health conduct reviews to determine appropriate administrative actions against Marion VAMC leadership and other staff responsible for the problems cited in this report, to include the Medical Center Director, the Chief of Staff, the Chief of Surgery, the Associate Director for Patient Care/Nursing Services, and the Associate Chief Nurse of the Surgical Service.

Concur

An Administrative Investigation Board (AIB) has been charged to investigate problems cited and issues raised at the VA Medical Center in Marion, IL, and to recommend appropriate administrative actions on their findings. The AIB will begin the investigation the week of January 28, 2008.

Planned

Estimated  
May 2008

**Recommendation 6:** The Under Secretary for Health issue guidance that clearly defines what constitutes evidence of current competence for use in the privileging process.

Concur

The 2008 Joint Commission Standards require each facility to define a Focused Provider Practice evaluation for new practitioners and new privileges requested by practitioners at their facility. Additionally, VHA's Health Care Failure Mode and Effects Analysis (HFMEA) Team has recommended the development of indicators to be used by facilities in defining provider profiles for ongoing monitoring of clinical competence. These will be specialty specific and developed by the appropriate clinical champions based on current medical evidence and national benchmarks and incorporated into the Provider Profile Library on the Office of Quality and Performance web site. These provider profiles will be developed in conjunction with Patient Care Services. Priority in development of these profiles will be given to General Surgery. In the interim, the DUSHOM will direct the field that any renewal or augmentation of clinical privileges will be carefully reviewed. DUSHOM action will be followed by publication of a directive developed by the Office of Quality and Performance.

In process

July 2008

**Recommendation 7:** The Under Secretary for Health consider the issues which are identified in this report for modifications to NSQIP and other related programs.

Concur

NSQIP is a nationally recognized surgical quality program designed to enhance the outcomes and efficiency of surgical and peri-operative care across the continuum of the episode of surgical care, beginning with the initial evaluation for a possible surgical problem and ending with long-term outcomes of surgery. NSQIP provides reliable and valid data on the processes, organizational attributes, outcomes, and costs of care at the patient or facility-level. These data are then aggregated, analyzed, and transformed into information.

The NSQIP has been successful in achieving this mission through enhancements to the ongoing collection, analysis, and dissemination of reliable and valid information about the outcomes, processes, organizational attributes, costs, and appropriateness of surgical and

peri-operative care. In 2001, the American College of Surgeons (ACS) began to take an active interest in the NSQIP and its results in reducing surgical mortality and morbidity rates. Based on the success of the pilot program, and in collaboration with the VA, the ACS applied for an Agency for Healthcare Research and Quality (AHRQ) grant to expand the program further into the private sector.

As surgical care and its associated challenges evolve, VHA will remain a leader in the field of surgical quality and safety. New strategies and goals are being developed to anticipate ongoing changes in surgical health care delivery. To that end, the Under Secretary for Health will launch a Surgical Quality Workgroup in January 17, 2008. This workgroup will be tasked with the following key deliverables:

- Assess current strategies for surgical quality improvement, including but not limited to, a review, comparison, and contrast of the current NSQIP model, Continuous Improvement in Cardiac Surgical Program (CICSP) and Neurosurgery Consultants Board processes.
- Employ state-of-the-art statistical methodologies to evaluate current processes of sampling, imputation modeling, and risk adjustment models to determine if there are any opportunities for improvement in current analysis methodologies that will further refine the success of the NSQIP program.
- Develop metrics/processes to enhance granular assessments of surgical program quality to supplement aggregated, risk-adjusted data.
- Define a core quality assessment process that each facility can use to assess ongoing quality on as ‘close to real time’ process as possible modeling and risk adjustment models to determine if there are any opportunities for improvement in current analysis methodologies that will further refine the success of the NSQIP program.

The work done by this workgroup will be in alignment with the findings of the *Operative Complexity and Infrastructure Standards Workgroup*.

The Under Secretary of Health will also charge the Surgery Program Office in the Office of Patient Care Services to develop a NSQIP operations manual that defines processes of data collection, sampling methodology, and analysis methodologies.

Other related programs identified in the report refer to the Cardiac Catheterization Laboratory. VHA has a Cardiovascular Assessment, Reporting and Tracking System for Catheterization Laboratories (CART-CL) program. The mission of the CART-CL project is to develop and implement a national VA reporting system, data repository, and quality



improvement program for procedures performed in VA cardiac catheterization laboratories. This program provides for a standardized data capture and reporting process across all VA catheterization labs, is a single national data repository for tracking and documenting cardiac procedures performed in VA cardiac catheterization labs, has core data elements that conform to the definitions and standards of the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) to allow for benchmarking, and it provides a centralized platform to support quality improvement, both locally and nationally and will allow for VA participation in the ACC-NCDR quality improvement program. The CART-CL project was initiated in 2003 with, after development and testing, a phased in implementation process that began in 2006. All facilities with cardiac catheterization labs will be fully on board by the end of 2008 (currently approximately 99 percent are installed). Local site reports have been developed that outline utilization and volume of cases in the labs. Now, with increased volume of cases and that soon all laboratories will be installed, the next phase of reporting will add quality indicators that will include benchmarking from the ACC- NCDR registry.

In process

September 2008

**Recommendation 8:** The Under Secretary for Health confer with the Office of General Counsel regarding the advisability of informing families of patients discussed in this report about their right to file tort and benefit claims.

Concur

Consistent with VHA Directive 2005-049, Disclosure of Adverse Events to Patients, institutional leaders at the Marion VAMC will review information, from the patients' medical records and subsequent findings in the report of the Office of the Inspector General, with patients or their representatives. In addition, patients and/or their representatives will be provided information regarding how to request compensation. Representatives from the VA's Regional Counsel will be ready to assist with this process. VHA institutional leaders will also apologize as part of communicating with patients and/or their families regarding these adverse events.

In process

Initiated immediately, completed as soon as possible but not later than 1 month from publication of the report.

**Recommendation 9:** The Under Secretary for Health ensure that Marion VAMC complies with VHA policies regarding peer review, mortality assessments, adverse event reporting, and the performance of root cause analyses.

Concur

VHA, through network leadership oversight and monitoring, will provide comprehensive training to ensure Marion VAMC complies with VHA policies regarding peer review, mortality assessments, adverse event reporting, and the performance of root cause analyses. Network leadership will report to the DUSHOM when Marion VAMC is compliant with these VHA policies.

Planned

March 2008

**Recommendation 10:** The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider National Practitioner Database results and document consideration of those results.

Concur

VHA, through network leadership oversight and monitoring of the Chief Medical Officer and Quality Management Officer, will require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to utilize National Practitioner Database results and document evaluation of results. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Planned

March 2008

**Recommendation 11:** The Under Secretary for Health ensure that Marion VAMC appropriately credentials providers with references executed in accordance with VHA Handbook 1100.19 and documents consideration of discrepancies in provider disclosures and information obtained from references.

Concur

VHA, through network leadership oversight and monitoring, will require that Marion VAMC staff appropriately credential providers with references executed in accordance with VHA Handbook 1100.19 and document evaluation of references in provider disclosures and information obtained

from references. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Planned

March 2008

**Recommendation 12:** The Under Secretary for Health require the Marion VAMC Chief of Surgery, Chief of Staff, and Professional Standards Session of the Clinical Executive Board to consider the health status of practitioners for credentialing and privileging purposes in accordance with VHA Handbook 1100.19.

Concur

VHA, through network leadership oversight and monitoring, will require the Professional Standards Session of the Clinical Executive Board to consider and document the health status of practitioners for credentialing and privileging purposes in accordance with VHA Handbook 1100.19. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Planned

March 2008

**Recommendation 13:** The Under Secretary for Health require the Marion VAMC Chief of Staff to sign and complete the certification correctly on VA Form 10-2850, *Application for Physicians, Dentists, Podiatrists and Optometrists*.

Concur

VHA, through network leadership oversight and monitoring, will require the Marion VAMC Chief of Staff sign and complete the certification correctly on VA Form 10-2850, *Application for Physicians, Dentists, Podiatrists and Optometrists*. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Planned

February 2008

**Recommendation 14:** The Under Secretary for Health require the Professional Standards Session of the Clinical Executive Board at Marion VAMC to consider and resolve discrepancies in the number of malpractice claims disclosed by a practitioner and the number obtained through primary source verification.

Concur

VHA, through network leadership oversight and monitoring, will require the Professional Standards Session of the Clinical Executive Board at Marion VAMC consider and resolve discrepancies in the number of malpractice claims disclosed by a practitioner and the number obtained through primary source verification. This resolution must be documented. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Planned

March 2008

**Recommendation 15:** The Under Secretary for Health require that the Marion VAMC Chief of Surgery Service and the Professional Standards Session of the Clinical Executive Board record the documents reviewed and rationale for the conclusions reached with respect to privileging process.

Concur

VHA, through network leadership oversight and monitoring, will require that the Marion VAMC Chief of Surgery Service and the Professional Standards Session of the Clinical Executive Board record the documents reviewed, with a rationale for the conclusions reached with respect to the privileging process. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Planned

March 2008

**Recommendation 16:** The Under Secretary for Health require that the Marion VAMC Chief of Surgery, Chief of Staff, and Professional Standards Session of the Clinical Executive Board document consideration of quality assurance data in accordance with VHA Handbook 1100.19 in the re-privileging of medical providers.

Concur

VHA, through network leadership oversight and monitoring, will require that the Marion VAMC Chief of Surgery Service, Chief of Staff, and the Professional Standards Session of the Clinical Executive Board document consideration of quality assurance data in accordance with VHA Handbook 1100.19 in the re-privileging of medical providers. Network leadership will

report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Planned

March 2008

**Recommendation 17:** The Under Secretary for Health ensure that the new cardiac catheterization laboratory at Marion VAMC fully institutes quality management measures, performs appropriate competency evaluations for staff, and evaluates the privileging of catheterization laboratory providers in according with VHA policy.

Concur

VHA, through network leadership oversight and monitoring, will require that the new cardiac catheterization laboratory at Marion VAMC fully institutes quality management measures, performs appropriate competing evaluations for staff, and evaluates the privileging of catheterization laboratory providers in accordance with VHA policy. Network leadership will report to the DUSHOM when the Marion VAMC is compliant with this recommendation.

Planned

April 2008

## Glossary

ABI – Administrative Board of Investigation.

ACN – Associate Chief Nurse.

ACS – American College of Surgeons.

AD – Associate Director.

ADC – Average Daily Census.

ASA – American Society of Anesthesiology.

C&P – Credentialing and Privileging, a program for health care professionals. Although this is also the acronym for Compensation and Pension, a Veterans Benefits Administration program, it is only used in this report to mean Credentialing and Privileging.

CBOC – Community Based Outpatient Clinic.

CCRM – Care Coordination and Resource Management.

CCSHS – Center for Cooperative Studies in Health Services.

CEB – Clinical Executive Board.

CMO – Chief Medical Officer.

CMS – Centers for Medicare & Medicaid Services.

COS – Chief of Staff.

CPT Code – Current Procedural Terminology Code.

Credentialing (Credentials) – the process of verifying an independent licensed practitioner’s education, training, licensure and health status.

CSP – Cardiac Surgery Program.

DDAC – Denver Data Analysis Center.

DNR – Do Not Resuscitate.

DPM – Director, Performance Management.

ELC – Executive Leadership Council.

EPRP – External Peer Review Program.

FSMB – Federation of State Medical Boards.

FTE – Full time employee equivalent.

FY – Fiscal Year.

HHS – The United States Department of Health and Human Services.

Hx – History [medical].

ICD-9 Code – International Statistical Classification of Diseases and Related Health Problems.

ICU – Intensive Care Unit.

IRR – Inter-Rater Reliability.

ISC – Information Systems Center.

JCAHO – Joint Commission on Accreditation of Healthcare Organizations, now known as “The Joint Commission.”

LIP – Licensed Independent Provider.

M & M – Mortality and Morbidity.

Mg/dl and gm/dl – Metric system units for milligrams per deciliter and grams per deciliter. Mg/dl is also referred to as “mg percent [mg %].”

NCPS – National Center for Patient Safety.

NELB – Network Executive Leadership Board.

NPDB – National Practitioner Databank.

NSQIP – National Surgical Quality Improvement Program.

NVASRS – National VA Surgical Risk Study.

OHI – Office of Healthcare Inspections.

OIF – Operation Iraqi Freedom.

OIG – Office of Inspector General.

OMI – Office of the Medical Inspector.

OQP – Office of Quality and Performance.

OR – Operating Room.

PACU – Post-Anesthesia Care Unit.

PCC – Primary Care Clinic.

PCP – Primary Care Provider.

PIMS – Patient Information Medical System.

PIP – Performance Improvement Plan.

Privileging (Privileges) –the process of determining what specific services or procedures a licensed independent practitioner can provide at a certain facility.

Prn – *Pro re nata* (Latin); in medicine, generally “as needed” or “as required.”

PSB – Professional Standards Board; for purposes of this report, this refers to the Professional Standards Session of the CEB.

PSM – Patient Safety Manager.

Pt – Patient.

QM – Quality Management.

QMO – Quality Management Officer.

QMS – Quality Management System.



RCA – Root Cause Analysis.

RFI – Requirements For Improvement.

RVU – Relative Value Unit.

S/p – After; “status following.”

SCNR – Surgical Clinical Nurse Reviewer.

Sic – *sicut* (Latin) meaning “thus” or “so”; used to indicate that a quoted passage, especially one containing an error or unconventional spelling, has been retained exactly as shown in its original form.

TQI – Total Quality Improvement.

UC/ER – Urgent Care/Emergency Room.

UR – Utilization Review.

VA – Department of Veterans Affairs.

VAMC – Veterans Affairs Medical Center.

VHA – Veterans Health Administration.

VISN – Veterans Integrated Service Network.

VISTA – Veterans Information System and Technology Architecture.

## OIG Contact and Report Acknowledgements

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|             |   |
|-------------|---|
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