



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Concern Regarding a
Patient Death and Alleged
Conflicts of Interest at the
VA Western Colorado
Health Care System
Grand Junction



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to allegations from an anonymous complainant referred by the Office of Special Counsel. The allegations involved a patient's death following a urology procedure, and conflicts of interest at the VA Western Colorado Health Care System (facility) in Grand Junction. Specific allegations are listed below:

- A facility urologist ordered an extracorporeal shock wave lithotripsy (ESWL) procedure for a patient with significant risk factors who was not a suitable candidate for the procedure.¹ The patient died due to a resultant hematoma.²
- The Chief of Surgery, who also held a position as the Associate Chief of Staff for Acute Care Services (ACOS), hired several urologists from a private practice in possible violation of the Standards of Ethical Conduct for Employees of the Executive Branch, (conflict of interest regulation) which prohibits government employees from using public office for private gain.³
- The urologists hired by the ACOS increased the use of ESWL for treating urinary tract stones because they own an ESWL machine, in possible violation of the conflict of interest regulation.
- On more than one occasion, urologists hired by the ACOS failed to respond to the facility when on call.

During the inspection, the OIG team identified an additional concern related to action not taken by a facility primary care provider on the patient's abnormal pathology laboratory result.

The OIG substantiated that a facility urologist ordered an ESWL procedure for a patient who died 25 days later. However, the patient met several indications for an ESWL procedure, did not have significant risk factors, and was a suitable candidate for the procedure. The patient developed a hematoma after an ESWL procedure, was transferred to a non-VA hospital, and died within 25 days of receiving the procedure. Without an autopsy, the OIG could not determine the exact cause of death.

¹ Lithotripsy is the breaking of a calculus (stone) in the urinary system into pieces small enough to flow through urine.

² Hematoma is a mass, usually of partially clotted or clotted blood, that forms in the body spaces as a result of a broken blood vessel.

³ *Standards of Ethical Conduct for Employees of the Executive Branch*, 5 C.F.R. § 2635.702; VHA Handbook 1004.07, *Financial Relationships Between VHA Health Care Professionals and Industry*, November 24, 2014; VA Handbook 8002, *Financial Disclosure Reports*, July 1, 2015.

The OIG found an abnormal result in the electronic health record of the patient for a pathology report of a blood smear examination, which should have been addressed by the patient's primary care provider. The ordering provider failed to consult with the facility pathologist and address the abnormal pathology blood smear result with the patient.

The OIG did not substantiate that the ACOS hired urologists from a private practice in violation of the conflict of interest regulation. The ACOS was associated with the private practice; however, facility leaders other than the ACOS approved the recruitment of five 0.1 full-time employee equivalent urologists.⁴

The OIG was unable to determine that there was an increase in ESWL procedures due to the facility urologists' ownership of an ESWL machine. Equipment used to perform ESWL is expensive and is only needed a few times a year; therefore, the facility rents this equipment instead of purchasing its own machine. In recent years two companies, one in Grand Junction, and one in South Dakota, provided the facility with the equipment needed to perform ESWL procedures. The urologists had a financial interest in the local company in Grand Junction, which presented a risk for violation of the conflict of interest regulation. While there was an increase in the amount the facility expended on ESWL rental since the hiring of the urologists, the OIG could not attribute the increase to the urologists having an ownership interest in the company. The OIG found facility leaders were aware of the potential conflict of interest and sought guidance from the VA Office of General Counsel. Although, the General Counsel found "no actual conflict of interest" given the facts offered, the OIG found that these facts may have contained inaccurate statements.

The OIG did not substantiate that urologists failed to respond to the facility when on call. The complainant identified two patients for incidences where urologists were unavailable to facility staff when on call. The OIG team reviewed the two patients' electronic health records and found no documentation to suggest that the urologists on call were asked to respond to facility staff and failed to do so.

The OIG made two recommendations to the Facility Director related to abnormal blood test results and conflicts of interest.

⁴ A full-time employee equivalent or FTE reflects the number of regular hours worked by employees divided by the number of hours allowed for compensation in a year (stated in a ratio). One (1.0) FTE is equal to a full-time employee.

Comments

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

A handwritten signature in black ink, reading "John D. Daigh, Jr., M.D." in a cursive script.

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

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Abbreviations

ACOS	Associate Chief of Staff
CBC	complete blood count
CT	computed tomography
EHR	electronic health record
ESWL	extracorporeal shock wave lithotripsy
FTE	full-time employee equivalent
OGC	Office of General Counsel
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to allegations from an anonymous complainant regarding a patient's death following a urology procedure, and conflicts of interest at the VA Western Colorado Health Care System (facility), Grand Junction Urology Department.

Background

The facility, part of Veterans Integrated Service Network (VISN) 19, includes four community-based outpatient clinics located in parts of Colorado and Utah. The Veterans Health Administration (VHA) classifies the facility as a Level 2—Medium Complexity facility.⁵

In fiscal year 2018, the facility served 14,959 patients and had a total of 61 hospital operating beds, including 31 inpatient beds and 30 community living center beds. The facility provides primary and secondary care including acute medical, surgical, and psychiatric inpatient services, as well as a full range of outpatient services. Patients requiring tertiary care are referred to the VA Salt Lake City Health Care System, Utah, or the VA Eastern Colorado Health Care System, Denver. The facility has academic affiliation agreements with colleges and universities in Colorado, Utah, Arizona, Kansas, North Carolina, and New Mexico.⁶

Kidney Stone

A kidney stone is a hard object of mineral salts that forms in the kidneys. Small kidney stones are able to pass through the [urinary tract](#) without any treatment. Large stones can cause severe pain as they travel through the urinary tract and if left untreated, can block the urinary tract, increase the risk for infection, and add strain to the kidney. Treatment for larger stones includes the management of pain and removal of the stones. Methods to remove kidney stones can include insertion of a narrow tube called a stent that allows urine to pass through, surgery, or [lithotripsy](#), which uses shock waves to break up the stone.

⁵ 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.

⁶ Tertiary care is highly specialized medical care involving advanced procedures or treatments in state-of-the-art facilities.

Extracorporeal Shock Wave Lithotripsy

Extracorporeal shock wave lithotripsy (ESWL) is a procedure used in the treatment of kidney stones.⁷ ESWL is performed by a urologist who is a physician that specializes in treatment of diseases of the urinary tract. A urologist uses an ESWL machine, which generates shock waves to break up the stones into tiny pieces that can be passed in the urine. ESWL is indicated for patients with recently treated urinary tract infection, symptoms caused by the stone, a stone less than 15 millimeters, and stone growth. Although ESWL is considered noninvasive, it may require sedation or light anesthesia. Risks of ESWL include bleeding, infection, or kidney damage.

Conflict of Interest

The Standards of Ethical Conduct for Employees of the Executive Branch (conflict of interest regulation) prohibit government employees from using public office for private gain, including the private gain of friends, relatives, or persons who the employee is affiliated with in a nongovernment capacity.⁸

Allegations and Related Concern

On December 17, 2018, the Office of Special Counsel forwarded the OIG allegations received from an anonymous complainant related to the facility's Urology Department. The OIG reviewed the allegations and opened a healthcare inspection on January 7, 2019. The specific allegations are listed below:

- A facility urologist ordered an ESWL procedure for a patient with significant risk factors who was not a suitable candidate for the procedure. The patient died due to a resultant [hematoma](#).
- The Chief of Surgery who also held a position as the Associate Chief of Staff for Acute Care Services (ACOS), hired several urologists from a private practice in possible violation of the conflict of interest regulation.
- The urologists hired by the ACOS increased the use of ESWL for treating urinary tract stones because they owned an ESWL machine, in possible violation of the conflict of interest regulation.

⁷ Lithotripsy is the breaking of a calculus in the urinary system into pieces small enough to flow through urine. <https://www.mayoclinic.org/diseases-conditions/kidney-stones/diagnosis-treatment/drc-20355759>. (The website was accessed on April 25, 2019.)

⁸ 5 C.F.R. § 2635.702; the OIG uses the term "conflict of interest regulation" throughout the report to refer to the *Standards of Ethical Conduct for Employees of the Executive Branch*, 5 C.F.R. § 2635.702; VHA Handbook 1004.07, *Financial Relationships Between VHA Health Care Professionals and Industry*, November 24, 2014; VA Handbook 8002, *Financial Disclosure Reports*, July 1, 2015.

- On more than one occasion, urologists hired by the ACOS failed to respond to the facility when on call.

During the inspection, the OIG team identified an additional concern related to action not taken by a facility primary care provider on the patient's abnormal pathology laboratory result.

Scope and Methodology

The OIG initiated the inspection on January 7, 2019, and conducted a site visit from March 4 through March 7, 2019.

The OIG team conducted 28 interviews from January 17 through April 4, 2019, which included the ACOS, Acting Chief of Surgery, urologists and general surgeons, physician assistants, nurse practitioners, nurse managers, administrative staff, a human resource specialist, the Compliance Officer, the Chief of Quality, the facility's Strategic Planner, and other key staff.⁹

Relevant VHA directives, handbooks, and federal regulations were reviewed. Additionally, the team reviewed facility bylaws and rules of the medical staff, policies and procedures, facility meeting minutes, peer reviews, physician call schedules, strategic plans, productivity and utilization reports, and other related documents relevant to the allegations.

The OIG reviewed the electronic health record (EHR) of a patient who died after an ESWL procedure, and the EHRs of two patients identified by the complainant as having been treated in the facility's Emergency Department for urologic conditions when the availability of an on-call urologist was in question.

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.

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.

⁹ A physician assistant is a person certified to provide basic medical services usually under the supervision of a licensed physician; a nurse practitioner is a registered nurse qualified through advanced training to assume some of the duties and responsibilities formerly assumed only by a physician. On call is defined being available when summoned.

Patient Case Summary

The patient, who was in their 80s, had a past medical history that included kidney stones, coronary artery disease, high blood pressure, high cholesterol, and gastroesophageal reflux disease.¹⁰

In late 2017, one of the facility's Emergency Department provider treated the patient for a second urinary tract infection due to [Escherichia coli \(E. coli\) bacteria](#) within one month. The Emergency Department provider entered a consult to the facility's Urology Service to evaluate the patient for recurrent urinary tract infections.

In early 2018, a urologist assessed the patient for recurrent urinary tract infections and the presence of blood in the urine ([hematuria](#)). The urologist ordered a [computed tomography \(CT\) hematuria study](#) and a [cystoscopy](#).

In spring 2018, the patient was seen by the primary care provider for an annual visit. During the evaluation, the patient's [white blood count](#) on a [complete blood count \(CBC\)](#) test was recorded as elevated at 16,270 cells per microliter.¹¹ The provider documented notification to the patient as, "I don't think [there is] anything to be concerned [about] at this time," and ordered follow-up complete blood count testing in three months.

A few days after the 2018 annual visit, the patient underwent a cystoscopy, which revealed no clear reason for the patient's hematuria. The CT hematuria study showed a left kidney stone noted to have increased in size when compared to a 2010 CT scan. After discussion of treatment options and risks and benefits of varying approaches with the urologist, the patient elected to undergo left kidney ESWL for the kidney stone.

Anesthesia staff cleared the patient for an ESWL procedure that was performed eight days after the cystoscopy. The ESWL procedure was noted to be without complications and the patient was discharged home.

The day following the ESWL procedure, the patient was seen in the Urology Clinic for significant post-procedure pain. The patient complained of abdominal pain and decreased urination. Laboratory studies and a CT scan of the abdomen were ordered. The abdominal CT scan revealed a large hematoma behind the patient's left kidney. The patient was sent to the facility's Emergency Department and was subsequently transferred to a non-VA hospital for a higher level of care.

The Urology Service at the non-VA hospital planned to transfuse the patient with blood as needed and to monitor closely. Providers' notes in the patient's non-VA chart documented a

¹⁰ The OIG uses the singular form of they in this instance for privacy purposes.

¹¹ White blood count reference range (normal) is 4,500–11,000 cells per microliter.

large increase in the white blood count (16,270 cells per microliter to 56,860 cells per microliter). A hematologist/oncologist was consulted.¹²

Multiple medical problems—[atrial fibrillation](#) with rapid heart rate, [respiratory failure](#) with possible pneumonia, fluid overload secondary to suspected [congestive heart failure](#), [anemia](#), and [myelodysplastic syndrome](#)—complicated the patient’s non-VA hospital course leading to a worsening health status.

The hematology/oncology consultant recommended further workup including laboratory studies and a possible bone marrow [biopsy](#). The laboratory evaluation of the elevated white blood count indicated an atypical myelodysplastic syndrome, a type of cancer. However, the patient declined the bone marrow biopsy test, which would have given a definitive diagnosis. Ultimately, the patient decided to go home with hospice services and was discharged home with hospice care. The non-VA hospital transfer coordinator notified the facility that the patient died approximately two weeks later. No autopsy was obtained.

Inspection Results

1. Alleged Patient Death as a Result of an ESWL Procedure

The OIG did not substantiate that the patient, who underwent an ESWL procedure and died 25 days later, had significant risk factors that made the patient an unsuitable candidate for the procedure. The patient developed a hematoma the day after the procedure and was transferred to a non-VA hospital. An autopsy was not performed on the patient; therefore, the OIG could not determine the exact cause of death.

The patient met several indications for an ESWL procedure of the kidney stone including a recently treated urinary tract infection, symptoms caused by the stone, a stone less than 15 millimeters, and stone growth. Discussions related to treatment options were documented in the patient’s EHR. An informed consent was obtained from the patient before the procedure explaining risks of an ESWL procedure including “injury to the kidney or surrounding tissue.” The patient underwent pre-operative testing and evaluation.

The day following the ESWL procedure, the patient developed a hematoma near the kidney. A hematoma is a rare (less than one percent) but known complication of an ESWL procedure. The patient was seen in the facility’s Emergency Department and transferred to a non-VA hospital for a higher level of care and was diagnosed with cancer. The patient subsequently developed multiple medical problems, and while the hematoma stabilized during the non-VA hospital stay,

¹² Hematology is a medical science that deals with blood and blood forming organs. Oncology is a branch of medicine concerned with the prevention, diagnosis, treatment, and study of cancer.

other conditions deteriorated. The patient chose hospice care and died approximately 25 days after the procedure.

The care of the patient involved two urologists. The first urologist ordered the ESWL procedure and the second urologist performed the procedure. Medical staff leaders completed required peer reviews of patient care provided by both urologists and found no concerns.

Other Finding: Abnormal Pathology Laboratory Results

The OIG found the patient's facility primary care provider failed to address abnormal results related to a blood test (CBC), and a pathology report of a blood smear examination.¹³

Unrelated to the kidney stone, the patient had an annual physical examination performed by the primary care provider in spring 2018. Just prior to the annual physical, a CBC test was drawn. The CBC revealed a high white blood count (infection fighting cells).¹⁴ The white blood count was 16,270 cells per microliter. The primary care provider wrote an EHR note indicating an awareness of the patient's elevated white blood count and that the patient's CBC was also high on laboratory tests a year prior. The primary care provider's EHR note stated, "[w]e'll have pathologist review CBC. May need hematology consult." The primary care provider then ordered a blood smear examination to be completed by pathology using the same blood sample that had been obtained from the patient just prior to the annual physical.

The blood smear examination was completed the day following the patient's annual physical. The pathology report showed abnormal results. The pathologist documented seeing in the blood smear [myelocytes](#) and [metamyelocytes](#), which are immature white blood cells not normally seen in the circulating blood.¹⁵ These abnormal results also showed an elevated white blood count with a [left shift](#). This left shift found in the blood smear examination indicated an increase in the development of immature white blood cells in the body, which can be associated with cancer, infection, and inflammation.

In the face of an elevated white blood count with immature cells, the OIG would have expected the provider to immediately repeat the CBC for confirmation of the abnormal results. However, that same day, the primary care provider sent the patient a notification letter stating, "I don't think [there is] anything to be concerned [about] at this time." A repeat or follow-up test for the CBC was not ordered by the primary care provider until three months later.

¹³ A blood smear, a test of the blood specimen that gives information about the number and shape of blood cells, may be requested to evaluate an increase in the white cells in the complete blood count.

¹⁴ White blood count reference range (normal) is 4,500–11,000 cells per microliter.

¹⁵ The official pathology report stated, "[Leukocytosis](#) with left shift, including some myelocytes and metamyelocytes. Some reactive-appearing [lymphocytes](#) are present. Increased numbers of [monocytes](#). No immature cells such as [blasts](#) identified."

As per VHA Directive 1088, patient notifications and subsequent clinical actions must be documented in the patient's EHR by the ordering provider in response to critical, urgent, and clinically significant test results that require therapeutic intervention or action.¹⁶ The OIG would have expected the provider to document in the EHR acknowledgment of the abnormal blood smear result, as well as a more timely intervention to repeat the patient's CBC.

2. Alleged Conflict of Interest in Hiring Urologists

The OIG did not substantiate that the ACOS hired urologists from a private practice in violation of the conflict of interest regulation.

The OIG team reviewed a document signed by facility leaders dated March 2017, requesting immediate recruitment of five 0.1 full-time employee equivalent (FTE) urologists to fill vacancies in the Urology Department.¹⁷ While the ACOS was associated with the same private practice group as the hired urologists, the ACOS did not sign the request to recruit for the urologist positions.

In addition, the rationales offered by facility leaders to hire several part-time physicians at 0.1 FTE instead of one physician were credible and included the following:

- Difficulty recruiting full-time physicians, particularly specialists, based on the facility's rural location
- A similar staffing model used for physician staffing in another area of the facility in the past
- Use of multiple physicians allowing for coverage of call, leave, and physician turnover

3. Alleged Increased Use of ESWL Procedures and Conflict of Interest Due to Urologists' Ownership of an ESWL Machine

Increased Use of ESWL Procedures

The OIG was unable to determine that there was an increase in ESWL procedures due to the facility urologists' ownership of an ESWL machine.

Equipment used to perform ESWL is expensive and only needed a few times a year; therefore, the facility rents ESWL equipment instead of purchasing it. According to receipts provided by facility staff, two companies (one local in Grand Junction and one out of state in South Dakota) provided the facility with the equipment needed to perform ESWL procedures in fiscal years

¹⁶ VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

¹⁷ A full-time employee equivalent or FTE reflects the number of regular hours worked by employees divided by the number of hours allowed for compensation in a year (stated in a ratio). One (1.0) FTE is equal to a full-time employee. Vacancies were created by a VA urologist reducing work hours to 0.5 FTE and a 0.2 FTE unfilled urologist position at the facility.

2016, 2017, and 2018. The urologists hired around the start of fiscal year 2018 had a financial interest in the local company, which presented a risk for a violation of the conflict of interest regulation. Facility leaders paid the local company approximately \$16,000 in fiscal year 2018, compared to approximately \$8,000 in fiscal year 2017, and \$14,250 in fiscal year 2016, for use of the ESWL machine. Facility leaders paid the out of state company approximately \$9,000 in fiscal year 2018, compared to zero in fiscal years 2017 and 2016, for the use of the ESWL machine. The approximate cost of ESWL is \$2000 per procedure. The cost included the use of the ESWL machine, the transportation of the machine via truck to the facility, and an accompanying technician. While there was an increase in the amount the facility paid for ESWL machine rental since the hiring of the urologists, the OIG could not attribute the increase to the urologists having an ownership interest in the company.

The OIG reviewed facility coding data of interventions done to treat urinary tract stones. Data from fiscal year 2017, which was prior to hiring the urologists, was compared to fiscal year 2018, after the hiring. The total number of interventions to treat urinary tract stones between fiscal years 2017 and 2018 decreased from 40 to 37. However, the OIG was unable to definitively determine how many of these interventions were ESWL procedures versus other methods to treat urinary tract stones. ESWL is a common and acceptable form of treatment for urinary tract stones; the motivation for a urologist to choose this over another treatment option would be difficult to assess.

Conflict of Interest Due to Urologists' Ownership of an ESWL Machine

The OIG found facility leaders were aware of the potential for a violation of the conflict of interest regulation and sought guidance from the VA Office of General Counsel (OGC) for review of practices to ensure they were not violating regulations.¹⁸ OGC found “no actual conflict of interest” given the facts offered to them by facility leaders with the following two conditions:

1. The facility keeps the part-time urologists associated with the ESWL machine out of any decision process that would lead to referral or decision to go to their practice or use their machines.
2. Another VA physician with no financial relationship to these urologists or their private practice is the decision-maker regarding which lithotripsy machine to use.

The facility could not provide evidence of any follow-up to ensure compliance with OGC's guidance. The OIG found the request from facility leaders to OGC may have contained inaccurate statements.

¹⁸ VA Office of General Counsel offers interpretation of laws to the Department of Veterans Affairs.

4. Alleged Failure of Urologists to Respond When On Call

The OIG team did not substantiate that facility urologists failed to respond to the facility when on call. The facility's medical staff bylaws require staff to arrive at the medical center within 30 minutes of notification.¹⁹ A schedule is maintained by Surgical Service staff at the facility, including a list of providers from all surgical services offered, and coverage for on-call shifts.

The complainant identified two patients for incidences where facility urologists were unavailable to the facility when on call. The OIG team reviewed the two patients' EHRs and found no documentation to suggest that the urologists on call were asked to respond to the facility and failed to do so. The OIG team was told in interviews that is a rare occurrence for providers not to respond to calls. The facility had no incident reports or patient advocate complaints regarding urologists' failure to respond when on call.

Conclusion

A facility urologist ordered the ESWL procedure for treatment of a kidney stone. The OIG did not substantiate that the patient had significant risk factors that made the patient an unsuitable candidate for the procedure. The patient met several indications for the procedure. The patient developed a hematoma after the procedure and died in hospice care approximately 25 days later. Without an autopsy, the OIG could not determine the exact cause of death.

In a separate finding, the OIG found an abnormal result for a CBC and a pathology report of a blood smear examination in the patient's EHR, which should have been addressed by the patient's primary care provider. The ordering provider should have consulted with the facility pathologist and addressed the abnormal pathology result with the patient.

The OIG did not substantiate that the ACOS hired urologists from a private practice in violation of the conflict of interest regulation. Facility leaders approved the hiring of part-time urologists to meet the needs of the facility and patients. The ACOS did not sign the recruitment request for the 0.1 FTE positions in question.

The OIG was unable to determine that there was an increase in ESWL procedures due to facility urologists' ownership of an ESWL machine. While there was an increase in the amount the facility expended on ESWL rental, the OIG could not attribute the increase to the urologists having an ownership interest in the company. The OIG found facility leaders were aware of the potential for a violation of the conflict of interest regulation and sought guidance from the VA OGC. The OIG found the request from facility leaders to OGC contained several misleading or inaccurate statements.

¹⁹ Facility MCM 11-2, *Bylaws and Rules of the Medical Staff*, September 2017.

The OIG did not substantiate that facility urologists failed to respond when on call. The OIG team found no documentation showing that on-call urologists were asked to respond to the facility and failed to do so.

Recommendations 1–2

1. The VA Western Colorado Health Care System Director ensures the VA Western Colorado Health Care System Chief of Staff evaluate the management of the identified patient's abnormal test results and provide re-education to all primary care providers on their duties when alerted to abnormal blood smear results.
2. The VA Western Colorado Health Care System Director requests a conflict of interest review from the VA Office of General Counsel regarding the urologists' ownership of the extracorporeal shock wave lithotripsy company and provides an accurate description of the alternate forms of treatment and the comparable costs associated with those treatments.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: December 10, 2019

From: Director, VA Rocky Mountain Network, Glendale, Colorado (10N19)

Subj: Healthcare Inspection—Concern Regarding a Patient Death and Alleged Conflicts of Interest at the VA Western Colorado Health Care System, Grand Junction

To: Director, Office of Healthcare Inspections (54HL06)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed the findings, recommendations, and action plan of the Western Colorado Health Care System, Grand Junction VA. I am in agreeance with the above.

(Original signed by:)

Elliott R. VanderStek
VISN 19 CFO
Acting Network Director, VISN 19

For:
Ralph Gigliotti
Network Director, VISN 19

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 27, 2019

From: Director, VA Western Colorado Health Care System, Grand Junction, Colorado (575)

Subj: Healthcare Inspection—Concern Regarding a Patient Death and Alleged Conflicts of Interest
at the VA Western Colorado Health Care System, Grand Junction

To: Director, VA Rocky Mountain Network, Glendale, Colorado (10N19)

1. Thank you for the opportunity to review and comment on the draft report, Concern Regarding a Patient Death and Alleged Conflicts of Interest at the VA Western Colorado.
2. I have reviewed and concur with the findings, recommendations and action plans as submitted. The action plans will be followed through to completion and ongoing sustainment.
3. If you have any questions or require additional information, please contact Christie McVay, Chief, Quality, Safety & Value (QSV) at 970-242-0731, extension 2317.

(Original signed by:)

Patrick A. Hull, MT, MBA
Interim Director

Facility Director's Response

Recommendation 1

The VA Western Colorado Health Care System Director ensures the VA Western Colorado Health Care System Chief of Staff evaluate the management of the identified patient's abnormal test results and provide re-education to all primary care providers on their duties when alerted to abnormal blood smear results.

Concur.

Target date for completion: April 2020

Director Comments

Facility clarified for Primary Care providers the time frame requirements for notifying patients of test results as per VA Directive 1088. Primary Care providers will be educated to document in the Electronic Medical Record (EMR) the acknowledgment of abnormal blood smear results and to timely repeat lab work when appropriate, if results are abnormal.

Recommendation 2

The VA Western Colorado Health Care System Director requests a conflict of interest review from the VA Office of General Counsel regarding the urologists' ownership of the extracorporeal shock wave lithotripsy company and provides an accurate description of the alternate forms of treatment and the comparable costs associated with those treatments.

Concur.

Target date for completion: April 2020

Director Comments

On November 22, 2019, the VISN 19 Quality Office contacted the Office of General Counsel to request initiation of a conflict of interest review regarding urologists' ownership of the extracorporeal shock wave therapy company and to provide an accurate description of the alternate forms of treatment and the comparable costs associated with those treatments. VISN 19 will take appropriate actions where indicated.

Glossary

anemia. Low levels of red blood cells that carry oxygen to the organs of the body.²⁰

atrial fibrillation. An irregular heart beat in which the heart's upper two chambers (the atria) beat irregularly and out of coordination with the heart's lower two chambers (the ventricles). It increases the risk of stroke and other heart-related complications.²¹

biopsy. The removal and examination of tissue, cells, or fluids from the living body.²²

blasts. An immature cell from the bone marrow released into circulating blood. It is a blood cell precursor (either white cell or red cell) in the earliest stage of development that is visibly obligated to maturing along a defined cell line.²³

complete blood count. A blood count that includes separate counts for red and white blood cells and platelets.²⁴

computed tomography. Radiography in which a three-dimensional image of a body structure is constructed by computer from a series of plane cross-sectional images made along an axis.²⁵

CT hematuria study. Radiography imaging study with three-dimensional images from the kidneys to the bladder. The CT hematuria study is a dedicated CT protocol for the clinical indication of hematuria—also known as hematuria protocol, CT urography.²⁶

congestive heart failure. A condition that occurs when the heart is not able to pump well enough to maintain enough circulation of blood in the body's tissues or to pump out venous blood returned to the heart from body's tissues and organs by the veins.²⁷

cystoscopy. The use of a scope to examine the bladder.²⁸

²⁰ <https://www.merriam-webster.com/dictionary/anemia>. (The website was accessed on May 7, 2019.)

²¹ Mayo Clinic, *Atrial fibrillation*. <https://www.mayoclinic.org/diseases-conditions/atrial-fibrillation/symptoms-causes/syc-20350624>. (The website was accessed on April 18, 2019.)

²² <https://www.merriam-webster.com/dictionary/biopsy>. (The website was accessed on April 18, 2019.)

²³ <https://www.merriam-webster.com/medical/blast%20cell>. (The website was accessed on May 22, 2019.)

²⁴ <https://www.merriam-webster.com/medical/complete%20blood%20count>. (The website was accessed on April 11, 2019.)

²⁵ <https://www.merriam-webster.com/dictionary/computed%20tomography>. (The website was accessed on May 7, 2019.)

²⁶ Radiology Rounds Newsletter, Mass General Hospital, *CT Hematuria Study* https://www.massgeneral.org/imaging/news/radrounds/november_2003/november_2003.pdf. (The website was accessed on April 18, 2019.)

²⁷ <https://www.merriam-webster.com/dictionary/congestive%20heart%20failure>. (The website was accessed on April 18, 2019.)

²⁸ <https://www.merriam-webster.com/medical/cystoscopy>. (The website accessed on June 4, 2019.)

Escherichia coli (E. coli) bacteria. A bacterium used in public health as an indicator of fecal pollution. Occurs in various strains that may live as harmless inhabitants of the human lower intestine or may produce a toxin causing intestinal illness.²⁹

hematoma. A mass, usually of partially clotted or clotted blood, that forms in the body spaces as a result of a broken blood vessel.³⁰

hematuria. The presence of blood or blood cells in the urine.³¹

left shift. In the context of leukocytosis, elevated white blood cell count, a left shift is the development of more immature white blood cells (promyelocytes, myelocytes, metamyelocytes, and blasts) in the blood. This can be associated with cancer, infection, and inflammation.³²

leukocytosis. An increased number of white blood cells in the blood.³³

lithotripsy. The breaking (as by shock waves or crushing with a surgical instrument) of a calculus (stone) in the urinary system into pieces small enough to be voided or washed out.³⁴

lymphocytes. Cells that originate from stem cells and differentiate in lymphoid tissue and are the cellular elements of lymph, such as T cells and B cells. They make up 20 to 30 percent of the white blood cells.³⁵

metamyelocyte. One of the most immature granulocytes (white blood cells) present in the blood that are characterized by cytoplasmic granulation with a kidney shaped nucleus.³⁶

monocyte. A large white blood cell formed in the bone marrow.³⁷

myelocyte. A bone marrow cell that develops into the granulocytes (white blood cells) of the blood and occurs abnormally in the circulating blood.³⁸

²⁹ <https://www.merriam-webster.com/dictionary/E.%20coli>. (The website was accessed on January 24, 2019.)

³⁰ <https://www.merriam-webster.com/dictionary/hematuria#medicalDictionary>. (The website was accessed on January 24, 2019.)

³¹ <https://www.merriam-webster.com/dictionary/hematuria#medicalDictionary>. (The website was accessed on April 17, 2019.)

³² George, "Malignant or benign leukocytosis," *Hematology* 2012, no. 1 (December 8, 2012): 475-484.

³³ <https://www.merriam-webster.com/dictionary/leukocytosis>. (The website was accessed on May 21, 2019.)

³⁴ <https://www.merriam-webster.com/dictionary/lithotripsy>. (The website was accessed on January 24, 2019.)

³⁵ <https://www.merriam-webster.com/dictionary/lymphocytes>. (The website was accessed on May 21, 2019.)

³⁶ <https://www.merriam-webster.com/medical/metamyelocyte>. (The website was accessed on May 21, 2019.)

³⁷ <https://www.merriam-webster.com/dictionary/monocyte#medicalDictionary>. (The website was accessed on June 4, 2019.)

³⁸ <https://www.merriam-webster.com/dictionary/myelocyte>. (The website was accessed on May 21, 2019.)

myelodysplastic syndrome. Any of a group of bone marrow disorders that are marked especially by an abnormal reduction in one or more types of circulating blood cells due to defective growth and maturation of blood-forming cells in the bone marrow and that sometimes progress to acute myelogenous leukemia.³⁹

respiratory failure. The inability of the lungs to properly exchange gas between the air and the blood, thereby not providing enough oxygen to the body.⁴⁰

urinary tract. The anatomical term for parts of the body through which urine passes. It consists of the kidney, the ureters, bladder, and urethra.⁴¹

white blood count. The total number of the white blood cells in the blood, usually stated as the number in one cubic millimeter.⁴²

³⁹ <https://www.merriam-webster.com/medical/myelodysplastic%20syndrome>. (The website was accessed on April 16, 2019.)

⁴⁰ <https://medlineplus.gov/respiratoryfailure.html>. (The website was accessed on May 7, 2019.)

⁴¹ <https://www.merriam-webster.com/medical/urinary%20tract>. (The website was accessed on January 24, 2019.)

⁴² <https://www.merriam-webster.com/dictionary/white%20blood%20count>. (The website was accessed on April 11, 2019.)

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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Inspection Team	Judy Montano, MS, Director Amanda Barry, MSW Virginia Booth, MSN, RN Dannette Johnson, DO Jennifer Kubiak, MPH, RN Tanya Smith-Jeffries, LCSW, MBA
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Other Contributors	Felicia Burke, MS Sheyla Desir, MSN, RN Christopher Dong, JD Chastity Osborn, DNP, RN Natalie Sadow, MBA Clifford Stoddard, JD April Terenzi
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