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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Orthopedic Surgery Department and Other Concerns at the Carl T. Hayden VA Medical Center

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Executive Summary

The VA Office of Inspector General (OIG) conducted an inspection to evaluate allegations that an orthopedic surgeon at the Carl T. Hayden VA Medical Center (facility) in Phoenix, Arizona, failed to adequately assess two patients (Patient Red and Patient Blue), which resulted in delays in care. The OIG team evaluated additional allegations related to the facility's improper use of fee-for-service (fee) orthopedic surgeons and facility leaders' responsiveness to concerns about the Orthopedic Surgery Department. As a result of the initial assessment of these allegations, the OIG team also evaluated orthopedic surgeons' responsiveness to physician assistants (PAs), and select aspects of infrastructure, support services, clinical privileging, and PA scopes of practice.¹

The OIG substantiated that the orthopedic surgeon did not physically evaluate Patient Red or take responsibility for the patient's orthopedic care. Patient Red experienced a delay in diagnosis and treatment due to a variety of issues. While waiting for a definitive diagnosis, Patient Red developed significant mental status changes and septic shock. On the second day of Patient Red's hospitalization, a PA sought help from multiple attending orthopedic surgeons over several hours before one of the surgeons came to assess Patient Red. A planned procedure was canceled on the second day of hospitalization when a shoulder ultrasound was interpreted as negative for a drainable abscess or fluid collection. Patient Red's clinical course met the Veterans Health Administration's (VHA's) definition of an adverse event, but as of August 8, 2018, a disclosure had not been completed.

The OIG team determined that an orthopedic surgeon should have promptly taken responsibility and continued to manage Patient Red's care, particularly because the patient had complex comorbidities and was in the process of progressing to septic shock. Orthopedic surgeons' accountability for the coordination of patient care with the PAs was not clearly outlined either by policy or clearly defined expectations. The OIG concluded that the care of Patient Red was an example of leadership weaknesses and lack of accountability in the Orthopedic Surgery Department.

The OIG substantiated that the orthopedic surgeon's decision not to admit Patient Blue placed the patient at risk for medical decompensation given that the patient lived more than three hours away and had a history of a complicated hip infection with signs of a new infection. Patient Blue presented to the facility's Emergency Department in January 2018 complaining of progressive

¹ VHA Directive 1063, *Utilization of Physician Assistants (PA)*, December 24, 2013. "A PA is a health care professional trained...and credentialed to provide medical services to patients within a defined Scope of Practice. PAs receive over 2,000 hours of...training in the medical sciences and over 2,000 hours of supervised clinical training." Two other allegations related to facility orthopedic surgeons' (1) work hours and (2) practices placing other clinical staff at risk for malpractice were not evaluated. The OIG did not have specifics to evaluate the work hours allegation and the malpractice allegation was outside the scope of the inspection.

swelling, pain, and redness at the incision site of a previous hip replacement. The Emergency Department PA found a fluid-filled mass located above the surgical scar and called for orthopedic surgery and infectious disease consults. The plan was for ultrasound-guided aspiration of the mass and admission to the Orthopedic Surgery Service. The aspiration was completed as planned but Patient Blue was not admitted; rather, the patient was discharged home before the aspirate culture results were available for review.

Although Patient Blue was reportedly pleased with the plan for discharge home, it would have been prudent for the orthopedic surgeon to provide information to Patient Blue about his/her condition and the risks, benefits and alternatives to disposition planning.

The Orthopedic Surgery Department tolerated a practice where on-call orthopedic surgeons did not consistently take responsibility for managing complex patient care needs. Specifically, some on-call orthopedic surgeons would tell PAs to find another surgeon rather than taking responsibility for making an attending-to-attending surgeon contact to arrange for the needed evaluation and care. As a result, PAs had to seek assistance from any other provider willing to offer it, sometimes requiring multiple telephone calls and potentially delaying care. One PA told the OIG in August 2018, several months after the OIG's site visit, that the attending surgeon nonresponsiveness had improved in the previous few months.

The OIG team reviewed more than 1,500 encounters of patients seen in the Emergency Department, more than 1,100 of which had a primary orthopedic-related diagnosis between early 2017, and spring 2018. The OIG found that documentation of orthopedic care was generally consistent with requirements. Further, the facility's orthopedic surgery 30-day morbidity and mortality rates were not concerning for the date range reviewed.

While the OIG substantiated that the facility used in-house fee and community-based orthopedic providers, the use of non-VA providers was not concerning from a quality of care perspective given the existing staffing and other limitations in the Orthopedic Surgery Department. The facility's decision to augment its orthopedic staff with fee providers who specialized in specific parts of the body, such as hands, or specific procedures, such as complex total hip replacements, was appropriate to ensure quality of patient care. However, the Orthopedic Surgery Department's long-standing tolerance of on-call surgeons declining to assist and not taking responsibility for coordinating patient care may have contributed to the need to utilize fee orthopedic surgeons in some cases.

The OIG was unable to determine whether fee surgeons performed procedures that facility surgeons could have performed, primarily because it is difficult to determine, retrospectively and definitively, whether specific patients needing orthopedic surgeries could have or should have received that care from a facility surgeon rather than a fee surgeon.

The OIG did not substantiate that critical patients were ignored because the Orthopedic Surgery Department claimed not to have surgical expertise when it really did. The OIG did not identify,

nor was the OIG told about, critically ill patients who did not receive needed orthopedic care. In those cases where the OIG found that care may have been delayed (Patients Red and Blue), the OIG did not find evidence that the sole reason those delays occurred was because a qualified facility surgeon refused to provide the service. Further, because the Orthopedic Surgery Department was not staffed with a comprehensive array of orthopedic generalists and sub-specialists, it had to rely on qualified fee surgeons to assure timely access and specialized orthopedic services. Therefore, the OIG did not consider fee costs to be improper.

The OIG did not substantiate that facility leaders failed to respond to concerns about the Orthopedic Surgery Department. The new Director and Chief of Staff started at the facility in October 2016 and initiated a Clinical Efficiency Team in September 2017 to assess a variety of service-level operations and find opportunities to improve access, reimbursement, specialty provider group practice productivity, overall data capture, and managerial cost accounting procedures.

The facility's surgical complexity designation is complex, meaning that it requires the highest level of facility infrastructure and performs the most complex procedures. Maintaining a complex surgical designation requires a certain infrastructure and partnerships. The OIG team found that several elements needed to support infrastructure and partnerships at the facility were inefficient, including operating room staff and Orthopedic Surgery Department communications, anesthesia staffing and operations, and Sterile Processing Services space, equipment, and loaner instrument tracking systems. Facility leaders retain responsibility for assuring resource availability and ongoing performance improvement.

The OIG also determined that the facility was not in compliance with VHA guidelines regarding surgeons' core clinical privileges and data collection and analysis requirements for ongoing professional practice evaluation. The facility was not compliant with VHA requirements related to having a PA utilization policy, appropriately completing PA ongoing professional practice evaluations, documenting collaborating physician input into periodic PA assessments, and listing surgical first assist duties in PA scopes of practice. The Chief of Orthopedic Surgery retains ultimate responsibility for ensuring orthopedic PA-related policies and performance requirements are met. The OIG team found that PAs who performed procedures in the Emergency Department appeared to be functioning within their individual scopes of practice.

The OIG made 12 recommendations to the Facility Director related to the provision of care for Patient Red and Patient Blue; interdepartmental communications and process efficiencies; anesthesia and Sterile Processing Services operations; orthopedic surgeon privileging; and PA scopes of practice.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan. The Facility Director had a different perspective on some aspects of Patient Red's clinical course. (See Appendixes B and C, pages 31–43 for the Directors' comments.) The OIG considers all recommendations open and will follow up on the planned actions until they are completed.

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Abbreviations

CIC	Care in the Community
COS	Chief of Staff
CRNA	certified registered nurse anesthetist
ED	Emergency Department
EHR	electronic health record
fee	fee-for-service
HD	hospital day
ICU	intensive care unit
OIG	Office of Inspector General
OPPE	Ongoing Professional Practice Evaluation
OR	operating room
PA	physician assistant
SPS	Sterile Processing Services
VASQIP	VA Surgical Quality Improvement Program
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted an inspection to evaluate allegations that an orthopedic surgeon (Surgeon A) at the Carl T. Hayden VA Medical Center (facility) failed to adequately assess two patients, which resulted in delays in care. Other allegations that the OIG team evaluated were (1) whether the facility's use of fee-for-service (fee) orthopedic surgeons was improper because the Orthopedic Surgery Department had orthopedic surgeons on staff who were capable of providing the services, and (2) facility leaders' responsiveness to reported concerns. While not allegations, the OIG team evaluated the following areas due to their impact on the Orthopedic Surgery Department's quality and efficiency: orthopedic surgeons' responsiveness to physician assistants (PAs), select infrastructure elements needed to support a complex surgical program, partnerships supporting operating room (OR) efficiency, clinical privileging, and PA scopes of practice.²

Background

The facility is composed of the Carl T. Hayden Veterans Affairs Medical Center and nine community based outpatient clinics. It is categorized as a Clinical Referral Level 1b facility that provides acute inpatient medical, surgical, and mental health care.³ In fiscal year 2017, the facility had 294 beds and served more than 91,000 patients.⁴ The facility is part of Veterans Integrated Service Network (VISN) 22.

In recent years, the facility has been at the center of multiple internal reviews and congressional hearings, some of which received national media attention and resulted in changes in the facility's top leaders. A new leadership team started in 2016, including the Chief of Surgery in June, and Medical Center Director and Chief of Staff (COS) in October. OIG reports involving the facility from January 1, 2015, through April 17, 2018 can be accessed at <u>www.va.gov/oig</u>.

Surgery Program Complexity and Infrastructure

VHA policy requires that VA medical facilities with an inpatient Surgical Program have "(1) surgical complexity designation of either standard, intermediate, or complex based upon the facility infrastructure; and (2) that the scheduled (nonemergent) surgical procedures performed

² VHA Directive 1063, *Utilization of Physician Assistants (PA)*, December 24, 2013, states that, "A PA is a health care professional trained...and credentialed to provide medical services to patients within a defined Scope of Practice. PAs receive over 2,000 hours of...training in the medical sciences and over 2,000 hours of supervised clinical training."

³ A Level 1b facility is considered high complexity as defined by very large levels of volume, patient risk, teaching, and research.

⁴ The facility had 166 inpatient, 24 domiciliary, and 104 community living center beds in fiscal year 2017.

are not to exceed the infrastructure capabilities of the facility." ⁵ The facility's surgical complexity designation is complex, meaning that it requires the highest level of facility infrastructure and performs the most complex procedures. To support the complex surgical designation, various clinical services must be available 24 hours-per-day, 7 days-per-week. The facility has six ORs that are fully operational until about 3:30 p.m., at which time OR capacity reduces to three rooms. After 5:30 p.m., only one OR is routinely staffed and available for emergencies and add-on procedures.⁶

To ensure quality care and timely access to surgical procedures, various surgical departments must rely on and work in conjunction with other teams and services:

- Sterile Processing Services (SPS) is responsible for ensuring a continuous flow of processed (cleaned and sterilized) instruments to all points of use, including the ORs.⁷
- OR specialists and partnering teams, which include anesthesiologists, certified registered nurse anesthetists (CRNAs), OR nurses, and technicians. Staff are responsible for working in the OR, Same Day Surgery, Preprocedure Clinic, and the postanesthesia care unit.
- Prosthetic and Sensory Aid Service manages prosthetic devices and implants prescribed and ordered for individual patients. Prosthetics and implants are devices that support or replace the loss of a body part or function.⁸
- Logistics manages medical supplies including surgical dressings and equipment such as infusion pumps.

Orthopedic Surgery Department Profile and Limitations

According to the American Academy of Orthopaedic Surgeons, an orthopedic surgeon is a physician "devoted to the diagnosis, treatment, prevention and rehabilitation of injuries, disorders and diseases of the body's musculoskeletal system. This system includes bones, joints, ligaments, muscles, nerves and tendons." Further, American Academy of Orthopaedic Surgeons states that "[w]hile orthopaedic surgeons are familiar with all aspects of the musculoskeletal

⁵ VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. This VHA directive expired May 31, 2015, but has not been updated. A facility infrastructure refers to: diagnostic evaluation; consultation; surgical physician staffing; operating room staffing, instruments, equipment, coverage, and radiology; anesthesia services; post anesthesia care unit; intensive care unit; supply, processing, and distribution; and other support services related to a surgical procedure.

⁶ According to an OR staff member, add-on procedures are cases added to the already published surgery schedule.

⁷ In VHA Directive 2010-018, Sterile Processing Services is referred to as "Supply, Processing, and Distribution (SPD)."

⁸ VHA Handbook 1173.1 *Eligibility*. November 2, 2000. This handbook was scheduled for recertification on or before the last working day of July 2005, but has not been recertified.

system, many orthopaedists specialize in certain areas, such as the foot and ankle, hand, shoulder and elbow, spine, hip or knee."

As of April 2018, the facility's Orthopedic Surgery Department was staffed with seven full- and part-time VA surgeons and six PAs, which had not been an adequate staffing model to meet demand. The Chief of Orthopedic Surgery told OIG inspectors about difficulties recruiting orthopedic surgeons, citing pay disparities between VA and the private sector.⁹ The Chief of Orthopedic Surgery also reported that over the years, some of the facility's orthopedic surgeons elected to specialize in a particular joint (such as the knee or hip) and had lost other surgical skills through lack of practice.

The Orthopedic Surgery Department largely focused on elective orthopedic surgeries that permit pre-planning. The Orthopedic Surgery Department did not perform <u>hip arthroscopy</u>, tumor or oncological cases, complex spine surgeries (such as <u>lumbar fusion</u>), or trauma with the exception of fractures that could be treated on a scheduled/elective basis. The Orthopedic Surgery Department had limited ability to perform primary hip <u>arthroplasty</u> and complex hip or knee <u>arthroplasty</u> revision due to the limited number of surgeons with those specialty skill sets.

As of March 2018, the Orthopedic Surgery Department was meeting the technical requirement to provide 24-hour-per-day, 7-day-per-week on-call coverage. However, a variety of staffing, infrastructure, and accountability issues had compromised the Orthopedic Surgery Department's responsiveness, resulting in other healthcare providers developing alternative practices to assure patient orthopedic needs were met. For example, facility and [in-house] fee orthopedic surgeons rarely operated after normal business hours or on weekends.¹⁰ Several non-VA avenues for care provision ensured that veterans received appropriate, timely, and accessible orthopedic care:

- The facility augmented its orthopedic staff with seven in-house fee surgeons who operated on veteran patients in the facility's OR. Reportedly, the orthopedic fee surgeons were hired to provide two types of care: (1) specialty care that could not be provided by facility orthopedic surgeons such as complex joint reconstruction, revision, infection, and upper extremity issues; and (2) general orthopedic assistance in the clinics and OR to improve access. Collectively, facility and fee surgeons performed 1,402 orthopedic surgeries from January 1, 2017, through March 31, 2018.
- The facility authorized services through the Care in the Community (CIC) Program when it could not provide the care or could not schedule an appointment for the care within 30 days of the patient's preferred date (or the clinically indicated date). CIC consults could also be

⁹ Orthopedic surgeons are one of the highest paid surgical specialties and some VHA healthcare facilities have difficulty recruiting orthopedists due to federal government pay bands which can be lower than the private sector.

¹⁰ Forty-seven of the 1,402 (3 percent) orthopedic surgeries from January 1, 2017, through March 31, 2018, were performed on weekends, holidays or after 3:30 p.m.

authorized when the patient resided more than 40 miles from the closest VA medical facility. From January 1, 2017, through March 31, 2018, providers requested 433 orthopedic-related CIC consults.¹¹

• *The facility referred to appropriate non-VA medical providers when it was unable to provide the care or services.*¹² The Emergency Department (ED) transferred 43 patients in need of selected orthopedic services to non-VA providers from early 2017, through spring 2018.

For many years, the facility sought to reduce its reliance on non-VA orthopedic providers but has been hampered by space limitations and an inability to recruit an adequate number of orthopedic surgeons.

Allegations

In January 2018, the OIG received a complaint alleging that (1) Surgeon A did not physically evaluate or review the clinical findings of a patient (Patient Red) who was admitted to the facility for shoulder pain and had laboratory and history and physical examination findings concerning a septic shoulder and (2) Surgeon A's failures to evaluate or review clinical findings resulted in a delay in treatment and care as Patient Red was experiencing significant mental status changes and <u>sepsis</u> the day after hospital admission.¹³

A few days later, the OIG received a second complaint about Surgeon A's handling of Patient Blue, who had a history of prosthetic hip infections and new fluid accumulation that was suspicious for <u>abscess</u>. Reportedly, Patient Blue needed hospital admission and "semi-urgent" irrigation and debridement of the hip.¹⁴ However, Surgeon A discharged Patient Blue from the ED without physically evaluating the patient, which placed Patient Blue at risk for sepsis and death.¹⁵ Patient Blue had to travel more than three hours back to the facility the next day, which was allegedly an undue burden on the patient and the patient's family. The complainant made several specific allegations related to this case:

¹⁴ Irrigation and debridement is a "procedure commonly used for the treatment of acute periprosthetic infection." Debridement is the "surgical removal of lacerated, devitalized, or contaminated tissue." <u>https://www.sciencedirect.com/science/article/pii/S0883540310001373</u>. (The website was accessed on December 13, 2018); <u>https://www.merriam-webster.com/dictionary/debridement</u>; <u>https://www.merriam-webster.com/dic</u>

¹¹ Nearly half (214) of the CIC consults were subsequently canceled or discontinued. The OIG team found that, in general, the reasons for cancellation or discontinuation were appropriately documented and that patients needing orthopedic services either received the services or had a subsequent contact with a provider (reflecting an opportunity to voice additional complaints about the orthopedic problem, if needed).

¹² A variety of factors would determine whether an urgent or emergent orthopedic condition could appropriately be treated within the facility including the complexity of the surgery, and the timely availability of the surgical specialist and required instruments sets and implants, if needed.

¹³ Septic arthritis is the inflammation of a joint due to a bacterial or fungal infection.

¹⁵ A consulting orthopedic surgeon would not discharge a patient from the ED; this responsibility would belong to the ED physician or ED PA. A more precise explanation is that Surgeon A did not admit Patient Blue to the hospital and suggested discharge home with follow-up in two days.

- Surgeon A claimed there was no [facility] surgeon available to perform the irrigation and debridement. However, an irrigation and debridement procedure is basic surgical practice and can be done by any orthopedic surgeon.
- Patient Blue's irrigation and debridement procedure was completed by an in-house fee surgeon, which delayed Patient Blue's treatment.
- The use of a fee surgeon constituted an unnecessary expense (as facility orthopedic surgeons could have performed the procedure).

The complainant also made several general allegations:

- Patients are referred to community providers or in-house fee surgeons are used, which is problematic because facility orthopedic surgeons can perform the procedures. Critical patients are ignored [because the Orthopedic Surgery Department] claims not to have surgical expertise when that is not accurate.
- Some facility leaders have not been responsive to concerns about the Orthopedic Surgery Department.

The OIG team could not adequately evaluate general allegations related to some facility orthopedic surgeons leaving work at 2:00 p.m. and refusing cases they were "perfectly able to handle." Because the OIG was not provided specific surgeons' names and dates when the alleged behaviors occurred, there was no reasonable way for OIG to retrospectively evaluate the allegations across the Orthopedic Surgery Department. Another allegation—that Surgeon A's decision to discharge Patient Blue placed the ED PA and another consulting physician at risk for malpractice—was beyond the scope of this inspection.

The OIG categorized the above allegations into three issues. Issue 1 (a) addresses the orthopedic surgery quality of care and orthopedic surgeon responsiveness to orthopedic surgery PAs in relation to the two patients identified above and (b) discusses the OIG's review of patients who presented to the ED with orthopedic conditions between early 2017, and spring 2018. Issue 2 explores various aspects of fee surgeon matters, and Issue 3 examines facility leaders' responses to concerns.

During the review, the OIG team identified and evaluated concerns related to (Issue 4) select infrastructure elements and partnerships needed to support a complex surgical program and OR efficiency; and (Issue 5) clinical privileging and PA scopes of practice.

Scope and Methodology

The OIG initiated the inspection on February 28, 2018, and conducted a site visit April 23–26, 2018. The OIG team's data review included selected documents spanning early 2017, to spring 2018.¹⁶ Prior to the site visit, the OIG team interviewed the complainant, Facility Director, COS, Chief of Surgery, VA Surgical Quality Improvement Program (VASQIP) nurses, CIC Program Coordinator, and the Chief of Orthopedic Surgery. During the site visit, the OIG team interviewed facility orthopedic surgeons, PAs, the SPS Chief, the OR charge nurse, Group Practice Managers, the Chief of Infectious Disease, the ED Director, and others with knowledge of the issues.

The OIG team reviewed applicable facility policies and VHA directives and handbooks. Additionally, the team reviewed facility quality and internal management reports, clinical privileging and scope of practice data, patient advocate reports, surgical scheduling and efficiency reports, and other documents relevant to the allegations. Electronic health record (EHR) reviews were completed that involved more than 1,500 encounters, over 1,100 of which were patients seen in the ED with a primary orthopedic-related diagnosis between early 2017, and spring 2018.¹⁷ An orthopedic specialist was consulted on several cases. The OIG team also reviewed a subset of 43 patients transferred directly from the ED to non-VA facilities during the period early 2017 through spring 2018 for conditions that were primarily orthopedic-related.¹⁸

For privacy reasons, the OIG has generalized narratives and case scenarios and de-identified protected patient information. However, after the site visit, the OIG team discussed with clinical leaders the patient cases included in this report to allow leaders to fully understand the sequence of events and the OIG's concerns about the cases.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take

¹⁶ To assure an understanding of the clinical scenarios, OIG inspectors also reviewed relevant EHR documentation prior to 2017 in some cases.

¹⁷ For the purposes of this inspection OIG excluded patient encounters for which the ED provider's final diagnosis indicated a need for podiatry or orthopedic spine services, pain management, or conditions related to chronic back pain.

¹⁸ The OIG team found that given the patients' presenting conditions, and the Orthopedic Surgery Department's known limitations in terms of staffing and infrastructure challenges, the transfers were justifiable to ensure timely and quality care. Orthopedic-related ED transfers are not addressed further in this report.

place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

The OIG team acknowledges that retrospectively evaluating a provider's clinical decisions is an imperfect approach because the provider is making decisions in the context of information and circumstances present at that time.

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

Patient Case Summaries

Patient Red

Patient Red was in his/her late 60s and had multiple medical problems including diabetes and kidney failure requiring dialysis.¹⁹ In early 2017, Patient Red was admitted to a non-VA hospital and found to have methicillin resistant *Staphylococcus aureus* (MRSA) infection in the blood and a right shoulder abscess. The patient was treated with intravenous antibiotics and the abscess was drained. Patient Red left the non-VA hospital against medical advice. Several hours later, the patient presented to the facility's ED complaining of "MRSA, all through my whole body." A facility hospitalist agreed to admit Patient Red for social reasons while waiting for records from the non-VA hospital (Hospital Day (HD) 1).²⁰

At approximately 9:00 a.m. on HD 1, the inpatient admitting medical team requested multiple consults (including renal, orthopedics, and infectious disease). At approximately 3:00 p.m., that afternoon, an orthopedic PA (PA-1) evaluated Patient Red and found that the patient had an unremarkable shoulder exam (no skin changes and no pain with movement). PA-1 discussed with Surgeon A the results of Patient Red's non-VA radiology studies and concerns that Patient Red might have an abscess (in the skin outside the joint) or <u>septic arthritis</u>. PA-1 documented the plan to obtain an <u>magnetic resonance imaging (MRI)</u> study and, based on the results, possibly schedule Patient Red for surgery the next day.²¹ The <u>Infectious Disease physician</u> evaluated the patient on HD 1 at approximately 5:00 p.m. and documented a suspicion for persistent bacteremia. The Infectious Disease physician also noted "will defer shoulder/wrist to ortho [orthopedic team] however I will say that conservative therapy with IV [intravenous] antibiotics were tried and have failed."

Overnight, Patient Red's mental status worsened and the MRI that had been scheduled could not be completed. In the morning of HD 2, PA-1 discussed Patient Red's condition with Surgeon B.²² During the day, Patient Red underwent hemodialysis. At 3:46 p.m., the Infectious Disease physician evaluated Patient Red and noted signs and symptoms that were indicative of "septic right shoulder vs extra aurticular [*sic*] abscess - either way this needs to be drained as this is most likely source of sepsis..."

¹⁹ The OIG uses "his/her" to protect patients' privacy.

²⁰ A hospitalist is a physician who provides care to hospitalized patients. Hospitalists typically spend their entire shift in the hospital.

²¹ Surgeon A cosigned PA-1's assessment note, which generally indicates agreement with the plan of care.

²² PA-1 documented a discussion about Patient Red with Surgeon B who examined the patient; Surgeon B did not write a note in Patient Red's EHR.

PA-1 discussed Patient Red's increasing white blood cell count and low blood pressure with Surgeon A, who recommended contacting the <u>interventional radiologist</u> (IR) to have the fluid removed from Patient Red's shoulder. The IR was reluctant to perform the procedure without first obtaining an <u>ultrasound</u>. The orthopedic team ordered a STAT ultrasound at 4:22 p.m.; Patient Red was scheduled to have the ultrasound study later that evening.²³ After speaking with the Infectious Disease physician, PA-1 called Surgeon A and asked if it was appropriate to refer Patient Red to a non-VA facility. While waiting for Surgeon A's decision, PA-1 discussed Patient Red's condition with a third orthopedic surgeon (Surgeon C). Surgeon C was available and examined Patient Red; a surgical procedure was planned to drain the fluid from the shoulder joint if the ultrasound was positive. The ultrasound, that was completed at 5:33 p.m., did not identify an abscess. The radiologist recommended "further evaluation with limited contrast enhanced CT [computed tomography] or MRI if clinically indicated." Surgeon C canceled the planned surgery.²⁴

Due to Patient Red's worsening condition, the patient was transferred to the intensive care unit (ICU) at approximately 7:00 p.m. The ICU resident ordered a CT scan of the right upper extremity that was completed at 10:32 p.m. The CT scan showed a large fluid collection which was "highly suspicious" for septic arthritis and bone infection.

On the morning of HD 3, Patient Red's respiratory status deteriorated and the patient had to be placed on a ventilator. Patient Red was diagnosed with aspiration pneumonia and started on an additional antibiotic to treat the new infection.²⁵ An attending orthopedic surgeon (Surgeon D) described Patient Red as "critically ill." Surgeon D took Patient Red to the OR at approximately 11:00 a.m., removed "frank pus" from the patient's shoulder, and diagnosed septic arthritis. Laboratory testing of the "pus" confirmed MRSA.

Patient Red was periodically agitated and confused throughout the hospital admission. On HD 10, Patient Red was transferred out of the ICU and later discharged to a group home because of continued confusion on HD 53.²⁶

²³ For patients with infections, the body tries to mount an immune response by producing more white blood cells to fight the infection. In the process of mounting an immune response, the patient's temperature may rise. Patient Red did not have a temperature high enough to be considered a fever, likely because of multiple medical problems.

²⁴ Per the radiologist's interpretation of the ultrasound, findings were "suggestive of right shoulder soft tissue edema/cellulitis with no discrete abscess identified."

²⁵ Aspiration pneumonia typically occurs when patients have an altered state of consciousness and are unable to protect their airway. Food matter from the stomach may regurgitate into the trachea, causing an infection in the lungs.

²⁶ The facility was notified that Patient Red died a few months later. The cause of death was not documented.

Patient Blue

At the time of the events discussed in the report, Patient Blue was in his/her mid-60s with a history of diabetes, hypertension, and <u>degenerative joint disease</u>. Patient Blue underwent a left hip replacement at a non-VA facility in early 2017.

In spring 2017, Patient Blue developed an infection in the left hip prosthesis. That summer, Patient Blue was treated at the facility with antibiotic therapy and admitted multiple times for surgical procedures to treat infections and other post-surgery complications. By fall 2017, Patient Blue was "infection free" and both the Infectious Disease physician and orthopedic surgeon agreed to delay any future hip surgery for as long as possible.²⁷ A hip spacer that was impregnated with antibiotics to keep the appropriate space and length in the patient's leg had been placed until a new prosthesis could be implanted.

In winter 2018, Patient Blue called the Orthopedic Clinic complaining of increased left hip pain. PA-2 advised "resting, icing, and monitoring for 24 hours." Patient Blue was also told to go to the nearest ED if symptoms worsened.

Twelve days later, Patient Blue presented to the facility's ED complaining of progressive swelling, pain, and redness at the left hip incision site. On physical exam, the ED PA found a "tennis ball size" fluid-filled mass located above the left hip surgical scar and called for orthopedic surgery and infectious disease consults. Patient Blue's inflammatory markers, that had been normal, were elevated. The ED PA wrote that the plan was to have IR perform an ultrasound-guided <u>aspiration</u> of the mass. Patient Blue would then be admitted to the Orthopedic Surgery Service.

PA-2 examined Patient Blue in the ED and signed out to PA-3 to arrange for the aspiration of the left hip fluid collection and "discharge home vs. [versus] admit." A radiologist completed the left hip aspiration at 2:15 p.m. and sent a specimen for laboratory analysis.²⁸

PA-2 did not document the examination or findings in the EHR. PA-3, who did not evaluate Patient Blue directly, documented discussing Patient Blue's condition with Surgeon A at 3:25 p.m. along with the plan to not admit, but instead, to discharge the patient home with a follow-up appointment in the Orthopedic Clinic two days later.²⁹ The ED PA documented that Patient Blue was "very pleased with this plan." Patient Blue was discharged home (more than three hours

²⁷ The plan was to re-implant a new prosthesis in the hip once the infection cleared.

²⁸ "Under ultrasound guidance, a 5 French Yueh needle/catheter was advanced into the [subcutaneous] fluid collection" in the lateral left upper thigh. "Approximately 130 cc [cubic centimeters] of purulent appearing fluid was aspirated from the collection" and sent for laboratory analysis.

²⁹ An appointment was scheduled but subsequently canceled due to the inpatient admission.

away) at 3:30 p.m. with instructions to return to the ED if fever, chills, or other signs of infection developed. The laboratory results related to the aspirate were available in the EHR at 4:08 p.m.

The Infectious Disease physician, who had been caring for Patient Blue since summer 2017, also evaluated the patient while the patient was in the ED and documented a note at 4:50 p.m.³⁰ The Infectious Disease physician's initial understanding was that Patient Blue would be admitted but later learned that the patient was discharged. In the evening, after Patient Blue had been sent home, the Infectious Disease physician entered an addendum note at 6:31 p.m. that stated: "I disagree with the plan that was implemented" and the "[p]atient should have been admitted." This note was cosigned by Surgeon A the next day. The Infectious Disease physician called Patient Blue in the evening and advised the patient to return to the ED if symptoms worsened.

The following morning, the orthopedic surgeons discussed Patient Blue's case and decided that Patient Blue needed to be admitted for an "irrigation and debridement" and possible repeat spacer versus girdlestone procedure.³¹ Patient Blue was notified of this decision, returned to the facility, and was admitted that afternoon. The next day, Patient Blue underwent an irrigation and debridement of the left hip, with removal of the hip spacer and placement of <u>antibiotic beads</u>. Except for issues with wound closure, Patient Blue recovered well during the course of this hospitalization. Approximately two weeks after surgery, the patient was transferred to a VA community living center for rehabilitation.

In spring 2018, Patient Blue was admitted for another irrigation and debridement of the left hip. The patient recovered well and was discharged home four days later. During a subsequent visit to the Orthopedic Clinic, an orthopedic surgeon noted in the EHR that the patient was healing well and to follow-up on an as-needed basis.

³⁰ The OIG recognizes a discrepancy in the timing that the patient was reportedly discharged (3:30 p.m.) and the timing of the Infectious Disease physician's note (4:50 p.m.).

³¹Cordero-Ampuero, Jose, Girdlestone Procedure: When and Why, *Hip International* Vol 22 Supplement 8_Suppl (July-August 2012): 36-39. "Girdlestone is one of the options for treating an infected hip arthroplasty (along with isolated antibiotics, debridement, and one or two-stage exchange). The choice must be based on a list of previous considerations."

Inspection Results

Issue 1: Quality of Orthopedic Surgery Care

Review of Specific Patients

Patient Red

The OIG team substantiated that Surgeon A did not physically evaluate Patient Red, who was admitted to the facility for shoulder pain, underwent a history and physical examination, and had laboratory findings concerning for <u>septic arthritis</u>. Patient Red experienced a delay in diagnosis and treatment due to a variety of issues. While waiting for a definitive diagnosis, Patient Red developed significant mental status changes and <u>septic shock</u>.

Patient Red's initial presentation to the ED was atypical for septic arthritis; the hospitalist only admitted the patient for "social" reasons.³² However, Patient Red decompensated the next day, requiring transfer to the ICU on the evening of HD 2 for confusion, low blood pressure, and increasing body temperatures—signs and symptoms that are indicative of septic shock. At that point, Patient Red's risk of death was greater than 40 percent.³³ The treatment in this case was an incision and drainage of the septic arthritis. Because Patient Red's critical medical condition required rapid diagnosis, the most expeditious way to diagnose septic arthritis was by aspiration of the joint (arthrocentesis).³⁴

An arthrocentesis could have been performed by orthopedic surgeons or orthopedic PAs at Patient Red's bedside. Imaging studies do not provide a definitive diagnosis of septic arthritis. The additional time to obtain imaging (ultrasound and CT scan) caused diagnostic delays in this critically ill patient.

Ultrasound can be sensitive to finding small amounts of fluid. In Patient Red's case, the HD 2 ultrasound did not identify a discrete abscess and Surgeon C canceled a planned arthrocentesis. A few hours after the negative ultrasound, Patient Red underwent a CT scan which was "highly suspicious" for septic arthritis. The radiology report of the CT scan issued at 10:32 p.m. concluded "SIGNIFICANT ABNORMALITY, ATTN [attention] NEEDED" but did not reflect if this abnormality was verbally communicated to the ordering provider. At 7:10 a.m. on HD 3, an orthopedic surgery PA called Patient Red's nurse and informed the nurse that Patient Red would be going to the OR at noon.

³² Patients with septic arthritis typically present with severe pain in a joint that is worse on movement. It is commonly associated with redness and swelling over the joint.

³³ Mervyn Singer et al., "The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)," *JAMA* 315, no. 8 (February 2016): 801-810.

³⁴ Arthrocentesis is aspiration of a joint by use of a needle.

Patient Red was taken to the OR at 10:41 a.m. on HD 3. The OIG was unable to determine why the patient was not taken to surgery immediately after the CT scan results were available for review on the evening of HD 2. Patient Red's condition significantly improved after undergoing drainage of the septic arthritis. Patient Red was discharged to a group home after the hospitalization because the patient remained confused. The delay in providing definitive surgical treatment for Patient Red may have contributed to the development of septic shock, resulting in a prolonged hospital stay.

As of August 8, 2018, the facility had not conducted an institutional disclosure of the adverse event. Institutional disclosure is warranted for "[a]dverse events that cause death or disability, lead to prolonged hospitalization, require life-sustaining intervention or intervention to prevent impairment or damage..." VHA defines institutional disclosure of adverse events as "a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse."³⁵

PA-1 sought help from multiple attending orthopedic surgeons over several hours before one of the surgeons came to assess Patient Red on HD 2. The OIG team determined that an orthopedic surgeon should have promptly taken responsibility and continued to manage the patient's care, particularly because the patient had complex comorbidities and was in the process of progressing to septic shock from an orthopedic issue.

Patient Blue

Alleged Increased Risk and Undue Burden to the Patient Related to Discharge

The OIG team substantiated that after speaking with PA-3, Surgeon A decided not to admit Patient Blue although Surgeon A had not physically evaluated the patient. The OIG team further substantiated that the decision not to admit Patient Blue placed the patient at risk for medical decompensation given that the patient lived more than three hours away. The history of a complicated hip infection with signs of a new infection including a "tennis ball size" mass and newly elevated inflammatory markers placed Patient Blue at risk for developing sepsis. While Surgeon A told the OIG that Patient Blue was stable and wanted to go home, the OIG team did not interview Patient Blue about the experience and therefore could not determine whether Patient Blue insisted on going home or whether the patient could have been persuaded to stay.

While reviewing this case, the OIG team identified several additional concerns:

³⁵ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. This VHA handbook was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018 which contains the same or similar language related to the definition of institutional disclosure.

- PA-2 initially saw Patient Blue in the ED and signed the patient out to PA-3 to arrange IR drainage and disposition. PA-2 did not document physical exam findings in the EHR, and PA-3 did not meet Patient Blue prior to carrying out the plan.
- Neither the ED PA nor PA-3 reviewed Patient Blue's joint aspirate results prior to discharging the patient home with the instruction to return in two days for a clinic visit.³⁶ Patient Blue's joint aspirate showed 155,668 white blood cells (which were not available until after the patient's ED discharge), and when taken in consideration of the patient's other clinical findings, met criteria for septic arthritis.
- The OIG was told that the ED PA, PA-3, and the Infectious Disease physician were not comfortable with sending Patient Blue home. However, neither of the PAs spoke directly with Surgeon A regarding their concerns, nor did the ED PA involve the ED attending physician in Patient Blue's care.³⁷ As the PAs do not have the authority or knowledge base to question Surgeon A regarding a treatment decision, it would have been beneficial for the PAs to contact the Infectious Disease physician or the ED physician so that an attending-level discussion with Surgeon A could have occurred.

The OIG was unable to determine whether a physical evaluation by Surgeon A or PA-3 would have changed the Orthopedic Surgery team's decision related to the discharge from the ED. However, the OIG determined that it would have been prudent for Surgeon A and PA-3 to personally evaluate the patient, to review the aspiration results, and to provide information to Patient Blue about his/her condition and the risks, benefits and alternatives to disposition planning so that both the medical team and Patient Blue could make an informed decision about the discharge plan.

Surgical Procedure

While the OIG confirmed that a fee surgeon performed Patient Blue's irrigation and debridement instead of Surgeon A, the team did not substantiate the implied inappropriateness of this action. The patient needed not only an irrigation and debridement, but also removal of the hip spacer and placement of antibiotic beads. One of the orthopedic surgeons stated that an irrigation and debridement procedure is basic surgical practice and can be done by any surgeon. However, Patient Blue had a complicated history of hip infections and would be best served by a hip specialist. Although Patient Blue did not receive an irrigation and debridement for two days after first presenting to the ED, the patient's medical condition was stable so the benefit of waiting for an appropriate specialist outweighed the risk of disease progression. The OIG was unable to

³⁶ The Infectious Disease physician reviewed the joint aspirate results in the evening, after Patient Blue was discharged.

³⁷ The Infectious Disease physician did not know that Patient Blue was being discharged and could not have spoken to Surgeon A about changing the disposition plan.

determine whether Patient Blue would have had the procedure earlier if the patient had been admitted the day the patient presented to the ED.

Orthopedic Surgeon Responsibilities for Care Management

In reviewing the EHRs of Patient Red and Patient Blue, the OIG team concluded that Surgeon A could have more proactively participated in, or taken responsibility for, managing care and resources for these two patients. In reviewing orthopedic surgery on-call responsibilities and other processes, the OIG team found that some deficiencies potentially jeopardized the Orthopedic Surgery Department's ability to consistently deliver high quality care.

The OIG team was told in interviews that PAs were the first orthopedic providers on-call. For example, the ED would notify the on-call orthopedic PA when a patient arrived needing an orthopedic consult. The PA would assess the patient's orthopedic condition and needs. If the patient needed surgery or otherwise had a complex presentation, the PA would call the orthopedic surgeon on-call.³⁸

PAs reported, and OIG confirmed through interviews with other staff members, that some orthopedic surgeons would tell the PAs to find another surgeon for the surgery, ostensibly because they would not be performing the needed procedure. Further, some of these on-call surgeons would not take responsibility for contacting an appropriate surgeon to arrange for the needed evaluation and care.³⁹ Surgeon A defended this process, saying that the PA (as the first evaluator) had the most relevant information and that requiring an attending-to-attending contact added an unnecessary middleman. However, this noncollaborative, nonresponsive approach by some orthopedic surgeons, which had been improperly tolerated within the department, placed PAs in the position of seeking assistance from any other provider willing to offer it, sometimes requiring multiple telephone calls and potentially delaying care. Apparently, over time and in an effort to secure timely services, some PAs have bypassed certain on-call surgeons, knowing they would decline, and made contact with more responsive surgeons.

The generalist orthopedic surgeons (Surgeons B and D) and the Chief of Surgery stated that it was not the PA's job to find an attending surgeon to perform a surgery—that duty falls to the on-call orthopedic surgeon.⁴⁰ Surgeon B told the OIG team that it would be more appropriate for on-call surgeons to do what they can to help, even if they do not ultimately perform the surgery.

³⁸ VHA Directive 1063, *Utilization of Physician Assistants (PA)*, December 24, 2013. This directive states that the collaborating physician is responsible for "[p]roviding appropriate clinical oversight, consultation, and patient care management assistance to the PA assigned" and for "[p]roviding readily available consultation and collaboration."

³⁹ According to several PAs, Surgeon E would routinely refuse to respond to their requests when on-call. Surgeon E, a full-time orthopedic surgeon, performed less than two surgeries per week between early 2017 and spring 2018. Surgeon E retired in spring 2018.

⁴⁰ An orthopedic generalist is an orthopedic surgeon that does not specialize in certain areas of the body such as shoulders and/or hips.

The Chief of Orthopedic Surgery stated that the Chief is generally tasked with ensuring that processes within the Department are efficient and comply with patient care and safety guidelines. Orthopedic surgeons' accountability for the coordination of patient care and surgical resources with the PAs was not clearly outlined either by policy or clearly defined expectations. The OIG concluded that the care of Patients Red and Blue were examples of leadership weaknesses and lack of accountability in the Orthopedic Surgery Department. PA-3 told the OIG in August 2018 that the attending surgeon nonresponsiveness had improved in the previous few months.

Review of ED Patients with Orthopedic Conditions

Orthopedic Surgery Department Documentation

Based on findings related to Patient Red and Patient Blue, and reports about periodic nonresponsiveness of some on-call orthopedic surgeons, the OIG team expanded its review population to evaluate Orthopedic Surgery Department documentation including relevant consultations, clinic progress notes, diagnostic testing, operative notes, and follow-up.⁴¹

The OIG team performed EHR reviews involving more than 1,500 encounters of patients seen in the ED, over 1,100 of which had a primary orthopedic-related diagnosis or condition between early 2017 and spring 2018.⁴² The OIG team's review centered on whether documentation reflected

- The orthopedic provider's response to an ED provider's request for consultation was timely,⁴³
- The orthopedic assessment relevant to the presenting complaint or condition was comprehensive, and
- Referrals, as appropriate, were made for follow-up appointments in the Orthopedic Clinic.

For patients admitted from the ED to the facility for a primary orthopedic-related diagnosis or condition, the OIG team reviewed documentation to determine if

- A history and physical was completed within 24 hours of admission,
- Admission notes contained required elements,
- PA supervision was adequately reflected, when appropriate,⁴⁴

⁴¹ VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

⁴² The OIG team excluded encounters involving chronic back pain, pain management, spinal, and podiatry conditions.

⁴³ For the purposes of this inspection, the OIG considered a timely response either telephonically or in-person to be within 60 minutes.

⁴⁴ VHA Directive 1063, Utilization of Physician Assistants (PA), December 24, 2013.

- An orthopedic treatment plan was established within 24 hours of admission, and
- A discharge note was completed in accordance with facility policy.⁴⁵

In general, the OIG team determined that the documentation of orthopedic care was consistent with VHA requirements and facility policy.

Overall Orthopedic Surgery Outcomes

VHA maintains and collects surgical morbidity and mortality data through the VASQIP to measure the quality of surgical outcomes and improve the management of surgical care.⁴⁶ VASQIP data are reported quarterly as 30-day morbidity and mortality rates (both unadjusted and risk-adjusted). "Aggregate reports of observed to expected (O/E) ratios for morbidity and mortality outcomes for each facility are the foundation for monitoring and improving the quality of care."⁴⁷ The O/E ratio is calculated by dividing the actual (observed) number of events by the expected number of events.⁴⁸ The ratio of observed-to-expected events (referred to as "O/E ratio") is used to assess whether the hospital had more events than expected (ratio > 1.0), the same number of events as expected (ratio = 1.0), or fewer events than expected (ratio < 1.0). Lower numbers are desirable.

The facility's surgery 30-day mortality O/E ratio was comparable to, or slightly better than, other VHA facilities in VISN 22 with the same surgical complexity designation ending December 31, 2017. However, the facility underperformed in the 30-day morbidity O/E ratio. The OIG team identified two patient deaths that occurred within 30 days of orthopedic surgery within calendar year 2017 and determined that the deaths of these medically complex patients were not directly attributable to the orthopedic surgical procedures.

Issue 2: Orthopedic Surgery Department's Use of Fee Surgeons

While the OIG team substantiated that the facility used in-house fee and community-based orthopedic providers, the team did not find this to be concerning from a quality of care perspective given current staffing and other limitations in the Orthopedic Surgery Department. The Orthopedic Surgery Department has had staffing and efficiency challenges and has been partially reliant on fee-based orthopedic care for what appears to be many years. The OIG team

⁴⁵ Phoenix VAHCS Policy, *Medical Record Management*, Memorandum No. HIMS-01, February 10, 2014.

⁴⁶ VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013. This VHA Handbook was scheduled for recertification on or before the last working date of January 2018 but has not been recertified.

⁴⁷ National Surgery Office (NSO), VA Surgical Quality Improvement Program, VASQIP Process. The website is an internal one and is not accessible by the public.

⁴⁸ Morbidity rate refers to the number of complications or undesirable side effects following surgery or medical treatment. Mortality rate is the number of a particular group of patients who die each year. <u>https://www.merriam-webster.com/dictionary</u>. (The website was accessed on August 15, 2018.)

determined that the facility's decision to augment its orthopedic staff with fee providers who specialized in specific joints or complex procedures, was appropriate. Further, the OIG team concluded that the volume of work for some orthopedic subspecialties or procedures was low enough and specialized enough that a fee-for-service approach was both economically and clinically appropriate.

As noted above, some on-call orthopedic surgeons did not consistently take responsibility for managing complex patient care needs, which may have contributed to the need to utilize fee orthopedic surgeons.⁴⁹

The Orthopedic Surgery Department did not have adequate processes and accountability in place to ensure that on-call attending orthopedic surgeons took responsibility for complex cases or cases where the surgery would not be performed by that surgeon. One PA told the OIG team that fee surgeons were often responsive when on-call facility surgeons declined procedures.

While the OIG confirmed Orthopedic Surgery Department inefficiencies (see Issue 3) regarding several findings of the facility's Clinical Efficiency Team (CET) that resulted in the actual or perceived need to rely on fee orthopedic surgeons, facility leaders were aware of the inefficiencies and were taking actions to enhance operations. Therefore, the OIG team evaluated the use of fee surgeons in the context of whether the orthopedic care was being delivered by a provider who could optimize the patient's outcomes at the time the care was needed, regardless of whether the provider was a facility orthopedic surgeon, a fee surgeon, or a community surgeon. Given the facility orthopedic surgeons' expertise and limitations, the OIG team determined that the use of fee surgeons was necessary to ensure quality patient care.

Use of Fee Surgeons versus Facility Orthopedic Surgeons

The OIG team was unable to determine whether fee surgeons performed procedures that facility surgeons could have performed, primarily because it was difficult to determine, retrospectively and definitively, whether specific patients needing orthopedic surgeries could have or should have received that care from a facility surgeon rather than a fee surgeon.

Table 1 below reflects several common orthopedic surgeries that facility staff surgeons routinely performed.⁵⁰ As shown, while facility surgeons performed most of the selected procedures, there were occasions when fee surgeons performed those procedures.

⁴⁹ Both facility and in-house fee orthopedic surgeons were included in the on-call schedule. According to the PAs, the surgeons who most often failed to take responsibility were facility surgeons.

⁵⁰ OIG specifically excluded more complex, specialty, and low-volume procedures such as total joint revisions, procedures done less than six times, hand and elbow-related procedures, and procedures below the knee.

Procedure	Facility Surgeons	In-House Fee Surgeons
Total Shoulder Arthroplasty	38	2
Total Hip Arthroplasty	32	15
Total Knee Arthroplasty	133	30

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Source: VA OIG extraction of selected CPT codes from VHACDWA01.CDWWork

The OIG team reviewed the 47 cases performed by fee surgeons. While EHR documentation generally did not include specific discussions of why facility orthopedic surgeons could not perform the procedures, the EHRs reflected surgeon schedule and expertise, and patient and surgeon availability, as reasons that fee surgeons performed the surgeries.

In order to provide a patient the best option for a successful surgical outcome, a variety of factors must be considered in real time, including the availability of a surgeon with the correct skill set and comfort level performing the required procedure, the availability of the OR and support staff, specialized instruments and/or implants, and appropriate postoperative care. Too many variables existed for the OIG to determine whether the use of fee surgeons in the common orthopedic procedures reviewed was improper or avoidable.

Critical Patients

The OIG team did not substantiate that critical patients were ignored because the Orthopedic Surgery Department claimed not to have surgical expertise when it really did. The OIG did not identify, nor was the OIG told about, critically ill patients who did not receive needed orthopedic care. In those cases where OIG found that care may have been delayed (as identified in the quality of care section of this report), OIG did not find evidence that the sole reason those delays occurred was because a qualified facility surgeon refused to provide the service.

Unnecessary Costs

The OIG did not substantiate that some fee costs were improper. Because the Orthopedic Surgery Department was not staffed with a comprehensive array of orthopedic generalists and sub-specialists, it had to rely on qualified fee surgeons to assure timely access and specialized orthopedic services. Therefore, the OIG generally did not consider fee costs to be improper.⁵¹

Issue 3: Leaders Responsiveness to Orthopedic Surgery Department-Related Issues

The OIG team did not substantiate that facility leaders responded inadequately to reported concerns about the Orthopedic Surgery Department. Although the OIG team learned of a letter

⁵¹ Per contract, the fee surgeons received between \$1,500 and \$3,500 per procedure.

sent in early spring 2017 to the Chief of Surgery outlining concerns about Surgeon A's decision-making in relation to Patient Red, the OIG could not confirm that the Chief of Surgery received the complaint letter. The Chief of Surgery did not recall receiving the complaint regarding Patient Red's care, and Surgeon A reported not knowing of the complaint until shortly before OIG's visit in April 2018. The OIG team also reviewed patient advocate reports related to the Orthopedic Surgery Department for the period January 1, 2017, through February 26, 2018 and did not identify patterns or trends indicating systemic or pervasive problems in the department.

The OIG determined that facility leaders and responsible managers identified challenges in the Orthopedic Surgery Department over the years, and while some corrective actions may have been successful at the time, efficiency and infrastructure improvements had not kept pace with current conditions and demand. When interviewed, the Chief of the Orthopedic Surgery Department reported being Chief for more than 10 years and provided OIG with documents showing intermittent efforts to secure space and equipment, improve efficiency and access, and update supervisors about the Orthopedic Surgery Department's needs. The Chief of Orthopedic Surgery reported providing an overview of the department's workload, staffing, and challenges to the new Chief of Surgery in late summer 2016.

When interviewed, the new Director reported starting at the facility about the same time as the COS in October 2016. Together, they initiated an evaluation of the Orthopedic Surgery Department. Upon arrival, the Facility Director asked about department-level productivity and found that the Orthopedic Surgery Department was "one of the worst." According to the Facility Director and COS, this concern prompted them to initiate a CET in fall 2017, to assess a variety of Orthopedic Surgery Department-level operations and find opportunities to improve access, reimbursement, provider productivity, overall data capture, and managerial cost accounting procedures. The CET identified deficits in the OR scheduling process; a lack of administrative support and senior administrative staff assigned to the orthopedic department; compressed work schedules that did not promote access to care; and inadequate workload capture structures, among other issues.

According to members of the CET who collected data and made recommendations to enhance Orthopedic Surgery Department access and efficiency, improvement actions were slow to take shape. In addition, some changes that were made appeared to decrease clinic access. The COS was reportedly frustrated at the lack of progress in addressing Orthopedic Surgery Department issues, and the Chief of Surgery issued a letter of expectation to the Chief of Orthopedic Surgery Department in spring 2018 outlining corrective actions and timelines for completion. Prior to its site visit, the OIG requested the status of the action plan in response to the letter of expectation. The OIG team received a copy of the action plan and the status of specific action items; however, inadequate time had elapsed for the team to assess the effectiveness of the actions. Neither the COS, the Facility Director, nor the Chief of Surgery expressed concerns about the quality of orthopedic care, and while all said they had heard about cases when orthopedic care did not meet expectations, they did not report concerns about the quality of orthopedic care in general.

Issue 4: Other Finding—Infrastructure and Partnerships

The OIG determined that several elements of the facility's infrastructure and partnerships required to support a complex surgery designation and OR efficiency were not consistently functioning at a level needed to achieve optimal results in perioperative care.

Interdepartmental Communication and Collaboration

Based on multiple interviews, the OIG team concluded that, at times, the relationship between the OR and the Orthopedic Surgery Department was strained, particularly when surgical cases fell outside of normal and established processes (for example, add-on cases). Further, the OIG team perceived a hesitance among some orthopedic staff and OR staff to step beyond the "status quo" and proactively problem-solve. For example, staff perceived the issue of add-on cases very differently. Some Orthopedic Surgery Department staff reported that efforts to schedule add-on cases were consistently met with resistance by the OR staff; the OR charge nurse and an OR staff member reported orthopedic providers sometimes scheduled add-on cases for the convenience of the surgeons or made late changes to the surgery such that SPS and OR staff were not prepared for the case. As a result of the mixed perceptions, multiple parties interviewed on the topic of add-on surgeries expressed some level of frustration with the process.

Anesthesia

In late 2017, the Anesthesiology Service Chief and OR Nurse Manager from another VA medical center completed a consultative site visit at the facility to evaluate OR productivity. In addition to issues such as preoperative scheduling and clearances, communication, and the lack of a permanent administrative officer, the consultative team identified other concerns:

- The postanesthesia care unit closed early, and the ICU was often at capacity which forced patients to be recovered by OR nurses and CRNAs within the actual OR many evenings. Thus, staff were less willing to start cases late in the day, leading to surgery cancellations.
- The anesthesia on-call system for CRNAs was not standardized; cases were sometimes canceled due to lack of staff. CRNAs had to be asked if they were willing to stay [to participate in late cases].
- Anesthesia Service overstaffed the OR with a 1:1 or 1:2 physician to CRNA staffing ratio instead of a more appropriate 1:3 or 1:4 ratio. This model unnecessarily limited the number of anesthesia staff available for cases.

At the time of the OIG team's review, the facility had not implemented all of the consultative team's recommendations.

SPS

"SPS supports the medical facility by ensuring a continuous flow of processed critical and semi-critical instruments to all points of use" including the OR.⁵² The OIG learned about multiple SPS challenges through interviews with the Chiefs of SPS and Surgery:

- SPS did not have sufficient space, sterilizers, or equipment to manage the volume of work.
- In 2010, construction on a new building that would house SPS and the OR was started but not completed.
- Although VHA policy requires loaner instrument trays to be delivered to SPS for processing 48 hours prior to surgery, the facility's loaner instrument policy requires 72 business hours.⁵³ While this adjustment was made for safety reasons due to the volume of loaner trays SPS processes, it created a barrier to timely surgery in some cases.
- SPS did not have CensiTrac®, an electronic instrument tracking system.⁵⁴ Rather, SPS manually entered loaner instrument information into a log book for each tray received preoperatively and returned after use. The OIG noted that the lack of an electronic loaner system would negatively impact the facility's ability to increase the volume and complexity of surgical cases in the future.
- The facility lacked space to appropriately store some implants used during orthopedic surgeries. Because implants must be ordered (rather than being immediately available on a shelf), some common orthopedic conditions such as hip fractures were sent to community providers.

While the Chief of SPS identified issues that interfered with SPS supporting an increase in OR productivity, the Chief also confirmed that communication between SPS and the Orthopedic Surgery Department needed improvement.

⁵² VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016.

⁵³ VHA Directive 1116(2); Phoenix VA Health Care System Policy Memorandum No. 118S-07, *Management of Loaner Instrumentation*, November 4, 2016; Loaner instrumentation includes reusable surgical instruments that are not owned or stored in the Phoenix VA Health Care System. Due to the purchase cost of orthopedic instrumentation, the Orthopedic Surgery Department used loaner instruments for some low-volume cases.

⁵⁴ CensiTrac® was the first surgical instrument tracking system capable of tracking to the instrument-level and has evolved to a comprehensive surgical inventory management solution.

The OIG team determined that Orthopedic Surgery Department leaders should take a more proactive and collaborative approach to improve the process deficiencies affecting the Department as delineated above.

Issue 5: Other Finding—Clinical Privileges and Scopes of Practice

The OIG team identified deficiencies in orthopedic provider privileging and PA scopes of practice. In the context of this finding, the Chiefs of Surgery and Orthopedic Surgery would largely be responsible for assuring compliance with requirements.

Orthopedic Surgeon Clinical Privileges

VHA policy defines clinical privileging as the method by which facility leaders grant a provider privileges to perform specified medical or other patient care within the scope of the provider's license and within the facility's mission.⁵⁵ The OIG team identified multiple deficiencies in the Orthopedic Surgery Department.

Core Orthopedic Surgery Privileges Outside of the Facility's Mission

The facility was not in compliance with VHA guidelines related to core clinical privileges.⁵⁶ VHA requires that clinical privileges can only be granted within the scope of the VHA facility's mission. Only privileges for procedures provided by the VHA facility may be granted to a provider. At the facility, orthopedic surgeons were granted core privileges that included multisystem trauma, oncology, and metastatic disease-related procedures. Surgeon A and Surgeon D told OIG inspectors that orthopedic surgeons had limited capability to perform trauma orthopedic surgeries and did not perform oncologic and metastatic surgical procedures at the facility.

Inadequate Data to Support Reappraisal

The facility was not in compliance with reappraisal data collection and analysis requirements used to evaluate surgeon competence and grant clinical privileges. VHA requires ongoing monitoring of a provider's professional practice, referred to as Ongoing Professional Practice Evaluation (OPPE), in order to determine the provider's level of competence and evaluate the outcomes of care. Facility managers are to collect and maintain relevant provider-specific OPPE data. "The reappraisal process needs to include consideration of such factors as the number of procedures performed or major diagnoses treated, rates of complications compared with those of others doing similar procedures, and adverse results indicating patterns or trends in a provider's

 ⁵⁵ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was scheduled for recertification on or before the last working day of October 2017, but has not been recertified.
 ⁵⁶ VHA Handbook 1100.19.

clinical practice." ⁵⁷ The OIG team reviewed 14 (seven fee and seven facility staff) OPPE folders of orthopedic surgeons who were privileged by the facility to perform Orthopedic Surgery procedures at the time of the OIG team's site visit. The team requested but did not receive Surgeon A's OPPE folder. None of the 14 OPPE folders contained sufficient provider-specific data to support approval and/or continuation of privileges. For example, OIG inspectors found limited data and quality of care information.

Without appropriate supporting data, clinical leaders could not be assured of provider competence to grant privileges.

Orthopedic PA Scopes of Practice

PAs function as healthcare providers who exercise independent decision-making within their scopes of practice. "The [s]cope of [p]ractice defines the degree of oversight, consultation, and input required by the collaborating physician for specific patient care activities and is based on the PA's education and training, experience, demonstrated clinical skill and competency, and area of assignment."⁵⁸ To determine whether facility PAs were functioning within their scopes of practice in the ED, the OIG team reviewed the procedures performed by orthopedic PAs in the ED that were included in the OIG's EHR review population. All nine procedures were within the scopes of practice for the individual PAs.

The OIG identified other deficiencies relating to facility compliance with VHA requirements for PAs:

- The facility did not have a PA utilization policy.⁵⁹
- One PA did not have an OPPE folder.
- PA OPPE folders contained minimal or no chart review data and no procedure data to support the scope of practice.
- The OPPE folders reviewed by the OIG team contained minimal and inconsistent evidence of collaborating physicians' input or monitoring.⁶⁰
- The PA scopes of practice did not define the surgical first assistant responsibilities performed by the PAs in the OR, although operative notes reflected that PAs performed these functions in the OR.⁶¹

⁵⁷ VHA Handbook 1100.19.

⁵⁸ VHA Directive 1063, Utilization of Physician Assistants (PA), December 24, 2013.

⁵⁹ VHA Directive 1063.

⁶⁰ VHA Directive 1063. "The collaborating physician is a designated [p]hysician who provides clinical oversight, consultation, and patient care management assistance to the assigned PA."

⁶¹ A surgical first assist works with the primary surgeon to facilitate the procedure and duties can include harvesting surgical grafts, performing closure of incisions, and applying wound dressings.

The Chief of Orthopedic Surgery retains ultimate responsibility for ensuring orthopedic PArelated policies and performance requirements are met. Because the facility was not in compliance with VHA guidelines regarding clinical privileging and scopes of practice, facility leaders could not be assured the clinical staff were competent to provide certain elements of patient care.

Conclusion

The OIG team substantiated that Surgeon A did not physically evaluate Patient Red or take responsibility for the patient's orthopedic care. Patient Red experienced a delay in diagnosis and treatment due to a variety of issues. While waiting for a definitive diagnosis, Patient Red developed significant mental status changes and septic shock. PA-1 sought help from multiple attending orthopedic surgeons over several hours before one of the surgeons came to assess Patient Red. A planned procedure was canceled on HD 2 when a shoulder ultrasound was interpreted as negative for a drainable abscess or fluid collection. Patient Red's clinical course met VHA's definition of an adverse event, but as of August 8, 2018, a disclosure had not been completed.

The OIG team determined that an orthopedic surgeon should have promptly taken responsibility and continued to manage Patient Red's care, particularly because the patient had complex comorbidities and was in the process of progressing to septic shock.

The OIG team substantiated that Surgeon A's decision not to admit Patient Blue placed the patient at risk for medical decompensation given that the patient lived more than three hours away and had a history of a complicated hip infection with signs of a new infection. It would have been prudent for Surgeon A to provide information to Patient Blue about his/her condition and the risks, benefits and alternatives to disposition planning so that both the medical team and Patient Blue could make an informed decision about the discharge plan.

The Orthopedic Surgery Department tolerated a practice where on-call orthopedic surgeons did not consistently take responsibility for managing complex patient care needs. Specifically, some on-call orthopedic surgeons would tell the PAs to find another surgeon rather than taking responsibility for making an attending-to-attending surgeon contact to arrange for the needed evaluation and care. As a result, PAs sometimes had to seek assistance from another provider willing to offer it, sometimes requiring multiple telephone calls and potentially delaying care.

More than 1,500 patients' EHRs were reviewed by the OIG team. Of those, more than 1,100 patients were seen in the ED with a primary orthopedic-related diagnosis or condition between early 2017 and spring 2018. The team found that documentation of orthopedic care was generally consistent with requirements. Further, the facility's orthopedic surgery 30-day morbidity and mortality data were not concerning for the date range reviewed.

While the OIG team substantiated the facility used in-house fee and community-based orthopedic providers, the use of non-VA providers was not concerning from a quality of care perspective given current staffing and other Orthopedic Surgery Department limitations. The facility's decision to augment its orthopedic staff with fee providers who specialized in specific joints, such as hands, or specific procedures, such as complex total hip replacements, was appropriate to ensure quality of patient care. However, the Orthopedic Surgery Department's long-standing tolerance of on-call surgeons declining to assist and not taking responsibility for coordinating patient care may have contributed to the need to utilize fee orthopedic surgeons in some cases.

The OIG team was unable to determine whether fee surgeons performed procedures that facility surgeons could have performed. A variety of factors must be considered in real time when coordinating a patient's care, including the availability of a surgeon with the correct skill set, and the availability of the OR, specialized instruments and/or implants, and appropriate post-operative care.

The OIG team did not substantiate critical patients were ignored because the Orthopedic Surgery Department claimed not to have surgical expertise when it really did. Further, because the Orthopedic Surgery Department was not staffed with a comprehensive array of orthopedic generalists and sub-specialists, it had to rely on qualified fee surgeons to assure timely access and specialized orthopedic services. Therefore, the OIG did not consider fee costs to be improper.

The OIG team did not substantiate that facility leaders failed to respond to concerns about the Orthopedic Surgery Department. The new Director and COS started at the facility in October 2016 and initiated a CET in fall 2017 to assess a variety of service-level operations and find opportunities to improve access, reimbursement, specialty provider group practice productivity, overall data capture, and managerial cost accounting procedures.

Maintaining a complex surgical designation requires a certain infrastructure and partnerships. The OIG team found that several elements needed to support infrastructure and partnerships at the facility were not consistently functioning at a level to optimize perioperative care:

- The relationship between the OR and the Orthopedic Surgery Department appeared strained, with a hesitance among some orthopedic staff and support services to proactively problem-solve.
- In late 2017, the Anesthesia Service Chief and OR Nurse Manager from another VA medical center completed a consultative site visit at the facility to evaluate OR productivity. In addition to issues such as pre-operative scheduling and clearances, communication, and the lack of a permanent administrative officer, the consultative team, identified opportunities to improve postanesthesia care unit availability, the CRNA on-call system, and physician to CRNA staffing ratios.

• SPS did not have sufficient space, sterilizers, or equipment to manage the volume of work and did not have an electronic system to track loaner instruments.

The OIG team also found that the facility was not in compliance with VHA guidelines regarding surgeons' core clinical privileges, and data collection and analysis requirements for OPPE. Further, the facility was not compliant with VHA requirements related to PAs including the lack of a PA policy, appropriate completion of OPPEs, documentation of collaborating physician input into periodic PA assessments, and definition of surgical first assist duties in PA scopes of practice.

Recommendations 1–12

- 1. The Carl T. Hayden VA Medical Center Director conducts comprehensive reviews of all aspects of decision-making and care provided to Patient Red and Patient Blue, and takes action, as appropriate.
- 2. The Carl T. Hayden VA Medical Center Director considers conducting an institutional disclosure in Patient Red's case, and takes action as appropriate.
- 3. The Carl T. Hayden VA Medical Center Director continues efforts to assess and improve inefficiencies, including on-call surgeon accountability issues, within the Orthopedic Surgery Department.
- 4. The Carl T. Hayden VA Medical Center Director takes appropriate action relative to the letter of expectation issued to the Chief of Orthopedic Surgery Department.
- 5. The Carl T. Hayden VA Medical Center Director addresses inter-departmental communication, collaboration, and problem-solving challenges as discussed in this report.
- 6. The Carl T. Hayden VA Medical Center Director follows up on consultative recommendations made by the anesthesia and operating room site visit team.
- 7. The Carl T. Hayden VA Medical Center Director evaluates the adequacy of Sterile Processing Services space and the loaner instrument policy, and takes action as appropriate.
- 8. The Carl T. Hayden VA Medical Center Director assesses the feasibility of implementing an electronic instrument tracking system within Sterile Processing Services, and takes actions as appropriate.
- 9. The Carl T. Hayden VA Medical Center Director revises the orthopedic surgery core privileges description to accurately reflect procedures performed at the Carl T. Hayden VA Medical Center.
- 10. The Carl T. Hayden VA Medical Center Director ensures appropriate data collection, analysis, and reporting for orthopedic providers' ongoing professional practice evaluations.

- 11. The Carl T. Hayden VA Medical Center Director develops a physician assistant utilization policy as required by Veterans Health Administration.
- 12. The Carl T. Hayden VA Medical Center Director updates physician assistant scopes of practice to fully reflect the activities and listing of surgical first assist responsibilities for individual orthopedic physician assistants.

Appendix A: Glossary

Abscesses are localized collections of pus surrounded by inflamed tissue.

https://www.merriam-webster.com/dictionary/abscess

Antibiotic beads are a "method of treatment in the management and prevention of osteomyelitis" (bone infection). "Antibiotic beads provide high local concentrations of antibiotic at the site of infection without significant systemic toxicity."

https://augusta.pure.elsevier.com/en/publications/antibiotic-beads

Arthroplasty is a surgery of a joint (as the hip or knee) that involves the operative formation or restoration of a joint.

https://www.merriam-webster.com/medical/arthroplasty

Arthroscopy is a "procedure for diagnosing and treating joint problems." Arthroscopy is most commonly used to diagnose conditions of the knee, hip, shoulder, elbow, and wrist.

https://www.mayoclinic.org/tests-procedures/arthroscopy/about/pac-20392974

Aspiration within the context of this report, refers to the act of drawing "something in, out, up, or through by or as if by suction."

https://www.merriam-webster.com/dictionary/aspiration

Aspiration pneumonia occurs when an individual inhales food, drink, vomit, or saliva into the lungs. "Aspiration is more likely if something disturbs [the] normal gag reflex, such as a brain injury or swallowing problem, or excessive use of alcohol or drugs."

https://www.mayoclinic.org/diseases-conditions/pneumonia/symptoms-causes/syc-20354204

Computed tomography (CT) scans are a type of imaging study (scan) that "combines a series of X-ray images taken from different angles" and "uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside [the] body."

https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675

Degenerative joint disease (osteoarthritis) is a condition involving the gradual deterioration of cartilage that cushions the ends of bones in joints.

https://www.mayoclinic.org/diseases-conditions/osteoarthritis/symptoms-causes/syc-20351925

Hospitalists are physicians who specialize in treating hospitalized patients of other physicians. <u>https://www.merriam-webster.com/dictionary/hospitalist</u>

Infectious Disease physicians are doctors of medicine with additional specialized training in the diagnosing and treating a wide variety of infections in adults and adolescents.

http://idphysicians.net/PatientCenter.html

Interventional Radiologists are doctors of medicine with additional specialized training in performing minimally invasive procedures using radiologic modalities.

https://www.hopkinsmedicine.org/interventional-radiology/what_is_IR.html

Lumbar fusion is a surgical procedure that permanently connects (fuses) two or more vertebrae in the spine.

https://www.mayoclinic.org/tests-procedures/spinal-fusion/about/pac-20384523

Magnetic resonance imaging (MRI) is an imaging study that uses "a magnetic field and radio waves to create detailed images of the organs and tissues within [the] body."

https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768

Methicillin-resistant *Staphylococcus aureus* (MRSA) is an infection caused by a type of staphylococcus bacteria that has "become resistant to many of the antibiotics used to treat ordinary staph infections."

https://www.mayoclinic.org/diseases-conditions/mrsa/symptoms-causes/syc-20375336

Sepsis is "a potentially life-threatening condition caused by the body's response to an infection. The body normally releases chemicals into the bloodstream to fight an infection. Sepsis occurs when the body's response to these chemicals is out of balance, triggering changes that can damage multiple organ systems."

https://www.mayoclinic.org/diseases-conditions/sepsis/symptoms-causes/syc-20351214

Septic arthritis is an "inflammation of a joint due to a bacterial or fungal infection."

https://medlineplus.gov/ency/article/000430.htm

Septic shock is a condition resulting from sepsis that occurs when "certain changes in the circulatory system, the body's cells and how the body uses energy become more abnormal. Septic shock is more likely to cause death than sepsis is."

https://www.mayoclinic.org/diseases-conditions/sepsis/symptoms-causes/syc-20351214

Ultrasound is "an imaging method that uses high-frequency sound waves to produce images of structures within [the] body."

https://www.mayoclinic.org/tests-procedures/ultrasound/about/pac-20395177

Appendix B: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: 20 March 2019

- From: Director, Desert Pacific Health Care Network (VISN 22)
- Subj: Healthcare Inspection— Orthopedic Surgery Department and Other Concerns at the Carl T. Hayden VA Medical Center, Phoenix, Arizona
- To: Director, VAOIG OHI Rapid Response Team, (54RR)

Director, Management Review Service (VHA10eggoalaction@va.gov)

- 1. I have reviewed and concur with the findings and recommendations the draft report, *Healthcare Inspection- Orthopedic Surgery Department and Other Concerns at the Carl T. Hayden VA Medical Center, Phoenix, Arizona.*
- 2. If you have any questions, please contact me at (562) 826-5963. Thank you.

//original signed// Michael W. Fisher VISN 22 Network Director

Appendix C: Medical Center Director Comments

Department of Veterans Affairs Memorandum

- Date: March 13, 2019
- From: Director, Phoenix VA Health Care System, Phoenix, AZ (644/00)
- Subj: Healthcare Inspection— Orthopedic Surgery Department and Other Concerns at the Carl T. Hayden VA Medical Center, Phoenix, Arizona
- To: Director, Desert Pacific Health Care Network (VISN 22)
- 1. I have completed my review of the draft report, *Healthcare Inspection- Orthopedic Surgery* Department and Other Concerns at the Carl T. Hayden VA Medical Center, Phoenix, Arizona.
- 2. I concur with recommendations 1-12.
- I recommend closure of recommendations 1,4-10, and 12 on the final report. We have provided the explanation and evidence to satisfy the concerns for those recommendations in the response below. Recommendations 2 and 3 will be closed by April 30 2019 and Recommendation 11 will be closed by June 30 2019.
- 4. My response also includes the following Executive Summary and an update to Page 10 paragraphs 2 and 3 of the Draft Report Healthcare Inspection- Orthopedic Surgery Department and Other Concerns at the Carl T. Hayden VA Medical Center, Phoenix, Arizona, which are provided in order to present a more comprehensive reflection of the events.

a. Executive Summary: The VA Office of Inspector General (OIG) conducted an inspection to evaluate allegations that an orthopedic surgeon, at the Carl T. Hayden VA Medical Center (facility), Phoenix, Arizona, failed to adequately assess two patients (Patient Red and Patient Blue), which resulted in delays in care. The OIG team evaluated additional allegations related to the facility's improper use of fee-for-service (fee) orthopedic surgeons and facility leaders' responsiveness to concerns about the Orthopedic Surgery Department. As a result of the initial assessment of these allegations, the OIG team also evaluated orthopedic surgeons' responsiveness to physician assistants (PAs) on call, and select aspects of infrastructure, support services, clinical privileging, and PA scopes of practice.

The OIG substantiated that the orthopedic surgeon did not physically evaluate Patient Red or take sufficient responsibility for the patient's orthopedic care, although the Physician Assistant involved in the patient's care did review the patient by telephone with this attending. Patient Red experienced a delay in diagnosis and treatment due to a variety of issues. Patient Red had a developing pneumonia that led to respiratory failure and sepsis. Patient Red's blood cultures were clearing from the MRSA at the time of the patient's clinical deterioration. On the second day of Patient Red's hospitalization, a PA sought advice from multiple attending orthopedic surgeons over several hours before one of the surgeons came to assess Patient Red in person. A planned procedure was canceled on the second day of hospitalization when a shoulder ultrasound was interpreted as negative for a drainable abscess or fluid collection. A subsequent CT scan however led to the required definitive surgical care. It is the OIG's opinion that Patient Red's clinical course met VHA's definition of an adverse event, but as of August 8, 2018, a disclosure had not been completed.

The OIG team determined that an orthopedic surgeon should have promptly taken responsibility and continued to manage Patient Red's care, particularly because the patient had pre-existing pneumonia and complex comorbidities and was in the process of progressing to sepsis. Orthopedic surgeons'

accountability for the coordination of patient care with the PAs was not clearly outlined either by policy or clearly defined expectations. The OIG concluded that the care of Patient Red was an example of leadership weaknesses and lack of accountability in the Orthopedic Surgery Department.

The OIG substantiated that the orthopedic surgeon's decision not to admit Patient Blue placed the patient at risk for medical decompensation given that the patient lived more than three hours away and had a history of a complicated hip infection with signs of a new infection. Patient Blue presented to the facility's Emergency Department in early 2018 complaining of progressive swelling, pain, and redness at the incision site of a previous hip replacement. The Emergency Department PA found a fluid-filled mass located above the surgical scar and called for orthopedic surgery and infectious disease consults. The plan was for ultrasound-guided aspiration of the mass and admission to the Orthopedic Surgery Service. The aspiration was completed as planned but Patient Blue was not admitted; rather, the patient was discharged home at the patient's own request before the aspirate culture results were available for review.

Although Patient Blue was reportedly pleased with the plan for discharge home, it would have been prudent for the orthopedic surgeon to document the information provided to Patient Blue about his/her condition and the risks, benefits and alternatives to disposition planning.

The Orthopedic Surgery Department tolerated a practice where on-call orthopedic surgeons did not consistently take responsibility for managing complex patient care needs. Specifically, some on-call orthopedic surgeons who felt their expertise in orthopedics did not cover a particular joint or condition with which a patient presented, would leave to the PAs on call the need to find another orthopedic surgeon willing to assist in the patient's management rather than the attending taking responsibility for making an attending-to-attending surgeon contact to arrange for the needed evaluation and care. As a result, PAs had to seek assistance from other providers willing to offer it, sometimes requiring several telephone calls, which could potentially delay care. Because the Orthopedic Surgery Department was not staffed with a comprehensive array of orthopedic generalists and sub-specialists, it had to rely on qualified fee surgeons to assure timely access and specialized orthopedic services. However, the PAs were well aware of those qualified fee surgeons and their expertise and knew those to be called for specific conditions. One PA told the OIG in August 2018, several months after the OIG's site visit, that the attending surgeon's non-responsiveness had improved in the previous few months.

The OIG team reviewed more than 1,500 encounters of patients seen in the Emergency Department, more than 1,100 of which had a primary orthopedic-related diagnosis between early 2017, and spring 2018. The OIG found that documentation of orthopedic care was generally consistent with requirements. Further, the facility's orthopedic surgery 30-day morbidity and mortality rates were not concerning for the date range reviewed.

While the OIG substantiated that the facility used in-house fee and community-based orthopedic providers, the use of non-VA providers was not concerning from a quality of care perspective given the existing staffing and other limitations in the Orthopedic Surgery Department. The facility's decision to augment its orthopedic staff with fee providers who specialized in specific parts of the body, such as hands, or specific procedures, such as complex total hip replacements, was appropriate to ensure quality of patient care. However, the Orthopedic Surgery Department's long-standing tolerance of on-call surgeons declining to assist and not taking responsibility for coordinating patient care may have contributed to the need to utilize fee orthopedic surgeons in some cases, although this was not verified.

The OIG was unable to determine whether fee surgeons performed procedures that facility surgeons could have performed, primarily because it is difficult to determine, retrospectively and definitively,

whether specific patients needing orthopedic surgeries could have or should have received that care from a facility surgeon rather than a fee surgeon.

The OIG did not substantiate that critical patients were ignored because the Orthopedic Surgery Department claimed not to have surgical expertise when it really did. The OIG did not identify, nor was the OIG told about, critically ill patients who did not receive needed orthopedic care. In those cases where the OIG found that care may have been delayed (Patients Red and Blue), the OIG did not find evidence that the sole reason those delays occurred was because a qualified facility surgeon refused to provide the service. Further, because the Orthopedic Surgery Department was not staffed with a comprehensive array of orthopedic generalists and sub-specialists, it had to rely on qualified fee surgeons to assure timely access and specialized orthopedic services. Therefore, the OIG did not consider fee costs to be improper.

The OIG did not substantiate that facility leaders failed to respond to concerns about the Orthopedic Surgery Department. The new Director and Chief of Staff started at the facility in October 2016 and initiated a Clinical Efficiency Team in fall 2017 to assess a variety of service-level operations and find opportunities to improve access, reimbursement, specialty provider group practice productivity, overall data capture, and managerial cost accounting procedures.

The facility's surgical complexity designation is complex, meaning that it requires the highest level of facility infrastructure and performs the most complex procedures. Maintaining a complex surgical designation requires a certain infrastructure and partnerships. The OIG team found that several elements needed to support infrastructure and partnerships at the facility were inefficient, including operating room staff and Orthopedic Surgery Department communications, anesthesia staffing and operations, and Sterile Processing Services space, equipment, and loaner instrument tracking systems. Several individuals needed to improve efficiencies were under recruitment at the time of this visit. Facility leaders retain responsibility for assuring resource availability and ongoing performance improvement.

The OIG also determined that the facility was not in full compliance with Veterans Health Administration (VHA) guidelines regarding data collection and analysis requirements for ongoing professional practice evaluation and raised a concern about the range of orthopedic core privileges, with the recommendation for the facility to further review the breadth of privileges. The facility was not compliant with VHA requirements related to having a PA utilization policy, appropriately completing PA ongoing professional practice evaluations, documenting collaborating physician input into periodic PA assessments, and listing surgical first assist duties in PA scopes of practice. The Chief of Orthopedic Surgery retains ultimate responsibility for ensuring orthopedic PA-related policies and performance requirements are met. The OIG team found that PAs who performed procedures in the Emergency Department appeared to be functioning within their individual scopes of practice.

The OIG made 12 recommendations to the Facility Director related to the provision of care for Patient Red and Patient Blue; inter-departmental communications and process efficiencies; anesthesia and Sterile Processing Services operations; orthopedic surgeon privileging; and PA scopes of practice.

b. **Update to Page 10, paragraphs 2 and 3 of the Draft Report:** Due to Patient Red's worsening condition, the patient was transferred to the intensive care unit (ICU) at approximately 7:00 p.m. The ICU resident ordered a CT scan of the right upper extremity that was completed at 10:32 p.m. The CT scan showed a large fluid collection which was "highly suspicious" for septic arthritis and bone infection. The CT scan also demonstrate a right sided lung infiltrate and consolidation, compatible with atelectasis or pneumonia. The extent of this disease process likely predates the admission of the veteran to the PVA HCS. Despite the patient's continued antibiotic therapy, the morning of HD 3 Patients Red's respiratory status deteriorated, and the patient had to be placed on the ventilator. Patient Red was diagnosed with

aspiration pneumonia and the patient's antibiotic coverage was broadened. Patient Red became hypotensive and required resuscitation.

At 11:00 am, Patient Red was taken to the OR where the patient underwent incision and drainage of the right shoulder where "frank pus" was removed from the patient's shoulder. Patient Red was diagnosed with septic arthritis. Laboratory testing of the drainage fluid revealed MRSA. Later that day, 5:12 p.m., the veteran underwent a CT of the chest which demonstrated a "dense consolidation of the right upper lobe and to a lesser extent the right middle and lower lobes; which may represent multifocal pneumonia." Patient Red continued with antibiotic therapy and the patient's condition improved with time and intensive medical support. Blood cultures obtained when the patient required intubation demonstrated 1 of 2 bottles positive for MRSA, which had improved from the 2 of 2 blood cultures positive for MRSA on admission. Four days into the hospitalization the blood cultures were negative for any bacteria. The timing of the MRSA blood cultures clearance and the patient's worsening pneumonia suggests that it was the Enterobacter pneumonia that led to the patient's sepsis rather than the MRSA in the shoulder. The positive (2 of 2) blood cultures from the outlying hospital likely represented bacteremia from the patient's infected hemodialysis catheter which was recently removed at that hospital and not from the infected right shoulder. Had the bacteremia been from the infected shoulder, the second set of blood cultures obtained on admission, would likely have remained positive (but only 1 of 2 were positive) and the patient would not have cleared the bacteremia completely within 36 hours of his/her operation. On HD 4 bronchoscopy was performed and cultures were taken of the patient's pulmonary secretions which grew out Enterobacter cloacae and two lesser concentrations of gram-negative bacteria. It would appear that the patient was actually septic from pneumonia on HD 3 rather than from the right shoulder infection.

5. If you have any additional questions, please contact me at (602) 604-3914.

//original signed// RIMAANN O. NELSON Medical Center Director

Comments to OIG's Report

Recommendation 1

The Carl T. Hayden VA Medical Center Director conducts comprehensive reviews of all aspects of decision-making and care provided to Patient Red and Patient Blue, and takes action, as appropriate.

Concur.

Target date for completion: Completed.

Director Comments

The PVAHCS completed an initial internal review of these surgical cases at the onset of the reported concerns. PVAHCS provided the OIG with a detailed evaluation of each case as well as internal and external reviews. External reviews reviewed the orthopedic and infectious disease care provided to both patients. Those reviews did not demonstrate deficiency in the orthopedic management of clinical care or orthopedic provider techniques or treatment plans. Phoenix has reviewed all aspects of decision making and, clinical care concerns and has and is requesting closure of this recommendation based on evidence provided.

Recommendation 2

The Carl T. Hayden VA Medical Center Director considers conducting an institutional disclosure in Patient Red's case, and takes action as appropriate.

Concur.

Target date for completion: April 30, 2019.

Director Comments

PVAHCS initially determined Patient Red's case did not meet the conditions for an institutional disclosure. The patient's condition was exacerbated by a pre-existing pneumonia. After review of the record, it was determined that 12 hours lapsed from the time the CT results were available until the patient was taken to surgery. Although there is no clinical evidence that returning to surgery sooner would have produced a more desirable outcome in this case, PVAHCS will complete the Institutional Disclosure regarding the opportunity that existed to decrease the time between the CT finding and return to surgery, by April 30, 2019.

Recommendation 3

The Carl T. Hayden VA Medical Center Director continues efforts to assess and improve inefficiencies, including on-call surgeon accountability issues, within the Orthopedic Surgery Department.

Concur.

Target date for completion: April 30, 2019.

Director Comments

The Chief of Staff and the Chief of Surgery met with the Chief of Orthopedics to discuss the expectations by leadership in relation to on call responsibilities. Please observe the document labeled E-mail Leadership On-Call Expectations. in recommendation folder 3. The Orthopedic Section Chief, Assistant Chief, and members of the Surgical Service discussed some of the issues that were brought up during the OIG inquiry. One of the most important areas to be addressed was to better delineate the on-call responsibilities of the Orthopedic Section attending surgeons and physician assistants. Items discussed included how to handle complex cases or cases that may need a referral out to the community. In the case of the latter, there may or may not be a need for acute transfer, but one which can be partially addressed at our institution while a transfer to a receiving orthopedic surgeon is facilitated. Another area not mentioned in the report, but identified by our faculty, is "ownership" of the patient.

The Orthopedic Section implemented the "On-Call Protocol for Orthopedic Surgery". This document is very specific to the responsibilities of the physician assistants (PA) and the orthopedic surgeons. It delineates the surgeon's responsibility to the PA and patient when the surgeon believes she/he does not have the requisite skill set to manage the patient. Also addressed is the on-call relationship between the PA and the orthopedic surgeon on communication and the responsibilities of each. Specifically addressed is how to find another responsible provider to help manage or to take over the care of the patient if the on-call surgeon does not feel comfortable with their ability to manage the case.

The alternatives are delineated that include admitting the patient and finding another one of our orthopedic faculty to care for the patient, to admit and later transfer the care to another institution, and to transfer out to another institution from the ED. It is the surgeon's responsibility to have a direct conversation with another orthopedic surgeon about the case and not the responsibility of the PA to do so. This clarifies the roles much better and sets the expectation of who is the responsible/ accountable party.

Many changes to the orthopedic section have been made to improve the inefficiencies of the section. Space had been one of the biggest challenges in the ambulatory clinic area. Orthopedic surgery, which had 19,580 visits in Fiscal Year 2018, was one of the most challenged sections. Our administration moved some of the primary care clinics to outlying CBOC's making more

room for the medical and surgical specialties. Orthopedic surgery received half of one of the clinics totaling 13 exam rooms and one cast room. This is over a two-fold increase in the area which formally served the Orthopedic section. This allowed the Orthopedic Clinic to make more appointment openings for the patients and created a concentrated orthopedic area for evaluation and patient education.

There has been improvement on the inpatient orthopedic surgery patient rounding and chart documentation. This reflects more direct attending involvement in cases, most of which are post-operative patients.

Recommendation 4

The Carl T. Hayden VA Medical Center Director takes appropriate action relative to the letter of expectation issued to the Chief of Orthopedic Surgery Department.

Concur.

Target date for completion: Completed.

Director Comments

The letter of expectations given to the Chief of Orthopedic Surgery in 2018 conveyed an urgency to address the access challenges facing the Orthopedic Surgery section. There were two main requirements of the letter.

A. To delineate the orthopedic surgery section clinical activities.

1. By provider list clinical, surgical and administrative time.

2. Review clinic grids for the section and make recommendations for improved access and efficiency.

3. Optimize available operating room access by proposing a new "ideal" schedule for the orthopedic section.

The Chief of Orthopedics provided a spread sheet of the clinical times of the section members as well as the breakdown of admin time, non-clinical time, research and other minor time elements. The Chief delineated the reason behind the present scheduling and discussed potential opportunities for a change in a clinician's schedule to optimize his/her time. There were changes made to individual schedules to meet these opportunities. The changes made have improved access to the Orthopedic Services.

The Orthopedic Chief has met the letter of expectations requirements and continues to work with the appropriate medical center staff to improve the overall function of the Orthopedic section. Based on the evidence provided, the PVAHCS requests closure of this recommendation.

Recommendation 5

The Carl T. Hayden VA Medical Center Director addresses interdepartmental communication, collaboration, and problem-solving challenges as discussed in this report.

Concur.

Target date for completion: Completed.

Director Comments

PVAHCS developed a SOP for scheduling add-on cases and provided a copy to the OIG with this response. The SOP has a guideline for how to coordinate an afterhours "emergency" case in the OR.

Orthopedic Surgery and Infectious Disease meet regularly to discuss patients they are comanaging. They are establishing guidelines for the workup of common problems such as osteomyelitis, infected soft tissue disease, and joint infections. There is work being done on establishing diagnostic, therapeutic management and follow up for these cases.

Major orthopedic complications are presented at our surgical morbidity and mortality conference for discussion. Infectious disease is often present at these conferences when their specialty is involved in the case.

The Chiefs of Surgery and Medicine continue to work with their respective sections to promote collaboration and collegiality among the clinicians and to assist with problem solving when needed.

A multidisciplinary workgroup was formed and completed an evidence-based review of comorbid medical and surgical disease. We are utilizing this information to redesign the clinical preoperative pathways for our surgical patients. The team examined the literature on the management of common medications that need alteration in dosing or cessation prior to surgery. See attached file on co-morbid evidence based medical management in recommendation folder 5. PVAHCS provided the OIG with our present work in this area. Ongoing systems redesign for these projects continues, as do all our improvement activities. Based on the evidence provided, the PVAHCS requests closure of this recommendation.

Recommendation 6

The Carl T. Hayden VA Medical Center Director follows up on consultative recommendations made by the anesthesia and operating room site visit team.

Concur.

Target date for completion: Completed.

Director Comments

The PVAHCS Chief of Surgery and Chief of Staff, in collaboration with the VISN Chief Surgical Officer, also acting as Chief Medical Officer, requested a qualitative review of Anesthesia program operations. In late 2017, the Phoenix VA Operating Room Consultation with [Loma Linda VA Medical Center staff] occurred. The document titled "Anesthesia Efficiency Metrics" provided to the OIG describes specific areas of review, recommendations, and possible solutions, to those items that the Surgery Department considered for changes. PVAHCS also provided the OIG with it actions towards implementing the consultative team's recommendations. Each suggested solution is followed by current progress, again all part of our ongoing improvement efforts. Based on the evidence provided, the PVAHCS requests closure of this recommendation.

Recommendation 7

The Carl T. Hayden VA Medical Center Director evaluates the adequacy of Sterile Processing Services, space and the loaner instrument policy, and takes action as appropriate.

Concur.

Target date for completion: Completed.

Director Comments

The PVAHCS approved construction to address the SPS space constraints that limit capacity and productivity. The floor plans for the new Sterile Processing Building – "F" wing of the medical center – were provided to the OIG. This project is 95% complete for design, with approximately 9,000 square feet allocated for SPS. The final SPS and Logistics floorplan size is 7.1% over the 18,800 gross square feet approved in 30 March 2011. The additional floor space has been determined as part of a needs assessment to hold all the SPS equipment as well as support the future operative suites that will be built on top of SPS. Engineering has been advised to complete the design with the intent to solicit for construction and determine if the bids will return over budget. At that point VISN would support a review of a funding cap waiver.

The Sterile Processing Service currently has a Loaner policy (118S-07) that supports the service mission and current capabilities. The policy includes provisions for instances when the 72-hour threshold may not be met, including but not limited to emergencies. The Chief of Surgery, Assistant Chief of Surgery, Orthopedic Surgery Section Chief, Operating Room Nurse Manager, and SPS Chief have discussed the Loaner policy in perioperative huddle, determining the provisions within the Loaner policy are adequate. Informal afternoon huddles are used to plan and ensure instrumentation is available for the next surgery day. PVAHCS provided the OIG with a copy of the policy. PVAHCS requests the OIG close this recommendation in its final report based on the evidence provided.

PVAHCS has had more discussion with our supply chain representatives to make certain items needed for orthopedic surgical cases are available. The Orthopedic Section worked with Sterile Processing Service (SPS) so that supply and demands are best managed.

Recommendation 8

The Carl T. Hayden VA Medical Center Director assesses the feasibility of implementing an electronic instrument tracking system within Sterile Processing Services, and takes actions as appropriate.

Concur.

Target date for completion: Completed.

Director Comments

The Sterile Processing Service was funded, and a contract was awarded for the implementation of the Censi Trac Instrument Tracking System on September 24, 2018. The implementation started on March 11, 2019. PVAHCS provided the OIG with a copy of the purchase order in recommendation folder 8. PVAHCS requests the OIG close this recommendation on its final report.

Recommendation 9

The Carl T. Hayden VA Medical Center Director revises the orthopedic surgery core privileges description to accurately reflect procedures performed at the Carl T. Hayden VA Medical Center.

Concur.

Target date for completion: Completed.

Director Comments

PVAHCS will remove "multisystem trauma" from all orthopedic surgeons as an administrative act from the core privileges. This action will not impact their practice nor impact negatively on any state licensing board. This will be presented at the March 2019 Professional Standards Board/Medical Executive Board meeting.

After thoughtful review, we determined that all the other privileges are necessary to undertake the care of Veterans by the Orthopedic Section. PVAHCS would like to address three privileges suggested by the OIG for removal. Removing these privileges would be a disservice to our Veterans. Each surgeon knows his/her strengths and weaknesses and knows when to refer those cases that PVAHCS cannot manage to a community specialist.

1) **Trauma**: Patients present to the medical center with acute and chronic fractures of the extremities and minor non-operative pelvic fractures (rami fractures). Some, but not all, of

the fractures are able to be treated at our medical center. Those that cannot be treated here are sent out to the community for care.

2) **Metastatic disease**: Patients with pathologic fractures who need palliative care, which may be an open reduction and internal fixation, hip arthroplasty, or radiation referral are presently effectively managed at our institution.

3) **Orthopedic oncology**: We refer out to the community specialists complex and most primary orthopedic oncology cases. Multiple PVAHCS orthopedic surgeons are able to treat certain oncologic cases, including soft tissue debulking, extremity amputation, and radiation referrals for palliative care.

PVAHCS request the OIG close this recommendation in its final report based on the evidence provided.

Recommendation 10

The Carl T. Hayden VA Medical Center Director ensures appropriate data collection, analysis, and reporting for orthopedic providers' ongoing professional practice evaluations.

Concur.

Target date for completion: Completed.

Director Comments

All Orthopedic OPPE has been brought to current and routine OPPE has been placed on a regular schedule to ensure follow up and timely assessment to validate competency. The Chief of Surgery will monitor timely OPPE follow-up and documentation completion. OPPE completion is part of the performance expectation of the section chief. PVAHCS provided all current OPPE for orthopedic staff to the OIG in recommendation folder 10 of the SharePoint. PVHACS requests the OIG close this item on the final report based on evidence provided.

Recommendation 11

The Carl T. Hayden VA Medical Center Director develops a physician assistant policy as required by Veterans Health Administration.

Concur.

Target date for completion: June 30, 2019.

Director Comments

PVAHCS will write a local physician assistant policy in accordance with VHA Directive 1063.

Recommendation 12

The Carl T. Hayden VA Medical Center Director updates physician assistant scopes of practice to fully reflect the activities and listing of surgical first assist responsibilities for individual orthopedic physician assistants.

Concur.

Target date for completion: Completed.

Director Comments

The Physician Assistant Scope of Practice has been updated and is inclusive for surgical first assist as applicable. PVAHCS provided the OIG with the updated scope of practice. PVAHCS requests the OIG close this item on the final report based on evidence provided.

Staff Acknowledgments

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