

**STATEMENT OF
JOHN D. DAIGH, JR., M.D.
ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS
OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS
BEFORE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
ON
VA CREDENTIALING AND PRIVILEGING: A PATIENT SAFETY ISSUE
JANUARY 29, 2008**

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify today on the credentialing and privileging process of the Department of Veterans Affairs. As a way of explaining to you the importance of the credentialing and privileging process, I would like to review our findings from the Office of Inspector General (OIG) report *Healthcare Inspection, Quality of Care Issues, VA Medical Center, Marion, Illinois*. I am accompanied by Dr. George Wesley, Dr. Andrea Buck, Dr. Jerome Herbers, and Dr. Limin Clegg.

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, Missouri. We 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. We retained distinguished surgeons and an anesthesiologist not employed by the Federal government to further review cases in

question. We 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, we 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, we 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. In the report we discuss 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, we 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.

We 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. We 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.

We 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. We 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.

We 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.

We 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.

We 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. We 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

We 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. We were 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, we 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.

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 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 the 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 recommendations and submitted appropriate action plans. We found the Department's improvement plans acceptable and will follow up until all recommendations are implemented.

Mr. Chairman, thank you again for the opportunity to testify on this important issue. We would be pleased to answer any questions that you or other members of the Committee may have.