DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Disclosures and Quality Processes for Perforations Resulting from Urological Surgeries at West Palm Beach VA Medical Center in Florida

HEALTHCARE INSPECTION | REPORT #21-01049-39 | DECEMBER 9, 2021

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the West Palm Beach VA Medical Center (facility) in Florida in response to an allegation that a facility urologist (Urologist 1) perforated two patients' (Patient A and Patient B) organs during surgical procedures.[1] Based on a preliminary review of the patients' clinical care, the OIG conducted the healthcare inspection to assess the accuracy of the allegation regarding the perforations and to determine whether

- Urologist 1 performed clinical disclosures,
- facility leaders considered institutional disclosures, and
- facility managers completed quality reviews.

During the inspection, the OIG identified additional concerns regarding management reviews and the facility's process for delineating urologists' privileges.

The OIG substantiated that Urologist 1 perforated Patient A's bladder and colon as well as Patient B's prostatic capsule during urologic procedures. Based on electronic health record reviews and interviews with clinical staff involved in the procedures, and without directly observing the surgeries that resulted in the perforations, the OIG was unable to determine whether the complications were the result of Urologist 1 using poor technique. Management reviews of the urologist's practice were conducted and did not identify deficiencies with the urologist's surgical technique. Facility leaders took reasonable actions based on the results.

The OIG identified deficiencies in the facility's clinical and institutional disclosure processes. According to Veterans Health Administration (VHA) policy, the clinical disclosure process is a part of ongoing clinical care. During the clinical disclosure process, the clinician must inform the patient or the patient's representative of facts about adverse events. For adverse events that result in more than minor harm, VHA policy requires the practitioner responsible for the patient to provide the clinical disclosures, which must be documented. Clinical disclosures should occur as soon as reasonably practical.[2]

Although Urologist 1 reported making clinical disclosures to Patient A regarding the bladder and possible colon perforation, an indwelling urinary catheter that migrated through the bladder, and the confirmed colon perforation, the OIG did not find documentation describing the adverse events that were disclosed. Specifically, Urologist 1 reported disclosing the bladder and possible colon perforation after the patient's first surgery; however, the content of the documentation did

[1] The underlined terms in the text are hyperlinks to related sections in the report, such as the glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together. The urologist at issue is a surgeon.

[2] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

not reference the possible colon perforation.[3] Moreover, required documentation regarding the disclosure of the confirmed colon perforation was not located in the patient's electronic health record. The OIG did not find documentation showing that a clinical disclosure was made regarding the indwelling urinary catheter extending through the bladder; however, documentation was not required by VHA policy. Regarding Patient B, Urologist 1 documented completion of the clinical disclosure process four days after the patient's surgery, which was not as soon as reasonably practical as required.

The Chief of Staff and Risk Manager described a process to ensure documentation of clinical disclosures that included quality management staff reviewing electronic health records when patient safety events were reported. However, because not all of Patient A's and Patient B's adverse events were reported, the Risk Manager was unaware of the need to review electronic health records and the process failed to work.[4]

The OIG also identified neither patients' adverse events were considered for institutional disclosure. The facility's process for institutional disclosures included the Risk Manager notifying the Chief of Staff that a case needed consideration. Although the Chief of Staff acknowledged that complications meeting criteria for institutional disclosure could be identified through daily operational meetings and peer review processes, the Chief of Staff described relying on quality management staff referring cases for consideration. The Risk Manager, who was the quality management staff designated to make referrals, did not refer the patients' cases to the Chief of Staff due to a misapprehension of VHA policy that complications that were known risks of procedures were not considered for institutional disclosures.[5] The OIG is concerned that failures in disclosure processes may result in patients not being fully informed to make healthcare decisions or of the right to seek compensation for injuries.

The OIG identified deficiencies in quality processes involving patient safety reporting; the Surgical Workgroup's oversight of Surgical Service Morbidity and Mortality Conferences; and peer review processes.

Patient A's bladder and colon perforations as well as the indwelling urinary catheter extending through the patient's bladder, and Patient B's prostatic capsule perforation met VHA's definition of adverse events. According to VHA policy, all facility staff knowledgeable about an adverse event are expected to report it to the Patient Safety Manager.[6] The OIG learned a nurse reported

[3] VA OIG, *Facility Leaders' Response to Level 2 and Level 3 Pathology Reading Errors at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas*, Report No. 21-01677-259, September 21, 2021. The OIG recently made a recommendation to the Under Secretary for Health to clarify the content of clinical disclosure documentation; therefore, a recommendation regarding clinical disclosure documentation is not made in this report.

[4] The OIG found that facility staff did not consistently report adverse events and recommended that the Facility Director explore reasons for the deficiency.

[5] VHA Directive 1004.08.

[6] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

Patient A's bladder perforation and possible colon perforation to the Patient Safety Manager; however, facility staff failed to report the other adverse events. As a result, the Patient Safety Manager was not aware of the need to review the events to determine whether patient safety activities were indicated.

The two patients' care was presented at Surgical Service Morbidity and Mortality Conferences. The OIG did not find evidence that the Surgical Workgroup provided oversight of Surgical Service Morbidity and Mortality Conferences, as required by VHA policy.[7] The Surgical Workgroup minutes did not reflect the conclusions and recommendations from the Surgical Service Morbidity and Mortality Conferences, as required by facility bylaws.[8] The OIG concluded deficiencies in oversight could lead to delayed or missed opportunities to improve quality care.

The Risk Manager was unable to explain why a peer review that was planned after submission of the patient safety report regarding Patient A's bladder perforation was not completed. The Risk Manager recalled learning of Patient B's surgical complication four months after the patient's surgery when the Acting Chief of Surgery requested external peer reviews of Patient A's and Patient B's care. Due to the request for multiple reviews and the possibility of facility leaders taking a personnel or privileging action on Urologist 1, the cases were sent for external management reviews, consistent with VHA policy.[9]

Due to the failures in quality processes, several months elapsed between the occurrence of Patient A's and Patient B's surgical complications and the referral to the Risk Manager, who then identified the need for management reviews. Facility leaders took reasonable actions based on the management review results.

The OIG reviewed an example of the version of the urology privileging form in use to delineate privileges at the time of the inspection. The OIG found that the Acting Chief of Surgery did not complete the required annual review of the privileging form for appropriateness of available privileges.[10] The Acting Chief of Surgery, who had been in the position for less than two months prior to the urologists' privileging form being reviewed, was not knowledgeable about the VHA privileging requirement to consider the appropriateness of available privileges.

As a result, urologists' available privileges may not have been consistent with facility needs or available resources, such as equipment, space, and surgical competency. Additionally, the

[7] VHA Directive 1102.01(1), *National Surgery Office*, April 24, 2019, amended May 22, 2019.

[8] Facility, *Bylaws and Rules of the Medical Staff,* April 24, 2017 (adopted May 15, 2017) has been replaced by Facility, *Bylaws and Rules of the Medical Staff*, February 24, 2021, and contains the same language about meeting minute documentation requirements.

[9] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[10] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

OIG is concerned that a statement on the urologists' privileging form instructing that the list of granted privileges is not to be construed as a limitation, may have been interpreted to mean that additional procedures could be performed without the safeguards afforded through the required delineation of privileges process.

The OIG made seven recommendations to the Facility Director related to clinical and institutional disclosures, patient safety reporting, quality review processes, oversight of Surgical Service Morbidity and Mortality Conferences, and the privileging process.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
for Healthcare Inspections

Contents

Abbreviations

COS	Chief of Staff
EHR	electronic health record
ICU	intensive care unit
JPSR	Joint Patient Safety Report
OIG	Office of Inspector General
POD	post-operative day
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the West Palm Beach VA Medical Center (facility) in response to an anonymous complaint that alleged a facility urologist (Urologist 1) perforated two patients' (Patient A and Patient B) organs during surgical procedures.[1]

Background

The facility, part of Veterans Integrated Service Network (VISN) 8, provides a full range of patient care services to veterans in south Florida. The facility is classified by the Veterans Health Administration (VHA) as level 1c complexity.[2] From October 1, 2019, to September 30, 2020, the facility served 57,106 unique patients and had a total of 333 operating beds including 153 inpatient beds, 60 domiciliary beds, and 120 community living center beds. In addition, the facility operates six community-based outpatient clinics and a Post-Combat Trauma Clinic.

Allegation and Concerns

The OIG received the anonymous complaint on December 8, 2020, that alleged Urologist 1 perforated two patients' organs during surgical procedures at the facility. Based on a preliminary review of the patients' clinical care, the OIG conducted the healthcare inspection to assess the accuracy of the allegation. Additionally, the OIG sought to determine whether

- Urologist 1 performed clinical disclosures,
- facility leaders considered institutional disclosures, and
- facility managers completed quality reviews.

During the inspection, the OIG identified additional concerns regarding management reviews and the facility's process for delineating urologists' privileges.

[1]. The underlined terms in the text are hyperlinks to related sections in the report, such as the glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together. The urologist at issue is a surgeon

[2] "Facility Complexity Model," VHA Office of Productivity, Efficiency and Staffing, accessed January 5, 2021. The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

Scope and Methodology

The OIG initiated the inspection on January 13, 2021. Given travel and safety concerns due to the potential spread of COVID-19, a virtual site visit was conducted March 1–9, 2021.[3]

The OIG interviewed the Chief of Staff (COS); Acting Chief of Surgery; Chief of Quality Management; Patient Safety Manager; Risk Manager; VA Surgical Quality Improvement Program Registered Nurse; and 10 other clinicians with knowledge of the care provided to Patient A or Patient B, including Urologist 1.[4] Additionally, the Director of VHA Clinical Risk Management and a urology lead from the National Surgery Office were interviewed.

The OIG reviewed relevant VHA and facility policies, privileging documents, committee meeting minutes, electronic health records (EHRs), as well as quality and management review documents.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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[3] "Travel During COVID-19," Centers for Disease Control and Prevention, accessed February 08, 2021, https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-during-covid19.html. "Travel increases your chance of getting and spreading COVID-19. CDC recommends that you do not travel at this time. Delay travel and stay home to protect yourself and others from COVID-19." World Health Organization, *Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It,* accessed on February 08, 2021, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. COVID-19 (coronavirus disease) is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

[4] Clinicians interviewed included a general surgeon, a nephrologist, a pulmonologist, a radiologist, certified registered nurse anesthetists, intensivists, and urologists. Since the time of the virtual site visit, the acting Chief of Surgery is no longer in that role.

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 A

Patient A was in their 70's with a history of heart disease, high blood pressure, traumatic brain injury, posttraumatic stress disorder, alcohol dependence, nerve damage with resulting inability to walk, an enlarged prostate with chronic urinary retention and incontinence, and a chronic left pelvic fluid collection.[5]

In spring 2020, the patient presented to the facility's Emergency Department with lower abdominal pain and pain with urination. Imaging of the abdomen and pelvis revealed a fluid collection in the left pelvis that appeared to be related to a bladder perforation with abscess formation.

On the same day, the patient was admitted to the general medicine service and the on-call urologist (Urologist 2), was consulted. Urologist 2 documented seeing the patient and speaking with the patient's primary urologist, Urologist 1, as well as an interventional radiologist regarding the plan of care. There was no further documentation by a Urologist until hospital day six when Urologist 1 saw the patient and noted the intention to take the patient to surgery that day. The patient signed an informed consent for multiple urologic procedures including bladder cystoscopy, bladder biopsy, ablation of bladder diverticulum, and a possible dilation of bladder neck. As documented on the informed consent, Urologist 1 explained to the patient that the main risks were the persistence of diverticulum and bladder perforation.

Urologist 1 performed surgery that morning and in the operative note documented converting an extraperitoneal bladder perforation to an intraperitoneal perforation and entering the peritoneal cavity.[6] The patient initially returned to the medicine unit following surgery, but was later transferred to the intensive care unit (ICU) due to uncontrolled pain, the possibility of cauterization of the small bowel, and the need to closely monitor the patient for sepsis and intestinal ischemia.

On post-operative day (POD) 1, a general surgery consult was requested due to the patient experiencing persistent right lower quadrant pain. The General Surgeon responding to the consult ordered a computerized tomography (CT) scan of the abdomen to assess for an intraperitoneal bladder perforation and noted that bowel injury could not be ruled out. The CT

[5] The OIG uses the singular form of they (their) in this instance for privacy purposes.

[6] Prior to surgery, Patient A had a chronic bladder perforation that opened into the extraperitoneal space. During the surgery, in the process of performing a biopsy of the abnormal lesion on the dome of the bladder, Urologist 1 inadvertently created a new perforation that opened into the intraperitoneal space.

scan confirmed a bladder perforation and showed that the tip of the indwelling urinary catheter had passed through the dome of the bladder into the peritoneal cavity.

In the evening of POD 1, Urologist 1 noted that Patient A's abdominal exam worsened, with more diffuse pain. On the morning of POD 3, Critical Care Physician 1 spoke with Urologist 2, who was on call for the weekend, and discussed a plan to take the patient back to the operating room later that day. Urologist 2 obtained informed consent from the patient for numerous procedures including tumor resection, cystoscopy, exploratory laparotomy, and possible bowel resection. The on-call General Surgeon and Urologist 2 took the patient to surgery with Urologist 1 assisting. The operative note documented a post-operative diagnosis of "bladder opening [and] sigmoid colon perforation [with] gross spillage of colonic contents in abdominal cavity." The procedures performed included a colon resection and colostomy, bladder closure, and placement of a suprapubic catheter. Two days after the second surgery, Urologist 2 changed the post-operative diagnosis to "suspected chronic colo-vesical fistula [*sic*]."

Following the surgery, the patient returned to the ICU on mechanical ventilation and blood pressure support medication. The patient remained hospitalized for over seven weeks and was discharged to a long-term care facility with a colostomy and feeding tube.

Patient B

Patient B was in their 80's with a history of high blood pressure, elevated cholesterol, mild chronic lung disease, an enlarged prostate gland, bladder stones treated with laser fragmentation in 2009, and chronic kidney disease.

In early 2020, the patient saw Urologist 1 at the facility for evaluation of recurrent bladder infections. A CT scan showed an enlarged prostate and a large stone in the bladder. Urologist 1 consented the patient for three urologic procedures: cystolitholapaxy, cystoscopy, and transurethral resection of the prostate.

The urologic procedures were performed in early summer 2020. In the operative note, Urologist 1 documented that the patient's abdomen was distended at the end of the procedure and that the distension was potentially due to an extraperitoneal prostate capsule perforation.[7] The operative note also stated that the abdominal distension restricted the patient's breathing, which resulted in the patient being intubated.

Following surgery, the patient was admitted to the ICU for post-operative management. Urologist 1 recommended conservative medical management with diuretics, supportive care, and consideration of drain placement if the patient did not improve.

[7]A perforation of the capsule can lead to excessive bleeding, urine collections in the abdominal cavity, and infection of adjacent structures.

On POD 1, Urologist 1 completed bedside testing, which indicated urine could have been leaking into the body cavity.

On POD 2, due to the patient's worsening kidney function, Nephrologist 1 was consulted and, based on a review of the patient's medical record, recommended intravenous fluids. Critical Care Physician 2 noted the patient had no urine output and bladder irrigation consistently yielded reduced return. The patient had a CT scan of the abdomen and pelvis that revealed a possible bladder rupture.

On POD 4, Nephrologist 1 entered a brief note stating that the patient had a perforated urinary bladder, septic shock with a possible urine leak, low blood pressure requiring blood pressure support medication, and worsening kidney function. Also, on POD 4, Urologist 1 documented having the opinion that the patient had a "prostate capsule perforation rather than [a] bladder perforation."

On POD 6, Nephrologist 1 saw the patient and recommended a definitive procedure to determine whether the patient had a bladder perforation and expressed the opinion that the patient had a very poor prognosis.

Also, on POD 6, Urologist 1 documented disagreeing with Nephrologist 1 about the need to perform a procedure to definitively diagnose a bladder perforation. Urologist 1 noted, that even if the patient had a bladder perforation, based on the patient's condition, treatment with continued nonsurgical management was indicated rather than a surgical repair. The patient was extubated and started hemodialysis.

On POD 14, a CT scan of the abdomen and pelvis with cystogram revealed a possible bladder perforation. An assessment for an active bladder leak was attempted but was limited because of difficulty injecting contrast into a bladder that was filled with blood product.

The patient remained in the ICU for just over eight weeks and underwent placement of a tracheostomy tube and a gastrostomy tube; intermittent hemodialysis; and mechanical ventilation. Attempts were made to wean the patient off mechanical ventilation. The patient was ultimately discharged to a long-term care facility on a ventilator.

Inspection Results

1. Perforations During Urological Procedures

The OIG substantiated that Urologist 1 perforated organs of Patient A and Patient B during surgical procedures.[8] Specifically, through EHR review, the OIG found evidence of perforations of Patient A's bladder and colon. Additionally, the OIG determined Patient B's prostatic capsule was perforated.[9] Based on EHR reviews and interviews with clinical staff involved in the procedures, and without directly observing the surgeries that resulted in the perforations, the OIG was unable to determine whether the complications were the result of Urologist 1 using poor technique.[10]

2. Deficiencies in Disclosures

The OIG identified deficiencies in the facility disclosure processes. The OIG determined that Urologist 1 did not consistently follow VHA policy regarding communicating and documenting clinical disclosures for Patient A and Patient B. Additionally, the OIG determined that the COS relied on the Risk Manager for notification of patient care adverse events that may need institutional disclosure; the Risk Manager did not alert the COS due to a misunderstanding of VHA policy.

VHA policy requires disclosure processes to be used to inform patients or their representatives of "harmful or potentially harmful adverse events," including known potential complications, "to maintain trust between patients and VA health care professionals, and to ensure uniform practice across all VA medical facilities."[11] Adverse events that warrant disclosure are defined broadly, to include those that have a perceptible effect on a patient or increase a patient's risk of future health consequences.[12] VHA policy provides procedures for three types of disclosures that may

[8] The details of the perforations are discussed in the *Patient Case Summaries* section.

[9] VHA Handbook 1004.01(4), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended January 4, 2021. The handbook describes requirements in effect during the period under review. VHA requires patients to be informed of known risks of procedures and the patient's consent to the procedures must be documented in the EHR; however, informing patients of known risks does not relieve providers of the obligation to perform procedures with care. According to the patients' signed informed consent forms, reviewed by the OIG, both patients were informed of the risk of perforation prior to undergoing the surgeries.

[10] The facility conducted management reviews that did not identify deficiencies in Urologist 1's technique. The reviews are discussed in the Management Reviews section of this report.

[11] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018; VHA defines an adverse event as "untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers." Additionally, the policy instructs that if a complication is "deemed to be untoward or preventable, then an appropriate disclosure is required" even if discussed as a possible complication during the informed consent process.

[12] VHA Directive 1004.08.

be used individually or in combination, depending on the circumstances: clinical, institutional, and large scale.[13]

Clinical Disclosures

According to VHA policy, the clinical disclosure process is a part of ongoing clinical care. During the clinical disclosure process, the clinician must inform the patient or the patient's representative of facts about an adverse event.[14] For adverse events that result in more than minor harm, VHA policy requires, as soon as reasonably practical, the practitioner responsible for the patient to provide the clinical disclosure, which must be documented.[15] However, VHA policy does not provide specific requirements regarding the contents of clinical disclosure documentation.[16]

During OIG interviews, the COS and Risk Manager described processes at the facility to ensure clinical disclosures were made. The COS reported that surgeons were expected to complete clinical disclosures for any complication, regardless of whether the complication was anticipated. The COS informed the OIG that quality management staff review the patient EHR to check if a clinical disclosure occurred. The Risk Manager described a process of checking EHR documentation for clinical disclosure and making recommendations as needed, after being informed of a patient safety event.

During an OIG interview, Urologist 1 described the clinical disclosure process and reported providing clinical disclosures for adverse events when warranted. However, through EHR review and interviews, the OIG learned that clinical disclosures were not consistently documented for either Patients A or B.

The OIG identified that Patient A had three events and Patient B had one event that met VHA's definition of an adverse event and required clinical disclosures. Two of the adverse events affecting Patient A and the adverse event affecting Patient B resulted in harm that was more than minor and, therefore, Urologist 1, as the patients' responsible practitioner, was required to communicate and document clinical disclosures of these adverse events.

Patient A

The OIG determined that clinical disclosures were required for the bladder perforation that occurred during the first surgery, the indwelling urinary catheter extending through the bladder

[13] VHA Directive 1004.08. Large scale disclosures are a process VHA officials use for notification of actual or potential harm to multiple patients due to a system issue and are not discussed in this report.

[14] VHA Directive 1004.08.

[15] Patient safety reports are discussed in the *Deficiencies in Quality Processes and Delayed Management Reviews* section of this report.

[16] VHA Directive 1004.08.

perforation that was discovered post-operatively, and the perforated colon that was confirmed during the second surgery.

During OIG interviews, Urologist 1 reported disclosing the bladder and possible colon perforation to the patient after the first surgery. Urologist 1 documented "patient informed of injury" in the EHR, consistent with VHA policy. The documentation mentioned the bladder perforation but did not reference the possible colon perforation. The OIG acknowledges that VHA policy does not provide specific guidance regarding the contents of clinical disclosure documentation. However, documentation that includes details about the content of a disclosure discussion would enhance communication among the healthcare team, memorialize the contents of the discussion, and help ensure uniform practice across all VHA medical facilities.[17]

Although Urologist 1 reported the practice of notifying patients of adverse events, the OIG did not find clinical disclosure documentation in Patient A's EHR for the two additional adverse events. The OIG did not find documentation of a disclosure regarding the indwelling urinary catheter extending through the bladder perforation or the colon perforation that was confirmed during the second surgery.

During an OIG interview, Urologist 1 stated that the catheter extending through the bladder perforation was not an adverse event because the event was a known possibility, an assertion that was inconsistent with VHA's definition of an adverse event.[18] In response to an OIG question about informing the patient of the misplaced catheter, Urologist 1 indicated the need to check documentation on the matter in the patient's EHR. When the OIG informed Urologist 1 that documentation on this topic was not found in the patient's EHR, the response was that Urologist 1 would have informed the patient of the misplaced catheter. According to policy, because the adverse event did not result in harm that was more than minor, Urologist 1 was not required to document a disclosure.

The OIG did not locate EHR documentation of a clinical disclosure regarding the perforated colon that was confirmed during the second surgery. Although Urologist 1 reported including the possible colon injury in the disclosure that was made after the first surgery, the OIG determined a documented clinical disclosure was required when the perforation of the colon was confirmed. During an OIG interview, Urologist 1 reported making the disclosure of the confirmed colon perforation and that the lack of documentation was an error.

[17] VA OIG, *Facility Leaders' Response to Level 2 and Level 3 Pathology Reading Errors at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas*, Report No. 21-01677-259, September 21, 2021. The OIG recently made a recommendation to the Under Secretary for Health to clarify the content of clinical disclosure documentation; therefore, a recommendation regarding clinical disclosure documentation is not made in this report.

[18] VHA Directive 1004.08. This interview occurred approximately 17 months after the event.

During an OIG interview, the Risk Manager recalled checking Patient A's EHR and finding the documentation of a clinical disclosure following the first surgery. The Risk Manager reported not being informed of the subsequent adverse events experienced by Patient A.[19]

Patient B

The OIG determined that Urologist 1 made a clinical disclosure to Patient B's family regarding the prostate capsule perforation but that the disclosure was not made as soon as reasonably practical.

During an OIG interview, Urologist 1 recalled informing the patient's family about the prostate capsule perforation on the day of the surgery. The OIG reviewed EHR documentation that reflected that Urologist 1 had a conversation with the family the day after surgery, but the progress note did not demonstrate a clinical disclosure regarding the prostate capsule perforation. Urologist 1 acknowledged to the OIG that failing to document that the clinical disclosure was included in the conversation with the patient's family was a lapse in documentation.

Although Urologist 1 reported making the clinical disclosure but failing to document the discussion, EHR documentation suggested that Urologist 1 was not the clinician who disclosed the prostate capsule perforation. Four days after surgery, Urologist 1 documented that Patient B's family reported being informed about the prostate capsule perforation by an ICU staff member. Urologist 1 documented answering the family's questions, which the OIG considered completion of the clinical disclosure process.

During an OIG interview, the Risk Manager reported being informed of Patient B's adverse event by the Acting Chief of Surgery approximately four months after the event occurred. Therefore, the Risk Manager did not know to check the patient's EHR for clinical disclosure documentation until long after the clinical disclosure process was completed.

The OIG concluded that, although knowledgeable about the clinical disclosure policy and reporting routinely notifying patients of adverse events, Urologist 1 did not document clinical disclosures to Patient A regarding an indwelling urinary catheter extending through the bladder or the confirmed colon perforation. Urologist 1 also failed to provide a clinical disclosure regarding Patient B's prostatic capsule perforation as soon as reasonably practical. The OIG was informed that the Risk Manager reviewed EHRs after receiving notifications of patient safety events to provide guidance on clinical disclosures, but because the Risk Manager was not informed about some of the adverse events, the process failed.

[19] Deficiencies in reporting adverse events are discussed in the *Deficiencies in Quality Processes and Delayed Management Reviews* section.

Institutional Disclosures

According to VHA policy, institutional disclosure is a formal process for facility leaders to inform a patient of an adverse event that has or is expected to result in death or serious injury.[20] During an institutional disclosure, clinical information regarding the adverse events must be shared with the patient or the patient's representative and information regarding potential compensation must be offered.[21] The policy lists adverse events requiring prolonged hospitalization as one indicator of a serious injury requiring an institutional disclosure.[22] Once facility risk managers are aware of an adverse event that may require an institutional disclosure, they are responsible for notifying facility leaders, including the COS.[23]

Both patients experienced prolonged hospitalizations due to adverse events; therefore, facility leaders should have considered conducting institutional disclosures. However, during interviews, the OIG learned that institutional disclosures were not considered for either patient.

During an OIG interview, the COS accurately described indications for institutional disclosure as adverse events that lead to serious injury or death. The COS acknowledged that potential cases for institutional disclosure may be identified through daily operational meetings and peer reviews, but reported relying on the quality department referring cases for consideration.[24] The COS also reported not being advised of the need to consider institutional disclosures for Patient A or Patient B. The Chief of Quality Management confirmed that the Risk Manager was responsible for making institutional disclosure referrals.

During an OIG interview, the Risk Manager confirmed having responsibility for referring cases that may require institutional disclosure to the COS. The Risk Manager acknowledged being notified through a patient safety report about Patient A's bladder perforation and possible colon perforation, and that the Acting Chief of Surgery reported Patient B's perforated prostate capsule approximately four months after the complication occurred. However, the Risk Manager stated complications that were known risks were not considered for institutional disclosures, which is contrary to VHA policy.[25]

Due to the OIG's concern that adverse events needing consideration of institutional disclosures may not be recognized, the Chief of Quality Management was contacted about the Risk

[20] VHA Directive 1004.08.

[21] VHA Directive 1004.08.

[22] VHA Directive 1004.08.

[23] VHA Directive 1004.08.

[24] The COS reported that results of peer reviews may indicate the need to consider institutional disclosures; however, peer reviews were not conducted for these cases.

[25] VHA Directive 1004.08. All adverse events that occurred during a patient's care that resulted in or was reasonably expected to result in death or serious injury must be reported to the patient or patient's representative as an institutional disclosure.

Manager's misunderstanding of policy. Upon this notification, the Chief of Quality Management informed the OIG of the intent to review the institutional disclosure policy with the Risk Manager. Additionally, the Chief of Quality Management reported that, since the summer of 2020, quality staff and the VA Surgical Quality Improvement Program Registered Nurse reviewed all reported adverse events from the previous day(s) during daily High Reliability Organization Huddles.[26] The Chief of Quality Management stated that the huddle served as a venue to identify missed opportunities.

The Associate Chief of Quality Management informed the OIG that the Risk Manager attended Risk Management Boot Camp training conducted by VHA's Clinical Risk Management Program in 2014. The OIG interviewed the VHA Director of Clinical Risk Management who confirmed that institutional disclosures were covered during bootcamp training, including known complications not being excluded from disclosure. The Director also reported that institutional disclosures were intermittently discussed during quarterly calls with risk managers.

The OIG concluded that the COS did not consider making institutional disclosures to either patient. The Risk Manager misunderstood VHA policy regarding criteria for disclosure and did not refer the cases to the COS for consideration. Furthermore, although the COS reported that complications meeting criteria for institutional disclosure could be identified through daily operational meetings and peer review processes, these activities did not lead to identification of the adverse events needing consideration for an institutional disclosure. The OIG is concerned that failures in disclosure processes, including the reliance on a single individual to make referrals for consideration of institutional disclosures, may result in patients not being fully informed to make healthcare decisions or of the right to seek compensation for injuries.

3. Deficiencies in Quality Processes and Delayed Management Reviews

The OIG determined that the facility conducted quality and management reviews of Urologist 1's practice regarding the care of Patients A and B. However, the OIG identified deficiencies in quality processes involving patient safety reporting; the Surgical Workgroup's oversight of Surgical Service Morbidity and Mortality Conferences; and peer review processes. These deficiencies contributed to management reviews of Urologist 1's practice being initiated several months after the surgical complications occurred, which led to delays in facility leaders receiving information from the reviews. Ultimately, facility leaders took reasonable actions based on the management review results.

[26] Events taking place Friday through Sunday are reviewed on Monday.

Patient Safety Reporting

VHA policy requires VHA personnel who are aware of an adverse event to inform the patient safety manager through a web-based reporting system known as the Joint Patient Safety Reporting system.[27] According to VHA policy, the patient safety manager reviews joint patient safety reports (JPSRs) to determine appropriate next steps that may include a patient safety investigation or referral of the patient safety event to another program for action.[28]

The OIG determined Patient A's bladder and colon perforations as well as the indwelling urinary catheter extending through the patient's bladder, and Patient B's prostatic capsule perforation, met VHA's adverse event definition, and were required to be reported to the Patient Safety Manager. During an OIG interview, Urologist 1 reported thinking that JPSRs were submitted for both Patient A and Patient B. The OIG confirmed that not all reportable events experienced by Patient A and Patient B were submitted. The failure of staff to report patient safety events impeded the Patient Safety Manager from assessing the events to determine appropriate next steps, such as completing patient safety reviews.

Seven of the eight other direct patient care clinicians interviewed acknowledged being familiar with the process of reporting adverse events through the JPSR system; however, none of the interviewed staff entered a JPSR regarding the patients' surgical adverse events. Although knowledgeable about the JPSR system, several clinicians incorrectly indicated that the person who created the adverse event is the person responsible for entering the report. One clinician, who was familiar with the process and recognized having the ability to enter JPSRs, noted that the attending surgeon should be the person to enter a JPSR on a surgical complication to ensure accurate information is submitted.

The Patient Safety Manager reported that any staff aware of an adverse event were expected to submit a JPSR. The COS and Patient Safety Manager shared several mechanisms in place to train and encourage staff to use the JPSR system; however, the Patient Safety Manager acknowledged that JPSRs were not always submitted.[29]

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[27] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011; VHA National Center for Patient Safety, *2020 | JPSR Business Rules and Guidebook*, July 2020; Department of Defense, *JPSR User Guide for the Reporting and Investigating of Patient Safety Events*, February 12, 2018; VHA Directive 1320, *Quality Management and Patient Safety Activities That Can Generate Confidential Records and Documents*, July 10, 2020.

[28] VHA Handbook 1050.01.

[29] Mechanisms described by the COS and the Patient Safety Manager to train and encourage staff to enter JPSRs included: ensuring a culture in which staff are not fearful of submitting JPSRs; presentations to new staff; as needed trainings to staff who need to submit a report; convenient placement of the JPSR icon to enter reports; and encouragement from facility leaders.

In addition to training efforts, the Patient Safety Manager informed the OIG that the facility's use of High Reliability Organization Huddles facilitated discussion about quality concerns. However, the huddle process had not been implemented at the time of the events discussed in this report.

The OIG concluded that staff failed to report Patient A's indwelling urinary catheter migration through the bladder or the confirmed colon perforation, and Patient B's perforated prostate capsule through JPSRs. As a result, the Patient Safety Manager was not informed of the adverse events and therefore did not review the events to determine whether additional patient safety actions were indicated.

Lack of Surgical Workgroup Oversight

VHA's National Surgery Office policy requires a facility's surgical work group, chaired by the facility chief of surgery, provide oversight of Morbidity and Mortality Conferences.[30] With the purpose of improving the quality of care, Morbidity and Mortality Conferences are confidential discussions about care provided to a patient who experienced complications or died.[31] The VHA National Surgery Office policy does not have mandatory criteria for the type of surgical cases presented at the Morbidity and Mortality Conferences.[32] The facility bylaws require meeting minutes to include "issues discussed, conclusions, actions, recommendations, evaluation and follow up."[33]

The Acting Chief of Surgery reported serving as the chair of the facility's Surgical Workgroup and that generally all surgical complications were presented at Morbidity and Mortality Conferences. The Acting Chief of Surgery explained that Morbidity and Mortality Conferences at the facility were usually conducted once the patient was discharged, after full details were available. Additionally, the Acting Chief of Surgery reported that during 2020, some Morbidity and Mortality Conferences were delayed because of the COVID-19 pandemic.

The OIG learned through document review that Patient A's and Patient B's cases were presented at Morbidity and Mortality Conferences in the summer and fall of 2020 respectively. The OIG staff reviewed Surgical Workgroup minutes for evidence of oversight of the conferences. The Surgical Workgroup minutes reflected the number of patient cases presented at Morbidity and Mortality Conferences. However, contrary to the facility bylaws, the minutes lacked details about the cases presented such as conclusions and recommendations.

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[30] VHA Directive 1102.01(1), *National Surgery Office*, April 24, 2019, amended May 22, 2019.

[31] VHA Directive 1320, *Quality Management and Patient Safety Activities That Can Generate Confidential Records and Documents*, July 10, 2020.

[32] VHA Directive 1102.01(1).

[33] Facility, *Bylaws and Rules of the Medical Staff,* April 24, 2017, (adopted May 15, 2017), has been replaced by Facility, *Bylaws and Rules of the Medical Staff*, February 24, 2021, and contains the same language about meeting minute documentation requirements.

Having not found evidence of oversight in the Surgical Workgroup minutes, the OIG asked the Acting Chief of Surgery about tracking Morbidity and Mortality Conference recommendations. The Acting Chief of Surgery reported that the primary means of tracking recommendations was through the COS's office and risk management. However, during OIG interviews, the COS and Risk Manager did not report tracking recommendations from Morbidity and Mortality Conferences.

The OIG concluded that documentation in Surgical Workgroup minutes did not meet the criteria outlined in the facility bylaws such as conclusions, and recommendations, which represented a lack of oversight. The OIG is concerned that deficiencies in oversight could lead to delayed or missed opportunities to improve quality care.

Peer Review Processes

Peer reviews for quality management (peer reviews) are confidential, non-punitive, focused reviews of providers' clinical decision-making, completed by similarly qualified providers with the intent of promoting quality of care.[34] VHA policy assigns facility directors the responsibility for the overall functioning of facility peer review programs.[35] The COS is required to provide clinical oversight and serve as the chair of a mandated facility peer review committee.[36] The policy also requires that certain clinical events, such as major morbidities related to surgical care, are evaluated to determine whether a peer review is indicated.[37]

Based on documentation received from the facility, the OIG learned that the Risk Manager was responsible for coordinating the peer review program. During an OIG interview, the Risk Manager reported receiving referrals for peer review from multiple sources, including JPSR, occurrence screen reviews, facility executive leaders' concerns, and the Chief of Surgery.[38]

The OIG determined that the bladder and colon perforations experienced by Patient A, and the prostatic capsule perforation experienced by Patient B resulted in major morbidities that required an evaluation of the patients' surgical care to determine if peer reviews were needed.

[34] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[35] VHA Directive 1190.

[36] VHA Directive 1190.

[37] VHA Directive 1190. "Major morbidities associated with clinical care including, but not limited to, operative (inpatient, outpatient, and same day surgery) and invasive procedures (e.g., chemotherapy, cardiac catheterization, interventional radiology, colonoscopy, and radiation therapy)."

[38] VHA Directive 1320. VHA Directive 1190. Occurrence screen is a tool used to identify episodes of care meeting specific criteria to help identify possible problems in patient care. The tool can be generated through the Veterans Health Information Systems and Technology Architecture occurrence screen programs or a locally developed equivalent process and identifies events, such as an unplanned return to the operating room, which may require further review.

The Risk Manager acknowledged planning a peer review in the spring of 2020 following notification of the complications that occurred during Patient A's first surgery. However, the Risk Manager confirmed that the planned peer review was not completed. Although uncertain of the reason the peer review was not done, the Risk Manager explained that the peer review may have been missed due to additional duties and quality staff reassignments in response to the COVID-19 pandemic.[39]

The Risk Manager reported first learning of the need to consider initiating a peer review about Patient B's surgical care in the fall of 2020, more than four months after the surgery occurred. According to the Risk Manager, the Acting Chief of Surgery had asked that external peer reviews be initiated for Patient A's and B's cases. The Risk Manager also told the OIG that, because peer reviews of multiple cases were requested, the cases were sent for external management reviews.

The OIG concluded that a planned peer review of Urologist 1's care of Patient A was not completed and an evaluation of Patient B's care to decide whether to initiate a peer review was delayed due to the Risk Manager not being informed of the patient's surgical complication. Failures in the peer review process contributed to a delay in the cases being referred for management reviews.

Management Reviews

Several months elapsed between the occurrence of the patients' surgical complications and the referral to the Risk Manager, who then identified the need for management reviews. Once the need was identified, management reviews were initiated. The OIG determined that the facility took reasonable action based on the results of external management reviews of Urologist 1's practice for Patient A and Patient B.

According to VHA policy, a management review is a type of non-protected review that must be used if the purpose of the review is to "provide a basis for an action that may affect personnel status or clinical privileges."[40] VHA policy instructs facility leaders to initiate a management review when concerned that a provider's practice may require a personnel or privileging action.[41]

Management reviews of Patient A's and Patient B's cases were completed in winter 2020. The management review for Patient A's surgery was completed more than seven months after Patient A's initial surgery. The management review for Patient B's surgery was completed more than five months after the surgery. According to the COS and Chief of Quality Management, once the

[39] The OIG acknowledged the unprecedented challenges brought by the coronavirus and received documentation describing staff reassignments.

[40] VHA Directive 1190.

[41] VHA Directive 1190.

management review results were received, the Acting Chief of Surgery, credentialing committee, and COS instituted a focused professional practice evaluation for cause for Urologist 1.

The OIG inspected the management review results and concluded that facility leaders took reasonable action. Factors that contributed to the delayed management reviews included staffs' failure to report adverse events to the Patient Safety Manager; lack of Surgical Workgroup oversight; the Risk Manager's failure to follow up on a planned peer review; and the delay notifying the Risk Manager of adverse events.

4. Delineation of Privileges Concerns

The OIG found that the facility's privileging process for urologists was inconsistent with VHA policy.[42] Specifically, the Acting Chief of Surgery did not complete the required annual review of the form used to delineate urologists' privileges. As a result, privileges available to urologists may not be consistent with available resources to support safe patient care, such as equipment, space, and surgical competency. Additionally, the privileging form included a statement implying urologists may perform procedures beyond those listed on the privileging form.

VHA policy and facility bylaws require service chiefs to review available privileges annually and consider whether adequate resources are available to support the privileges.[43] VHA policy requires that facility leaders privilege providers for procedures actually performed at the facility.[44] Additionally, facility directors are required to ensure credentialing and privileging training is completed by medical staff leaders within three months of assuming a role with credentialing and privileging responsibilities.[45]

The OIG was informed by the Credentialing and Privileging Manager that the facility process for the required annual review of privileging forms included

- the service chief meeting with section chiefs to review current privileges to ensure the privileges meet the facility's needs,
- the service chief sending the reviewed privilege forms to the credentialing and privileging office, and
- the privilege forms being presented to the Medical Executive Council through the professional standards board for approval from the Facility Director.

The OIG reviewed an example of the version of the urology privileging form in use at the time of the inspection. The form contained a reviewed date, without an indication of the reviewer; a

[42] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.
[43] VHA Handbook 1100.19; Facility, *Bylaws and Rules of the Medical Staff*, February 24, 2021.
[44] VHA Handbook 1100.19.
[45] VHA Handbook 1100.19.

credentialing committee approved date; and a Medical Executive Council approved date.[46] The Credentialing and Privileging Manager provided the OIG with an email that included the following statement from a surgical staff member: "we reviewed the attached documents [including the urology privileging form] and do not believe there are any changes [other than removing a person's name from the template]." The Acting Chief of Surgery was copied on the email.

When asked during an OIG interview about being involved with the review and approval of the urology privileging form, the Acting Chief of Surgery was unable to recall. The Acting Chief of Surgery was uncertain of how privileges came to be listed on the urology privileging form and stated that the listed privileges were based on procedures within core services that any urologist can perform.

The Acting Chief of Surgery described not being the official chief of service and gaining knowledge informally. The Acting Chief of Surgery who had been in the position for less than two months prior to the privileging form being reviewed was not knowledgeable about the VHA requirement to review privileging forms annually.

Additionally, the OIG asked the Acting Chief of Surgery to explain the meaning of a sentence on the urology privileging form:

> The following list of procedures or techniques is not construed as limiting a urologist's ability. It is presented to provide urologists with a broad outline of the types of procedures and techniques expected of a urologist.

The Acting Chief of Surgery responded that the list of procedures was not an all-inclusive list and that the statement permitted a urologist to perform additional procedures in an emergency. The OIG determined the statement was broader than the interpretation described by the Acting Chief of Surgery and could be understood as allowing urologists to perform unprivileged procedures under non-emergent situations.[47]

The OIG concluded that the process of approving the form delineating urologists' privileges without review by the Acting Chief of Surgery did not comply with the VHA requirement. The OIG is concerned that without the Chief of Surgery's active involvement during the required annual review of privileging forms, privileges may be granted to urologists at the facility without consideration of resources available to support safe patient care, such as equipment, space, and surgeon competency. Additionally, the language contained in the urologists' privileging form, stating that the list of granted privileges is not to be construed as a limitation, may have been

[46] The COS confirmed through an interview that the local Professional Standards Board was equivalent to a credentialing committee.

[47] Through a review of Urologist 1's surgical procedures, the OIG determined that Urologist 1 performed only the procedures that were contained on the urology privileging form.

interpreted to mean that additional procedures could be performed without the safeguards afforded through the required delineation of privileges process.

Conclusion

Urologist 1 perforated both patients' organs during surgical procedures. Based on EHR reviews and interviews with clinical staff involved in the procedures, and without directly observing the surgeries that resulted in the perforations, the OIG was unable to determine whether the complications were the result of Urologist 1 using poor technique.

The OIG determined that Urologist 1 did not consistently follow VHA policy regarding communicating and documenting clinical disclosures of adverse events. Although Urologist 1 reported making clinical disclosures to Patient A regarding the bladder and possible colon perforation, an indwelling urinary catheter that migrated through the bladder, and confirmed colon perforation, the OIG did not find documentation describing the adverse events that were disclosed. Regarding Patient B, Urologist 1 documented completion of the clinical disclosure process four days after the patient's surgery, which was not as soon as reasonably practical as required.

The COS and Risk Manager described a process to ensure clinical disclosures were documented that included quality management staff reviewing EHRs when patient safety events were reported. However, because not all of Patient A's and Patient B's adverse events were reported, the process failed to work.

The COS did not consider institutional disclosures for either Patient A or Patient B. The Risk Manager misunderstood VHA policy regarding criteria for disclosure and did not refer the cases to the COS for consideration. The COS acknowledged that complications meeting criteria for institutional disclosure could be identified through daily operational meetings and peer reviews but reported relying on the quality department (the Risk Manager) referring cases for institutional disclosure. The OIG concluded that failures in the disclosure process, including the reliance on a single individual to make referrals for consideration of institutional disclosures, may result in patients not being fully informed to make healthcare decisions or of the right to seek compensation for resulting injuries.

Staff did not report some adverse events experienced by Patient A and Patient B. A nurse informed the Patient Safety Manager about Patient A's bladder and possible colon perforation after the first surgery. However, staff did not report additional adverse events for Patient A or the adverse event for Patient B. As a result, the Patient Safety Manager was not aware of the need to review the events to determine next steps.

The Surgical Workgroup is required to provide oversight to the Morbidity and Mortality Conferences. The Surgical Workgroup minutes did not meet the criteria outlined in the facility bylaws to include specific information such as conclusions and recommendations, which

represented a lack of oversight. The OIG is concerned that deficiencies in oversight could lead to delayed or missed opportunities to improve quality care.

The Risk Manager confirmed a planned peer review regarding Patient A's care was not completed. Additionally, an evaluation for peer review of Patient B's care was delayed due to the Risk Manager not being informed of the patient's surgical complication.

Several months elapsed between the occurrence of the patients' surgical complications and the referral to the Risk Manager, who then identified the need for management reviews. Once the need was identified management reviews were initiated. Facility leaders took reasonable action based on the results of the management reviews. However, the management review for Patient A's surgery was completed more than seven months after the first surgery. The management review for Patient B's surgery was completed more than five months after the patient's surgery. Factors that contributed to the delayed management reviews, included staffs' failure to report adverse events to the Patient Safety Manager; Surgical Workgroup's lack of oversight of Morbidity and Mortality Conferences; and peer review process deficiencies.

Delineation of urologists' privileges did not comply with VHA and facility requirements. The OIG is concerned that without the Acting Chief of Surgery's active involvement during the required annual review of privileging forms, urologists may have been granted privileges at the facility without having adequate resources available to support safe patient care. Additionally, the language contained in the urologists' privileging form, stating that the list of granted privileges was not to be construed as a limitation, may have been interpreted to mean that additional procedures could be performed without the safeguards afforded through the required delineation of privileges process.

Recommendations 1–7

1. The West Palm Beach VA Medical Center Director evaluates clinical disclosure practices and takes action as warranted to ensure compliance with Veterans Health Administration Directive 1004.08.

2. The West Palm Beach VA Medical Center Director ensures that Patient A's and Patient B's episodes of care are reviewed to determine if an institutional disclosure is needed per Veterans Health Administration Directive 1004.08 and takes action accordingly.

3. The West Palm Beach VA Medical Center Director evaluates facility compliance with Veterans Health Administration Directive 1004.08 regarding institutional disclosure processes and takes corrective actions as needed.

4. The West Palm Beach VA Medical Center Director explores reasons Joint Patient Safety Reports were not entered for some adverse events experienced by Patient A and Patient B and takes action accordingly to ensure compliance with Veterans Health Administration Handbook 1050.01.

5. The West Palm Beach VA Medical Center Director confirms that the Surgical Workgroup's meeting minutes document oversight of the Surgical Service Morbidity and Mortality Conference by including issues discussed, conclusions, actions, recommendations, evaluations, and follow up in accordance with *Bylaws and Rules of the Medical Staff Department of Veterans Affairs Medical Center West Palm Beach, Florida*.

6. The West Palm Beach VA Medical Center Director identifies reasons a planned peer review was not completed in accordance with Veterans Health Administration Directive 1190 and takes corrective action as indicated.

7. The West Palm Beach VA Medical Center Director reviews processes for evaluation of urologists' privileging forms and takes action as necessary to ensure compliance with Veterans Health Administration Handbook 1100.19 and *Bylaws and Rules of the Medical Staff Department of Veterans Affairs Medical Center West Palm Beach, Florida*.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 27, 2021

From: Director, VA Sunshine Healthcare Network (10N08)

Subj: Healthcare Inspection—Deficiencies in Disclosures and Quality Processes for Perforations Resulting from Urological Surgeries at West Palm Beach VA Medical Center in Florida

To: Director, Office of Healthcare Inspections (54HL01)
Director, GAO/OIG Accountability Liaison office (VHA 10BGOAL Action)

I have reviewed the VAOIG's report as well as the West Palm Beach VA Medical Center Director's response. I concur with the findings, recommendations, and action plans therein.

The VISN 8 Quality Management Officer will be the point of contact for this report.

(*Original signed by*:)

Miguel H. LaPuz, M.D., MBA
Network Director, VISN 8

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: 10/22/2021

From: Director, West Palm Beach VA Medical Center (548)

Subj: Healthcare Inspection—Deficiencies in Disclosures and Quality Processes for Perforations Resulting from Urological Surgeries at West Palm Beach VA Medical Center in Florida

To: Director, VA Sunshine Healthcare Network (10N08)

I have reviewed the VAOIG's report and concur with the findings and recommendations. The West Palm Beach VA Medical Center has implemented actions in response to findings.

The West Palm Beach VA Medical Center's Associate Chief, Quality Management Service will act as the facility's point of contact for this report.

(*Original signed by*:)

Cory P. Price, FACHE
Medical Center Director

Facility Director Response

Recommendation 1

The West Palm Beach VA Medical Center Director evaluates clinical disclosure practices and takes action as warranted to ensure compliance with VHA Directive 1004.08.

Concur.

Target date for completion: ad hoc group will be created by 11/1/2021. Template revision and education by 12/31/21.

Director Comments

The Medical Center Director evaluated clinical disclosure practices and will establish an ad hoc group to review adverse events and ensure timely and appropriate clinical disclosure in compliance with VHA Directive 1004.08. This work group will be comprised of the Chief of Staff, Risk Manager, Chief and/or Associate Chief of Quality Management, and Chief of Service where adverse event occurred.

In collaboration with the Medical Record Committee, a clinical disclosure radio button will be added to the Brief Post-Op Note in [the Computerized Patient Record System] (CPRS) as a reminder to the treating provider to complete timely disclosure when necessary. All providers will be educated on the additional radio button added to the Brief Post-Op Note in CPRS.

For six (6) consecutive months, the ad hoc group will audit 100% of clinical disclosures to ensure compliance with the newly added feature.

Recommendation 2

The West Palm Beach VA Medical Center Director ensures that Patient A's and Patient B's episodes of care are reviewed to determine if an institutional disclosure is needed per VHA Directive 1004.08 and takes action accordingly.

Concur.

Target date for completion: 12/30/21

Director Comments

A review of episodes of care for patient A and patient B were conducted and it was determined that both required an Institutional Disclosure per VHA Directive 1004.08. The Risk Manager and Chief of Staff will provide notification to patient and/or family and, if patient/family agreeable, will conduct Institutional Disclosures on both patients A and B.

Recommendation 3

The West Palm Beach VA Medical Center Director evaluates facility compliance with VHA Directive 1004.08 regarding institutional disclosure processes and takes corrective actions as needed.

Concur.

Target date for completion: 11/1/21

Director Comments

The Medical Center Director evaluated the Institutional Disclosure practices and will establish an ad hoc group to review adverse events (anticipated or unanticipated) to ensure timely and appropriate Institutional Disclosure in compliance with VHA Directive 1004.08. This work group will be comprised of the Chief of Staff, Risk Manager, Chief and/or Associate Chief of Quality Management, and Chief of Service where adverse event occurred.

For six (6) consecutive months, the ad hoc group will audit 100% of Institutional Disclosures to ensure anticipated and unanticipated complications are disclosed accordingly to the patient and/family or Next of Kin.

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 4

The West Palm Beach VA Medical Center Director explores reasons Joint Patient Safety Reports were not entered for some adverse events experienced by Patient A and Patient B and takes action accordingly to ensure compliance with VHA Handbook 1050.01.

Concur.

Target date for completion: 12/31/2021

Director Comments

The Medical Center Director identified opportunities for additional JPSR training. A VHA initiative towards High Reliability Organization (HRO) was launched in March of 2021, at the West Palm Beach VA Medical Center which contained implementation of additional Joint Patient Safety Report (JPSR) training as a part of the HRO education module. This initiative was not in place at the time of the incident.

As of 10/15/2021, 86.33% (2,306) clinical and non-clinical staff have participated in HRO training inclusive of JPSR reporting, with a target goal of 90%.

In order to improve reporting adverse events through the Joint Patient Safety Reporting (JPSR), the facility Patient Safety Manager will conduct JPSR and Culture of Safety training to all clinical Operating Room employees.

Recommendation 5

The West Palm Beach VA Medical Center Director confirms that the Surgical Workgroup's meeting minutes document oversight of the Surgical Service Morbidity and Mortality Conference by including issues discussed, conclusions, actions, recommendations, evaluations, and follow up in accordance with Bylaws and Rules of the Medical Staff Department of Veterans Affairs Medical Center West Palm Beach, Florida.

Concur.

Target date for completion: 6/30/2022

Director Comments

The Medical Center Director identified an opportunity to improve Surgical Workgroup Meeting minutes. The Chief of Staff (COS) will ensure that the Chief of Surgery modifies the Surgical Workgroup meeting minutes to include oversight documentation of the Surgical Service Morbidity and Mortality Conference by including issues discussed, conclusions, actions, recommendations, evaluations, and follow up in accordance with Bylaws and Rules of the Medical Staff. Prior to approval of meeting minutes, a designated Quality Management Specialist will audit a draft of the Surgical Workgroup Meeting minutes to ensure inclusion of these items for 6 consecutive months.

Recommendation 6

The West Palm Beach VA Medical Center Director identifies reasons a planned peer review was not completed in accordance with VHA Directive 1190 and takes corrective action as indicated.

Concur.

Target date for completion: 12/31/2021

Director Comments

The Medical Center Director confirmed that a planned Peer Review was not completed by the former Risk Manager. An Administrative Review will be conducted by Associate Chief of Quality to address why a planned peer review was not completed by the previous Risk Manager who is no longer in this role in accordance with Veterans Health Administration Directive 1190. Opportunities will be included in the ad hoc review group in evaluating Peer Review process to ensure timely review of identified adverse events.

Recommendation 7

The West Palm Beach VA Medical Center Director reviews processes for evaluation of urologists' privileging forms and takes action as necessary to ensure compliance with VHA Handbook 1100.19 and Bylaws and Rules of the Medical Staff Department of Veterans Affairs Medical Center West Palm Beach, Florida.

Concur.

Target date for completion: 12/31/2021

Director Comments

The Chief of Staff and Health System Specialist for Credentialing and Privileging will review urologists privileging forms to determine accuracy, make appropriate corrections in compliance with VHA Handbook 1100.19 and the By Laws and Rules of Medical staff, with changes reported through Medical Executive Council.

Glossary

ablation (rollerball). A procedure that uses electricity through a special surgical instrument to remove an abnormal area of tissue or tumor within an organ like the bladder.[48]

abscess. "A collection of pus in any part of the body."[49]

adverse events. "Adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers."[50]

biopsy. "A procedure to remove a piece of tissue or a sample of cells from [the] body so that it can be analyzed in a laboratory."[51]

bladder. "The organ that stores urine."[52]

bladder diverticulum. "A pouch in the bladder wall that a person may either be born with […] or get later."[53]

chronic kidney disease. "The gradual loss of kidney function."[54]

clinical disclosure. "A process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient's care."[55]

colovesical fistula. An open channel between the colon and the bladder.[56]

computerized tomography scan. An imaging exam that uses computer processing to combine a series of x-rays to create images of bones, blood vessels, and organs inside the body.[57]

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[48] Saad Juma, "Transurethral Fulguration of the Prostate with the Roller Ball," *Urology* 47, no. 1 (January 1996): 53-58.

[49] MedlinePlus, National Library of Medicine, "Abscess," accessed May 10, 2021, https://medlineplus.gov/ency/article/001353.htm.

[50] VHA Directive 1004.08.

[51] Mayo Clinic, "Biopsy: Types of biopsy procedures used to diagnose cancer," accessed May 10, 2021, https://www.mayoclinic.org/diseases-conditions/cancer/in-depth/biopsy/art-20043922.

[52] NIH National Cancer Institute, "Bladder," accessed March 5, 2021, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/bladder.

[53] Urology Care Foundation, "What is a Bladder Diverticulum?," accessed March 8, 2021, https://www.urologyhealth.org/urology-a-z/b/bladder-diverticulum.

[54] Mayo Clinic, "Chronic kidney disease," accessed March 8, 2021, https://www.mayoclinic.org/diseases-conditions/chronic-kidney-disease/symptoms-causes/syc-20354521?p=1.

[55] VHA Directive 1004.08.

[56] Radiopaedia, "Colovesical fistula," accessed March 3, 2021, https://radiopaedia.org/articles/colovesical-fistula.

[57] Mayo Clinic, "CT scan," accessed March 31, 2021, https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675?p=1.

cystogram. An examination of the bladder and urethra using a thin flexible tube where contrast material is introduced into the bladder and then x-rays are taken.[58]

cystolitholapaxy. "A procedure to break up bladder stones into smaller pieces and remove them."[59]

cystoscopy. A procedure to examine the bladder and urethra with a thin tube-like instrument called a cystoscope.[60]

diuretics. "A type of drug that causes the kidneys to make more urine."[61]

dome of the bladder. The upper surface of the bladder that curves outward.[62]

exploratory laparotomy. Surgery that opens the abdomen to examine the abdominal organs.[63]

extraperitoneal. Located or taking place outside the peritoneal cavity.[64]

focused professional practice evaluation for cause. "A time-limited period during which the medical staff leadership assesses the provider's professional performance to determine if any action should be taken on the provider's privileges."[65]

gastrostomy tube. A tube that is inserted through the skin directly into the stomach to provide nourishment.[66]

incontinence. Inability of the body to control the evacuative functions of urination or defecation: partial or complete loss of bladder or bowel control.[67]

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[58] PeaceHealth, "Cystogram Exam," accessed March 6, 2021, https://www.peacehealth.org/peace-harbor/services/imaging-services/radiology/cystogram.

[59] Beth Israel Lahey Health–Winchester Hospital, "Cystolitholapaxy," accessed on March 6, 2021, https://www.winchesterhospital.org/health-library/article?id=620491.

[60] NIH National Cancer Institute, "Cystoscopy," accessed March 5, 2021, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cystoscopy.

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[66] MedlinePlus, National Library of Medicine, *Feeding tube insertion - gastrostomy*, accessed August 2, 2021, https://medlineplus.gov/ency/article/002937.htm.

[67] Merriam-Webster, "Definition of incontinence," accessed May 10, 2021, https://www.merriam-webster.com/dictionary/incontinence.

indwelling urinary catheter. A thin, flexible tube used to drain urine from the bladder.[68]

institutional disclosures. "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."[69]

intestinal ischemia. A condition that happens when there is not enough blood flow to the intestines.[70]

intraperitoneal. Existing within or administered by entry into the peritoneum.[71]

perforated. Having a hole.[72]

perforation. The penetration of a body part through accident or disease.[73]

peritoneal cavity. "The space within the abdomen that contains the intestines, the stomach, and the liver."[74]

sepsis. "A potentially life-threatening condition that occurs when the body's response to an infection damages its own tissues."[75]

sigmoid colon. "The S-shaped section of the colon that connects to the rectum."[76]

suprapubic catheter. A hollow flexible tube that is inserted into the bladder to drain urine through a cut in the belly.[77]

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tracheostomy tube. A tube that is inserted through the skin directly into the trachea to allow for breathing and removal of secretions from the lungs.[78]

transurethral resection of the prostate. "A surgery used to treat urinary problems that are caused by an enlarged prostate."[79]

urologist. A physician who specializes in the urinary or urogenital tract.[80]

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OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Barbara Mallory-Sampat, JD, MSN, Director Katherine Auerswald, MD Valerie Lumm, MHA, RN Glenn Schubert, BS, MPH Laura Snow, LCSW, MHCL
Other Contributors	Felicia Burke, MS Limin Clegg, PhD Jonathan Ginsberg, JD Adam Hummel, MPPA Carol Lukasewicz, RN, BSN Jeanne Martin, PharmD Natalie Sadow, MBA

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