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Final Report

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Quality of Surgical Care
Veterans Affairs Medical Center
Marion, Illinois

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Executive Summary

The Office of the Medical Inspector (OMI) was asked by the Principal Deputy Under Secretary for Health (PDUSH) to conduct a site visit to the Marion Veterans Affairs (VA) Medical Center, Marion, Illinois (IL), (hereafter, the Medical Center) to investigate concerns about the delivery of surgical care.

Analysis of the Medical Center's National Surgical Quality Improvement Program (NSQIP) data for the first half of Fiscal Year (FY) 2007 (October 2006 thru March 2007) revealed an increase in the observed to expected (O/E) mortality ratio. The Medical Center's O/E mortality ratio for FY 2006 was 0.88. The O/E mortality ratio for the first two quarters of FY 2007 was 4.3, a significantly higher ratio.

This elevated O/E ratio stimulated a site visit by a team from the NSQIP Executive Committee which took place August 29-30, 2007. The NSQIP team found a number of areas of concern, including inadequacies in the facility's monitoring of its quality improvement activities. The team also cited potential deficiencies in the facility's credentialing and privileging process, in adverse events and quality oversight, and in communication skills and ability of the facility staff to work as a team to address problems in these areas. They reported a general fear of retaliation that discouraged the staff from expressing the seriousness of the problems to management. The NSQIP team recommended the suspension of all surgery requiring inpatient hospitalization.

The OMI conducted a site visit to the Medical Center September 5-6, 2007. After reviewing the site visit results and other information gathered after the site visit and after peer reviewing a large number of surgical/procedure cases, the following conclusions are reached.

1. The OMI has determined that during FY 2006 and FY 2007 the number of surgery-associated cases at the Medical Center that did not meet the standard of care is excessive. There is a clustering of sub-standard care in the practice of two surgeons.

2. The OMI has serious concerns about the leadership in place during FY 2006 and most of FY 2007 at the Medical Center.

    a. The Medical Center leadership did not ensure that there was appropriate infrastructure to support expansion of its surgical program. Particular areas of concern are operating room (OR) scheduling practices, Post Anesthesia Care Unit (PACU) staffing, continuity and coordination of care with hospitalists, and after hours support by respiratory therapy in the Intensive Care Unit (ICU).

    b. Informed oversight of the quality functions and performance of the Surgery Service was neglected by the Medical Center Director and Chief of Staff. There was no facility level oversight of clinical care peer reviewed as Level 1.

c. There were repeated questions raised about the organizational preparedness for the new surgical services that were being offered and the competence of some practitioners. Individuals who attempted to report concerns were dismissed or ignored.

d. Neither the Chief of Staff nor the Nurse Executive was effective in responding to staff concerns.

e. The QM Director lacked the ability to perceive problems and the capacity to propose solutions to the hospital's leadership to effect change.

3. The clinical leadership and clinicians in the Medical Center Surgery Service lacked the ability and experience to support a quality surgery program. There was not a proactive approach that would contribute to best possible surgical outcomes and a strong organizational performance.

   a. The Medical Center medical staff and support systems did not adequately anticipate, recognize and manage patient factors related to peri-operative cardio-pulmonary risk.

   b. The Medical Center medical staff and quality systems did not recognize trends and take appropriate action in response to deaths and complications of procedures.

   c. Although individual technical breaches are difficult to identify and trended data are limited, the OMI is concerned about the incidence of bladder perforations, peripheral nerve injury with vascular surgery, and infectious complications of total joint replacements.

4. The quality management program was ineffective.

   a. Cases were discussed in isolation and there was no evidence that complications were evaluated as they related to the number and type of cases performed by individual surgeons. The leadership was unable to integrate trends and patterns to assess root causes.

   b. The Surgical Case Review Committee reported all of their morbidity and mortality reviews as peer reviews. The reviews that were done were superficial and did not reflect a professionally critical self-appraisal. Evaluation of care did not look beyond the technical aspects of the procedure and failed to assess elements of pre- and post-operative care.

   c. The Medical Center performed a large number of peer reviews but many were poorly done. Reviews on complex cases were often performed by colleagues with widely dissimilar training, not true peers. Reviews lacked thoroughness and insight into appropriate standards of care.

d. The Surgery Service was not integrated into the Patient Safety and Quality Improvement Programs of the Medical Center. Quality Management (QM) had multiple mechanisms for capturing morbidity and mortality at the Medical Center; however, the QM staff and the Surgery Service did not work together to analyze and interpret these complications.

e. OMI is concerned that the care of patients who died in "Do Not Resuscitate" (DNR) status was not subject to rigorous oversight at either the Service or Medical Center level.

5. OMI found deficiencies in the credentialing and privileging process.

   a. The OMI believes that the initial decision to hire Surgeon A was reasonable, based on the personal references and the licensing and malpractice information available in early 2006.

   b. The Medical Center could have done more to ascertain Surgeon A's status after they were informed in August 2006 that he had entered into a non-disciplinary agreement not to practice in the state of Massachusetts and that an investigation was ongoing.

   c. Across the board, surgeons were granted clinical privileges without a critical interpretation of the available performance data and without an analysis of their current clinical outcomes or direct observation of competence.

   d. The OMI team found that the template conclusion statement in the "Summary Analysis of Quality Assurance Folder" prepared by the QM Director, i.e., *"the general review of the clinical performance folder on this provider reveals sufficient evidence to support clinical competence and the recommendation is to grant clinical privileges,"* was used inappropriately and did not reflect either an analysis of available data or senior clinician oversight.

6. The OMI found that the NSQIP data were not effectively integrated into the Medical Center's quality oversight processes.

   a. NSQIP identified all circumstances in which patients died within 30 days of a major surgical procedure. NSQIP is not designed to track procedural mortality beyond that period and relies upon local processes to identify those long-delayed mortal complications.

   b. The NSQIP web-based release of facility reports is an effective means of communicating critical data to a broad audience.

   c. The Medical Center did not submit all NSQIP identified deaths to peer review as required by VHA Directive 2004-054.

d. The NSQIP report showing an elevated mortality O/E in the first quarter of FY 2007 was correlated with a significant number of cases that did not meet the standard of care.

e. The NSQIP report for FY 2006 had a lower than expected O/E but OMI review of the individual cases indicated that a majority did not meet the standard of care. The local peer review process failed to identify that problematic care.

The OMI makes the following recommendations.

1. The Medical Center, Veterans Integrated Service Network (VISN) 15 and VHA should take appropriate personnel actions as indicated by the results of OMI's quality of care evaluation and case reviews.

2. The Medical Center, with VISN, VHA, VA (Office of General Counsel) support, should notify patients and family members affected by substandard care in a manner consistent with VHA policy on disclosure of adverse outcomes.

3. VHA should assess the Medical Center's leadership and take appropriate actions.

4. The Medical Center should improve its patient safety and medical staff culture by encouraging blame free reporting in a non-punitive environment and open communication among all levels of its staff.

5. VHA should take appropriate actions to ensure that adequate infrastructure and oversight is in place to support the planned surgical services at the Medical Center. Particular attention should be focused on OR scheduling practices, PACU staffing, continuity and coordination of care with hospitalists, consideration of intensivists staffing, and after hours support by respiratory therapy and other ancillary services in the ICU.

6. The VISN/VHA should conduct a complete assessment of the Medical Center's Quality Management program focusing on identification of problematic cases, trending, and interpretation and analysis of data.

   a. The Medical Center should take all necessary actions to improve its peer review program to bring it into compliance with VHA directives.

   b. As the Medical Center re-establishes its surgical scope of services, quality management and medical staff should pay particular attention to tracking and trending post-operative fluid management complications such as respiratory failure or un-planned intubation; post operative cardiovascular events; orthopedic infections; urologic bladder perforations; complications of bowel resections; and all peripheral nerve injuries from vascular surgery.

c. Based on individual adverse outcomes or the results of trended data, the Medical Center should perform root cause analyses (RCAs) to determine factors influencing complications and provide action plans for improvement. Clinicians, including frontline surgeons, need to be an integral part of this key patient safety and quality improvement activity.

7. The Medical Center should ensure that the credentialing and privileging processes include all required credentialing documents necessary for the privileges requested.

   a. Ensure that these documents contain the necessary quantitative data portion of quality improvement activities for the continued evaluation of professional performance, judgment, clinical and technical competence and skills.

   b. Case denominators must be included to enable the analysis required for approval of continued privileges or newly requested ones.

   c. Summative evaluations for practitioners should be attested to by a senior clinician. And the inclusion of a template statement on all physician profiles prepared by QM Director in regard to clinical competence and the granting of privileges in the "Summary Analysis of QA Folder" must cease.

8. VHA should establish a policy and procedure for evaluating the scope of services at medical centers to ensure that the resources, professional staff, physical infrastructure and clinical volume are sufficient to support consistent, high quality outcomes.

9. In regard to individual provider peer review, VHA should:

   a. clarify that the screening criteria for peer review or other quality of care reviews should not be affected by the diagnosis of a terminal illness, the existence of an advance directive, or the designation of DNR status.

   b. address the challenges facing small facilities that have limited affiliations and/or an insufficient number of specialists to support a comprehensive, robust peer review program.

   c. establish consistent instruction in peer review responsibilities and processes for all professional staff.

   d. provide training and other ongoing support to Chiefs of Staff and other senior clinical leaders on the best processes and practices in peer review. This should also address the critical relationships to patient safety, quality improvement and risk management activities.

   e. systematically and regularly collect information on peer review performance at all medical centers and develop a mechanism for early identification of quality of care issues.

10. In regard to the NSQIP, VHA should:

    a. establish a reporting timeframe and format for NSQIP reporting that provides actionable information in the most timely manner practicable.

    b. establish a consistent trigger for intervention by the NSQIP Executive team. This should include consideration of the timeframe covered, the index clinical volume, and the degree of deviation. There should be specific thresholds for action, a range of intensity of interventions and explicit timelines for response and follow-up.

    c. train and regularly update Chiefs of Surgery in the use of NSQIP and the CPRS Surgery Package and require that both sources of information be fully integrated into local peer review and quality improvement activities.

11. VHA should take appropriate actions based on the OIG investigation.

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I. Introduction

The Office of the Medical Inspector (OMI) was asked by the Department of Veterans Affairs (VA) Principal Deputy Under Secretary for Health (PDUSH) to conduct a site visit to the Marion Veterans Affairs Medical Center (VAMC), Marion, Illinois (IL), to investigate concerns about the delivery of surgical care. The OMI conducted a site visit to the Medical Center on September 5-6, 2007.

II. Background

On August 30, 2007, the VAMC, Marion, Illinois (hereafter, the Medical Center) initiated a stand down of the inpatient surgery program. The suspension of the inpatient surgery program was undertaken per recommendation by a National Surgical Quality Improvement Program (NSQIP) team that visited the Medical Center August 29-30, 2007. The team initiated a review in response to a statistically high mortality outlier for NSQIP data for the first two quarters of Fiscal Year (FY) 2007 for non-cardiac operations, as well as several recent surgical deaths.

VA's NSQIP is a national outcomes reporting system for major non-cardiac surgical procedures performed in VA medical centers that provides participating institutions with risk-adjusted morbidity and mortality data. NSQIP does not attempt to capture data on all surgical cases but uses a sampling strategy to ensure a representative sample of cases.[1] This reporting system uses prospective data collection to assess preoperative patient risk factors. Dedicated, trained staff collect data reflecting on well-defined peri-operative adverse outcomes, morbidities, and mortality. NSQIP is unique among widely applied outcomes reporting systems, providing comparable validated information on patient preoperative risk factors, processes of care during surgery, and 30 day morbidity and mortality on major surgical procedures.

In 2001, a collaboration between the VA and the American College of Surgeons resulted in a grant from the Agency for Healthcare Research and Quality to assess implementation of the NSQIP in private sector hospitals. The study results showed that the program could be successfully implemented and the NSQIP methodology worked well in the private sector. In October of 2002, the Institute of Medicine named the NSQIP the "best in the nation" for measuring and reporting surgical quality and outcomes. Across VA, unadjusted 30 day mortality rate for major non-cardiac surgery has fallen from 3.16% in FY 1992 to 1.66% in FY 2006.

The national NSQIP team prepares regular reports on non-cardiac surgical mortality and morbidity for each of the 125 participating VAMCs, the 21 Veterans Integrated Service Networks (VISNs) and for a national roll-up. NSQIP data are reported as an observed to expected (O/E) ratio of both mortality and morbidity. For example, a mortality O/E ratio of 1.0 means that the number of observed deaths is equal to be number of expected

[1] Daley J, Khuri S, Henderson WG, et al. The Department of veterans Affairs' NSQIP: The first national , validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. Ann Surg, 1998:228:491-507.

deaths. Expected deaths (mortalities) and morbidities are calculated from the actual pre-operative risk factors for each VAMC and a predictive model based on the current year overall performance of the entire VA. An O/E ratio of less than 1.0 is desirable, indicating outcomes better than expected. An O/E ratio that is significantly above 1.0 suggests opportunity to improve care. NSQIP reports identify VAMCs that are statistically above or below the expected number of morbidities or mortalities among surgery patients. Beginning originally as annual reports, in 2007 NSQIP information became available quarterly via a secure Web site. VAMCs with an unexpected high number of morbidities or mortalities are required to provide an internal assessment and corrective action plan. Persistent or intermittent outliers may be reviewed on site by NSQIP quality of care review teams.

III. Facility Profile

The Medical Center is located in rural south central Illinois. The town of Marion itself has a population of about 16,000. The Medical Center, a part of VISN 15, operates 55 acute beds and a 60 bed Nursing Home Care Unit (NHCU) and provides primary and specialty medical, surgical, extended and psychiatric care. The Medical Center includes four Community Based Outpatient Clinics (CBOCs) at Mount Vernon, IL; Paducah, Kentucky (KY); Effingham, IL; and Hanson, KY. There is also a satellite Outpatient Clinic in Evansville, Indiana. Patients needing care beyond the Medical Center's capability are referred, if appropriate, to the St. Louis VAMC, about two and a half hours away by automobile. The Medical Center has academic affiliations with the Southern Illinois University School of Medicine and a number of other academic institutions covering social work, pharmacy, and nursing. The Medical Center has approximately 44,000 unique patients, up from approximately 20,000 in 1997.

IV. Methods

The OMI team consisted of the Medical Inspector, the Senior Surgical Investigator, the Senior Medical Investigator, and a Clinical Program Manager (a Registered Nurse). Prior to the site visit, the OMI spoke with the members of the NSQIP team that had visited the Medical Center and reviewed their preliminary report. The OMI team made a site visit to the facility on September 5-6, 2007. Entrance and exit briefings were held with Medical Center leadership. The OMI team toured the hospital building including the operating rooms (ORs), post anesthesia care unit (PACU), intensive care unit (ICU), post operative ward, and the new cardiac catherization laboratory and recovery area. Interviews were conducted with a large number of physician, nursing, and administrative personnel. OMI reviewed the relevant VHA and Medical Center policies, reports, committee minutes, and quality management documents, to include:

a. VHA Handbook 1100.19, *Credentialing and Privileging.*
b. VHA Directive 2004-051, *Quality Management (QM) for Patient Safety Activities that can generate Confidential Documents*
c. VHA Directive 2004-054, *Peer Review for Quality Management*
d. VHA Directive 2004-061, *Veterans Rural Access Hospitals*

e. VHA Directive 2005-056, *Mortality Assessment*
f. VHA Handbook 1004.3 *Do Not Resuscitate (DNR) Protocols within the Department of Veterans Affairs (VA)*
g. NSQIP FY 2006 VAMC Report
h. VISN 15 Policy 15C-00-10, *Policy for the Consolidated and Centralized Program for Credentialing and Privileging.*
i. Medical Center Memorandum11-11-06-023, *Clinical Executive Board*
j. Medical Center Memorandum 11-11-06-195, *Medical Staff Appointments and Clinical Privileges*
k. Medical Center Memorandum 00-00-07-201, *Governance, Executive Leadership, and Management*
l. Medical Center Memorandum QM-00Q-06-57, *Quality Management Systems (QMS) Performance Improvement Plan*
m. Medical Center Memorandum SS-112-07-205, *Surgical case TQI Review Committee*
n. Medical Center Memorandum MA-136-06-131, *Advance Directives*

Upon return to VA Central Office (VACO), the OMI briefed the PDUSH and the Under Secretary for Health (USH) on its preliminary findings. The OMI expressed serious concerns about clinical care at the Medical Center and recommended to the USH that the halt to inpatient surgery be continued and a more comprehensive investigation be undertaken. Since the site visit, the OMI has been in constant contact with the Medical Center requesting additional documents and information, as well as reviewing Computerized Patient Record System (CPRS) records on over 200 patients.

Based on the NSQIP and OMI teams' verbal reports, the USH made a number of decisions in regard to management actions and further investigations at the Medical Center.

V. Findings

A. Findings related to Medical Center clinical services

Over the past 2 years, the Medical Center leadership has made a concerted effort to increase services to its growing patient population by increasing the scope and complexity of the surgeries performed within the Medical Center. This expansion was undertaken to decrease the cost of fee-based care in the community and to accommodate the local veterans' reluctance to travel to the St. Louis VAMC for care. This expansion of services included a new total joint replacement program, an increase in vascular surgery, the introduction of thoracic surgery, as well as more complicated general surgery. The table below shows that both the number of NSQIP eligible cases and their complexity have increased over the past few years.

Year	# NSQIP cases	% complex cases†
FY 2003	299	7.6
FY 2004	412	7.5
FY 2005	332	8.6
FY 2006	564	10.6
FY 2007	641*	17**

† surgeries that fall into the top 20 percent of all VA surgeries based on Resource Based Relative Value Scale values
* annualized based on 1st, 2nd and 3rd quarter FY 2007
** 1st, 2nd and 3rd quarter FY 2007

In the face of the expansion of surgical services, the basic infrastructure of the Medical Center remained unchanged, with 40 acute medical beds, 6 acute surgical beds, and 8 mixed (i.e., surgical and medical) ICU beds. There are four procedure suites. Two are utilized as full service ORs, one is used solely for storage and one is dedicated to endoscopic procedures. The PACU is open from 8:00 am until 4:30 pm and is staffed by a rotation of OR nurses. Surgical cases finishing late or after normal duty hours are taken to the ICU to recover at a time of diminished ancillary support. Often complex in-hospital emergencies were done at the end of the day after the scheduled, elective cases were completed.

There is a hospitalist[2] service during normal duty hours (8:00 AM to 4:30 PM) Monday through Friday. Evening and overnight hours in the Medical Center are covered by the physician present in the Emergency Room. Weekend days are covered by a rotation of hospitalists and primary care physicians. Attending surgeons are available to respond to their patient's needs 24/7 with a cross coverage arrangement. The surgical staff during the index period (FY 2006-2007) consisted of two urologists, three general surgeons, one orthopedic surgeon, a podiatrist and two ophthalmologists. Part time fee-based community surgeons provide additional support. Anesthesia services were provided by two anesthesiologists and a series of locum tenens providers. After regular duty hours, on weekends and holidays, there is no in-hospital respiratory therapy, pharmacy or radiology technician support. Respiratory services, including initiation and management of ventilator care, are provided by ICU nurses who are supported by special training and an annual competency program.

B. Findings related to Medical Center and VISN response to NSQIP

In January 2006, the NSQIP Executive Team requested that the Medical Center develop an action plan to address concerns about their FY 2005 NSQIP data including a mortality O/E ratio of 1.7. In October 2006, the Medical Center received notification that their plan addressing the NSQIP concerns had been accepted and that no further actions were

[2] Physicians who provide inpatient care only

required. In January 2007, the FY 2006 NSQIP report was released showing the Medical Center's O/E mortality ratio was 0.88 based on five NSQIP eligible deaths for the year.

During the week of April 26, 2007, VISN 15 received the Medical Center's first quarter FY 2007 NSQIP data that showed an O/E mortality ratio of 4.3 which represented seven NSQIP eligible deaths in the 3 month period with fewer than 2 deaths expected. The next week, the VISN 15 Chief Medical Officer (CMO) met with the Medical Center Director at a previously scheduled gathering in Kansas City and discussed the data. Medical Center leadership had seen the NSQIP data earlier in April and were working on a response. An April 30, 2007, memo from the Medical Center's Chief of Surgery outlined the facility plan which included a "cross review" of cases within the Medical Center that found care to be appropriate in all of the mortal cases. At the May 2007, VISN 15 executive meeting, the CMO again spoke with the Medical Center Director, who stated that the follow-up surgery case reviews had not identified any problems. The Medical Center was also working to implement some of the staffing and operational changes that had been suggested by a visiting NSQIP nurse consultant in October 2006.[3] In mid-July, the VISN CMO became aware of the Medical Center's second quarter FY 2007 NSQIP data and was reassured by the fact that there had only been two additional NSQIP eligible deaths during the second quarter even though the 6 month O/E remained high because of the first quarter spike.

About August 10, 2007, the Medical Center Chief of Staff notified the VISN CMO that there had been four additional surgery-related deaths at the Medical Center within the preceding 2 months. The VISN CMO directed that the cases be peer-reviewed outside of the Medical Center. A general surgeon involved in several of the cases (surgeon A) resigned the following week.

During the week of August 13, 2007, the NSQIP Executive Committee notified VISN 15 and the Medical Center that they would be conducting an urgent site visit. A general surgeon, an anesthesiologist and the NSQIP National Nurse Executive, visited the Medical Center on August 29-30, 2007. The NSQIP team found a number of areas for concern, including inadequacies in the facility's monitoring of its quality improvement activities. The team also cited deficiencies in the facility's credentialing and privileging process, in adverse events and quality oversight, and in communication processes and the ability of the facility staff to work as a team to address problems in these areas. The NSQIP team reported a general fear of retaliation that discouraged the staff from expressing the seriousness of the problems to management. These findings in the NSQIP team's preliminary report and their recommendation to suspend all surgery requiring inpatient hospitalization led the PDUSH to request the OMI site visit.

C. Findings related to Medical Center staff concerns

Interviews with numerous staff nurses, including supervisors, revealed that nurses felt they were not prepared to care for the more complex cases in vascular surgery, thoracic surgery, orthopedics, and general surgery that had recently been undertaken at the

[3] See page 7 following

Medical Center. The nurses felt that they were sometimes asked to do things that were not safe for their patients. Many felt that the facility was attempting to provide services without the proper infrastructure to support them. They expressed concern that the expansion of services to more complex cases had not been done properly and was undertaken without an overall plan.

Some staff felt that, when they voiced patient safety concerns (including those about the rapid expansion of surgical scope of services), their concerns were dismissed as unimportant. Nurses who took their concerns to the Chief of Surgery were told, "...that's the way the Chief of Staff wants it." One senior nurse took concerns directly to the Director and was told, "...my hands are tied." Interviews with a number of staff indicated that there was no feedback provided on significant adverse events that had been identified. Staff had a clear sense that dissenting opinions were not welcome. Nurses told the OMI that, when they heard that peer reviews done within the Medical Center had concluded that care was appropriate, they expressed their concerns about the validity of these peer review findings. They felt like their concerns about the competency of certain providers at the Medical Center were not addressed.

OMI's initial review of several cases revealed evidence of poor surgical judgment; poor fluid management; airway management problems; delay in diagnosis and treatment; and lack of timely initiation of appropriate actions during periods of clinical deterioration. In several of these OMI reviews, some or most experienced, competent practitioners *would have* managed the case *differently* in one or more aspects of care. This assessment contrasted with the peer reviews performed by the Medical Center which determined that most experienced, competent practitioners would have handled the case similar in all aspects.[4] A more detailed review of cases is addressed below beginning on page 16.

D. Findings related to Medical Center leadership

The OMI review of the Medical Center leadership was focused at the facility level and within the Surgery Service and the services supporting surgery (e.g., OR, ICU, hospitalists).

The senior leadership team at the Medical Center has been stable in their current roles for a number of years. The exception is the Associate Director who departed earlier in 2007 with the position currently being filled by an acting Associate Director. During the OMI entrance and exit brief, the Director did not take a leading role in discussions and deferred most questions to the Chief of Staff (COS) and the Manager for Clinical

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[4] In VA, individual provider peer reviews are assigned one of three levels, they are:
Level 1 - Most experienced, competent practitioners would have managed the case similarly in all aspects.
Level 2 - Most experienced, competent practitioners might have managed the case differently in one or more aspect.
Level 3 - Most experienced, competent practitioners would have managed the case differently in one or more aspect.

Services for the COS. In the staff interviews, there was little mention of the Director's role.

In the third quarter of FY 2005, the clinical services at the Medical Center were realigned so that nursing personnel no longer reported to the COS but instead were supervised exclusively by the Nurse Executive who reported directly to the Medical Center Director. Functional areas were organized into care lines and a number of Associate Chief Nurse positions were created to partner with physician care line directors. A series of key policies were reissued in March 2006 to support this reorganization (Clinical Executive Board, Medical Staff Appointments and Clinical Privileges, Focused Practitioner Performance Review Process and Quality Management System Performance Improvement Plan).

In early 2006, the Chief of Surgery resigned and was replaced by an ophthalmologist from the St. Louis VAMC. That incumbent Chief of Surgery reported to OMI that he had had no significant prior administrative experience. There was little interest in administrative roles among the Medical Center surgeons as evidenced by the fact that a podiatrist often serves as the Acting Chief of Surgery. This change in surgical leadership occurred at the same time that a number of new surgeons were added to the Medical Center staff (including surgeons A and C), surgical services were expanded and OR throughput increased.

The increase in surgical case load and complexity led the Medical Center to request help in assessing their needs. A nurse manager (who was also a NSQIP Coordinator) from Lexington VAMC visited the Medical Center in October 2006 to consult on their perioperative services. Her report provided a thorough review of staffing models, OR utilization, quality structures and use of the CPRS surgery package. A number of specific recommendations were made for the Medical Center including the admonition, that "expanding surgical programs…before your OR is on solid ground…can lead to adversity." The nurse manager then cited a number of areas for consideration and concluded that "requiring a business plan before a new type of service is offered will prevent problems at a later date." The Medical Center did not generate a business plan for expansion of their surgical services as they had done with their recent expansion of cardiology services.

This nurse consultant visit was followed by a visit in December 2006 by the Chief of Surgery from Hines VAMC in Chicago. His focus was also on perioperative performance, and he made a number of recommendations to increase OR efficiency. He also suggested changes in oversight including the formation of an OR Committee and better coordination between the Chief of Surgery and the local NSQIP nurse. His final suggestion was to "follow the recommendations contained in the report from the nurse consultant."

In May 2007, the Medical Center Memorandum on Governance, Executive Leadership and Management was re-issued. This revised and redefined some of the responsibilities and duties of the key committee structure and defined a new format for committee

reporting. In the summer of 2007, an ad hoc OR committee began to meet and a Chief, Anesthesia Service was appointed.

The relationship between the Nurse Executive and the COS did not seem to be working well. This could have been due to the structural changes over the past 2 years or to inter-personal differences, or more likely a combination of the two. There have been struggles over "boundary issues" and this has led to a passive approach to critical issues. A senior staff member commented that there is a "war between the Chief of Staff and the nurses." The COS is seen as directive and arbitrary and not respectful of differing opinions. The poor working relationships among the senior leadership contributed to poor morale and undermined organizational performance.

Several nurses said that they were intimidated by the COS and Director. They said there was a poor leadership climate and that the environment for taking their concerns up the leadership chain was ineffective. They believed that nurses were blamed for everything including recent bad surgical outcomes. Several individuals, including some senior nursing and medical staff stated that they felt that their jobs would be in jeopardy if they were identified as speaking out. There was obvious concern about maintaining anonymity during the OMI visit and in phone calls OMI received from Medical Center staff after the visit. OMI was told of one provider who had a proficiency rating marked down because the provider had complained about quality of care. OMI did not interview that provider.

E. Findings related to Medical Center quality management

The Medical Center's Quality Management (QM) team is comprised of a total of 22.5 Full Time Equivalent Employees (FTEEs), 9 of whom are dedicated to the facility's utilization review and fee basis monitoring programs. The remaining staff are allocated to quality programs including infection control, NSQIP, risk management, and patient safety. The QM Director reports directly to the Medical Center Director. The Medical Center Performance Improvement Plan describes a decentralized strategy wherein the clinical care lines monitor quality activities and are responsible for addressing improvement opportunities. This approach requires each clinical area to develop and implement a service/program-specific quality monitoring and management plan, evaluate its effectiveness, and make appropriate modifications annually. For the Surgical Care Line, critical monitors were identified as infection control, NSQIP, utilization management, patient safety, risk management, and peer reviews.

The OMI team interviewed the QM Director, who has held this position for 10 years, to determine how the surgery program was integrated within the hospital QM program activities. When questioned about the NSQIP data, she became defensive about the Medical Center's failure to detect and respond to the recent increase in surgical mortality. The QM Director had limited knowledge of the NSQIP program in general and the VAMC's specific performance in that program. She stated that the NSQIP coordinator had run the program autonomously until her retirement in April 2007. The QM Director had sanctioned this independence and did not provide oversight to this activity. Since the

NSQIP coordinator's retirement, two nurses from QM have been assigned NSQIP monitoring as a collateral duty and are undergoing training with the NSQIP National Nurse Executive.

The QM Director's primary function appeared to be one of assembling data and charts but she did not seem to have the capacity or relationships to partner with the Medical Center clinical leadership to effect change. She said that she had "...given up on Surgery Service years ago" when the previous Chief of Surgery had asked her to "...leave things alone." She indicated that QM support of surgery was limited to providing the Chief with a list of occurrences from NSQIP or other sources for inclusion in their monthly Total Quality Improvement (TQI) meeting and then tracking peer review findings of Levels 2 or 3, a notably rare event in their peer review process. In addition to the occurrence screening by QM, the Surgery Service attempted to collect monthly mortality and morbidity (M&M) sheets from their surgeons. Not all surgeons, to include the Chief of the Surgery Service, were aware of this effort. There was evidence that the surgeons had all received the requests for M&M information, and each had, on at least one occasion, turned sheets into the service secretary. This hands-off attitude and failure to follow through on spotty performance was a common finding in many activities at the Medical Center.

The QM Director indicated that the Risk Manager (RM) for the facility had been in that role for only 2 weeks. Prior to that, the QM Director also performed the RM duties. She explained that her activities as RM were limited to processing "tort claim" requests and discussing these with Regional Counsel.

The OMI team reviewed the minutes of the Surgical Case Review Committee meetings from January 2006 to August 2007. These minutes summarize their staff meetings which encompassed their service-specific quality improvement work, M&M reviews, and peer review. It was found that, from January to July 2006, the minutes followed a format with a relatively comprehensive summary of cases that appear to have been triggered by occurrence screens generated by QM. In most cases, the reviewers assigned a peer review level, almost exclusively level 1. There was little documentation that cases were discussed openly in the collaborative, lessons-learned manner that is generally associated with M&M review. There are reports from September 2006 and February-April 2007 with a 4 month gap in committee minutes from October 2006 through January 2007. The committee's ongoing reviews of surgical occurrences and perioperative complications were inconsistent and superficial. Despite the scanty documentation, a peer review level was assigned to each case discussed—again, almost exclusively a level 1.

Because of the small size of the surgical staff, "peer reviews" were often performed by surgeons in dissimilar practices (e.g., a urologist reviewed orthopedic cases or an ophthalmologist reviewed general surgery). This practice is not in compliance with VHA Directive 2004-054, *Peer Review for Quality Management* which defines a peer as "an individual of similar education, training, licensure, and clinical privileges." Of 28 mortalities and about 180 morbidities discussed in the last 2 years during the Medical

Center's M&M conferences and peer reviewed by Surgery Service, all cases but two were evaluated as Level 1. The two other cases were both rated Level 2. At the time of the OMI visit, one as yet not reviewed case that the OMI voiced concern about was evaluated as a Level 3.

Cases were evaluated in isolation with a limited exploration of root causes and without viewing outcomes in a larger context. The May 7, 2007, minutes of the Clinical Executive Board summarized the April 2007 mortality analysis by concluding that "...the number of deaths is increasing; the higher number of deaths correlates with the number of patients with terminal illness and DNR[5]; and no adverse trends were noted." This analysis included the timeframe of the alarming NSQIP first quarter FY 2007 report of increased surgical mortality.

OMI interviewed the Patient Safety Manager (PSM) to explore how the surgery program was integrated into the facility Patient Safety Program. The PSM is a licensed practical nurse with a baccalaureate in social work reported and has been in the position for the past 2 years. She indicated that Surgery Service participated in the program by having appointed one of the surgeons as a member of a recent root cause analysis (RCA) team exploring systems issues related to a recent, unexpected death following a laparoscopic cholecystectomy. She also stated that the OR Nurse Manager was a member of the facility Patient Safety Council. A review of the Patient Safety Council minutes from February 2006 to July 2007 was conducted with the assistance of the PSM. This revealed that the Patient Safety Council meetings did not include any Surgery Service activities that would suggest active participation in the Patient Safety Program monitoring. During the interview, the PSM reported that, in addition to verbal disclosures of events, staff members were required to complete an electronic incident report when they became aware of an incident or close call. These reports would be screened and scored using the safety assessment code (SAC), and the QM Director would then determine which improvement method would best address the problem. The PSM reported that Surgery Service mostly submitted reports of contact (ROC), which went directly to the QM Director. If the incident required a root cause analysis (RCA), then the report would be forwarded to her. The RCA tracking spreadsheets dating from FY 2006 to the fourth quarter 2007 were reviewed with the participation of the PSM. There were no RCAs of surgical events during this time, except for the very recent one to explore if there were any systems issues related to an unexpected death following a laparoscopic cholecystectomy.

F. Findings related to credentialing and privileging

The credentialing and privileging (C&P) process at the Medical Center is part of the VISN 15 Consolidated and Centralized Program for Credentialing and Reappraisal. This office is responsible for obtaining all credentialing documentation necessary for a candidate to request initial clinical privileges as outlined in VHA Handbook 1100.19, *Credentialing and Privileging*. The Medical Center's Credentialing Coordinator reported to OMI that her position operates organizationally under the COS. She has been with VA

[5] DNR - do not resuscitate

for 28 years and assumed her position as Credentialing Coordinator in November 2004. The C&P process includes receiving the job application from Human Resources and sending it to the VISN's Consolidated and Centralized Program for Credentialing and Reappraisal at the Leavenworth VAMC for credential verification, National Practitioner Data Bank (NPDB) screening, and all other elements delineated in the VHA Handbook 1100.19. Once a completed application packet is received, she gives it to the COS's administrative assistant. In what would appear to be an unusual arrangement, the Credentialing Coordinator explained that she does not attend the Professional Standards Board (PSB) during which the packet would be reviewed.

The OMI team reviewed the credentialing files of four Surgery Service physicians. These files were kept by the Credentialing Coordinator. Of particular interest was the file of a general surgeon (surgeon A) who resigned his position with the Medical Center in August 2007 following the deaths of several of his patients. OMI constructed a timeline of events related to the credentialing and privileging of surgeon A based on Medical Center files, discussions with VISN C&P staff and queries to state licensing authorities.

- November 25, 2005 – Surgeon A applied for surgical privileges at the Medical Center

- December 23, 2005 – Massachusetts (MA) license verified as full and unrestricted by MA Board of Registration in Medicine (MA Board).

- January 17, 2006 – Illinois (IL) license verified as inactive without any disciplinary actions. Surgeon A also has an inactive New York license that is considered to be in good standing.

- January 20, 2006 – Medical Center notified of NPDB report on two malpractice payments
    - $350,000 – incident April 24, 2002 – alleged negligent surgery resulting in death
    - $700,000 – incident March 27, 2000 – alleged negligent surgery resulting in complications and subsequent death of patient several months after first surgery

- January 20, 2006 – With the endorsement of the Acting Director, Surgical Specialty Care Line and the COS, Medical Center Professional Standards Board (PSB) granted Surgeon A privileges in surgery based on the available credentialing data. Licensure was verified; references were good;[6] and education, training and Educational Commission for Foreign Medical Graduates certificate

[6] Comments from the Chief of Surgery where he had practiced for 30 years include, "technically excellent surgeon", "manages full scope of general surgery and thoracic surgery", "extremely dependable, always around to help even when not on call" and "will miss him at our institution." The letters from three other peers were uniformly positive with all rating him satisfactory (the highest option) on all dimensions and all three recommending him without reservations. Comments included, "technically gifted", "busy and much in demand as a surgeon", and "I would hire him as a surgeon anytime."

were verified. Two of the letters of recommendations from the hospital where he had practiced for 30 years and had full and unrestricted privileges mentioned a period of monitoring in 2004 for medical records concerns. The PSB was aware of the NPDB reports mentioned above.

- January 26, 2006 – Surgeon A requested additional privileges for minimally invasive surgery procedures and thoracic surgery. The Medical Center queried the MA Board about his license and the license was verified it to be full and unrestricted. The NPDB had no new information. These additional privileges were granted by the PSB on February 2, 2006.

- February 27, 2006 – Surgeon A requested additional privileges for breast biopsy, simple and modified radical mastectomy, sentinel node biopsy and total abdominal hysterectomy only in association with surgery for cancer of the rectum/colon. The Medical Center queried MA about his license; the MA Board verified it to be full and unrestricted. The NPDB had no new information. These additional privileges were granted by the PSB on March 2, 2006.

- March 22, 2006 Surgeon A certified by the American Board of Surgery.

- July 7, 2006 – Surgeon A's Illinois (IL) license re-instated as full and unrestricted with no disciplinary history.

- July 7, 2006 – MA Board verified Surgeon A's MA license as full and unrestricted, and valid until February 1, 2007

- August 1, 2006 – VACO received a disciplinary alert that Surgeon A had signed an agreement with the MA Board on July 12, 2006 to voluntarily cease practice in the state of MA. The Board noted its action was non-disciplinary. The VISN 15 Credentialing Office was notified.

- August 2, 2006 – MA board confirmed that Surgeon A had signed an agreement to voluntarily cease practice of medicine in MA. Additional information was requested by the VISN Credentialing Office but there was no further public information. MA Board acknowledged there was an investigation in process. It was confirmed Surgeon A signed the agreement effective on July 12, 2006. MA Board reported this action to the Board of the Health Care Integrity and Protection Data Bank.

- August 2, 2006 – IL Board verified Surgeon A's license as active with no disciplinary history.

- August 2, 2006 – A NPDB query revealed the two previous known medical malpractice payments and the new licensure action again noted as non-disciplinary voluntary agreement to cease the practice of medicine in MA.

- August 21, 2006 – Surgeon A reported to Medical Center leadership that he signed the agreement because he no longer intended to practice in MA and provided a copy of his February 15, 2006 letter to the MA board. Surgeon A mentioned in this letter that the hospital where he had held privileges for 30 years had disciplined him for inadequate record keeping.[7]

- May 3, 2007 – Surgeon A applied for additional privileges for esophagectomy at the Medical Center. At this time he did report an open investigation in MA related to a number of surgical complications experienced by patients in his former practice.

- June 3, 2007 – NPDB reported a third medical malpractice payment with date of incident being November 3, 1997. Payment of $600,000 was for alleged negligent performance of an inguinal hernia repair resulting in sutures retained in the urinary bladder.

- June 15, 2007 -- Surgeon A's request for additional privileges for esophagectomy were granted by the PSB based on the fact that he had held this privilege before at another hospital. The PSB minutes do not reflect discussion of the ongoing investigation in MA. There was no discussion of surgeon A's recent eye surgery.[8]

- August 13, 2007 -- Surgeon A resigns from his position at the Medical Center VAMC

OMI notes some discrepancies in the number of reports on surgeon A to the NPDB with some documents recording three while others record four. Given the information available to the OMI at this time, Surgeon A had a full and unrestricted license from MA at the time of his initial credentialing and privileging at the Medical Center. Surgeon A reactivated his IL license and had a full and unrestricted license from IL at the time of his voluntary agreement with MA to cease practice in that state. Surgeon A reported that he signed the agreement because he no longer intended to practice in MA and provided VISN credentialing staff with a copy of his February 15, 2006 letter to the MA Board. Surgeon A mentioned in this letter that the hospital where he had previously held privileges had disciplined him for inadequate record keeping.

A December 19, 2005, Memorandum from the Acting Deputy Under Secretary for Operations and Management (10N), Subject, Implementation and Compliance with Title

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[7] According to the Chief of Surgery where he had practiced for many years, his privileges were "restricted" in that another surgeon had to review and approve his cases before surgery. After a several month period of monitoring, his record keeping improved and the monitoring was stopped. The MA Board stated that the hospital reported this to them in March 2004 as an education/training/ counseling/monitoring event and that the MA Board did not consider this a restriction by their statutory definition even though the hospital had used that term in their report to the Board.

[8] See page 15-16 following

38 U.S.C. section 7402(f) addresses providers that are licensed in two or more states. Paragraphs 2 and 3 of the Memorandum follow below.

> 2. Background. Title 38 U.S.C. section 7402, Qualifications of appointees, was amended by Public law 106-117, section 209. The amended provision, 38 U.S.C. section 7402(f), provides that a physician, dentist, nurse, podiatrist, optometrist, pharmacist, psychologist, social worker, chiropractor, expanded-function dental auxiliary, licensed physical therapist, licensed practical nurse, or licensed vocational nurse may not be employed in such a position if:
>
> a. the person is or has been licensed, registered or certified (as applicable to such a position), in more than one State; and
>
> b. either
>
> 1. any of those States has terminated such license, registration, or certification for cause; or
>
> 2. the person has voluntarily relinquished such license, registration, or certification in any of those States after being notified in writing by that state of potential termination for cause.
>
> 3. In defining "for cause" VHA looked to other policies to ensure consistency throughout the Administration. The definition of "for cause" is "substandard care, professional misconduct or professional incompetence."

The OMI has been unable to determine if anyone from the Medical Center or the VISN 15 Consolidated and Centralized Program for Credentialing and Reappraisal made any further inquires of the MA Board after being told that surgeon A's agreement to cease practice was voluntary and non-disciplinary, and that there was no further public information. The VISN 15 Consolidated and Centralized Program for Credentialing and Reappraisal was told by the MA board that an investigation was ongoing but there is no record of anyone calling back at a later date to determine the results of that investigation. There is no evidence that the Medical Center made any effort to evaluate the underlying circumstances of Surgeon A's agreement with the MA Board not to practice and there was no follow-up on the ongoing MA investigation. In May 2007, when surgeon A was granted additional privileges at the Medical Center and mentioned the ongoing investigation in MA, apparently no one queried this issue.

The OMI has learned that the MA Board issued a Statement of Allegations to surgeon A on January 24, 2007. Even though surgeon A's MA license expired on February 1, 2007, the MA Board continued their action. Surgeon A "appealed" and had a hearing scheduled before the Division of Administrative Law in late October 2007. However, on October 19, 2007 he signed a document resigning his MA license (a disciplinary action) and agreeing to "resign any other licenses contemporaneously...and...make no attempt to seek licensure elsewhere." [9]

[9] http://www.massmedboard.org/public

The Medical Center's PSB minutes for the meetings in which surgeon A had additional privileges added reported that "...Members [of the PSB] based competency on previously held privileges at another hospital." VHA Handbook 1100.19, *Credentialing and Privileging,* paragraph 6c(1)(b) states "...Each service chief must establish additional criteria for granting of clinical privileges within the service consistent with the needs of the service and the facility. Clinical privileges must be based on evidence of an individual's current competence. When privilege delineation is based primarily on experience, the individual's credentials record must reflect that experience and the documentation must include the numbers, types, and outcomes of related cases." [10]

The OMI also reviewed quality profiles used for privileging maintained by the facility's QM Director. The files were found to contain the required credentialing documents necessary for requesting initial privileges. However, for the portion of quality improvement activities for the continued evaluation of professional performance, judgment, clinical and technical competence and skills, the quantitative data lacked case denominators. Therefore, the required analysis for approval of continued or newly requested privileges could not have been adequately performed.

The OMI team found that surgeon A's file included a "Summary Analysis of Quality Assurance (QA) Folder" written by the QM Director. The document contained quality indicator data on [redacted] for FY 2007. "...There were [redacted] The conclusion by the QM Director was "...General review of the clinical performance folder on this provider reveals sufficient evidence to support clinical competence and the recommendation to grant clinical privileges." The QM Director reported that this conclusion was the template she was instructed to use when she became QM Director about 10 years ago and was applied to all such practitioner reports to the PSB. There was no evidence of senior clinician review of the data or summary statement.

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After the Medical Center site visit, OMI became aware through a newspaper article that Surgeon A had undergone an ophthalmologic procedure early in 2007. This was the first indication that surgeon A had any visual problem. A review of the VistA Surgery Package revealed that surgeon A conducted no surgery between February 21 and March 14, 2007. His attendance record was obtained from the Medical Center administration and it showed that [redacted] However, the events resulting in that record were complicated. Originally, a request was approved on January 5 by the COS for [redacted] On February 20, the Chief of Surgery approved [redacted] On March 14, a leave adjustment was made changing the period of [redacted]

[10] The VHA handbook quoted is dated March 6, 2001. A new VHA Handbook 1100.19 was issued on October 2, 2007.

[redacted]

OMI interviewed the Chief of Surgery who corroborated the leave period and filled in some gaps. Surgeon A did not show up for work on Friday, February 23, 2007, and Medical Center staff contacted him the next week on his cell phone. Surgeon A told the Chief of Surgery that he had suffered a retinal detachment and had sought care in the local community on Friday, February 23, 2007. Surgeon A then had a follow-up evaluation near his previous home in Massachusetts. Surgeon A stated that he had been treated with laser therapy in the local community and that his Massachusetts ophthalmologist had told him that the care he had received was appropriate and sufficient. The Chief of Surgery (an ophthalmologist) contacted the local treating ophthalmologist who indicated that Surgeon A had presented with an acute, non-traumatic peripheral retinal detachment that had been treated with laser. The Chief of Surgery adjusted Surgeon A's absence to reflect [redacted]

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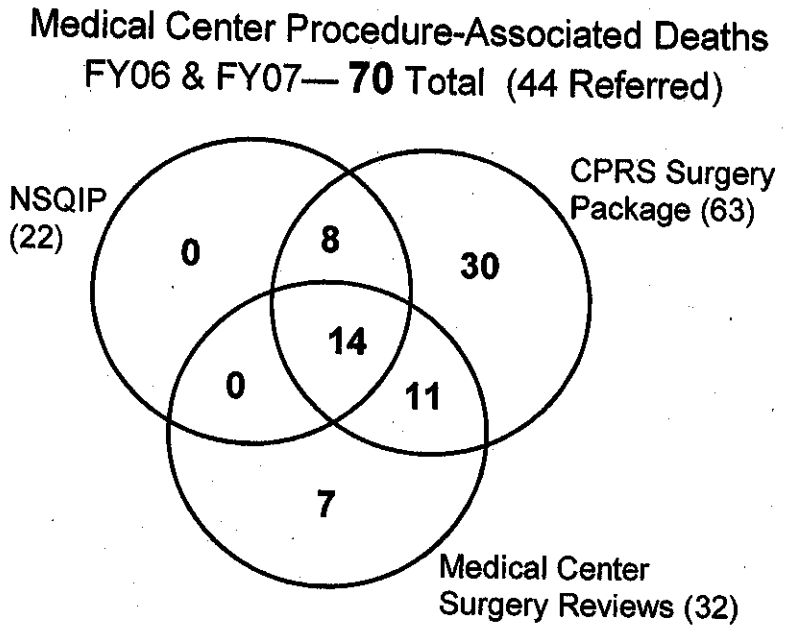
On March 14, 2007, Surgeon A returned to his full surgical practice. There is no indication in the PSB minutes or in Surgeon A's occupational health record that his vision was ever assessed following his retinal detachment and therapy. The Chief of Surgery, himself an ophthalmologist, stated that the peripheral nature of the detachment should not have interfered with his central vision but does not have recollection of a formal evaluation. Records from the treating ophthalmologist were not obtained. At a subsequent PSB, Surgeon A was granted additional privileges for esophagectomy and no mention was made of his potential visual difficulties.

It is not possible to determine from the pattern of care that there was any difference in Surgeon A's technical (visual) performance before or after the retinal detachment. Many cases which were judged to not meet the standard of care occurred prior to the detachment. At a minimum, this sequence of events reveals a lack of experience and a failure of oversight in returning a physician to duty with a potentially significant medical condition without an objective evaluation of any potential degree of impairment.

G. Peer reviews of mortality and morbidity during FY 2006-2007

The inquiry into clinical activities at the Medical Center was triggered by an unusual number of deaths that occurred within 30 days of surgery during the first half of FY 2007. Following the site visit, the OMI initiated a systematic review of surgery-associated deaths and complications for the last two fiscal years. This was done in order to evaluate the contribution of individuals and systems to the overall quality of care and to identify cases with adverse outcomes where it would be appropriate to disclose the circumstances of care to veterans or their families.



The OMI evaluation began with an inventory of procedure-associated mortality. The NSQIP national program office provided a list of 22 deaths which had occurred within 30 days of a NSQIP assessed case at the Medical Center for FY 2006 and through most of third quarter FY 2007. From the FY 2006 and FY 2007 quality assurance minutes for the Medical Center Surgical Services Care line, OMI identified 28 mortality cases that had been evaluated. Four additional cases were identified but not yet formally discussed at the time of the OMI site visit. The Medical Center surgery peer reviews covered a broad array of cases which had been identified from multiple sources. There was considerable overlap between the NSQIP mortality cases and the Medical Center reviews, with 14 cases common to both lists. However, 8 deaths captured by NSQIP had not been reviewed by the Medical Center surgeons and 18 cases reviewed by the Medical Center were not in NSQIP. This was not a failure of NSQIP as only two of the 18 were major surgical cases and they had occurred so recently that they had not yet been entered into the NSQIP database. The other 16 cases did not meet NSQIP criteria for inclusion. One veteran died after being transferred to a community hospital for a surgical procedure, six were major surgical cases where the veteran died more than 30 days after the procedure, and nine were deaths which had occurred after minor procedures which would not be included in NSQIP. The latter included colonoscopy, bronchoscopy, cataract surgery, and prostate biopsy. All death cases from NSQIP and the Medical Center minutes were sent for independent peer review as detailed below.

In addition to reconciling the NSQIP and Medical Center Surgery review lists, OMI extracted all procedures from the CPRS VistA Surgery Package. This included identification of any death which occurred within 30 days of any procedure entered into the Surgery Package. At the Medical Center, the Surgery Package is used to track not

only major surgical cases (i.e., NSQIP) but all same-day minor surgeries and endoscopies. The CPRS file is likely to be the most complete source of mortality data as the date of death is derived from administrative data sources and does not require an entry by clinical personnel. Consequently, and importantly, death within the 30 day window does not imply a judgment that the death was related to or caused by the procedure. The Medical Center CPRS Surgery Package contained 63 deaths, including all of the NSQIP cases and many of the non-NSQIP cases reviewed by the Medical Center surgeons. However, there were 30 additional cases where the veteran died within 30 days of non-NSQIP procedures and which had not been previously identified. OMI staff reviewed those 30 cases and identified 4 where there was a concern about the quality of care. Those four cases were also sent for independent peer review.

OMI worked with VACO's Office of Patient Care Services (PCS) to obtain independent peer reviews of the 44 mortality cases. A case review form that had previously been used by PCS was adapted for this purpose. Reviewers from outside of VISN 15 were chosen by PCS leadership from among experienced VA staff physicians in appropriate specialties. Each case was sent to a reviewer who was asked to evaluate the individual case and to offer an opinion as to whether the standard of care was met. It was the intent of the OMI to base a standard of care determination on a review of each patient's entire course of care, including care that lead to the decision that surgery was indicated, as well as pre-operative and post-operative care. OMI staff studied the comments of the reviewers and examined the primary case records. OMI's Senior Surgical Investigator and Senior Medical Investigator held discussions with reviewers to resolve questions and differences. A final determination of standard of care was arrived at by consensus. Providers were not interviewed about the specifics of each case.

A similar approach was used to identify cases where there were procedure-associated complications (morbidities) that did not result in death. To meet its mandate for consistency and relevancy across the VA, NSQIP has a rigorous definition of morbidities in 21 well-defined categories. The CPRS Surgery Package supports the NSQIP definitions but offers many other possible classifications of complications for facility specific tracking and quality assurance purposes. OMI started by compiling non-mortal complications that had been discussed and documented in the Medical Center Surgical Services Care line minutes. To this were added cases from the CPRS Surgery Package with any noted complication. From this combined list, veterans were excluded whose cases were already under review because of their death. This resulted in a total of 192 procedures with complications. The list comprised 183 veterans. OMI staff reviewed the records of all 192 procedures and identified 36 where there were questions about some significant aspect of the care provided—14 in FY 2006 and 22 in FY 2007. PCS again distributed the individual cases to VA specialists using the same review form. OMI staff collected the reviewers' opinions and reconciled differences in a manner similar to the mortality cases.

b3

	FY 2006 and 2007 Cases	Cases Less endoscopies	Deaths peer reviewed externally	FY 2006 & 2007 Complications reviewed by OMI	Complications Peer reviewed externally
Total			44	192	36
Surgeon A	481	475	[redacted]		
Surgeon B	614	391			
Surgeon C	597	467			
Surgeon D	349	NA			
Surgeon H	79	NA			
Surgeon E	402	NA			
Surgeon F	502	NA			
Other	NA	NA	8	32	1

Medical Center Surgical Services case volumes and independent peer reviews of deaths and complications. FY 2007 data are complete as of September 19, 2007.

The table above summarizes the findings of the OMI standard of care reviews for both mortality and morbidity cases. In order to put the incidence of these adverse outcomes in perspective, one must consider the volume of cases performed at the facility and by each surgeon. The table shows the total number of procedures in the CPRS Surgery Package for FY 2006 and FY 2007 (through September 19, 2007) for the Medical Center surgical staff. Those total numbers are further adjusted because the Medical Center Surgery Package includes all procedures, major and minor, and the general surgeons at Medical Center performed a significant number of endoscopies (principally colonoscopies). The number of deaths reviewed was similar for the three general surgeons (approximately 2% of non-endoscopy cases). One general surgeon had [redacted] reviewed that did not meet standard of care, another general surgeon had [redacted] reviewed that did not meet standard of care. Four other surgeons had a total of five cases that did not meet standard of care. Therefore, 18 of the 44 mortality cases reviewed did not meet the standard of care.

The same pattern was evident in the morbidity review with 5-8% of general surgery cases having some complication but the number of complications which did not meet standard of care greater for the same two general surgeons. One had [redacted] that did not meet the standard of care and the other had [redacted] that did not meet the standard of care. The nine other cases that were judged to not have met the standard of care were spread among five other providers. One of the patients identified in the complication review died 45 days after his surgical procedure and OMI felt his death was attributable to a delay in recognition of a post-operative complication, making him

the nineteenth mortality that did not meet standard. While the privileges of the three general surgeons were not identical, they cared for a similar number of patients and, during FY 2007 each performed a similar number of colectomies (12, 14 and 11), laparoscopic cholecystectomies (29, 35 and 16) and inguinal hernia repairs (28, 32 and 46). The data for the other surgical specialists are not amenable to such a within-center, within-specialty comparison. There was only one orthopedic surgeon, one part time (fee-based) vascular surgeon and two urologists. The rates of questionable care were much lower for these other surgeons.

PERIOD	PROCEDURE	STANDARD NOT MET
FY2006	Prostate biopsy	Post procedure management
FY2006	I & D foot abcess	Delay in diagnosis or treatment
FY2006	Removal of small intestine	Delay in diagnosis or treatment; Adequacy of technique
FY2006	Bronchoscopy	Post procedure management; Delay in diagnosis or treatment
FY2006	Partial colon removal	Delay in diagnosis or treatment
FY2006	Gangrenous appendicitis	Delay in diagnosis or treatment
FY2006	Gastrojejunostomy and suture ulcer	Delay in diagnosis of post operative complication
FY2006	Exploratory Lap	Incorrect teatment
FY2007	Left hip hemiarthroplasty	Post procedure management
FY2007	Perforated bowel	Incorrect teatment
FY2007	Exploratory Lap	Post procedure management; Delay in diagnosis or treatment
FY2007	Removal of colon/ileostomy	Post procedure management; Delay in diagnosis or treatment
FY2007	Place gastrotomy tube	Delay in diagnosis or treatment; Post procedure management
FY2007	Appendectomy	Delay in diagnosis or treatment
FY2007	Carotid endarterectomy	Incorrect teatment
FY2007	Lap cholecystectomy	Adequacy of technique; Anesthesia/airway management
FY2007	Spleenectomy	Adequacy of technique
FY2007	Removal of infected mesh	Incorrect treatment
FY2007	Esophagectomy	Adequacy of technique; Post procedure management; Delay in diagnosis or treatment

The table above summarizes the timeframe, procedure or diagnosis, and the failed core processes for the Medical Center procedural mortality cases that did not meet standard of care. The underlying process problems where the same in the morbidity cases that did not meet standard of care. While some individual practitioners showed a lack of knowledge, judgment and skill, the failure to provide appropriate care at the Medical

Center was not limited to the technical proficiency of one or two general surgeons and it was not confined to the first half of FY 2007. The Medical Center did not have the infrastructure necessary to support complex inpatient surgical care to a high risk elderly population. There was not a consistent, contemporary approach to mitigating peri-operative risks and to deal with the challenges of post-operative cardiovascular and fluid management. Responsibility for care was often unclear or fragmented. Some patients with catastrophic clinical courses were made DNR just prior to death thereby disarming a critical look at outcomes. Ultimately, the safety net of quality oversight and peer review processes failed to recognize the individual and systemic deficiencies in care so that they could be addressed.

H. Comparison of Medical Center performance to VA facilities with similar surgical volume

The Medical Center operates in a relatively rural portion of Southern Illinois and historically has relied on several local community hospitals and the distant St. Louis VAMC for some higher complexity procedures. Over the last several years, Medical Center surgeons have increased the complexity of the cases they handled. In order to assess whether recent Medical Center surgical practice varied greatly from other like-sized VAMCs, OMI worked with the NSQIP Data Center to identify a matched cohort of VAMCs. All VAMCs were rank-ordered by NSQIP assessed case volume for FY 2006 and the 10 VAMCs just below and the 10 just above Medical Center were selected as a like-sized cohort. Aggregate performance data from this sample of 21 VAMCs are compared to Medical Center statistics in the table below. The data show that the surgical practice at the Medical Center did not differ significantly from that in like-sized VAMCs in terms of the number of high volume index cases tracked by NSQIP for general surgery and orthopedics.

	NSQIP Assessed Volume	Colectomy	Laparoscopic Cholecystectomy	Inguinal Hernia	Total Knee Replacement#
Medical Center FY 2006	572	27	69	107	23
Medical Center FY 2007*	641	37	80	106	29
VAMC Cohort Mean FY 2006	600	31	31	86	38
VAMC Cohort St.Dev.	3.3	9.9	20.2	28.0	19.2
VAMC Cohort Range	502-681	6-48	7-91	41-150	15-83

NSQIP case volume comparison between the Medical Center and a like-sized cohort of VAMCs.

*Medical Center FY 2007 assessed volume is an annualized number based on 9 months of data (481).
Excludes data from three VAMCs with 0 or 1 total knee replacement.

The VA Surgical Care Improvement Project (SCIP) offers a systematic look at some of the core clinical processes that support surgical care. External reviewers evaluate a sample of charts from each VAMC for key indicators. These data are provided back to the VISN and VAMC for improvement activities. The table below compares the FY 2007 performance at the Medical Center to that at the NSQIP like-volume VAMC cohort described above and the entire VHA. Notable differences for the Medical Center were the selection of the wrong antibiotics for colon surgery, the prolonged use of antibiotics in total knee replacements, the low use of beta-blockers peri-operatively and the low use of prophylaxis for venous thromboembolism (VTE). This comparison is congruent with OMI observations of gaps in care based on extensive Medical Center chart reviews.

	Medical Center Cases	Medical Center	Comparable VAMCs	VHA National
Correct Hair Removal	120	100%	100%	99%
Prophylactic Antibiotics Started	33	91%	95%	95%
Correct Prophylactic Antibiotic All	32	75%	97%	95%
Correct Prophylactic Antibiotic for Colectomy	11	27%	87%	85%
Prophylactic Antibiotics Stopped for All	32	66%	93%	87%
Prophylactic Antibiotics Stopped for TKR	14	43%	90%	87%
First Temperature in Range for Colectomy	30	97%	80%	79%
Beta Blocker Therapy Peri-Operative	56	34%	83%	84%
VTE Prophylaxis Ordered	85	61%	86%	82%
VTE Prophylaxis Received within 24hrs	85	61%	84%	80%

FY 2007 Surgical Care Improvement Project (SCIP) performance for Medical Center, like-sized cohort of VAMCs, and the entire VHA.

There is no comparable benchmark for such an extensive external review of the standard of care in a VAMC. However, a comparison may be made to the results of an OMI survey of VAMC peer review practices conducted in late 2006. Aggregate responses for VA showed that over a 7 quarter period (first quarter FY 2005 through third quarter FY 2006), a total of 1218 episodes of care were judged by internal peer review committees to be level 3—"most experienced, competent practitioners would have managed the case differently". This self-reported incidence of problematic care almost certainly underestimates the true frequency of variations in the standard of care in a system that provides approximately 5 million bed-days of care and 60 million outpatient visits annually. Thus the finding of one, or a small number, of aberrant cases is not unexpected over a 2 year period in a facility the size of the Marion Medical Center. In the like-sized cohort of VAMCs described above, responses to the 2006 OMI survey indicated an average for each facility of 16 level 3 peer review determinations over the 7 quarters.

This number represented all peer-reviewed care across all services (e.g., medicine, surgery, ambulatory care, nursing home, mental health). The Medical Center reported only 3 level 3 cases over this same period of time. This OMI review of the Medical Center is focused solely on procedure-based clinical activity—which is only a subset of all care provided—and the number of cases which did not meet standard of care appears to be excessive.

I. OMI impressions on overall Medical Center systems of care

OMI staff have had a unique opportunity to visit the facility and review in depth the record of care provided to several hundred veterans at the Medical Center over a period of 2 years. And, while these cases were singled out because of adverse outcomes, they have provided a broad overview of the systems of care in place at the Medical Center. Furthermore, the OMI observations about the Medical Center are corroborated by recent site visits by the NSQIP Executive Team and a team from the Inpatient Evaluation Center. The following narrative summarizes OMI senior staff concerns and conclusions about the care provided at the Medical Center.

The Medical Center was not prepared to meet the around the clock care needs of veterans with co-morbidities requiring complex surgery. The increase in the number and intensity of surgical cases is evident from the NSQIP data but this trend was not paralleled by an increase in support resources. The Medical Center has only four operating rooms with one used for storage and one dedicated to endoscopy. Nurses were rotated between the OR and PACU and thus did not develop a focused expertise in post-operative care. The PACU closed after normal duty hours and patients were transferred to the ICU. Respiratory therapy services were not available in the Medical Center at night and weekends. Computed tomography and plain film radiographs were available around the clock with techs on call but off hours radiologist support was limited. The Medical Center had built a hospitalist service but those most skilled and experienced inpatient physicians only consistently covered weekday daytime shifts. Nights and weekends were covered by a combination of Emergency Room physicians and a rotation of primary care physicians who practiced mostly in the ambulatory clinic. This was complicated by the common procedure of adding on urgent surgical cases at the end of the daily elective schedule. With this scheduling practice and the diurnal availability of resources, seriously ill, unstable surgery patients were often cared for during their most critical post-operative period in a general ICU without respiratory therapists in attendance, with limited imaging support, and with a rotating cast of outpatient internal medicine/primary care practitioners.

Patient care, particularly overnight and on weekend, was characterized by multiple handoffs and fragmentation. The records often lacked clarity as to who was ultimately responsible for medical decision-making. When medical consultants were called in, surgical notes--never comprehensive to begin with—became even sketchier and focused on the details of drains, dressings and discharge dates. Neither the medicine consultants nor the surgeons seemed to entertain a suitably broad differential diagnosis, failing to consider operative complications or pulmonary embolism in likely settings. The possible

causes of post-operative pain, tachycardia, tachypnea and fever were not vigorously pursued. In some cases, this resulted in a disastrous delay in the initial surgery, in a timely return to the OR, or in a crucial intervention. In particular, management of post-operative fluid balance was problematic. Intake and output (I&O) was dutifully recorded by nursing staff twice daily but rarely commented on in nursing or physician notes. Some patients with limited cardiac reserve would be given significant excess fluids each day until they evidenced florid pulmonary edema. Electrolyte shifts from various drainage sites were not anticipated.

In addition to variability in individual decision making, the core care processes in the Medical Center were not supportive of a high standard of care. Standard procedures and protocols were not current and did not support clinicians doing the right thing all of the time. As a result, Marion patients were much less likely than patients in comparable VAMCs to receive appropriate prophylactic antibiotics prior to abdominal surgery, to have beta blockers prescribed to reduce cardiac risk and to have low level anti-coagulation to prevent deep venous thrombosis. Nurses charted frequently but extracting key clinical information from long, highly structured notes could be problematic. The repeating of full notes with each addendum only served to clutter the record. The practice of adding on urgent cases at the end of an elective schedule resulted in the sickest patients coming out of the OR when the fewest resources were available. Review of OR records suggested that the OR may not have been optimally isolated during knee replacement surgery, with frequent traffic in and out of the room. Concern over sterility in this new program may have resulted in [redacted]

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The OMI record review focused on the adverse end of the spectrum of outcomes at Marion. Even accounting for this, OMI reviewers were struck by the number of patients who were placed in a "do not resuscitate" (DNR) status just prior to death. This occurred after a stormy post-operative course when resuscitation, in the event of a cardiac arrest, may indeed have been futile. The designation of DNR was accompanied by a withdrawal or substantial limitation of support and was shortly followed by the patient's death. There was limited documentation of prognosis, the details of discussion with patient or family, consideration of advance directives, and the specifics of the limitations of care. Poor documentation of these difficult discussions and decisions is common and hardly unique to the Medical Center. However, at the Medical Center, with its weak peer review process, it may have had the unintended consequence of lessening the scrutiny on the standard of care of these patients that died. Despite an overall increase in in-hospital deaths at the Medical Center in FY 2006 and FY 2007, the fact that most patients who died were either terminally ill or in DNR status was apparently viewed by hospital leadership as an adequate explanation. This likely could have delayed or diminished a critical look at underlying problems.

It was a mistake for Medical Center to take on a higher level of care than the infrastructure and staff were prepared to handle. But that error was allowed to persist because the peer review process failed to identify the individual and systems problems which led to so many adverse outcomes. The review process did not address all of the

problem cases and the reviews that were done were cursory and lacked a critical self-appraisal. The surgeons at Medical Center reviewed a large number of cases but found fault in none. Of 185 complication cases and 28 mortalities given a peer review level during FY 2006 and FY 2007, only one complication and one mortality were rated as level 2 and the remaining 211 adverse outcomes were evaluated as level 1, "most experienced, competent practitioners would have managed the case similarly." The review by OMI of those 28 mortalities showed 7 to not meet standard of care—a solid level 3. Cases were identified in a seemingly ad hoc manner, with referrals from the quality manager or identified by the surgeons themselves. When the first quarter 2007 NSQIP data showed an increase in mortality O/E ratio, the Medical Center surgeons instituted a re-look peer review. They concluded that "all cases are consistent with the accepted ... standards of care." The OMI evaluation was that four of those eight cases did not meet standard of care. An event-based retrospective peer review system requires a sensitive screen of adverse outcomes which is narrowed by critical review to cases which require deeper evaluation. The Medical Center surgeons did not leverage the NSQIP database to feed its peer review process with eight NSQIP deaths not reviewed by the service.

The Medical Center surgical service was small and this limited the pool of peers for review. To spread the work, cases were given to colleagues in only marginally "peer" training. An ophthalmologist reviewed orthopedic infections and a urologist reviewed a complication of a thoracotomy. A small size of the service may have made physicians reluctant to identify the care of a colleague as being sub-standard. This would particularly be the case in a tight knit medical community or one in which critical feedback is seen as punitive and not as an opportunity for improvement. In the final analysis, the Medical Center had much of the structure and process of a peer review program but none of the content. It was not a failure of policy but a failure of execution.

VI. Conclusions:

1. The OMI has determined that during FY 2006 and FY 2007 the number of surgery-associated cases at the Medical Center that did not meet the standard of care is excessive. There is a clustering of sub-standard care in the practice of two surgeons.

2. The OMI has serious concerns about the leadership in place during FY 2006 and most of FY 2007 at the Medical Center.

    a. The Medical Center leadership did not ensure that there was appropriate infrastructure to support expansion of its surgical program. Particular areas of concern are OR scheduling practices, Post Anesthesia Care Unit (PACU) staffing, continuity and coordination of care with hospitalists, and after hours support by Respiratory Therapy in the Intensive Care Unit (ICU).

b. Informed oversight of the quality functions and performance of the Surgery Service was neglected by the Medical Center Director and Chief of Staff. There was no facility level oversight of clinical care peer reviewed as Level 1.

c. There were repeated questions raised about the organizational preparedness for the new surgical services that were being offered and the competence of some practitioners. Individuals who attempted to report concerns were dismissed or ignored.

d. Neither the Chief of Staff nor the Nurse Executive was effective in responding to staff concerns.

e. The QM Director lacked the ability to perceive problems and the capacity to propose solutions to the hospital's leadership to effect change.

3. The clinical leadership and clinicians in the Medical Center Surgery Service lacked the ability and experience to support a quality surgery program. There was not a proactive approach that would contribute to best possible surgical outcomes and a strong organizational performance.

   a. The Medical Center medical staff and support systems did not adequately anticipate, recognize and manage patient factors related to peri-operative cardio-pulmonary risk.

   b. The Medical Center medical staff and quality systems did not recognize trends and take appropriate action in response to deaths and complications of procedures.

   c. Although individual technical breaches are difficult to identify and trended data are limited, the OMI is concerned about the incidence of bladder perforations, peripheral nerve injury with vascular surgery, and infectious complications of total joint replacements.

4. The quality management program was ineffective.

   a. Cases were discussed in isolation and there was no evidence that complications were evaluated as they related to the number and type of cases performed by individual surgeons. The leadership was unable to integrate trends and patterns to assess root causes.

   b. The Surgical Case Review Committee reported all of their morbidity and mortality reviews as peer reviews. The reviews that were done were superficial and did not reflect a professionally critical self-appraisal. Evaluation of care did not look beyond the technical aspects of the procedure and failed to assess elements of pre- and post-operative care.

c. The Medical Center performed a large number of peer reviews but many were poorly done. Reviews on complex cases were often performed by colleagues with widely dissimilar training, not true peers. Reviews lacked thoroughness and insight into appropriate standards of care.

d. The Surgery Service was not integrated into the Patient Safety and Quality Improvement Programs of the Medical Center. Quality Management (QM) had multiple mechanisms for capturing morbidity and mortality at the Medical Center; however, the QM staff and the Surgery Service did not work together to analyze and interpret these complications.

e. OMI is concerned that the care of patients who died in "Do Not Resuscitate" (DNR) status was not subject to rigorous oversight at either the Service or Medical Center level.

5. OMI found deficiencies in the credentialing and privileging process.

a. The OMI believes that the initial decision to hire Surgeon A was reasonable, based on the personal references and the licensing and malpractice information available in early 2006.

b. The Medical Center could have done more to ascertain Surgeon A's status after they were informed in August 2006 that he had entered into a non-disciplinary agreement not to practice in the state of Massachusetts and that an investigation was ongoing.

c. Across the board, surgeons were granted clinical privileges without a critical interpretation of the available performance data and without an analysis of their current clinical outcomes or direct observation of competence.

d. The OMI team found that the template conclusion statement in the "Summary Analysis of Quality Assurance (QA) Folder" prepared by the QM Director, i.e., *"the general review of the clinical performance folder on this provider reveals sufficient evidence to support clinical competence and the recommendation is to grant clinical privileges,"* was used inappropriately and did not reflect either an analysis of available data or senior clinician oversight.

6. The OMI found that the NSQIP data were not effectively integrated into the Medical Center's quality oversight processes.

a. NSQIP identified all circumstances in which patients died within 30 days of a major surgical procedure. NSQIP is not designed to track procedural mortality beyond that period and relies upon local processes to identify those long-delayed mortal complications.

b. The NSQIP web-based release of facility reports is an effective means of communicating critical data to a broad audience.

c. The Medical Center did not submit all NSQIP identified deaths to peer review as required by VHA Directive 2004-054.

d. The NSQIP report showing an elevated mortality O/E in the first quarter of FY 2007 was correlated with a significant number of cases that did not meet the standard of care.

e. The NSQIP report for FY 2006 had a lower than expected O/E but OMI review of the individual cases indicated that a majority did not meet the standard of care. The local peer review process failed to identify that problematic care.

VII. Recommendations

1. The Medical Center, VISN and VHA should take appropriate personnel actions as indicated by the results of OMI's quality of care evaluation and case reviews.

2. The Medical Center, with VISN, VHA, and VA (Office of General Counsel) support, should notify patients and family members affected by substandard care in a manner consistent with VHA policy on disclosure of adverse outcomes.

3. VHA should assess the Medical Center's leadership and take appropriate actions.

4. The Medical Center should improve its patient safety and medical staff culture by encouraging blame free reporting in a non-punitive environment and open communication among all levels of its staff.

5. VHA should take appropriate actions to ensure that adequate infrastructure and oversight is in place to support the planned surgical services at the Medical Center. Particular attention should be focused on OR scheduling practices, Post Anesthesia Care Unit (PACU) staffing, continuity and coordination of care with hospitalists, consideration of intensivists staffing, and after hours support by Respiratory Therapy and other ancillary services in the Intensive Care Unit (ICU).

6. The VISN/VHA should conduct a complete assessment of the Medical Center's Quality Management program focusing on identification of problematic cases, trending, and interpretation and analysis of data.

   a. The Medical Center should take all necessary actions to improve its peer review program to bring it into compliance with VHA directives.

   b. As the Medical Center re-establishes its surgical scope of services, quality management and medical staff should pay particular attention to tracking and

trending post-operative fluid management complications such as respiratory failure or un-planned intubation; post operative cardiovascular events; orthopedic infections; urologic bladder perforations; complications of bowel resections; and all peripheral nerve injuries from vascular surgery.

c. Based on individual adverse outcomes or the results of trended data, the Medical Center should perform root cause analyses (RCAs) to determine factors influencing complications and provide action plans for improvement. Clinicians, including frontline surgeons, need to be an integral part of this key patient safety and quality improvement activity.

7. The Medical Center should ensure that the credentialing and privileging processes include all required credentialing documents necessary for the privileges requested.

   a. Ensure that these documents contain the necessary quantitative data portion of quality improvement activities for the continued evaluation of professional performance, judgment, clinical and technical competence and skills.

   b. Case denominators must be included to enable the analysis required for approval of continued privileges or newly requested ones.

   c. Summative evaluations for practitioners should be attested to by a senior clinician. And the inclusion of a template statement on all physician profiles prepared by QM Director in regard to clinical competence and the granting of privileges in the "Summary Analysis of QA Folder" must cease.

8. VHA should establish a policy and procedure for evaluating the scope of services at medical centers to ensure that the resources, professional staff, physical infrastructure and clinical volume are sufficient to support consistent, high quality outcomes.

9. In regard to individual provider peer review, VHA should:

   a. clarify that the screening criteria for peer review or other quality of care review should not be affected by the diagnosis of a terminal illness, the existence of an advance directive, or the designation of DNR status.

   b. address the challenges facing small facilities that have limited affiliations and/or an insufficient number of specialists to support a comprehensive, robust peer review program.

   c. establish consistent instruction in peer review responsibilities and processes for all professional staff.

d. provide training and other ongoing support to Chiefs of Staff and other senior clinical leaders on the best processes and practices in peer review. This should also address the critical relationships to patient safety, quality improvement and risk management activities.

e. systematically and regularly collect information on peer review performance at all medical centers and develop a mechanism for early identification of quality of care issues.

10. In regard to the NSQIP, VHA should:

a. establish a reporting timeframe and format for NSQIP reporting that provides actionable information in the most timely manner practicable.

b. establish a consistent trigger for intervention by the NSQIP Executive team. This should include consideration of the timeframe covered, the index clinical volume, and the degree of deviation. There should be specific thresholds for action, a range of intensity of interventions and explicit timelines for response and follow-up.

c. train and regularly update Chiefs of Surgery in the use of NSQIP and the CPRS Surgery Package and require that both sources of information be fully integrated into local peer review and quality improvement activities.

11. VHA should take appropriate actions based on the OIG investigation.

VIII. Acceptance Memorandum from the Under Secretary for Health

Department of Veterans Affairs

Memorandum

Date: JAN 2 3 2008

From: Under Secretary for Health (10)

Subj: Acceptance of Recommendations Contained in the Office of the Medical Inspector's Final Report: Quality of Surgical Care Veterans Affairs Medical Center, Marion, Illinois

To: Principal Deputy Under Secretary for Health (10A)
Deputy Under Secretary for Health for Operations and Management (10N)
Office of the Medical Inspector (10MI)

1. This memorandum is to advise your offices that the recommendations in the subject report are accepted as submitted.

2. Please work together to implement the recommendations found in the report.

Michael J. Kussman

Michael J. Kussman, MD, MS, MACP