



Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 13-01988-253

Healthcare Inspection

Review of a Patient with Medication-Induced Acute Renal Failure Amarillo VA Health Care System Amarillo, Texas

July 29, 2013

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to Congressman Randy Neugebauer's request to review an allegation that a patient at the Amarillo VA Health Care System, Amarillo, TX, received negligent care resulting in permanent kidney damage, which led to multiple other medical problems. It was alleged that:

- A patient with a history of renal cell carcinoma¹ who had his right kidney removed was prescribed medication that led to a 4-day hospital admission for acute renal failure (ARF).²
- The patient now has permanent damage to his remaining kidney as a result.
- Other medical problems have resulted from this kidney damage.

We substantiated that a newly prescribed blood pressure and cardiac medication, lisinopril, contributed to or caused the patient to develop ARF. However, in view of the totality of the patient's medical condition, we concluded that the lisinopril prescription was justifiable.

We did not substantiate that the patient has permanent damage as a result of the ARF or that the patient's current medical problems are a result of the ARF. The patient's kidney returned to its baseline function approximately 2 months after the episode.

Additionally, we found that the patient did have other medical issues that do not appear to be sufficiently addressed by providers; however, they were not caused by the episode of ARF.

We recommended that the System Director consult with Regional Counsel to determine if disclosure of the events related to the patient's episode of ARF, as discussed in this report, is indicated and that the Chief of Staff conduct a thorough review of the care provided to this patient by the system.

The Veterans Integrated Service Network and System Directors concurred with our recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 8–10, for the Directors' comments.) We will follow up on the planned actions for Recommendation 2 until they are completed, and we consider Recommendation 1 closed.



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

¹ Renal cell carcinoma is a cancer of the kidney.

² ARF is the rapid loss of the kidney's ability to remove waste and help balance fluids in the body.

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review in response to an allegation that a patient of the Amarillo VA Health Care System, Amarillo, TX (system) received negligent care resulting in permanent kidney damage, which in turn, led to multiple other medical problems. The purpose of the review was to determine whether the allegation had merit.

Background

The Thomas E. Creek VA Medical Center (facility) is located in Amarillo, TX, and is part of the system and Veterans Integrated Service Network 18. The facility provides primary, specialty, and extended care to veterans throughout the Texas and Oklahoma panhandles, eastern New Mexico, and southern Kansas. Approximately 25,000 patients are treated annually. Inpatient care is provided with 44 general medical, surgical, and intensive care beds. Geriatric and extended care is provided in a 120-bed skilled nursing home care unit. The system also provides health care to veterans residing in rural areas through three community-based outpatient clinics (CBOCs) located in Lubbock, TX; Childress, TX; and Clovis, NM.

Allegations

In March 2013, Congressman Randy Neugebauer requested the OIG review an allegation that facility physicians and medical staff were negligent in their care of a patient. Specifically, the allegations were that:

- A patient with a history of renal cell carcinoma³ who had his right kidney removed was prescribed medication that led to a 4-day hospital admission for acute renal failure (ARF).⁴
- As a result, the patient now has permanent damage to his remaining kidney.
- Other medical problems have resulted from this kidney damage.

Scope and Methodology

In order to address the allegation, we interviewed the patient, and his relevant caregivers at a system CBOC and the facility. We also reviewed the patient's electronic health record (EHR).

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

³ Renal cell carcinoma is a cancer of the kidney.

⁴ ARF is the rapid loss of the kidney's ability to remove waste and help balance fluids in the body.

Case Summary

The patient is a man in his sixties with a history of multiple medical problems including coronary artery disease (CAD);⁵ high blood pressure; high cholesterol; renal cell carcinoma, treated with removal of his right kidney in 2008; chronic renal insufficiency; an enlarged prostate gland with obstructive symptoms;⁶ multiple head injuries; chronic headaches; and major depressive disorder.

Since 2007, the patient has received his primary care at the CBOC. A non-VA cardiologist, nephrologist, and urologist were also caring for him. In 2012, the patient transferred his specialty care to the facility. He was referred to and is currently followed by the facility's Urology Service for his renal cell carcinoma. He was also referred to the facility's cardiologist in January 2012.

In May 2012, the patient was seen again by the facility's Cardiology Service. At that time, he was taking hydrocodone, simvastatin (statin), terazosin, aspirin, atenolol (beta-blocker), and fish oil. The cardiology provider noted that the patient's blood pressure was slightly elevated at 118/83 mm Hg.⁷ No second or "repeat" blood pressure measurement was documented in the EHR.

The provider wrote:

His blood pressure is slightly elevated today. I will consult with Dr. [a cardiologist] to see if there are any contraindications to ACE [angiotensin-converting enzyme] inhibitor given that he has had a kidney removed. I have found none... The patient is currently not on an ACE inhibitor. I have researched this and we will start the patient on 2.5 mg [milligram] oral daily. Patient instructed to call if blood pressure is over or under target range....

The provider then added a low dose of lisinopril⁸ to the patient's medication regimen. When asked about the lisinopril prescription, the provider told us to the effect, "he [the patient] had known CAD and guideline recommendations include ACE, statins, and beta-blockers; I reviewed his medications and he wasn't on one of those so I added it. Just core measures, I commented that it was a low dose and that there were no real

⁵ CAD is the most common type of heart disease and is caused by hardening and narrowing of arteries that supply blood to the heart.

⁶ Obstructive symptoms include a hesitation before urine flow starts, straining when urinating, weak or intermittent urinary stream, a sense that the bladder has not emptied completely, or dribbling at the end of urination or leakage afterward.

⁷ Blood pressure is typically recorded as the systolic pressure (pressure in the arteries when the heart beats) (the "upper number") over the diastolic pressure (the pressure in the arteries between heartbeats) (the "lower number") in millimeters of mercury (mmHg).

⁸ Lisinopril is an angiotensin-converting enzyme (ACE) inhibitor class drug utilized in the treatment of hypertension, congestive heart failure, and myocardial infarction. It is also employed as first-line therapy for diabetic nephropathy (kidney disease) in patients with Type 2 diabetes mellitus and hypertension, <http://www.drugs.com/monograph/lisinopril.html>, accessed June 19, 2013.

contraindications for putting him on it, even though he had the nephrectomy [removal of a kidney].”

At the end of May 2012, the patient presented to a community hospital emergency department complaining of dizziness and nausea of 1 day’s duration. The patient stated he was drinking a lot of water but unable to urinate. At that time, he was taking three prescribed medications each of which could have a blood pressure lowering effect, even though all three were not necessarily prescribed for elevated blood pressure. For example, the patient’s terazosin was prescribed for his prostate symptoms. His blood pressure was documented as 76/46 mmHg. He was diagnosed with ARF, admitted to the community hospital, and seen by a nephrologist. All of the patient’s blood pressure medications were discontinued and intravenous fluids were started.

The patient had been seen at this hospital in the past, and laboratory results from 1 year prior showed the patient had moderate chronic kidney disease (CKD).⁹ Based on current laboratory results and the patient’s medical history, the nephrologist’s assessment at the time of admission was that the patient had ARF related to low blood pressure superimposed on already existing CKD. The patient was discharged 4 days later with a diagnosis of ARF and low blood pressure caused by medications. The patient’s blood pressure and kidney function were improving at discharge. The patient was discharged on half the dosage of one blood pressure medication. The lisinopril was discontinued.

At the end of June 2012, the patient presented to the CBOC complaining of intermittent dizziness, “passing out,” balance problems, and falling asleep in mid-conversation during the past month. He was diagnosed with orthostatic hypotension¹⁰ and his blood pressure medication was decreased.

At his next appointment in August 2012, he continued to complain of dizziness and feeling sleepy. His symptoms were documented as inconsistent with his previous diagnosis of orthostatic hypotension. His laboratory results showed that his kidney function had returned to the same level of functioning prior to the episode of ARF. There were no treatment changes at this appointment.

In early September 2012, the patient began having chest pain, described as a tightening in his mid-chest with no radiation of pain. Additionally, the patient had struck his head on his van, fell to the ground, and lost consciousness. The next morning when he awoke, he was still having chest pain, was sleepy, and having problems staying awake. He was transported by ambulance to the community hospital.

Upon examination in the emergency department, the patient’s vital signs were found to be stable. He was drowsy but had no documented abnormal neurological findings and

⁹ CKD is a condition characterized by a gradual loss of kidney function over time. The two main causes of CKD are diabetes and high blood pressure, which are responsible for up to two-thirds of cases.

¹⁰ Orthostatic hypotension is a form of low blood pressure that happens when one stands up from sitting or lying down. Orthostatic hypotension can make one feel dizzy or lightheaded, and possibly faint.

his laboratory tests were at his baseline levels. His chest pain was evaluated and a myocardial infarction was ruled out. The patient received a computed tomography (CT) scan of his head, which was normal. He was evaluated by physical therapy for safety because of his complaints of weakness and dizziness. He was provided with a walker and therapy recommended constant supervision out of concern for him falling. There was no cause identified for his dizziness. He was discharged home 4 days after admission.

Three days after discharge, the patient presented to the CBOC complaining that he was confused and was having difficulty making decisions. A primary care physician evaluated him and documented that the patient stated, "...during the last 4 years he felt like he lost interest in things, he feels fatigued and weak, has no energy, and that he feels depressed." The patient stated that he felt his symptoms were worsening. Prior depression screenings were negative. He denied suicidal ideation. The patient was referred to the CBOC Mental Health Clinic (MHC) for evaluation.

The patient missed his first MHC appointment. He was seen in early November 2012, by a MHC social worker and a psychiatrist. The patient told the social worker that his symptoms were worsening. He also stated that his girlfriend told him he falls asleep in the middle of conversations, but he has no recollection of this happening. He declined therapy as he would be unable to attend due to working nights. In addition to the patient's depressive symptoms, the psychiatrist noted a history of snoring and the need for an evaluation for sleep apnea and headaches that started after a head injury in 1985 that was accompanied by loss of consciousness. The patient asked for a neurological evaluation. The patient was advised to not drink alcohol, and he was prescribed an antidepressant. He was scheduled to return to MHC in 2 months.

In early January 2013, the patient returned to the CBOC MHC complaining of headaches, irritability, depression, anxiety, and anger. He never started the antidepressant he was prescribed at the previous appointment. He was transferred to the facility for severe depression and voluntarily admitted for treatment of his symptoms at a community hospital. A urine drug screen at the facility prior to admission was positive for amphetamines.¹¹

During the hospitalization, he was started on an antidepressant, a benzodiazepine,¹² and a sleeping pill. He was discharged after 5 days at his request. He was seen by a social worker at the CBOC MHC the next week. The note documents that the patient reported he could not remember the reason for his hospitalization, he was heavily medicated during the hospitalization, and he was not provided with a prescription for medications on discharge. The social worker discussed why he had been admitted. No other concerns were addressed. The patient had a follow-up appointment previously scheduled with his psychiatrist the next week; however, he canceled that appointment.

¹¹ An amphetamine is a central nervous system stimulant used in the treatment of certain conditions, such as attention deficit hyperactivity disorder and narcolepsy, and has the potential for abuse.

¹² A benzodiazepine is a type of drug used to decrease emotional stress, lessen anxiety, and bring about sleep.

At the end of January 2013, the patient was seen by his primary care provider. Consults for cardiology and a sleep study were submitted to evaluate the patient's "feeling like he is passing out briefly or falling asleep" and fatigue. The patient was instructed not to drive until these evaluations were completed. The cardiology appointment was scheduled in March and the sleep study in May 2013.

In early March 2013, the patient was seen by cardiology at the facility. He reported falling asleep when he sits down to talk to someone and gets dizzy when he moves too fast. He also stated that his pulse gets fast throughout the day. His blood pressure medicine was decreased, and a test to measure his heart rate and rhythm over a 24-hour period was ordered. The patient cancelled the appointment for the test and did not reschedule it.

In early April 2013, the patient presented to the CBOC MHC with depression and suicidal thoughts. He was transferred to the facility for severe depression and voluntarily admitted for treatment of his symptoms at the same community hospital where he was previously treated. His routine urine drug screen at the facility prior to admission was positive for amphetamines. He was discharged after 5 days.

Inspection Results

Issue 1: ARF

We substantiated that the addition of the new antihypertensive medication, lisinopril, led to the patient's ARF. The nephrologist who evaluated the patient during the episode of ARF documented that the ARF occurred because of low blood pressure related to medication.

The EHR indicates that the primary reasons behind the addition of this medicine was the patient's questionably elevated blood pressure. However, in our interview, the provider stated a somewhat different rationale, indicating that lisinopril was prescribed because "CAD guideline recommendations include ACE, statins, beta-blockers..." just core measures."

Additionally, we found that the patient's blood pressure was well controlled prior to the cardiology appointment. During this appointment, documentation states that an additional blood pressure medication was added for better blood pressure control. Clinical practice guidelines¹³ for patients with CAD state that blood pressure less than 130/80 mmHg should be maintained. During this appointment the patient's blood pressure was 118/83 mmHg. However, over the prior 3 years, the patient's blood pressure readings were less than 120/80 mmHg and his medications had not changed during that period of time.

¹³ Hypertension: Clinical Practice Updates website, <http://www.accp.com/docs/bookstore/psap/p7b01sample01.pdf>, accessed April 30, 2013.

After discontinuing lisinopril, the patient's kidney returned to its baseline function. The only time the patient developed ARF was after the initiation of a very low dose of lisinopril.

Issue 2: Permanent Kidney Damage

We did not substantiate that the medication or episode of ARF caused irreversible damage to the patient's remaining kidney. Based on laboratory results, the patient's kidney function indicated moderate kidney damage prior to the episode of ARF. Three months after the ARF episode and through April 2013, the patient's laboratory levels still showed moderate kidney damage.

Issue 3: Current Medical Problems Due to ARF

We did not substantiate that the patient's current medical problems resulted from the medication or the episode of ARF. The patient's kidney is functioning as it was prior to the brief trial of lisinopril.

Issue 4: Medical Conditions Not Addressed

During our review of the patient's EHR we did find that some of his medical issues were not being addressed. The patient had a history of CKD prior to the episode of ARF; however, this was never discussed with the patient. The patient tested positive for amphetamines on two separate occasions, and no one has addressed this with the patient. A review of the patient's vital signs over the past 1.5 years showed that the patient's oxygen saturation¹⁴ is consistently low, and the patient's pulmonary status has never been evaluated. The patient also has a history of multiple head injuries and has not been evaluated for traumatic brain injury.

Conclusions

We believe that prescribing low dose lisinopril for the patient was not unreasonable in view of his CAD and CKD. We concluded that these were the most compelling reasons for the prescription of lisinopril, as opposed to hypertension. Thus, at least insofar as the EHR documents, lisinopril may have been the "right drug for the wrong reason."

We also concluded that in a patient with only one kidney and CKD, a newly prescribed ACE inhibitor should have caused his providers to promptly recheck and closely follow his renal function. For example, baseline and follow-up renal function tests in 1–3 weeks were indicated.

We noted that the provider that prescribed lisinopril expressed the intent in the EHR to consult with a cardiologist. However, it is unclear from the EHR if this occurred, as there was no documentation of input from the cardiologist.

¹⁴ Oxygen saturation is a measure of how much oxygen the blood is carrying as a percentage of the maximum it could carry.

The patient's EHR does not list CKD as one of his medical conditions. During our interview with the patient, he stated that he was never told that his remaining kidney had damage prior to the episode of ARF and that he was first told about his remaining kidney having damage by a private nephrologist after his episode of ARF. This appears to be what led him to believe that the ARF resulted in his CKD. However, evidence of chronic renal insufficiency is documented in the patient's EHR well before the events discussed in this report.

Further, the patient interview and EHR review indicate that he is having significant medical issues. From our review, we did not find sufficient evidence of all issues being addressed or managed.

Recommendations

1. We recommended that the System Director consult with Regional Counsel to determine if a disclosure of the events related to the patient's episode of acute renal failure, as discussed in this report, is indicated.
2. We recommended that the System Director ensure that the Chief of Staff conduct a thorough review of the care provided to this patient by the system.

Veterans Integrated Service Network Director Comments

Department of
Veterans Affairs

Memorandum

Date: July 9, 2013

From: Director, VA Southwest Health Care Network (10N18)

Subject: Healthcare Inspection – Review of a Patient with Medication-Induced Acute Renal Failure, Amarillo VA Health Care System, Amarillo, TX

To: Director, Dallas Office of Healthcare Inspections (54DA)

Thru: Director, VHA Management Review Service (VHA 10AR
MRS OIG Hotlines)

I concur with the recommendations for improvement contained in the Healthcare Inspection Review at the Amarillo VA Health Care System. If you have any questions or concerns, please contact Sally Compton, Executive Assistant to the Network Director, VISN 18, at (602) 222-2699.



Susan P. Bowers
Network Director, VA Southwest Health Care Network (10N18)

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: July 3, 2013

From: Director, Amarillo VA Health Care System (504/00)

**Subject: Healthcare Inspection – Review of a Patient with
Medication-Induced Acute Renal Failure, Amarillo VA Health
Care System, Amarillo, TX**

To: Director, VA Southwest Health Care Network (10N18)

Thank you for the opportunity to review the draft report of the recommendations from the OIG Healthcare Inspection – Review of Patient with Medication-Induced Acute Renal Failure conducted at the Amarillo VA Health Care System. We have reviewed the report from the review and concur with the recommendations; corrective action plans with target dates for completion are attached.



ANDREW M. WELCH, MHA, FACHE
Director, Amarillo VA Health Care System (504/00)

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the System Director consult with Regional Counsel to determine if a disclosure of the events related to the patient's episode of acute renal failure, as discussed in this report, is indicated.

Concur

Target date for completion: June 17, 2013

System response: The Nephrologist completed a clinical disclosure with this patient in June 2013, at which time he had a discussion with the patient regarding the use of ACE inhibitors, reassuring no permanent damage was incurred due to the previous administration of an ACE inhibitor. The patient has an appointment with his primary care physician in September 2013.

Recommendation 2. We recommended that the System Director ensure that the Chief of Staff conduct a thorough review of the care provided to this patient by the system.

Concur

Target date for completion: May 13, 2013

System response: The Acting Chief of Staff conducted a thorough review of the care provided to the patient. Risk Manager, Nephrology and Mental Health Peer Reviews were completed in May 2013, after a conference call was held with the OIG.

The patient has continued to be seen by a Mental Health Provider with repeat drug testing positive for amphetamines. The patient denies any illicit drug use and continued to decline referral into a substance abuse program. The patient was seen by a Nephrologist in June 2013; evaluated with a Sleep Study in May 2013; and has a home oxygen study scheduled for September 2013. The patient cancelled the neurology appointment that was scheduled for June 2013, for evaluation of traumatic brain injury. The neurology appointment has been rescheduled for July 2013.

The patient has future appointments with Mental Health, Urology and the Primary Care Provider in September 2013. The Health Care System will continue to follow-up with the patient to ensure that appropriate care is provided.

OIG Contact and Staff Acknowledgments

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