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Office of Healthcare Inspections

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Healthcare Inspection

Alleged Mismanagement and Quality of Care Issues in Surgical Service John D. Dingell VA Medical Center Detroit, Michigan

June 19, 2017

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Executive Summary

The VA Office of Inspector General conducted a healthcare inspection in response to complaints concerning Surgical Service mismanagement and quality of care issues in general surgery at the John D. Dingell VA Medical Center (facility), Detroit, MI.

Specifically, the allegations stated that the Associate Chief of Staff (ACOS) of Surgical Service had:

- Negative personnel interactions with operating room (OR) staff that created an environment detrimental to patient care.
- Instances of unprofessional behavior that leadership did not effectively address.
- Reduced access of general surgeons to surgical cases and OR time.
- Altered the daily surgical schedule to accommodate elective cases as emergencies resulting in major patient delays of cases already scheduled and a large number of patient complaints.
- Difficulty adhering to guidelines established by Veterans Health Administration (VHA), Accreditation Council for Graduate Medical Education (ACGME), and Center for Medicare and Medicaid Services (CMS) with respect to surgical resident supervision.
- Scheduled the vast majority of his elective colonoscopy procedures in the OR, which artificially increased his surgical case volume and diluted morbidity and mortality reporting data.
- Performed colonoscopy examinations without having the equipment available to treat patients' pathology during these procedures.
- Exercised poor clinical decision making, which has resulted in negative outcomes for many patients, including patient deaths.

We substantiated that the ACOS had negative interactions with OR staff; however, we did not substantiate that these interactions resulted in adverse patient outcomes. We recognize that good communication between staff in an OR environment is an essential component of ensuring patient safety. The VA Office of Quality, Safety and Value requires that facilities provide an atmosphere where staff can openly voice concerns in situations they feel could cause patient harm.[1]

We did not substantiate that the ACOS had instances of unprofessional behavior that leadership did not address.

We substantiated that the ACOS reduced general surgeons' access to surgical cases and OR time. We found that the ACOS was performing a majority of the general

[1] VA Office of Quality, Safety and Value, http://www.qualityandsafety.va.gov/StoptheLine/StoptheLine.asp. Accessed December 29, 2016.

surgery cases, and his actions were supported by the Chief of Staff. Therefore, we made no recommendation. Despite complaints by other surgeons and OR staff, the Chief of Staff was aware and approved of the number of surgeries the ACOS performed.

We substantiated that the ACOS altered the daily surgical schedule over a 2-year time frame (2013–2015) to accommodate his elective cases which resulted in significant patient delays for the previously scheduled cases and a number of patient complaints. We found that the facility developed a policy to minimize disruption in the surgical schedule; however, the new policy was not consistently followed.

We substantiated that the ACOS did not adhere to VHA and facility policy[2] with respect to supervision of surgical residents. We reviewed surgical cases and found:

- The ACOS' presence during surgeries was not correctly documented in the operative reports.
- The ACOS did not communicate a designated backup supervising surgeon to the surgical team during his absence from the OR.
- The ACOS did not ensure that residents' post-operative notes were properly completed immediately following surgeries.

We substantiated that the ACOS performed elective colonoscopy procedures in the OR. While these procedures increased OR utilization time, the practice did not violate VHA or facility policy. We did not substantiate the allegation that performing these procedures in the OR diluted morbidity and mortality reporting data.

We did not substantiate that the ACOS performed colonoscopy examinations without having the equipment available to treat patients' pathology during these procedures.

We did not substantiate that the ACOS exercised poor clinical decision making that resulted in negative outcomes for many patients including patient deaths. However, we reviewed 53 cases with quality of care concerns and found 3 instances of patient care involving the ACOS where clinical judgement may have affected patients' adverse outcomes. We also found that in a specific patient death (Patient 1 of this report), the family requested an autopsy, but the autopsy was not done.

During our assessment of quality of care reviews, we found that the facility did not fully comply with the VHA directive for peer review.

[2] We reviewed relevant VHA and facility policy which incorporated ACGME and CMS guidelines.

We recommended that the Facility Director ensure that:

- Measures to improve communication and interpersonal dynamics in the OR are explored and implemented.
- Providers follow processes for scheduling add-on OR cases and monitor compliance.
- The ACOS complies with facility policy for completion of post-operative notes immediately following surgeries.
- The presence of the ACOS during surgeries is accurately documented in operative reports.
- The ACOS communicates a designated backup surgeon to the surgical team in the event of his absence from the OR.
- The cases identified in this report are reviewed, and for patients who suffered adverse outcomes and poor quality of care, confer with the Office of Chief Counsel regarding the appropriateness of institutional disclosures to patients and families.
- Reasons are explored as to why an autopsy was not performed per a family's request (Patient 1 of this report) and take action as necessary.
- Facility staff comply with the VHA policy on peer review and the care of Patient 4 is evaluated and a peer review is completed.

Comments

The Veterans Integrated Service Network reviewed the report; the Facility Director concurred with our findings and recommendations and provided acceptable action plans. (See Appendixes A and B, pages 18–24 for the Directors' comments.) We will follow up on the planned actions until they are completed. The facility considers Recommendations 1, 2, 5, and 7 completed; however, we consider all recommendations open until we receive and review documentation of the facility's completion of the proposed actions.

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Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess the merit of allegations made by a confidential complainant concerning Surgical Service mismanagement and quality of care issues in general surgery at the John D. Dingell VA Medical Center (facility), Detroit, MI.

Background

The facility, part of Veterans Integrated Service Network (VISN) 11, provides a broad range of inpatient and outpatient health care services to a veteran population of approximately 330,000 in Wayne, Oakland, Macomb, and St. Clair counties. The facility is a 108-bed full service teaching medical center that offers primary, secondary, and tertiary patient care with state-of-the-art technology as well as education and research. Services provided in both inpatient and outpatient settings include medical, surgical, neurological, dermatological, and psychiatric. Most endoscopy procedures are completed in the Endoscopy suite, located in an area separate from the operating room (OR).

The Surgical Service provides a wide range of surgical care and treats veterans in the following surgical specialties:

- General Surgery
- Head and Neck Surgery
- Vascular Surgery
- Non-Cardiac Thoracic Surgery
- Plastic Surgery
- Podiatry
- Ophthalmology
- Orthopedic Surgery
- Otorhinolaryngology
- Urology
- Gynecology

Surgical Service currently includes an OR suite with eight operating rooms, a minor procedure room, and post-anesthesia care unit; a step-down and inpatient unit; an intensive care unit; a preadmission testing area; and surgery, otorhinolaryngology, eye, gynecology, urology, and dental clinics. Surgical Service operates 24 hours per day with the main services being provided between 8:00 a.m. and 4:30 p.m., Monday through Friday, during which time they are fully staffed. During all other hours,

clinical staff are on call for emergency purposes. The facility is affiliated with the Wayne State University School of Medicine and supports 75.2 resident[3] full-time employees.

Allegations. In February 2015, a confidential complainant contacted OIG's Hotline Division with allegations concerning Surgical Service mismanagement and quality of care issues in general surgery. Specifically, the complainant alleged that the Associate Chief of Staff (ACOS) of Surgical Service had:

- Negative personnel interactions with OR staff that created an environment detrimental to patient care.
- Instances of unprofessional behavior that leadership did not effectively address.
- Reduced access of general surgeons to surgical cases and OR time.
- Altered the daily surgical schedule to accommodate elective cases[4] as emergencies resulting in major patient delays of cases already scheduled and a large number of patient complaints.
- Difficulty adhering to Veterans Health Administration (VHA), Accreditation Council for Graduate Medical Education (ACGME),[5] and Center for Medicare and Medicaid Services (CMS)[6] guidelines with respect to surgical resident supervision.
- Scheduled the vast majority of his elective colonoscopy procedures in the OR, which artificially increased his surgical case volume and diluted morbidity and mortality reporting data.
- Performed colonoscopy examinations without having the equipment available to treat patients' pathology during these procedures.
- Exercised poor clinical decision making which resulted in negative outcomes for many patients, including patient deaths.

Scope and Methodology

We conducted this review from April 8, 2015 through May 6, 2016. We made site visits to the facility May 11–15, 2015 and June 15–19, 2015.

We interviewed the complainant, Chief of Staff, ACOS of Surgical Service, eight surgeons, two anesthesiologists, four certified registered nurse anesthetists, two nurse practitioners, a surgical resident, a Patient Advocate, the Associate Chief Nurse Surgical Services, OR Nurse Manager, VA Surgical Quality Improvement Program

[3] The term "resident" refers to an individual who is engaged in an accredited graduate training program for physicians, dentists, optometrists, and podiatrists; and who participates in patient care under the direction of supervising practitioners.
[4] Elective cases are cases that are requested in the future up to 120 days in advance of the service date.
[5] ACGME is responsible for the actual accreditation of residency training programs for physicians in the United States.
[6] Center for Medicare and Medicaid Services, September 24, 2011.

(VASQIP) nurse, surgery scheduler, surgical technicians, Risk Manager, Patient Safety Officer, and Compliance Officer. For October 1, 2013 through May 31, 2015, we reviewed the facility's OR schedules, VASQIP data, peer reviews, staffing levels and patient advocate data. We received the names of 53 patients with quality of care concerns from an interviewee, and we reviewed these electronic health records (EHRs). We also reviewed EHRs of patients who had surgeries and endoscopy procedures in the facility's General Surgery Department. In addition, we reviewed relevant VHA and facility policies, data from VHA Corporate Data Warehouse, and other documents pertinent to this inspection.

We evaluated the allegation that the ACOS had difficulty adhering to VHA, ACGME, and CMS guidelines with respect to surgical resident supervision within the context of VHA policies. The VHA policy on resident supervision[7] incorporates ACGME requirements for accreditation. The facility's policy[8] incorporated the CMS guidelines about overlapping procedures and resident supervision.

VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010, cited in this report, expired June 30, 2015. We considered the policy to be in effect as it had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),[9] the VA Under Secretary for Health (USH) mandated the "…continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."[10] The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "…the timely rescission or recertification of policy documents over which their program offices have primary responsibility."[11]

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

[7] VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012.
[8] John D. Dingell VA Medical Center Policy 11S-8.
[9] VHA Directive 6330(1), *Controlled National Policy/Directives Management System,* June 24, 2016, amended January 11, 2017.
[10] VA Under Secretary for Health Memorandum, *Validity of VHA Policy Document,* June 29, 2016.
[11] Ibid.

Inspection Results

Issue 1: Staff Interaction

We substantiated that the ACOS had negative interactions with OR staff; however, we did not substantiate that these interactions resulted in adverse patient outcomes. From our interviews with OR staff, we found that the ACOS did have multiple conflicts with staff. Several of the staff we interviewed stated that poor communication occurred between the ACOS and both administrative and clinical staff. Examples of ACOS communication issues included:

- Berating staff in front of others.
- Not acknowledging the presence of some staff members who were physically in the OR or surgical areas.
- Restricting communication with select staff to email only.
- Failing to communicate his offsite status to appropriate personnel.
- Scheduling OR surgeries without communicating those additions to the OR staff.

The Chief of Staff acknowledged that the ACOS could be a better communicator. The ACOS stated that the complaints to OIG were related to his own high standards and work ethic that some staff did not follow. During our interviews with OR staff, they did not indicate specific patient incidents resulting from the ACOS' communication issues. We recognize that good communication between staff in an OR environment is an essential component of ensuring patient safety. The VA Office of Quality, Safety and Value requires that facilities provide an atmosphere where staff can openly voice concerns in situations they feel could cause patient harm.[12]

Issue 2: Facility Leaders' Response to OR Staff Concerns

We did not substantiate that the ACOS had instances of unprofessional behavior that leadership did not address. We found three incidents in which the ACOS had conflict with OR employees, and leadership was made aware of the incidents. We also found that leadership took action in all three of the incidents; however, we did not find evidence that the actions were effective in improving the ACOS' interpersonal interactions with OR staff.

In one of the three instances, the ACOS refused to speak directly to a surgical nurse following an incident between the two, even when both were present in the OR. Facility managers removed the surgical nurse from the ACOS' operating team. However, the surgical nurse was on the emergency response team and remained on the emergency on-call schedule with the ACOS, and potentially, both needed to work in the OR

[12] VA Office of Quality, Safety and Value, http://www.qualityandsafety.va.gov/StoptheLine/StoptheLine.asp, Accessed December 29, 2016.

together. We also found two other surgical staff who facility managers removed from working with the ACOS: a Certified Registered Nurse Anesthetist who was kept separated from him and a nurse who facility managers transferred to another surgical specialty.

Issue 3: Reducing General Surgeons' OR Time

We substantiated that the ACOS reduced general surgeons' access to surgical cases and OR time.

The ACOS told us that he was recruited from the community and started at the facility in November 2012. He said that general surgery staffing at that time was one full-time and three part-time general surgeons. He also stated that 65 percent of the time assigned for general surgery was unused before his arrival at the facility. In addition, the ACOS noted that patients were repeatedly coming back to the surgical clinic and the Emergency Department (ED) with the same problems and were not getting surgically treated (for example, hernia and thyroid goiter).

At the time of our review, the General Surgery Department had five surgeons: two full-time (including the ACOS), one part-time with expertise in colorectal surgery, and two intermittent general surgeons. We reviewed OR schedules from FY 2014 and FY 2015 (through May 2015) and found that the ACOS was performing essentially all of the major general surgery cases including laparoscopic (for example, cholecystectomy, hernia repairs, and exploratory laparoscopy) and colonoscopy procedures with an assigned resident.

We found that the other full-time surgeon had completed surgical residency training prior to the widespread use of laparoscopy. Because he was not formally trained to do laparoscopic procedures, this surgeon focused on head and neck surgery for which he had extensive training. A month after the ACOS' arrival, the part-time colorectal surgeon's OR time was reduced so that he could perform colonoscopies in the Endoscopy suite to clear a backlog. In June 2016, the colorectal surgeon's main role was to perform colonoscopies and hemorrhoid procedures. In addition, several OR staff told us that the ACOS dominated the OR schedule and surgeons' OR time was limited.

Although the ACOS was performing most of the major general surgery cases, we found this was a facility management decision supported by the Chief of Staff.

Issue 4: Daily Surgical Schedule Changes

We substantiated that the ACOS altered the daily surgical schedule over a 2-year time frame (2013–2015) to accommodate his elective cases which resulted in significant patient delays for the previously scheduled cases and a number of patient complaints. We found that the facility had a standard operating procedure for boarding[13] elective surgery patients to support the coordination of the surgeries with the surgeon, clinical

[13] Boarding is a process for scheduling surgical cases in the OR.

coordinators, and the OR scheduler. The boarding process involved a clinic visit to identify a surgical need, and a boarding request from the resident or surgeon to the coordinator who ensured that necessary pre-admission testing was done, a request for surgery was completed, and a surgery date assigned.

The master schedule consisted of elective and non-urgent cases. Cases requested after completion of the master schedule were prioritized based on patient acuity, time available, length of procedure, and availability of resources. These cases were considered "add-ons" (emergent or urgent cases). Staff told us that the process required a resident or surgeon to complete a "Surgery Requests for Today" form for all add-on cases for that day.

We determined that the ACOS or his surgical residents were not completing the "Surgery Requests for Today" form consistently. OR staff told us that the ACOS would add-on cases that were not emergent or urgent and reclassify them as emergent or urgent to get them added on the surgery schedule. The OR staff noted that when cases were added to the surgery schedule the same day without being properly boarded, it caused surgical delays and sometimes cancellations of patients already present and prepared for surgery. In some instances, patients already in the holding (pre-operative) area became frustrated with the excessive waiting and left. In our review of the OR schedules, we found several instances where patients had left the holding area due to an excessive wait time while other surgical cases were unexpectedly put ahead of their planned procedures. OR staff told us that patients were instructed to report their concerns to the patient advocate. We reviewed patient advocate data from October 1, 2013 through May 13, 2014 and found three complaints concerning excessive wait time.

We found that the frequent disruption in the surgery schedule led the facility's Rapid Performance Improvement Workgroup to revise the "Surgical Requests for Today" form to include a case acuity algorithm. The algorithm outlines Emergency/Urgent classifications that should be used as guidelines for determining acuity when scheduling add-on cases. The following are the case acuity classifications:

- Class I Emergency - Life-threatening conditions requiring immediate surgery.
- Class II Emergency - Life or limb threatening condition requiring surgery as soon as possible, but not "immediate." Typically within 2–4 hours.
- Class III Urgent - Non-life threatening emergencies that need to be done within the next 6–8 hours.
- Class IV Urgent - Patient referrals or patients admitted to the hospital requiring surgical intervention within 8–48 hours.

The workgroup also developed a policy[14] that required the surgeon or resident to complete the revised "Surgery Requests for Today" form for all add-on cases. The policy also required that the surgeon or resident define a case acuity classification or

[14] John D. Dingell VA Medical Center Policy 11S-50, *Scheduling Cases for Surgery*, March 26, 2015.

designate the case as non-urgent. The revised form was implemented, and the new policy became effective March 26, 2015. However, we found that the new policy was not consistently followed.

Issue 5: Resident Supervision

We substantiated that the ACOS did not follow VHA[15,16] and facility policy[17] for three specific aspects of surgical resident supervision. We found deficiencies in the following areas: documentation of ACOS presence in surgeries, designation of supervisory backup in the absence of the ACOS, and documentation of post-operative notes.

ACOS presence in the OR. We determined that the surgery attending physician can assign the level of required supervision for residents with the exception of PGY-1 residents (first year surgical residents). For surgical residents at a training level above PGY-1, the attending surgeon may be in the OR for "key portions" and not for the entire surgery according to facility policy.[18] However, facility policy[19] requires the attending's presence in the OR with the resident during the entirety of a colonoscopy procedure (from the insertion to the removal of the endoscope). During our review of the OR schedules from FY 2015 to FY 2016 through May 31, we found multiple days where the ACOS was the attending for a colonoscopy procedure and a separate surgery that overlapped in time. We found that the ACOS would often schedule a surgery in an OR and a colonoscopy procedure in an adjacent OR within the same block of time.

Interviewees told us that the ACOS was present for the entirety of the colonoscopy procedures. We did not find evidence that contradicted the interviewees' statements concerning the ACOS' presence during colonoscopies. However, for the concurrently scheduled surgeries, the ACOS said he was present only for the critical portions. For multiple surgical cases reviewed from October 2013 through May 2015, the residents' documentation in the operative report noted that the ACOS was "present for the entirety" of the surgeries." As the surgeries we reviewed overlapped in time with colonoscopy procedures, the documentation that the ACOS was present for the entirety of both procedures could not be accurate. The ACOS told us that the residents' statement of the attending being present for the entire surgery should have been changed to "attending present for the critical portions of the case." The ACOS told us that an addendum had not been entered to correct the original note, but the residents had been instructed to document "critical portions." We did not find addenda to the operative reports reviewed that corrected the original notes.

[15] VHA Handbook 1907.01, *Health Information Management and Health Records,* July 22, 2014. This handbook was updated and replaced with VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015. The current handbook contains the same or similar language regarding post-operative notes as the previous handbook.
[16] VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012.
[17] John D. Dingell VA Medical Center Policy 11S-8.
[18] Ibid.
[19] Ibid.

Lack of designated supervisory backup during surgery. Facility policy[20] states that outside the critical/key portion of the surgery, the attending surgeon must be immediately available.[21] The policy[22] also states that the attending surgeon should not physically leave the hospital until all surgeries being performed by the surgical team have been completed. In the event that the attending surgeon must leave the building during surgery, an appropriately credentialed backup surgeon must be designated. This backup surgeon must remain in the building during the time he/she is assuming supervisory responsibility. Further, the facility policy[23] notes that this transfer of supervisory responsibility will be known to the operating team, accompanied by a verbal hand-off between providers, and documented by the circulating nurse. We found two incidents where surgery residents were without documented supervisory backup. In the first incident, we reviewed a nurse's intraoperative note that indicated the ACOS left the OR at 1:30 p.m., which was 42 minutes before the patient was out of the OR. During our interviews with staff, we found that while the surgery was still in progress, the ACOS was out of the building. However, we did not find documentation in the EHR of a backup supervising surgeon as required by facility policy. In the second incident, we found that the ACOS left the building at 1:30 p.m. and returned at 3:20 p.m. while the case was still in progress. We did not find documentation in the EHR identifying a backup supervising surgeon in the ACOS' absence.

Documentation of surgery. A post-operative note must be written or directly entered into the patient's EHR immediately following surgery and before the patient is transferred to the next level of care according to VHA policy[24] and facility by-laws.[25] The surgical resident who participated in the patient's surgery completes the post-operative note under the supervision of the attending surgeon. In addition, the by-laws[26] require that an operative report be dictated and completed by the operating surgeon immediately following surgery. We confirmed through review of EHRs that 35 of the 37 patients the complainant identified who had surgery completed from February through June 2014 were missing post-operative notes.

Issue 6: Colonoscopy Procedures in the OR

We substantiated that the ACOS performed elective colonoscopy procedures in the OR and that these procedures increased OR utilization time. However, we did not

[20] John D. Dingell VA Medical Center Policy 11S-8.
[21] Immediately available is defined as the attending surgeon remains in the building and is uninvolved in other scheduled patient care activities. The supervising surgeon may perform rounds, check on patients in recovery, review charts in his or her office, and even begin another surgery or procedure. The attending surgeon may not see scheduled patients in a clinic but is permitted to see patients on an urgent or emergency basis or for a pre-operative visit.
[22] John D. Dingell VA Medical Center 11S-8.
[23] Ibid.
[24] VHA Handbook 1907.01.
[25] John D. Dingell VA Medical Center Policy 006, Appendix B, *Rules and Regulations of the Medical Staff*, June 15, 2014.
[26] Ibid.

substantiate the allegation that performing these procedures in the OR diluted morbidity and mortality data.

We confirmed that the ACOS routinely performed colonoscopy procedures in the OR instead of in the Endoscopy Suite. However, performing colonoscopy procedures in the OR is permissible practice and does not violate VHA or facility policy.

VASQIP[27] data is reported to National Surgery Office[28] staff who determine which cases are eligible to include in VASQIP outcome data based on Current Procedural Terminology codes. The VASQIP nurse collects surgical outcome data to include morbidity and mortality according to the National Surgery Office designated Current Procedural Terminology codes. We reviewed the National Surgery Office list of general surgery Current Procedural Terminology codes and determined that colonoscopy procedures were not included as part of the VASQIP data collection. Although the ACOS was performing colonoscopy procedures in the OR, these procedures were not included in the analysis of morbidity and mortality data and, therefore, could not dilute facility VASQIP morbidity and mortality rates.

Issue 7: Colonoscopy Screening Equipment

We did not substantiate that the ACOS performed colonoscopy examinations without having the equipment available to treat patients' pathology during these procedures. A nurse told us that it is the OR circulating nurses' responsibility to ensure that the proper equipment is available prior to the patient entering the procedure room and this nurse had not been aware of any case where equipment was not available. Our subject matter expert confirmed that the OR circulating nurse is responsible for ensuring the appropriate equipment is in the room.

Issue 8: Quality of Care Concerns

A. Concerns related to the ACOS

While we did not substantiate that the ACOS exercised poor clinical decision making resulting in negative outcomes for many patients, we did find three patients with negative outcomes. We reviewed the EHRs of 53 cases presented to us with quality of care concerns. We found three instances (Patients 1–3 described below) where the ACOS' clinical judgement may have contributed to the patients' adverse outcomes.

[27] VASQIP serves as the primary tool for measurement of the quality of surgical outcomes. VASQIP data are collected locally from all VHA facilities for designated types of surgeries based upon probability of post-operative adverse events in accordance with standardized data definitions. These clinically derived data are validated, formatted, and analyzed to characterize prevailing mortality and morbidity rates, both unadjusted and risk-adjusted.
[28] The National Surgery Office has been responsible for operational oversight and policy related to VHA surgical programs, including surgical outcomes data production and analysis, and associated data stewardship.

Patient 1. The patient was a male in his late 60s with a history of diverticulitis and peripheral vascular disease. In late 2011, he had an ultrasound[29] interpreted to show a deep vein thrombosis (DVT) of the left distal lower extremity and was begun on an oral anticoagulant (blood thinner A) by a non-VA physician.

In 2014, still on blood thinner A, the patient presented to his primary care provider complaining of abdominal pain and was referred to a non-VA hospital for prompt access to computerized tomography imaging of the abdomen. Due to findings which showed diverticulitis, complicated by abscess formation, the patient was admitted to the non-VA hospital for intravenous antibiotics; blood thinner A was discontinued during his admission.

Three weeks later, the patient developed new leg pain symptoms, was evaluated by his primary care provider, and had a lower extremity ultrasound interpreted as positive for femoral and popliteal thrombosis.[30] Following admission to the facility, the patient was anticoagulated with an intravenous anticoagulant (blood thinner B) and restarted on blood thinner A. The hospitalist documented the new lower extremity thrombus as a left proximal DVT.

After effective anticoagulation, the patient was discharged from the facility and referred to outpatient general surgery for assessment of his recurrent diverticulitis. Due to a history of three episodes of diverticulitis over 5 years and associated abscesses, he was admitted to the facility's surgery service for an abdominal computerized tomography scan and a colonoscopy. The abdomen was described as soft, non-tender, and non-distended. The colonoscopy revealed severe, almost obstructive, diverticular disease of a portion of the colon. In an EHR entry, a surgeon acknowledged the 2011 and 2014 DVTs. In anticipation of bowel surgery, the Medicine Service physician was consulted to see the patient. Noting the history of recurrent DVT, the medicine consultant documented discussing the case with a member of the surgical team and recommending that an opinion be obtained from the hematology service to guide anticoagulation management in the perioperative period. No consultation to the hematology service was made. A surgery EHR entry 6 days prior to an elective colon surgery reflected that the patient would not be taking blood thinners prior to the surgery

Surgery proceeded as planned, and was uneventful. However, within 24 hours post-operatively, the patient developed severe distress. He was transferred to the intensive care unit, experienced a series of cardiac arrests in subsequent hours, was ultimately unresponsive to resuscitative measures, and died. A bedside echocardiogram indicated a likely massive pulmonary embolus.[31] The patient's family

[29] Ultrasound is a type of imaging which utilizes sound waves to look at structures inside the body and is commonly used to quantitate the flow through blood vessels.
[30] Thrombosis (or "thrombus") is a collection of blood cells which become gelatinous to solid and obstruct blood flow through an affected area of the circulatory system. A thrombosis may cause serious complications if it migrates to a critical part of the circulation such as the lungs or brain.
[31] Pulmonary embolus occurs when a blood vessel (artery) in the lung becomes blocked, most often by a blood clot originating in a lower extremity.

gave consent for an autopsy to determine the actual cause of death, but the autopsy was not done. The patient's death within 24 hours of elective surgery was reportedly caused by a major thromboembolic event ("likely massive pulmonary embolus").

Several clinical aspects were important to the risk stratification of this patient for perioperative thromboembolic complications. He had a documented history of a clotting episode in 2011 and a subsequent DVT in 2014 that was proximal (above the knee). Proximal thromboses are regarded as having a greater association with subsequent embolic phenomenon than are distal (below the knee) thromboses.

Of note, in the lead up to the patient's colon surgery, he was seen in consultation by the Medicine Service as to guidance on medical management in the perioperative period. The medical consultant indicated that patient should be on blood thinners but advised the surgical team to consult with a hematologist.[32] However, the EHR does not contain documentation that the surgical team contacted the Hematology Service

After the patient's death on the first post-operative day, his family consented for an autopsy but it was not performed. The reason for non-performance of the autopsy is unclear based on review of the EHR; however, the autopsy should have been done.

Patient 2. The patient was a male in his late 60s with a history of coronary artery disease and diabetes who presented to the facility's ED with abdominal pain in 2014. The ED physician diagnosed the patient with acute gallstone pancreatitis. The admitting provider recommended an evaluation by a cardiologist prior to surgery; a cardiac stress test revealed no acute issues. The patient's weight was a little over 200 pounds at admission (day 1).

On hospital day 4, the ACOS removed the patient's gallbladder without complications. The next day, the surgery resident assessed the patient as having developed low urinary output and, in response, increased the patient's intravenous fluids. The surgery resident ordered urine tests to further assess fluid status and kidney function. The patient's blood tests the morning of hospital day 6 showed elevated creatinine and white blood cell (WBC) count. Repeat blood tests that evening showed a similar elevated WBC with 3 band cells[33] as well as a low sodium level. The patient complained of symptoms of shortness of breath. His oxygen level was within normal limits on supplemental O2. A chest x-ray report noted no active disease, but the report also cited the x-ray as not optimal for a full assessment because it was limited by technique (a single frontal portable view) and the patient's shallow inspiratory effort. On hospital day 7, the day of discharge, the patient's weight had increased almost 20 pounds. Another single view portable chest x-ray was obtained that day and showed no active disease. The patient was discharged home with instructions to follow up with the surgeon in 2 weeks.

[32] Generally, medical teams advise surgical teams regarding anticoagulation; in this instance, the medical team deferred to the hematology service that would have more specialized knowledge related to blood clotting disorders.
[33] A band cell is an immature form of a neutrophilic white blood cell, often associated with a developing infection.

The morning after discharge, the patient returned to the ED with shortness of breath, fever, and chills. A chest x-ray (both frontal and lateral views were obtained) showed evidence of mild pneumonia and bilateral pleural effusions. The patient was re-admitted for antibiotics and further workup. Following readmission, the WBCs remained elevated and trended higher;[34] the patient's kidney function worsened daily. Other than pneumonia, imaging and blood tests did not reveal additional potential sources of infection. Three days later, the patient was found pulseless in his room. Cardiopulmonary resuscitation was initiated but was without success.

We concluded that the ACOS did not adequately address the patient's several new clinical developments following the surgery including a significant change in WBC count, low sodium level, shortness of breath while on O2 supplementation, and weight gain as documented over a 1 week period. A more considered analysis of the patient's overall clinical status in the days after surgery may have prevented readmission less than 24 hours following discharge. Specific clinical aspects of the patient's hospitalization which were noteworthy included:

- The patient experienced a weight gain of 20 lbs. over the course of the admission. We found no documentation in the EHR related to the possible causes of the weight gain despite the development of shortness of breath that was not present prior to admission.
- Laboratory results showed an elevated serum creatinine and low urine output. The surgeon assessed the patient as requiring more fluid intake and ordered a urine test to help assess the patient's fluid status and kidney function. The patient's EHR does not document an analysis of urine electrolytes by the surgery team although it was the surgery team that had initiated the request for the test to be done. A review of the urine results may have provided guidance as to clinical decisions of fluid management for the patient. Despite surgery's assessment that the patient required more fluid, doses of a diuretic were given to increase urine output. Additionally, we did not find documentation in the EHR of consistent daily weights that would have helped to further clarify the patient's fluid status.
- Low sodium was evident on the first post-operative day and persisted until discharge 3 days later. Although a non-specific finding, the EHR does not reflect discussion of the low sodium or its possible meaning.
- Approximately 24 hours before discharge, the patient developed a marked change (elevation) in his WBCs. The ACOS' surgical team did not document in the patient's EHR that they considered the potential significance of the WBC increase and bandemia.[35]

[34] WBCs are cells of the immune system. An elevated WBC may represent an infectious process occurring in a patient. However, a more significant laboratory finding includes how the WBC counts change daily. A trend to a higher WBC count represents a continued response of the immune system and may indicate progression of an infectious process.
[35] Bandemia reflects the presence of an immature form of WBCs, which may indicate an acute infection.

Patient 3. The patient was a male in his 60s with a history of coronary artery disease, peripheral vascular disease, stroke, aortic aneurysm repair, diabetes, hypertension, and hyperlipidemia. He was a former smoker with a 40-pack-year history. In 2002, the patient had a cardiac catheterization, which revealed some coronary artery abnormalities. The patient had previous surgeries without perioperative cardiac complications, including lower extremity vascular surgery in 2010 and the aortic aneurysm repair in 2012. The patient had a myocardial perfusion imaging study completed prior to the aortic aneurysm repair. The report described a normal perfusion but noted a nonreversible wall defect in the lower part of the heart that may or may not have been artifact.

The general surgery team evaluated the patient in 2013 for an elective hernia repair. One month later, a surgical nurse practitioner completed the patient's pre-surgical testing for the hernia repair which included baseline laboratory testing and an electrocardiogram. The next month, the ACOS completed the patient's hernia repair without complications. After 3 uneventful post-operative days, a nurse found the patient on the bathroom floor. The nurse noted the patient was in distress. The patient was transferred to the intensive care unit where he suffered a cardiac arrest and could not be resuscitated. Per autopsy, the cause of death was myocardial infarction with two separate blood clots blocking the coronary blood flow.

The patient had a history of documented coronary artery disease as well as several other vascular comorbidities and ongoing cardiac risk factors of diabetes, hypertension, and hyperlipidemia. The hernia repair was an elective surgery. The patient's preoperative assessment consisted of a history and physical examination, basic laboratory work, and electrocardiogram. A myocardial perfusion imaging study was last completed in 2012, 21 months prior to the hernia repair and was inconclusive as to a portion of the cardiac wall. The American College of Cardiology outlines the approach to pre-operative assessments for patients undergoing surgery. Per the American College of Cardiology guidelines, this patient was in a higher risk category, requiring more extensive pre-operative testing than the one completed. The preoperative evaluation did not include a cardiology consult for cardiac risk stratification or for determination of whether another myocardial perfusion study was advisable based on the patient's extensive history of vascular disease.

B. Failure to Conduct a Peer Review

While we were reviewing patients' EHRs, we found documentation of an adverse outcome resulting in a patient's death that met the criteria for peer review, but was not submitted for a peer review (Patient 4 as described below).

Patient 4. The patient was a male in his early 50s with a history of pancreatitis and diabetes mellitus. In late 2014, he developed an abscess in the gluteal area but did not seek medical treatment for several months. In 2015, he was diagnosed with a severe

infection of the groin and buttock and underwent multiple debridements[36] and a colostomy[37] to prevent continued contamination of his sacral wound. In the postoperative period, the patient was diagnosed with a pulmonary embolus and placed on a blood thinner medication.

Several months later, in anticipation of having surgery for colostomy reversal and possible colon surgery, the patient had a colonoscopy.[38] The colonoscopy included entry into the colon first per ostomy and then per anus. The operative report describing the colonoscopy noted a large amount of thick formed stool throughout the colon that prevented full visualization. The patient's blood thinner, which he was receiving each evening, was held the day prior to the colonoscopy per physician instruction, and was to resume the day following the procedure. After completion of the colonoscopy, the patient was discharged to home. According to a family member, the patient complained of abdominal pain on the way home, was not feeling well later that day, and had a home reading of a very high capillary blood glucose.[39]

The family reported that the patient was found dead the next morning. Because an autopsy was not performed, the specific cause for the patient's death was not determinable. Facility staff were informed of the death on the following morning.

Because the death occurred within 24 hours of a colonoscopy done at the facility and the description in the EHR of the patient complaining on the way home about abdominal pain, a peer review[40] was indicated per VHA directive[41] but was not done. The peer review directive[42] outlines the requirements for initiating, conducting, and documenting peer review for quality management of care provided by an individual health care provider in VHA facilities.

[36] Debridement is the removal of non-living tissue from pressure ulcers, burns, and other wounds.
[37] Colostomy is a surgery in which an opening (ostomy) is formed by bringing one end of the colon (large intestine) through an incision in the abdominal wall. Stool moving through the intestine drains through the stoma (the end portion of the bowel which protrudes through the abdominal wall) into a colostomy bag.
[38] Colonoscopy is a procedure that allows an examiner to directly view the inside of the colon using a flexible tube containing a light source and camera.
[39] Capillary blood glucose is a procedure where a needle stick to the fingertip produces a drop of blood which is assessed for glucose content. A general reference range for blood glucose would be 74–106 mg/dL.
[40] Peer review is a process to analyze a case that evaluates an individual provider's care. The peer review analysis can also identify facility concerns that are independent of an individual provider's practice. VHA peer review directive denotes, specific clinical events, if found in a case, that would require a peer review for quality management. Cases that qualify for peer reviews but are not referred for such analysis, limit the facility's ability to provide evidence that the provider is practicing within the standard of care. Further, peer review can identify failures in facility-wide processes that contribute to poor clinical outcomes. Without this knowledge, patient harm can continue despite a provider practicing to the standard of care.
[41] VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This directive expired June 30, 2015 and has not been rescinded and replaced.
[42] Ibid.

In addition, the directive[43] includes a listing of clinical events that requires a peer review for quality management. For Patient 4, the following circumstances occurred, any one of which would serve as the basis for initiating a peer review:

- Lack of concordance between the patient's pre-mortem and post-mortem diagnoses.
- Lack of documentation indicating an explanation for the death.
- Lack of documentation indicating that the patient's death was expected.
- Death appeared to be related to a hospital-incurred incident or a complication of treatment.
- Death was suspected to be related to the original procedure.

Unexpected or negative occurrences include events in which a patient experienced a negative or unexpected outcome that may be related to the care provided and for which facility management considers peer review the best method for determining if the care was appropriate.

The directive outlines the responsibilities of the COS for initiating and facilitating peer review. The COS did not refer this case for peer review. We found that facility management did not perform a peer review for Patient 4.

Conclusions

We substantiated that the ACOS had negative interactions with OR staff; however, we did not substantiate that these interactions resulted in adverse patient outcomes. We recognize that to ensure a safe patient environment, communication issues must be addressed. Good communication between staff in an OR environment is an essential component of ensuring patient safety.

We did not substantiate that the ACOS had instances of unprofessional behavior that leadership did not address. We found three incidents in which the ACOS had conflict with OR employees and leadership was made aware of the incidents. Leadership took action in all three incidents; however, we did not find evidence that the actions were effective in improving the ACOS' interpersonal interactions with the OR staff.

We substantiated that the ACOS reduced general surgeons' access to surgical cases and OR time. We found that the ACOS was performing most of the major general surgery cases; however, this was a management decision that the COS supported. Therefore, we made no recommendation.

We substantiated that the ACOS altered the daily surgical schedule to accommodate elective cases which resulted in patient delays for the previously scheduled cases and patient complaints. We found that the facility developed a policy to minimize disruption in the surgical schedule; however, the new policy was not consistently followed.

[43]VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010.

We substantiated that the ACOS did not adhere to VHA and facility policy with respect to supervision of surgical residents. We found that of the surgical cases we reviewed, documentation of the ACOS' presence during surgeries was not correctly reflected in the operative reports, the ACOS did not communicate a designated backup supervising surgeon to the surgical team during his absence from the OR, and post-operative notes were not completed immediately following surgeries.

We substantiated that the ACOS performed elective colonoscopy procedures in the OR. While these procedures increased OR utilization time, the practice did not violate VHA or facility policy. We did not substantiate the allegation that performing these procedures in the OR diluted morbidity and mortality rates.

We did not substantiate that the ACOS performed colonoscopy examinations without having the equipment available to treat patients' pathology during these procedures.

While we did not substantiate that the ACOS exercised poor clinical decision making that resulted in negative outcomes for many patients including patient deaths, we did find three patients with negative outcomes. We reviewed 53 cases presented to us with quality of care concerns and found 3 instances where the ACOS' clinical judgement may have affected patients' adverse outcomes. We also found that in a specific patient death (Patient 1 of this report) the family requested an autopsy, but it was not done.

During our assessment of quality reviews, we found that the facility did not fully comply with the VHA directive for peer review.

Recommendations

1. We recommended that the Facility Director explore and implement measures to improve communication and interpersonal dynamics in the operating room.

2. We recommended that the Facility Director ensure that surgeons follow processes for scheduling add-on operating room cases and monitor compliance.

3. We recommended that the Facility Director ensure that the Associate Chief of Staff of Surgical Service complies with facility policy for completion of post-operative notes immediately following surgeries.

4. We recommended that the Facility Director ensure that the presence of the Associate Chief of Staff of Surgical Service during surgeries is accurately documented in operative reports.

5. We recommended that the Facility Director ensure that the Associate Chief of Staff of Surgical Service communicates a designated backup surgeon to the surgical team in the event of his absence from the operating room.

6. We recommended that the Facility Director ensure that the cases identified in this report are reviewed, and for patients who suffered adverse outcomes and poor quality

of care, confer with the Office of Chief Counsel regarding the appropriateness of disclosures to patients and families.

7. We recommended that the Facility Director explore reasons why an autopsy was not performed per a family's request (Patient 1 of this report) and take action as necessary.

8. We recommended that the Facility Director ensure that facility staff comply with Veterans Health Administration policies on peer review and the care of Patient 4 is evaluated and a peer review is completed.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: April 26, 2017

From: Director, VA Healthcare System (10N10)

Subj: Healthcare Inspection—Alleged Mismanagement and Quality of Care Issues in Surgical Service, John D. Dingell VA Medical Center, Detroit, Michigan

To: Director, San Diego Office of Healthcare Inspections (54SD)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Please find attached the response to the Healthcare Inspection – Alleged Mismanagement and Quality of Care Issues in Surgical Service, John D. Dingell VA Medical Center, Detroit, Michigan.

2. If you have any questions, please contact Jane Johnson, VISN 10 Quality Management Officer, at (513) 247-2838.

(original signed by:)
Robert P. McDivitt, FACHE

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: April 24, 2017

From: Director, John D. Dingell VA Medical Center (553/00)

Subj: Healthcare Inspection—Alleged Mismanagement and Quality of Care Issues in Surgical Service, John D. Dingell VA Medical Center, Detroit, Michigan

To: Director, VA Healthcare System (10N10)

1. The following facility director's comments are submitted in reference to the recommendations identified in the OIG Draft Report.

2. This response was completed by the Chief of Staff. Any questions regarding the above information can be addressed with Anna Lamb, Administrative Officer to the Chief of Staff, at (313) 576-3279.

Pamela Reeves, MD
Facility Director

Comments to OIG's Report

The following Facility Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Facility Director explore and implement measures to improve communication and interpersonal dynamics in the operating room.

Concur

Target date for completion: Completed

Facility response:

a) Initiated a quarterly 'Breakfast with Associate Chief of Staff (ACOS) for Surgery educational series in 2015 where he speaks with the entire OR staff at their meeting on Wednesday morning on a surgical subject of interest (hernias, gallbladder, colon, minimally invasive surgery, interesting/difficult cases) as a way to utilize his teaching skills as a vehicle to better connect with the OR staff and so that the staff better understands the rationale for and nature of these often complex procedures.

b) For several months beginning in March 2015, the Chief of Staff spent a total of 4 hours per month in the OR on an unannounced basis, with approximately half of the time dedicated to observing the ACOS for Surgery and patients of his undergoing surgery. He did not observe any deviations in performance or less-than-satisfactory interpersonal interactions, including pre-operative checklist/consent completion, time out, conduct of the case, communication with OR staff, presence during the key/critical portion(s) of the case, or surgical attire.

c) In 2015, the ACOS for Surgery completed a 360 degree evaluation assessment via the National Center for Organizational Development (NCOD) and discussed the results of his assessment with the Chief of Staff and identified several opportunities for improvement.

d) Currently, the ACOS for Surgery interpersonal relationship with the new ACNS for Surgery, who joined us in October 2016, has been outstanding; his relationship with the MD Anesthesiologist, Section Chief of Anesthesia, and CRNAs remains excellent; and we have not had any recent complaints regarding negative interactions with OR staff.

e) The ACOS for Surgery has facilitated the successful recruitment of surgeons in the following specialties: ENT, GYN, urology, vascular surgery, podiatry, thoracic surgery, and orthopedics.

Recommendation 2. We recommended that the Facility Director ensure that surgeons follow processes for scheduling add-on operating room cases and monitor compliance.

Concur

Target date for completion: Completed

Facility response: Policy 11S-50, SCHEDULING CASES FOR SURGERY, was last revised on March 26, 2015 to include procedures for scheduling add-on cases. Since then, compliance has been monitored on a monthly basis as part of an System Redesign project on OR Utilization and Scheduling, and has consistently been at 100 percent, with the only exceptions being due to new residents coming on service who forget to sign the form at the bottom, but include all other pertinent information, including the correct classification of the add-on case.

Recommendation 3. We recommended that the Facility Director ensure that the Associate Chief of Staff of Surgical Service complies with facility policy for completion of post-operative notes immediately following surgeries.

Concur

Target date for completion: February 2018

Facility response: As stated in our Medical Staff Bylaws Appendix B, Section 3- Medical Records, #17 (h) excerpted below, post-operative notes must be completed by the attending surgeon or resident before the patient leaves the PACU. The ACOS for Surgery, as well as all other surgical staff, have been completing these notes 98–100 percent of the time as monitored on a monthly basis.

"The Immediate Post-Operative Documentation: A post-operative progress note must be written, or directly entered into the patient's health record, by the surgeon immediately following surgery and before the patient is transferred to the next level of care."

Recommendation 4. We recommended that the Facility Director ensure that the presence of the Associate Chief of Staff of Surgical Service during surgeries is accurately documented in operative reports.

Concur

Target date for completion: August 31, 2017, 3 months of data will be audited

Facility response: The ACOS for Surgery and all other staff surgeons have been re-educated about policy requirements and procedural expectations that the expected resident author should sign the dictated operative note and the attending should cosign to demonstrate and document the level of supervision per the VHA Handbook 1400.01, *Resident Supervision*. Documentation in Patient Settings-Section 5.c.(5) Operating Room (OR) Procedures of VHA Handbook 1400.01 deals with resident documentation

of staff involvement. In addition, the presence of the privileged provider performing the procedure during time outs to ensure correct surgery is strictly enforced in the facility as per VHA Directive 1039 Ensuring Correct Surgery and Invasive Procedures. Both of the above have been reinforced at the Surgery Section Chiefs Meeting by the Chief of Staff.

Recommendation 5. We recommended that the Facility Director ensure that the Associate Chief of Staff of Surgical Service communicates a designated backup surgeon to the surgical team in the event of his absence from the operating room.

Concur

Target date for completion: Completed

Facility response: The ACOS for Surgery and all other staff surgeons have been re-educated about policy requirements and procedural expectations related to attending presence and supervision per the VHA Handbook 1400.01, *Resident Supervision*. Per this Handbook, immediate availability is defined as the physical presence of the supervising physician in the OR suite and this has been emphasized with the ACOS for Surgery and all other staff surgeons. Based on feedback from the National Surgery Office, the fact that simultaneous surgery is prohibited has been clearly emphasized with the ACOS for Surgery and all other staff surgeons.

In addition to compliance with the VHA Handbook 1400.01, *Resident Supervision*, it has been clearly emphasized in reference to the OIG recommendation that the attending surgeon will not leave the medical center until all surgical procedures being performed by the surgical team have been completed. If the attending surgeon must leave the facility during surgery or is otherwise not immediately available, an appropriately credentialed alternate surgeon must be designated. This alternate surgeon must remain immediately available during the time he or she is assuming supervisory responsibility. This transfer of supervisory responsibility will be known to the operating team, and accompanied by verbal hand off between providers. This change in supervising surgeon will be documented by the circulating nurse. Any major change in attending surgeon supervisory responsibility will be reflected in the operative dictation. Moreover, the facility will explore the use of the white boards for this purpose.

Recommendation 6. We recommended that the Facility Director ensure that the cases identified in this report are reviewed, and for patients who suffered adverse outcomes and poor quality of care, confer with the Office of Chief Counsel regarding the appropriateness of disclosures to patients and families.

Concur

Target date for completion: Cases 1 and 3 are completed. Case 2 will be completed by April 15, 2017, and Case 4 upon completion of external peer review.

Facility response:

a) Case 1. [Peer review material redacted per 38 U.S.C. 5705] An institutional disclosure was performed with the patient's niece (Next Of Kin) on July 7, 2015.

b) Case 2. [Peer review material redacted per 38 U.S.C. 5705] We did not perform an institutional disclosure, but will confer with general counsel regarding appropriateness no later than April 15, 2017.

c) Case 3. [Peer review material redacted per 38 U.S.C. 5705] We did not perform an institutional disclosure.

d) Case 4. This case was not peer reviewed. Consultation with our Risk Manager revealed the following:

"This event would not automatically trigger an occurrence screen for death review. I am uncertain of why the electronic notifications that I ordinarily receive did not identify him as an external death. I contacted the St. Clair County Medical Examiner's Office [in 2017] to inquire if an autopsy was performed and was told that it was not done." We will be sending this case for external peer review as soon as possible.

Recommendation 7. We recommended that the Facility Director explore reasons why an autopsy was not performed per a family's request (Patient 1 of this report) and take action as necessary.

Concur

Target date for completion: Completed

Facility response: The family signed the consent for an autopsy. Unfortunately, anatomic pathology did not receive the request/authorization and the body was released to the funeral home. As a result of this incident, a new Standard Operating Procedure (SOP) was developed and incorporated into the Policy 11LAB-11 AUTOPSY – AUTHORIZATION, ORDERING, SPECIAL CONSIDERATION to prevent this from occurring in the future. This SOP was developed with specific algorithms for coordination of procedures among: Physicians, Nursing Service, Patient Care Service, Business Practice, and Pathology and Laboratory Medicine. After hours processes were also outlined specifically.

Recommendation 8. We recommended that the Facility Director ensure that facility staff comply with Veterans Health Administration policies on peer review and the care of Patient 4 is evaluated and a peer review is completed.

Concur

Target date for completion: Upon completion of external peer review for case 4.

Facility response: Our processes for peer review are compliant with the VHA Directive and we will send Case 4 for external peer review as soon as possible.

OIG Comment: The Facility considers Recommendations 1, 2, 5, and 7 completed; however, we consider all recommendations open until we receive and review documentation of the Facility's completion of the proposed actions.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Inspection Team	Thomas Jamieson, MD Judy Montano, MS Thomas Wong, MD
Other Contributors	Derrick Hudson

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