DEPARTMENT OF VETERANS AFFAIRS

# OFFICE OF INSPECTOR GENERAL

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

# Quality of Care Concerns in the Hemodialysis Unit at the Wilmington VA Medical Center

## Delaware

HEALTHCARE INSPECTION | REPORT #17-03676-307 | SEPTEMBER 27, 2018


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# Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate allegations regarding the care of two patients in the Hemodialysis Unit (Unit) at the Wilmington VA Medical Center (Facility), Delaware.

On a day in 2017 (Day 1), a patient (Patient) received dialysis in the Facility's Unit.[1] The next day, the Facility's Chief of Police contacted the OIG to report that the Patient was found deceased in a vehicle on the Facility's property. The Facility's Chief of Police also reported that, approximately a week prior to finding the Patient deceased in the vehicle, a Unit nurse may have switched a valve [on a dialysis machine] in the wrong direction and staff called a "Code Blue"[2] (initiated cardiopulmonary resuscitation (CPR)) on a second dialysis patient (Patient 2).

In May 2017, the VA OIG Hotline Division received and reviewed the reported concerns and initiated a healthcare inspection in June 2017 to address those specific allegations:

- On Day 1, Unit nursing staff did not appropriately monitor the Patient's medical status following dialysis treatment.
- A Unit nurse may have switched a valve [on a dialysis machine] in the wrong direction and staff initiated cardiopulmonary resuscitation on Patient 2.

The OIG was unable to substantiate that the care the Patient received in the Unit on Day 1 contributed to the Patient's death, as the evidence was insufficient to make such a determination. Facility staff found the Patient was deceased in his/her car approximately 17 hours after exiting the Unit. An autopsy was performed on Day 3. The autopsy report indicated the Patient had cardiovascular and kidney disease and probably suffered a fatal cardiac arrhythmia. Although OIG staff was unable to determine if the dialysis care on Day 1 contributed to the Patient's death, based on the available information and review of the electronic health record (EHR), quality of care concerns were identified related to the Patient's clinical management while in the Unit.

Unit staff failed to obtain the Patient's finger-stick blood glucose (FSBG) prior to starting dialysis, as a Unit nephrologist ordered. Unit staff obtained the FSBG 38 minutes after starting dialysis and the FSBG was greater than (>) 500 milligrams per deciliter (mg/dL), which is critically high. A Unit registered nurse reported awareness of the order to test the Patient's FSBG before the dialysis treatment; however, the Unit nurse believed it was acceptable to test the Patient's FSBG within one hour of beginning dialysis. OIG staff found no policy to support that

[1] The OIG uses the term dialysis in this report to be synonymous with hemodialysis.

[2] Code Blue is a term used to indicate that a patient is in cardiopulmonary arrest.

practice, and the Unit Nurse Manager told the OIG team that the order required that Unit staff test the Patient's FSBG before starting the dialysis treatment.

OIG staff found that Unit nursing staff failed to follow Facility policy requiring STAT urgency when ordering a confirmatory venous blood glucose laboratory (lab) test after determining the Patient's FSBG was >500 mg/dL.[3] Unit nursing staff entered a request for a ROUTINE confirmatory test rather than STAT.[4] Despite ordering the test with a ROUTINE status, the Patient's lab test result turnaround time for the ROUTINE test was similar to what one would have expected for a STAT test: one hour and five minutes. However, failing to enter the correct STAT urgency to confirm critically high blood glucose has the potential to delay patient care.

The OIG determined that on Day 1, a Unit nephrologist entered an order for regular insulin NOW rather than STAT to treat the Patient's critically high blood glucose.[5] During an interview, the nephrologist explained to OIG inspectors that the expectation was that the regular insulin would be administered "right now" when selecting the NOW order urgency.[6]

The OIG determined because of the combination of the ROUTINE confirmatory venous blood glucose lab test order and the NOW order for regular insulin, 2 hours and 12 minutes elapsed between the recognition of the Patient's elevated blood glucose and treatment with insulin. Fifty-three minutes after the insulin was administered, a nurse checked the Patient's FSBG and documented a blood glucose of 138 mg/dL. After injection, regular insulin usually begins lowering blood glucose within 30 minutes, reaches its maximum strength between two to three hours, and is effective for approximately three to six hours. Therefore, OIG staff would not expect to see a 364 mg/dL reduction in blood glucose after 53 minutes, but rather a smaller reduction in this period of time. Unit staff released the Patient from the Unit approximately two hours after staff administered regular insulin; therefore, the regular insulin would have continued to lower the Patient's blood glucose. Staff did not recheck the Patient's blood glucose prior to release from the Unit.

[3] For STAT lab orders, the specimen is first priority and the turnaround time is generally within one hour after the specimen is received. Department of Veteran Affairs Medical Center, Wilmington, DE, 19808, *Pathology and Laboratory Medicine Ward Procedural Manual*, March 3, 2013.

[4] For ROUTINE lab orders, the specimen priority is lower than both STAT and PRIORITY and the turnaround time is generally within the shift during which the specimen is received. Wilmington *Pathology and Laboratory Medicine Ward Procedural Manual*.

[5] STAT medication orders require immediate attention within 15 minutes. VA Medical Center Wilmington, DE, Nursing Policy Memorandum No. A-11, *Validation of Medication and Treatment Order*, February 27, 2014.

[6] NOW medication orders should be implemented within one hour of the entered order. Wilmington Nursing Policy Memorandum No. A-11.

The OIG determined that the Patient's observation period following clonidine administration should have been longer than 18 minutes given the potential side effects.[7] Unit staff documented the Patient's blood pressure (BP) post-dialysis as 202 (systolic) over 96 (diastolic) millimeters of mercury (mmHg) with a heart rate (HR) of 66 beats per minute (bpm).[8] A Unit RN notified a nephrologist of the Patient's elevated BP; the nephrologist gave a verbal order to administer clonidine 0.1 mg. Nursing staff documented the clonidine as given orally at 3:28 p.m. After an 18-minute observation period post-clonidine treatment, the Patient was released from the Unit. The last recorded BP before release was 183/89 mmHg and an HR of 68 bpm. Clonidine reduces BP within 30 to 60 minutes with the maximum decrease in BP occurring within two to four hours. OIG staff found no documentation in the EHR that Unit staff conducted a full clinical assessment or provided the Patient with instructions regarding the effects of clonidine including drowsiness and a recommendation not to drive.

OIG staff found that on Day 1, Unit staff failed to clinically assess the Patient prior to release from the Unit after administering regular insulin and clonidine.

The OIG determined that one of the nephrologists failed to abide by Facility bylaws and a nurse failed to adhere to the Facility nursing policy when the nephrologist verbally ordered the nurse to administer clonidine 0.1 mg to the Patient. The nephrologist failed to enter the order into the Computerized Patient Record System (CPRS), and the nurse administered the medication to the Patient without a written order in CPRS.

The OIG determined that Unit staff placed the Patient at risk for hyperkalemia[9] when they failed to follow an order that had been entered approximately two weeks prior to Day 1 to change the dialysate.[10] In addition, the Patient's Epogen® treatment order was discontinued but was being administered and placed the Patient at risk for adverse effects, including high blood pressure.[11]

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[7] Clonidine is a medication used to reduce blood pressure.

[8] The normal blood pressure range for the systolic pressure (top number) is between 90-120 mmHg and the diastolic pressure (bottom number) is between 60-80 mmHg. The American Heart Association (AHA) considers blood pressure to be within the normal range when both the systolic and diastolic numbers are in these ranges. *How to Understand Blood Pressure Readings*. https://www.healthline.com/health/high-blood-pressure-hypertension/blood-pressure-reading-explained. (The website was accessed on November 29, 2017.)

[9] Hyperkalemia describes elevated potassium concentration in the blood. A normal potassium level is between 3.6-5.2 millimoles per liter (mmol/L). High potassium (hyperkalemia) https://www.mayoclinic.org/symptoms/hyperkalemia/basics/definition/sym-20050776. (The website was accessed on October 30, 2017.)

[10] Dialysate formula, also known as dialysis fluid or solution, is used to remove toxins from the blood. *What is hemodialysis*. https://www.davita.com/kidney-disease/dialysis/treatment/what-is-hemodialysis?/e/1350. (The website was accessed on October 23, 2017.)

[11] Epogen® is a prescription medicine used to treat a lower than normal number of red blood cells caused by chronic kidney disease in patients on dialysis to reduce or avoid the need for red blood cell transfusions.

OIG staff determined the Unit's nursing documentation inconsistencies placed patients at risk for adverse health outcomes because

- The Hemodialysis Treatment Record (treatment record) did not allow adequate space for thorough documentation and not all areas had sufficient space for staff to enter a time and signature for the writer, and
- At the time of the OIG's review in July 2017, the process in the Unit required nurses to transcribe handwritten documentation from the treatment record to the CPRS Procedure Report, which created duplicate information. The process required the transcribing nurse to document care that the transcribing nurse did not personally provide, creating a potential for error.

The OIG did not substantiate that a Unit nurse switched a valve on a dialysis machine in the wrong direction. The Unit was set up with 10 dialysis machine stations to treat chronic dialysis patients. Two of the machines were portable reverse osmosis types with a valve that could be turned. However, the other eight machines were non-portable and did not contain valves that could be turned in the wrong direction, according to information the OIG inspectors learned from a Facility Biomedical Support Specialist. Patient 2 received dialysis in the Unit where non-portable machines were used.

The OIG substantiated that Unit staff initiated CPR on Patient 2 and, further, that there were quality of care concerns related to Unit staff's response to Patient 2's emergency. When Patient 2 arrived on the Unit on the day in question, a Unit registered nurse determined that Patient 2 had a respiratory problem. Approximately two hours later, the Unit Nurse Manager became involved when Patient 2 became more distressed. However, when Unit staff evaluated Patient 2, they could not agree whether there was a pulse. Unit staff initiated CPR and activated the Rapid Response and the Code Blue teams. The EHR documentation and information acquired during interviews raised concerns regarding the Unit staff's ability to recognize the need for CPR intervention. OIG inspectors also found a lack of required Code Blue documentation forms and reporting to oversight committees. While onsite in July 2017, OIG staff learned that the education staff last conducted a mock code on the Unit on June 25, 2015.[12]

While reviewing the allegations, the OIG identified additional issues related to the Unit. Several of the Unit leaders and staff expressed a strained relationship between the Unit nurses and nephrologists. In August 2017, a non-Facility Nurse Manager conducted a review of the Facility's Unit nursing practices, processes, and staffing. The non-Facility Nurse Manager documented that the conflict between a nurse and the Unit Medical Director was a barrier to a

[12] Mock codes are training scenarios for medical staff participating in Code Blues.

cohesive environment and that in order to provide a culture of safety for the other Unit staff, a collaborative and respectful relationship must be created.

OIG staff determined that Facility leaders and mid-level managers did not assign a Safety Assessment Code or conduct a Root Cause Analysis to look at process or system issues.[13] A Root Cause Analysis may have identified harm or potential harm directly associated with the Patient's care or services provided in the Unit.

The OIG determined during the July site visit that Facility leaders did not disclose the quality of care the Patient received in the Unit on Day 1 to the Patient's next of kin. During the OIG's unannounced second site visit in November 2017, OIG staff asked the Facility Director if a disclosure had been conducted. OIG staff were provided documentation that a meeting had taken place between the Facility's Director, Acting Associate Director, and Chief of Police with the Patient's son and daughter.

The Unit also had staffing difficulties. Facility leaders reported that the Unit had staffing challenges and had hired three nurse managers over a 10-month period, all of whom resigned. The staffing challenges identified were multifactorial and included staff burnout, negative Unit culture, an unstable environment, and conflict between Unit nurses and providers. In spring 2017, the Unit had 13 approved support staff positions consisting of one nurse manager, seven registered nurses, one licensed practical nurse, and four medical instrument technicians. The Unit did not have a program assistant included in the approved staff positions and the access coordinator position was vacant.

The OIG determined that in the absence of a stable Unit nurse manager, new policies had not been developed, current policies had not been reviewed in a timely manner, and the Unit lacked an adequate organizational structure to ensure that the quality of care provided to dialysis patients met Veterans Health Administration guidelines. In addition, on Day 1, when staff released the Patient from the Unit, the nursing staff did not have established criteria to assess a patient for safe release. Two months following the Patient's death, Facility leaders developed and implemented a policy with discharge criteria to ensure safe release following dialysis treatment. Although the policy addressed some identified deficits, it did not include adequate patient assessment and education about medications given during dialysis treatment that were not routinely scheduled.

The OIG determined that Facility VA police officers violated policies and procedures by leaving the Patient's car in a visible illegal parking spot for more than 17 hours between Days 1 and 2. The OIG team found that the actions of the VA police officers were not in alignment with

[13] Safety Assessment Code assignment is the first step in assessing the degree of patient harm and determining if an RCA is required.

(1) VA Directive 0730 that charges VA police with protecting lives within its jurisdiction,

(2) A federal regulation that vehicles not be parked in unauthorized locations, and

(3) Facility police expectations that officers conduct hourly patrol checks when not on another call or doing a report.

The OIG made 14 recommendations related to Unit policy and processes, verbal medication orders, Code Blue documentation and reporting, and federal police policy.

## Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan. (See Appendixes B and C, pages 40-49 for the Directors' comments.) The OIG will follow up on the planned actions until they are completed.

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# Abbreviations

| | |
|---|---|
| BP | blood pressure |
| CCTV | closed-circuit television |
| CPR | cardiopulmonary resuscitation |
| CPRS | computerized patient record system |
| EHR | electronic health record |
| ESRD | end-stage renal disease |
| FSBG | finger stick blood glucose |
| FY | fiscal year |
| LPN | licensed practical nurse |
| MIT | medical instrument technician |
| NP | nurse practitioner |
| OIG | Office of Inspector General |
| RCA | root cause analysis |
| RN | registered nurse |
| SAC | safety assessment code |
| VA | Department of Veterans Affairs |
| VHA | Veterans Health Administration |
| VISN | Veterans Integrated Service Network |

# Introduction

## Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate allegations regarding the care of two patients in the Hemodialysis Unit (Unit) at the Wilmington VA Medical Center (Facility) in Delaware.

## Background

The Facility, part of Veterans Integrated Service Network (VISN) 4, provides primary and long-term care in medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, and extended care. The Facility operates 60 hospital beds and 60 community living center beds. The Facility, along with its associated community based outpatient clinics, served almost 30,000 veterans in fiscal year (FY) 2016.

The Facility also provides inpatient and outpatient dialysis services. The Unit's professional staff includes two physicians (Unit program director/full-time nephrologist and a part-time nephrologist), a Unit nurse manager, registered nurses (RNs), a licensed practical nurse (LPN), medical instrument technicians (MITs), and a transplant coordinator.

This outpatient Unit is open from 5:00 a.m. to 4:00 p.m., Monday through Saturday. In addition, the Unit has two rooms designed for inpatient use when needed. The Unit has the capacity to provide dialysis to 20 outpatients a day—with 10 patients beginning at 6:30 a.m. (first shift) and 10 patients beginning at 11:00 a.m. (second shift). Depending on their treatment needs, most patients are on the Unit for four hours, so Unit staff complete most treatments by 3:00 p.m. If a patient is not stable after treatment, Unit staff transfer outpatients to the Facility Emergency Department.

In FY 2016, Unit staff provided care to 423 patients (total of 4,143 dialysis treatments). In FY 2017 as of July 31, Unit staff provided care to 363 patients (total of 4,801 dialysis treatments).

### Diabetes

Diabetes is a disease that occurs when the body cannot effectively process sugar (glucose) due to not recognizing or producing little or no insulin, a hormone that regulates blood glucose. Patients with type 1 diabetes require insulin injections to regulate their blood glucose.[14] Patients with

[14] National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National Institutes of Health (NIH), https://www.niddk.nih.gov/health-information/diabetes. (The website was accessed on September 19, 2017.)

type 2 diabetes, the most common type, initially produce some insulin and use oral medications to regulate blood glucose.[15] However, some patients with type 2 diabetes develop insulin resistance over time and may eventually require insulin.[16]

### *Regular Insulin*

Insulin is a medication that is available in multiple formulations. The type of insulin formulation predicts how quickly the insulin will act, the time it should peak, and how long it stays in the body. [17] After subcutaneous injection, regular insulin usually begins lowering blood glucose within 30 minutes, reaches its peak in two to three hours, and is effective for approximately three to six hours.[18]

Providers treating patients with diabetes require knowledge of the formulations of insulin so that the treatment of elevated glucose minimizes the potential for hypoglycemia (see discussion below). For patients with diabetes already on insulin, the history of last insulin administration, previous responses to insulin, and upcoming procedures (for example, dialysis or surgery) are needed to provide a safe treatment plan to prevent hypoglycemia.

Lowering blood glucose to achieve an acceptable level is only part of a safe treatment plan. The timing of blood glucose monitoring after an insulin injection, or recheck, is essential to assessing the effectiveness of insulin. This is critical to providing a safe treatment plan to prevent and recognize insulin-induced hypoglycemia.

Facility policy identifies normal blood glucose range for finger-stick blood glucose (FSBG) as 70 to 100 milligrams per deciliter (mg/dL) and 74 to 118 mg/dL for serum. Values that are over or under these ranges represent hyperglycemia and hypoglycemia, respectively.

### *Hyperglycemia*

Hyperglycemia, or high blood glucose, occurs with abnormally elevated blood glucose levels in the body. Insulin is required to prevent elevated blood glucose levels. Untreated elevated blood

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[15] National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National Institutes of Health (NIH), https://www.niddk.nih.gov/health-information/diabetes. (The website was accessed on September 19, 2017.)

[16] *When patients are treated with insulin*. National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National Institutes of Health (NIH). https://www.niddk.nih.gov/health-information/diabetes. (The website was accessed on September 19, 2017.)

[17] The acting time is the expected time of when insulin begins onset of lowering glucose. The peak time is the expected time of when insulin is most effective. National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National Institutes of Health (NIH), https://www.niddk.nih.gov/health-information/diabetes. (The website was accessed on September 19, 2017.)

[18] A subcutaneous injection is a method of giving a medication in the fatty layer of tissue just under the skin. https://www.cc.nih.gov/ccc/patient_education/pepubs/subq.pdf. (The website was accessed on December 7, 2017.)

glucose may lead to dehydration and diabetic ketoacidosis (a serious condition that can lead to diabetic coma and death).[19] Chronically elevated blood glucose levels may cause blindness and kidney failure. Diabetes is also a risk factor for heart disease, stroke, and foot and leg amputations.[20]

## Hypoglycemia

Hypoglycemia, or low blood glucose, can result from insulin administration and can be a life-threatening condition because the body needs glucose to function.[21] Hypoglycemia may trigger the body to secrete a hormone called epinephrine,[22] which causes characteristic hypoglycemic symptoms such as palpitations,[23] sweating, and anxiety. Patients who experience hypoglycemic symptoms can take corrective actions (such as eating or drinking juice) to reverse the low glucose.

## Hypoglycemia Unawareness

Hypoglycemia unawareness is a complication of diabetes in which the body fails to secrete epinephrine in response to a drop in blood glucose. Consequently, patients with hypoglycemia unawareness do not experience the characteristic symptoms of hypoglycemia that serve to warn the patient and/or healthcare providers of the dropping blood glucose.[24]

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[19] *Hyperglycemia in Diabetes*. http://www.mayoclinic.org/diseases-conditions/hyperglycemia/basics/causes/con-20034795. (The website was accessed on September 19, 2017.)

[20] *Living with Diabetes.* http://www.diabetes.org/living-with-diabetes/complications/stroke.html. (The website was accessed on September 19, 2017.)

[21] Physiologic response to hypoglycemia in normal subjects with diabetes. https://www.uptodate.com/contents/physiologic-response-to-hypoglycemia-in-normal-subjects-and-patients-with-diabetes-mellitus?source=see_link. (The website was accessed on September 23, 2017.)

[22] *Hypoglycemia from a Cardiologist Perspective*. https://www.ncbi.nlm.nih.gov/pubmed/24895268. (The website was accessed on April 17, 2018.)

[23] Heart palpitations are feelings of having rapid, fluttering, or pounding heart. *Heart Palpitations.* https://www.mayoclinic.org/diseases-conditions/heart-palpitations/basics/definition/con-20034780. (The website was accessed on November 29, 2017.)

[24] https://www.uptodate.com/contents/management-of-hypoglycemia-during-treatment-of-diabetes-mellitus?source=search_result&search=hypoglycemia%20unawareness&selectedTitle=1~38. (The website was accessed on April 20, 2018.)

## Facility Medication Order Urgency Categories

The Facility's medication order urgency categories include "NOW" and "STAT." NOW medication orders should be implemented within one hour of the entered order and STAT medication orders require immediate attention within 15 minutes.[25]

## Facility Laboratory Testing Order Urgency Categories

In contrast, the Facility has three urgencies for laboratory (lab) testing turnaround time:[26]

- STAT—the specimen is first priority and the turnaround time is generally within one hour after the specimen is received.
- PRIORITY—the specimen priority is below STAT and the turnaround time is generally within two hours after the specimen is received.
- ROUTINE—the specimen priority is below STAT and PRIORITY and the turnaround time is generally within the shift during which the specimen is received.

## Glucometer Blood Glucose Testing

A glucometer is a point of care testing medical device that requires a small specimen of blood to measure blood glucose levels.[27] The specimen is obtained using a lancet for a finger prick or by accessing the patient's venous or arterial blood. The glucometer reading of the blood is commonly referred to as FSBG. The Facility glucometer glucose-testing procedures defines FSBG results greater than (>) 500 mg/dL or less than 40 mg/dL as critical values requiring provider notification.[28]

[25] VA Medical Center Wilmington, DE, Nursing Policy Memorandum No. A-11, *Validation of Medication and Treatment Order*, February 27, 2014.

[26] Department of Veteran Affairs Medical Center, Wilmington, DE, 19808, *Pathology and Laboratory Medicine Ward Procedural Manual*, March 2013.

[27] Point of care testing gives immediate results in non-laboratory settings to support more patient-centered approaches to healthcare delivery. National Institutes of Health and Human Services, https://report.nih.gov/nihfactsheets/Pdfs/PointofCareDiagnosticTesting (NIBIB).pdf. (The website was accessed on December 7, 2017.)

[28] A laboratory critical value indicates the test result(s) reflect potentially life-threatening or a high-risk clinical situation that requires immediate notification and intervention by the provider. *Reporting of Critical Laboratory Values*, Center Memorandum, No. 460-113-04, March 30, 2015.

The glucometer the Facility HD Unit staff used displayed a glucose test result less than 40 mg/dL as "Lo" and a result >500 mg/dL as either "RR [reportable range][29] Hi" or "Hi." Facility policy states that if providers require an accurate numerical value, the provider should request a STAT[30] venous confirmatory lab test that may be entered into the Computerized Patient Record System (CPRS) by nursing staff.[31]

## Hemodialysis

Kidneys are organs that filter the blood and remove waste and excess fluid from the body. Patients diagnosed with end-stage renal disease (ESRD) do not have functioning kidneys.[32] One treatment for ESRD is hemodialysis,[33] a process where a dialysis machine removes waste and excess fluid from the blood and returns clean blood, in order to achieve the patient's "dry weight."[34] Generally, patients with ESRD receive hemodialysis two to three times per week and the treatment lasts three to five hours each time.

Dialysis machines require the use of dialysate, a specific solution ordered by the provider. Providers adjust the solution formula based on a patient's lab results. Dialysate contains water, electrolytes and salts, and added substances (such as potassium and/or calcium) that allow the safe removal of waste, extra salt, and fluid from the patient's blood during dialysis.

## Hypertension

Also known as high blood pressure (BP), hypertension affects 85 million Americans.[35] Medical guidelines define hypertension as a BP higher than 140 (systolic) over 90 (diastolic) millimeters of mercury (mmHg) documented over time. There are two types of hypertension, primary and secondary. Primary hypertension is more common; it develops over time with no identifiable

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[29] Reportable range is an indicator that the FSBG result is either high or low as per what the laboratory has defined but is still within the Reportable Range of the glucometer. Any result that is reported as HI or LO by the glucometer is either less than 10 mg/dL or > 600 mg/dL.

[30] STAT orders are those orders that require immediate attention within 15 minutes.

[31] Wilmington VAMC Pathology and Laboratory Medicine, Ancillary Testing/Instrument Testing, February 1, 2017.

[32] End-stage kidney disease (ESRD), occurs when the gradual loss of kidney function in chronic kidney disease reaches an advanced state. In ESRD, the kidneys are no longer able to work to meet the body's needs. https://www.mayoclinic.org/diseases-conditions/end-stage-renal-disease/symptoms-causes/syc-20354532. (The website was accessed on November 5, 2017.)

[33] The OIG uses the term dialysis in this report to be synonymous with hemodialysis.

[34] Dry weight is a patient's weight without the excess fluid that builds up between HD treatments. How Dry weight and Fluid Gain Affect Dialysis Patients. https://www.davita.com/kidney-disease/dialysis/treatment-options/how-dry-weight-and-fluid-gain-affect-dialysis-patients/e/5273. (The website was accessed on September 21, 2017.)

[35] *Hypertension: Causes, Symptoms and Treatments*. https://www.medicalnewstoday.com/articles/150109.php. (The website was accessed on September 21, 2017.)

cause.[36] Secondary hypertension occurs quickly and can be more severe than primary hypertension. Several conditions may cause secondary hypertension; some of which are kidney or thyroid disease or use of illegal drugs.[37] The treatment goal for hypertension is a reduction of BP below 140/90 mmHg by utilizing lifestyle changes and/or medications.[38]

### Clonidine

Clonidine is a medication used alone or with other medications to treat hypertension. Clonidine works on the central nervous system to lower BP by slowing the heart rate and relaxing blood vessels.[39] After an oral dose, clonidine tablets start to reduce BP within 30 to 60 minutes with the maximum BP decrease occurring within two to four hours.[40]

Clonidine may increase the risk, severity, and/or duration of hypoglycemia in patients receiving insulin glargine (Lantus)[41] and certain antidiabetic medications.[42] The most common side effect of Lantus is hypoglycemia.[43] Therefore, treatment with clonidine and Lantus together places the patient at risk of hypoglycemia.[44] In addition, clonidine may mask some of the symptoms of hypoglycemia such as tremors, palpitations, and rapid heartbeat, making it more difficult for the patient to recognize an oncoming hypoglycemia episode.[45]

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[36] *Hypertension: Causes, Symptoms and Treatments.*

[37] *Hypertension: Causes, Symptoms and Treatments*; *Everything You Need to Know about High Blood Pressure*. https://www.healthline.com/health/high-blood-pressure-hypertension. (The website was accessed on March 30, 2018.)

[38] *Hypertension: Causes, Symptoms and Treatments*.

[39] *Clonidine (Oral Route*.) http://www.mayoclinic.org/drugs-supplements/clonidine-oral-route/description/drg-20063252. (The website was accessed on September 19, 2017.); *Catapres-clonidine Hydrochloride Tablet* https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d7f569dc-6bed-42dc-9bec-940a9e6b090d. (The website was accessed on September 19, 2017.).

[40] *Catapres-clonidine Hydrochloride Tablet.*

[41] *The Contribution of Medications to Hypoglycemia Unawareness.* http://spectrum.diabetesjournals.org/content/20/2/77. (The website was accessed on November 30, 2017.); Catapres. http://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Catapres%20TTS/CatapresTTS.pdf. (The website was accessed on April 17, 2018.).

[42] Antidiabetic medications help control blood glucose levels in people with diabetes mellitus. https://encyclopedia.thefreedictionary.com/Anti-diabetic medication. (The website was accessed on November 5, 2017.)

[43] *Lantus. Insulin Glargine Injection 100units/ml*. https://www.lantus.com/. (The website was accessed on September 19, 2017.)

[44] *The Contribution of Medications to Hypoglycemia Unawareness.*

[45] *Effects of Transdermal Clonidine on the Endocrine Responses to Insulin-induced Hypoglycemia in Essential Hypertension*. https://www.ncbi.nlm.nih.gov/pubmed/2649299. (The website was accessed on November 30, 2017.); The Contribution of Medications to Hypoglycemia Unawareness.

The kidneys remove clonidine from the body; therefore, clonidine levels may be increased in patients with kidney disease. Based on the degree of kidney disease, clonidine dosage adjustments and modifications may be necessary.[46]

## Allegations

The Facility's Chief of Police contacted the OIG to report that the Patient was found deceased in a vehicle on the Facility's property the day after the Patient received dialysis in the Facility's Unit. The Facility's Chief of Police also reported that approximately one week prior to finding the Patient in the vehicle, a Unit nurse may have switched a valve [on a dialysis machine] in the wrong direction and staff called a "Code Blue" (initiated cardiopulmonary resuscitation (CPR)) on a second dialysis patient (Patient 2).[47]

In May 2017, the VA OIG Hotline Division received and reviewed the reported concerns and initiated a healthcare inspection in June 2017 to address those specific allegations:

- On Day 1, Unit nursing staff did not appropriately monitor the Patient's medical status following dialysis treatment.
- A Unit nurse may have switched a valve [on a dialysis machine] in the wrong direction and staff initiated CPR on Patient 2.

[46] *Catapres-clonidine Hydrochloride Tablet.*

[47] A Code Blue is a state of medical emergency and call for medical personnel and equipment to attempt to resuscitate a patient especially when in cardiac arrest or respiratory distress or failure. https://www.merriam-webster.com/medical/code%20blue. (The website was accessed on December 7, 2017.)

# Scope and Methodology

The OIG initiated the healthcare review in mid-2017 and conducted a site visit at the Facility from July 11 through July 13. OIG staff took pictures of the Unit communication book in which staff told the OIG they entered upcoming lab tests to be drawn, changes in dry weight, and other patient-related information. OIG staff assessed the Unit physical space to understand how patients entered and left the Unit. They also reviewed select closed-circuit television (CCTV) footage of the Facility and parking area for Days 1 and 2. The OIG team reviewed pertinent portions of the EHRs of the Patient and Patient 2.

The inspection included a review of Veterans Health Administration (VHA) and Facility policies and procedures, Joint Commission standards, Facility meeting minutes, dialysis nurse certification records, Unit nursing assignment sheets, and other relevant documents.

OIG staff interviewed the following Facility personnel on-site: Director; Chief of Staff (COS); Associate Director for Patient Care Services; Associate Deputy for Patient Care Services—Acute Care; Chief of Police; Chief of Medicine; Chief of Quality Management; Patient Safety Manager; Risk Manager; a clinical pharmacist; a nephrologist; an endocrinologist; Director of the Unit; and the Unit Nurse Manager, RNs, an LPN, and MITs.

On September 6, OIG staff conducted a teleconference with Facility leaders regarding the inspectors' initial concerns with the Unit. The Facility Director provided the OIG with an action plan that included an October 1, 2017, implementation date. OIG inspectors conducted an unannounced site visit on November 1, 2017, to follow up on the action plan. (See Appendix A.)

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 substantiate an allegation when the available evidence is insufficient to determine whether an alleged event or action took place.

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

## The Patient

The Patient, who died in 2017, was in his/her 60s and lived independently. The Patient's medical history included insulin-dependent diabetes mellitus for 25 years,[48] with episodes of hyperglycemia and severe hypoglycemia,[49] as well as hypoglycemia unawareness, chronic bilateral foot ulcers, left foot transmetatarsal amputation,[50] hypertension, anemia, ESRD requiring dialysis three times a week, and other medical conditions.[51] The Patient had a left upper-arm arteriovenous fistula that was used for dialysis.[52]

The Patient initiated care at the Facility in 1996 for wound care and follow-up for diabetes in 1997. The Patient was noncompliant with diet instructions, checking blood glucose at home, taking insulin appropriately, and attending follow-up appointments on a consistent basis. According to the EHR, the Patient's diabetes was uncontrolled from 1997 to 2017. The Patient experienced hypoglycemic episodes, some of which were asymptomatic. Due to declining renal function that led to ESRD, dialysis was initiated in early 2016. A few months later, due to the

[48] Rodger W. *Insulin-dependent (type I) Diabetes Mellitus.* CMAJ: Canadian Medical Association Journal. 1991;145(10):1227-1237. Insulin dependent diabetes mellitus is a chronic disease characterized by hyperglycemia and the goal of treatment is to achieve blood glucose levels as close to normal as possible.

[49] Severe hypoglycemia is defined as blood glucose less than 54 mg/dL http://www.diabetes.org/newsroom/press-releases/2016/ada-issues-hypoglycemia-position-statement.html. (The website was accessed on April 20, 2018.)

[50] Transmetatarsal amputation is a surgical procedure that removes all or part of the patient's forefoot, which includes the metatarsal bones – the five long bones between the ankle and toes. *Transmetatarsal Amputation.* http://www.newhealthadvisor.com/Transmetatarsal-Amputation.html. (The website was accessed on November 21, 2017.)

[51] Other conditions included these four: (1) Diabetic retinopathy, which is damage to the blood vessels of the retina (the light-sensitive tissue at the back of the eye). See, *Diabetic Retinopathy* at https://www.mayoclinic.org/diseases-conditions/diabetic-retinopathy/symptoms-causes/syc-20371611. (The website was accessed on December 21, 2017.); (2) Secondary hyperparathyroidism that occurs with the over-production of parathyroid hormone in response to low blood calcium levels (low blood calcium levels occur in chronic kidney failure). See, *Secondary Hyperparathyroidism: Pathophysiology and Treatment*; Journal of the American Board of Family Medicine; (3) Hyperlipidemia (elevated levels of fats [cholesterols and triglycerides] in the blood); and (4) Osteomyelitis (an infection in the bone). See, https://www.mayoclinic.org/diseases-conditions/osteomyelitis/symptoms-causes/syc-20375913. (The website was accessed on April 17, 2018).

[52] An arteriovenous fistula is a connection, made by a vascular surgeon, of an artery and a vein used for dialysis. The fistula is normally placed in the forearm. Two needles are inserted into the fistula; one needle carries blood to the dialyzers and the other needle carries filtered blood back to the body. *Vascular Access for Hemodialysis.* https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis/vascular-access. (The website was accessed on September 21, 2017.)

Patient's labile diabetes, a nephrologist in the HD Unit (Nephrologist 1) ordered an FSBG prior to each dialysis treatment.[53]

The uncontrolled blood glucose and noncompliance with the insulin regimen led to hospitalizations at both the Facility and in non-VA hospitals. The Facility specialty care providers made efforts to assist the Patient with compliance to control the blood glucose. Examples of their assistance included

- Nutrition consults for uncontrolled diabetes and hyperkalemia,[54]
- Neurology consults to evaluate the Patient for memory loss and compliance concerns,
- Home health care consult for care beyond clinic visits,
- Social work services for support upon initiation of dialysis and for a kidney transplant assessment, and
- Endocrinology consults for uncontrolled blood glucose manifesting as both hyperglycemia and hypoglycemia.

In early 2017, the Patient was admitted to a non-VA hospital for hyperglycemia and diabetic ketoacidosis. The non-VA hospital staff treated and discharged the Patient with Novolog/Lantus[55] (basal/bolus insulin),[56] which is the recommended insulin therapy for most patients with diabetes requiring dialysis.

Approximately one month later, at a Facility post-hospitalization follow-up, a nurse practitioner (NP) who specialized in diabetes documented that the Patient had previously failed treatments of basal/bolus insulin prescribed by the Facility and non-VA hospitals; therefore, the Patient was transitioned back to Novolog/70/30,[57] 18 units twice daily. The Facility endocrinologist, who

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[53] Lability is the property of changing readily. http://www.webster-dictionary.org/definition/Lability. (The website was accessed on October 23, 2017.)

[54] Hyperkalemia describes elevated potassium concentration in the blood. A normal potassium level is between 3.6-5.2 millimoles per liter (mmol/L). *High potassium (Hyperkalemia).* https://www.mayoclinic.org/symptoms/hyperkalemia/basics/definition/sym-20050776. (The website was accessed on October 30, 2017.)

[55] Novolog/Lantus is insulin aspart and insulin glargine. https://www.drugs.com/drug-interactions/lantus-with-novolog-1344-803-1341-802.html. (The website was accessed on October 23, 2017.)

[56] Basal/bolus therapy, also known as multiple daily doses, is used for patients with stage 4–5 chronic kidney disease. *Management of Diabetes Mellitus in Patient with Chronic Kidney Disease*. https://clindiabetesendo.biomedcentral.com/articles/10.1186/s40842-015-0001-9. (The website was accessed on October 23, 2017.)

[57] Novolog/70/30 is insulin aspart protamine and insulin aspart. https://www.cornerstones4care.com/NovoLog-Mix-70-30.html. (The website was accessed on April 18, 2018.)

followed the Patient, agreed with this treatment regimen. During this timeframe, Providers treated the Patient's hypertension with various antihypertensive medications.[58]

On Day 1, the Patient arrived at the Facility for an 11:00 a.m. dialysis appointment. Nephrologist 2 documented that the Patient "rushed out this morning and did not take any …meds." A Unit RN (RN2) documented that the Patient had a viable left upper-arm arteriovenous fistula allowing the necessary vascular access to perform dialysis. Nephrologist 2's treatment orders for dialysis were to remove five kilograms of weight over a four-hour period using a dialysate formula with heparin. The Patient's primary Unit nurse (RN1), performed an assessment inclusive of vital signs, pain scale, and a screening evaluation that was documented on the treatment record.[59] The Patient's pre-dialysis vital signs were recorded as BP 101/81 mmHg, heart rate (HR) 82 beats per minute (bpm), respiratory rate of 18 breaths per minute, and temperature of 96.9 degrees Fahrenheit. (See Table 1.)

At 11:38 a.m., RN2 recorded the Patient's FSBG as high >500 mg/dL.[60] RN2 entered a ROUTINE order for a serum glucose confirmatory lab test and Nephrologist 2 signed the order. The blood sample was collected at 11:40 a.m. At 12:45 p.m., a laboratory technologist notified Nephrologist 2 that the Patient's serum blood glucose value was 502 mg/dL and at 12:47 p.m., Nephrologist 2 ordered four units of regular insulin "NOW."[61] At 1:22 p.m., RN2 gave the Patient calcium to treat a low serum calcium level of 7.1 mg/dL[62] and Epogen® for anemia.[63] At 1:50 p.m., RN2 subcutaneously injected 4 units of regular insulin to the Patient.

While in the Unit, the Patient's BP increased over a three-hour period from a pre-treatment reading of 101/81 mmHg to readings of 188/98 mmHg at 12:00 p.m. and 205/96 mmHg at 2:00 p.m.

At 2:43 p.m., RN2 repeated the Patient's FSBG and it was 138 mg/dL.

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[58] The regularly scheduled antihypertensive medications did not include clonidine.

[59] The screening evaluation used by nursing staff pre-dialysis included falls, location and type of access, and needles used for dialysis; the treatment record is a preprinted sheet of paper on which staff hand write information as it occurs. The treatment record is later scanned into the patient's EHR.

[60] A random blood glucose reading in a patient with diabetes is expected to be higher due to a non-fasting status but should be under 200 in a controlled diabetic.

[61] Wilmington VA Medical Center Nursing Policy, *Validation of Medication and Treatment Orders*, Memorandum No. A-11, February 27, 2014.

[62] The normal range for calcium is normal range is 8.8-10.7 mg/dL.

[63] Anemia is a condition in which blood is deficient in red blood cells, hemoglobin, or total volume. Anemia is diagnosed if the value is less than 13.5 gram/100 ml in males and 12.0 gram/100 ml in females. https://www.merriam-webster.com/dictionary/anemia. (The website was accessed on October 23, 2017.)

At 3:12 p.m. the Patient met the target weight loss and dialysis was completed. RN1 notified N Nephrologist 2 that the Patient's post-dialysis BP was 202/96 mmHg. At 3:28 p.m., RN1 gave the Patient clonidine 0.1mg.[64]

At 3:54 p.m., RN2's nursing note documented the Patient's BP as 183/89 mmHg. According to the nursing note, the Patient was ambulatory upon leaving the Unit.

OIG staff did not find documentation that Facility staff released the Patient from the Unit with instructions about the insulin and clonidine given during dialysis.

The following table provides a summary of events based on CCTV footage and EHR documentation.

[64] *Catapres*. https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017407s034lbl.pdf. (The website was accessed on September 21, 2017.) The Patient received clonidine in the Unit once before in late 2016, but did not receive insulin with the 2016 administration of clonidine.

**Table 1: Summary of Day 1 Patient Events from 10:52 a.m. through 3:54 p.m.**

| Time | Action |
|---|---|
| 10:52 a.m. | Entered Unit (CCTV time stamp). |
| **Pre-Dialysis** | BP 101/81 mmHg, HR 82 bpm, Weight 69 kilograms. |
| 11:00 a.m. | Dialysis treatment begins. |
| 11:38 a.m. | Blood glucose level: >500 mg/dL by FSBG testing. |
| 11:40 a.m. | Lab order placed for serum glucose. Urgency: ROUTINE. |
| 12:00 p.m. | BP 188/98 mmHg, HR 69 bpm. |
| 12:30 p.m. | BP 193/92 mmHg, HR 69 bpm. |
| 12:45 p.m. | Nephrologist 2 notified that the serum blood glucose value was 502 mg/dL. |
| 12:47 p.m. | Nephrologist 2 wrote insulin order in EHR: "4 units of regular insulin now". Urgency: NOW. |
| 1:00 p.m. | BP 178/92 mmHg, HR 69 bpm. |
| 1:22 p.m. | RN2 administered calcitriol and Epogen®. |
| 1:30 p.m. | BP 190/103 mmHg, HR 68 bpm. |
| 1:50 p.m. | RN2 administered 4 units of regular insulin subcutaneously. |
| 2:00 p.m. | BP 205/96 mmHg, HR 68 bpm. |
| 2:30 p.m. | BP 212/97 mmHg, HR 67 bpm. |
| 2:43 p.m. | Blood glucose level: 138 mg/dL by FSBG testing. |
| 3:00 p.m. | BP 200/94 mmHg, HR 67 bpm. |
| 3:12 p.m. | BP 183/96 mmHg, HR 67 bpm.; dialysis completed. |
| **Post-Dialysis** | BP 202/96 mmHg. HR 66 bpm. Weight 64.5 kilograms. Nephrologist 2 notified of BP. |
| 3:28 p.m. | RN1 administered clonidine 0.1mg. |
| 3:46 p.m. | Patient exited the Unit (CCTV time stamp). |
| 3:54 p.m. | Documented in EHR: BP 183/89 mmHg, HR 68 bpm. |

*Source: VA OIG analysis of the Patient's EHR and relevant Facility CCTV images*

A review of CCTV footage retrieved in the course of this inspection showed the Patient leaving the Unit and stepping into an elevator. The Patient appeared to be unsteady and was noted to catch the frame of the elevator door.

On Day 2, a Volunteer Service employee notified Facility Police Service that a patient was sleeping in a car on Facility grounds. The Patient was found in the car in front of the Facility valet parking with no pulse or spontaneous respirations.[65] A physician pronounced the Patient dead at 9:40 a.m. An autopsy was performed and listed the cause of death as cardiopulmonary arrest, probably secondary to fatal cardiac arrhythmia.

## Patient 2

At the time of the OIG's review, Patient 2 was between 55 and 60 years-old with a history of type 2 insulin-dependent diabetes mellitus, ESRD requiring dialysis, labile hypertension, and other chronic medical conditions.[66] Patient 2 required near total assistance with all activities of daily living. Patient 2 had dialysis at the Facility three times a week.

Patient 2 moved into the Facility's community living center (CLC) in early 2014. Patient 2 was initially admitted for a "short stay" to undergo physical therapy and occupational therapy but required long-term care due to continued loss of function.[67] EHR documentation showed that Patient 2 had a history of multiple rapid response team (RRT) assessments[68] and Code Blues.[69]

Approximately one week before the Patient events discussed above, staff transported Patient 2 from the CLC to the Unit at 11:00 a.m. According to a note entered by an RN2, Patient 2 arrived in a diaphoretic[70] and clammy state with difficulty breathing. RN2 notified Nephrologist 2 of Patient 2's condition, gave Patient 2 oxygen, and set the dialysis machine for removal of 3.0 kilograms of weight due to Patient 2's complaint of shortness of breath.

Staff documented in the treatment record that during dialysis, Patient 2 was stable with elevated BP at 11:30 a.m. and 12:00 p.m. RN2 documented that the vital signs were stable at 12:30 p.m.

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[65] Spontaneous respirations occur when a patient is breathing without assistance. https://www.merriam-webster.com/dictionary/respiration. (The website was accessed on December 7, 2017.)

[66] The other medical conditions included (1) Diabetic gastroparesis (a disorder of the digestive tract that causes food to remain in the stomach longer than average). See, https://www.healthline.com/health/type-2-diabetes/gastroparesis. (The website was accessed on December 7, 2017); and (2) Ambulatory dysfunction secondary to transverse myelitis (a neurological disorder caused by swelling across both sides of one level or segment of the spinal cord) that impaired this patient's ability to walk). Transverse Myelitis, http://www.nationalmssociety.org/What-is-MS/Related-Conditions/Transverse-Myelitis. (The website was accessed on October 23, 2017).

[67] OIG inspectors were unable to determine the transition date from short stay to long-term care.

[68] An RRT is a team of healthcare providers that responds to hospitalized patients with early signs of imminent clinical deterioration. The team of providers immediately assess and treat the patient with the goal of preventing intensive care unit transfer, respiratory or cardiac arrest and death.

[69] A Code Blue is a term used in a hospital or clinic to require a team of providers to rush to a specific location and begin immediate resuscitation for a patient in cardiopulmonary arrest. https://www.merriam-webster.com/medical/code%20blue. (The website was accessed on December 7, 2017.)

[70] Diaphoretic is excessive sweating.

and 1:00 p.m. At 1:12 p.m., the treatment goal was decreased from 3.0 to 2.6 kilograms of weight when Patient 2 began to lose consciousness.[71]

Statements in a Facility's Department of VA Police report indicated that at 1:21 p.m., a Facility operator recorded and called the RRT. Nine minutes later, the operator recorded announcing a Code Blue. The following events were documented in the EHR:

- RN2 entered a note that CPR began on Patient 2.
- The respiratory therapist noted that Patient 2 was not breathing, started Ambu bag breathing, and the call for RRT was changed to a Code Blue.[72]
- An anesthesiology provider responded to the Code Blue announcement and noted that Patient 2 had apneic breathing and placed an endotracheal tube for oxygen.[73]
- The physician who responded with the RRT documented that

  > Upon my arrival pt [patient]was unresponsive with agonal breathing. Chest compressions [CPR] initiated given no pulse, and started … [Ambu bag] by resp therapist. First rhythm was PEA.[74] pt received 2 mg of epinephrine. [75] Blood pressure elevated to 252/225...Pt got pulse back after 2 rounds of chest compressions.

- Nephrologist 2 acknowledged the change of an RRT to a Code Blue; RN2 documented that Patient 2 had respiratory compromise.

Patient 2 was transferred to the medical intensive care unit for evaluation and treatment. Patient 2 was discharged back to the Facility CLC after an approximately 12-day stay in the medical intensive care unit. Discharge diagnoses included acute respiratory failure, aspiration pneumonia, ESRD, and diabetes with diabetic gastroparesis.

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[71] The treatment goal was to remove excess fluid in order to achieve Patient 2's dry weight and improve respirations.

[72] The respiratory therapist was a member of the RRT; an Ambu bag is a medical device used to provide breathing assistance for patients. *What is an Ambu Bag?* https://healthyliving.azcentral.com/what-is-an-ambu-bag-12199957.html. (The website was accessed on November 16, 2017.)

[73] Apnea occurs when a patient stops breathing briefly. https://www.merriam-webster.com/dictionary/apnea. (The website was accessed on November 27, 2017.); Endotracheal intubation is a procedure by which a tube is inserted through the mouth down into the trachea (the large airway from the mouth to the lungs) to assist with breathing. http://www.medicinenet.com/endotracheal_intubation/article.htm.

[74] Pulseless electrical activity or PEA is an organized electrocardiogram activity without clinical evidence of a palpable pulse or heart contractions that can only be diagnosed if a heart rate/rhythm monitoring device is placed such as an automatic defibrillator. https://www.sciencedirect.com/topics/neuroscience/pulseless-electrical-activity. Although EHR documentation does not indicate a cardiac monitoring device was placed, the OIG team concluded that the notation of PEA indicated a cardiac monitoring device was placed on Patient 2.

[75] Epinephrine is a drug used by the Code Blue team in acute cardiac life support. https://acls-algorithms.com/acls-drugs/acls-and-epinephrine/. (The website was accessed on April 20, 2018.)

# Inspection Results

## Issue 1: The Patient's Quality of Care

The OIG was unable to substantiate that the care the Patient received in the Unit on Day 1, contributed to the Patient's death as the evidence was insufficient to make such a determination. Facility staff found the deceased Patient approximately 17 hours after exiting the Unit. An autopsy was performed two days later. The autopsy report indicated the Patient had cardiovascular and kidney disease and probably suffered a fatal cardiac arrhythmia. Although OIG staff was unable to determine if the dialysis care on Day 1 contributed to the Patient's death, based on the available information and review of the electronic health record (EHR), quality of care concerns were identified related to the Patient's clinical management while in the Unit.

### Failure to Appropriately Manage Blood Glucose

#### *Delayed FSBG*

The Unit staff failed to obtain the Patient's FSBG prior to starting dialysis as Nephrologist 1 ordered. Unit staff obtained the FSBG 38 minutes after starting dialysis and the FSBG was >500 mg/dL.[76] RN2 reported awareness of Nephrologist 1's order to test the Patient's FSBG before the dialysis treatment to the OIG team; however, RN2 believed it was acceptable to test the Patient's FSBG within one hour of beginning dialysis. OIG staff requested the Facility policy to support the practice of testing within an hour of starting dialysis when the order specified testing before dialysis; however, such a policy was not provided.

According to the Patient's EHR, Unit staff failed to test the Patient's FSBG prior to starting dialysis on all eight of the Patient's dialysis treatments prior to the Patient's death. (See Table 2.) The times between the start of dialysis and testing the Patient's FSBG ranged from 4 minutes to 4 hours and 26 minutes.

[76] According to Department of Veterans Affairs Medical Center, Wilmington, DE 19805, Pathology and Laboratory Medicine definitions of critical values, a blood glucose >500 mg/dL was considered a critically high value; RN1 documented on the treatment record and in the Patient's EHR that the FSBG was tested at 11:00 a.m. However, lab test result documentation that is obtained from downloading glucometer data, indicated the FSBG was tested at 11:38 a.m.

**Table 2: The Patient's Last Eight Dialysis Start Times and FSBG Times**

| Episode | HD Start Time | FSBG Time | Time Elapsed |
|---|---|---|---|
| Episode 1 (Day 1) | 11:00 a.m. | 11:38 a.m. | 38 minutes |
| Episode 2 | 12:50 p.m. | 1:13 p.m. | 23 minutes |
| Episode 3 | 11:09 a.m. | 12:30 p.m. | 1 hour 21 minutes |
| Episode 4 | 11:21 a.m. | 12:11 p.m. | 50 minutes |
| Episode 5 | 10:40 a.m. | 3:06 p.m. | 4 hours 26 minutes |
| Episode 6 | 11:51 a.m. | 11:55 a.m. | 4 minutes |
| Episode 7 | 11:34 a.m. | 12:22 p.m. | 48 minutes |
| Episode 8 | 11:40 a.m. | 11:49 a.m. | 9 minutes |

*Source: VA OIG analysis of the Patient's EHR*

## *Incorrect Confirmatory Venous Blood Glucose Order Urgency*

OIG staff found that Unit staff failed to follow Facility policy requiring STAT urgency when ordering a confirmatory venous blood glucose lab test after determining the Patient's FSBG was >500 mg/dL.[77] Despite ordering the test with a ROUTINE status, the Patient's lab test result turnaround time for the ROUTINE test was similar to what one would have expected for a STAT test: one hour and five minutes. Failing to enter the correct urgency in this case may not have delayed the Patient's care. However, failing to enter the correct STAT urgency to confirm critically high blood glucose has the potential to delay patient care.

The Patient had four episodes of critically high blood glucoses in the seven months preceding the Patient's death. Unit staff ordered confirmatory venous blood glucose tests ROUTINE, not STAT as required each time. (See Table 3.)

## *Incorrect Insulin Order Urgency*

The OIG determined that on Day 1, Nephrologist 2 failed to order regular insulin STAT to treat the Patient's critically high blood glucose.

Generally, critically high blood glucose is a medical emergency and should be treated immediately. During an interview, Nephrologist 2 explained to the OIG inspectors that Nephrologist 2's expectation was that the regular insulin would be administered "right now" when selecting the NOW order urgency at 12:47 p.m. RN2 was aware at least by 1:10 p.m. that Nephrologist 2 entered the regular insulin order when documenting, "…nephrologist ordered 4 unit[s] of regular insulin today times one only." OIG staff were unable to determine why RN2

[77] VAMC Wilmington, Delaware, *Pathology and Laboratory Medicine, Ancillary Testing, Instrument Testing,* ANC-INST.2100B.3, February 1, 2017.

waited until 1:50 p.m. to administer the regular insulin; however, RN2 essentially followed Nephrologist 2's NOW order and administered the Patient's regular insulin in one hour and three minutes.

According to the Patient's EHR, providers failed to select a STAT urgency when ordering regular insulin to treat the Patient's confirmed critically high (>500 mg/dL) blood glucose the four times the Patient had such high glucose levels in the seven months before the Patient's death. (See Table 3.)

**Table 3: The Patient's Critically High Blood Glucoses and Related Orders in the Seven Months Preceding Death**

| Episode | FSBG | Confirmation Blood Glucose Test Order Urgency | Confirmation Blood Glucose Result | Regular Insulin Order Urgency | Provider |
|---|---|---|---|---|---|
| Episode 1 (Day 1) | >500 mg/dL | ROUTINE | 502 mg/dL | NOW | Nephrologist 2 |
| Episode 2 | >500 mg/dL | ROUTINE | 888 mg/dL | NOW | Nephrologist 2 |
| Episode 3 | >500 mg/dL | ROUTINE | 442 mg/dL | ROUTINE | Nephrologist 2 |
| Episode 4 | >500 mg/dL | ROUTINE | 560 mg/dL | ROUTINE | Nephrologist 2 |

*Source: VA OIG analysis of the Patient's EHR*

## Delay in Insulin Administration

The OIG determined that because of the combination of the ROUTINE confirmatory venous blood glucose lab test order and the NOW order for regular insulin, two hours and 12 minutes elapsed between the recognition of the Patient's elevated blood glucose and treatment with insulin.

The Patient's actual blood glucose was unknown when RN2 administered the regular insulin two hours and 12 minutes after confirmation of elevated blood glucose. Fifty-three minutes after the insulin was administered, RN2 checked the Patient's blood glucose and documented a blood glucose of 138 mg/dL. After injection, regular insulin usually begins lowering blood glucose within 30 minutes, reaches its maximum strength between two to three hours, and is effective for approximately three to six hours. Therefore, OIG inspectors would not expect to see a 364 mg/dL reduction in blood glucose after 53 minutes, but rather a smaller reduction in this

period of time. In the circumstance of a blood glucose decline not consistent with expected results, further patient monitoring would be warranted to ascertain further blood glucose decline.

OIG staff discussed this scenario with a Facility clinician who indicated that good clinical practices mandate checking blood glucose two hours after an insulin treatment. [78] Due to the onset of action of regular insulin and predicted peak strength at two to three hours, timely clinical assessment and blood glucose recheck are important factors to consider for a safe release from the Unit. The Unit staff released the Patient from the Unit approximately two hours after the administration of regular insulin; however, the Patient's blood glucose was not rechecked at the time of release. As staff did not know the Patient's blood glucose at the time of the Patient's release, staff were not able to offer potentially needed monitoring or interventions.

## Clonidine Administration Issues

OIG staff determined that the observation period for the Patient, following clonidine administration, should have been longer than 18 minutes. Unit staff documented the Patient's post-dialysis BP as 202/96 mmHg with a HR of 66 bpm. RN1 notified Nephrologist 2 of the Patient's BP and Nephrologist 2 gave a verbal order to administer clonidine 0.1mg. RN1 documented giving clonidine orally in the EHR at 3:28 p.m.; however, a written order for the medication was not found in the Patient's EHR. After administering the clonidine, the Patient was observed for 18 minutes by RN 1 and then released from the Unit. At 3:54 p.m., RN1 documented the Patient's BP as 183/89 mmHg and a HR of 68 bpm.

Although EHR documentation does not reflect the time the Patient left the Unit, the CCTV footage time stamp showed the Patient exited the Unit at 3:46 p.m. The CCTV footage showed that the Patient caught the elevator frame for balance and demonstrated an unsteady gait exiting the building. According to a Facility report, "Patient appeared to be in medical distress… walked with a pronounced unsteady gait, staggering and weaving the length of the sidewalk which was approximately 100 feet…Patient is then observed falling against the driver side front fender of vehicle and eventually entered the driver compartment of the vehicle via the driver side door, closing the door after entering."

Clonidine reduces BP within 30 to 60 minutes with the maximum decrease in BP occurring within two to four hours.[79] Patients may experience a sedative effect, dizziness, blurred vision,

[78] Good Clinical Practice in the regular practice of medicine means practice that is the everyday practice of proper medicine. http://www.gcp-education.com/. (The website was accessed on November 30, 2017.)

[79] *Catapres-clonidine Hydrochloride Tablet*. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d7f569dc-6bed-42dc-9bec-940a9e6b090d. (The website was accessed on September 19, 2017.)

headache, and difficulty concentrating with the use of clonidine.[80] Patients should be cautioned about engaging in activities such as driving a vehicle or operating machinery.

Clonidine may also mask some of the symptoms of hypoglycemia such as tremors, palpitations, and sweating making it more difficult to recognize an oncoming hypoglycemic episode.[81]

OIG staff do not know the clinical impact of the delayed insulin administration or the use of clonidine just prior to the Patient's release. The Patient should have had a full clinical assessment, inclusive of an FSBG and documentation in the EHR prior to release from the Unit. Additionally, OIG staff found no documentation in the EHR that Unit staff provided the Patient with instructions regarding the effects of clonidine and a recommendation not to drive.

## Medication Orders Issues

### *Verbal Orders*

OIG staff determined that N2 failed to abide by Facility bylaws when Nephrologist 2 verbally ordered RN1 to administer clonidine 0.1 mg to the Patient. Nephrologist 2 failed to enter the order into CPRS, and RN1 administered the medication to the Patient without a written order in CPRS.

Facility bylaws state verbal orders are strongly discouraged except in emergency situations, such as during CPR, and require that providers enter all orders into CPRS.[82] Facility nursing policy requires that authorized prescribers enter all orders using CPRS and RNs must verify orders in CPRS for accuracy and appropriateness prior to administration.[83] OIG staff were not provided with a Facility nursing policy that addressed verbal orders.

Although the Patient's BP increased during dialysis, the documentation in the EHR does not indicate that the increase was a medical emergency. When interviewed, RN1 reported notifying N2 of the Patient's elevated BP after the dialysis treatment because dialysis patients were usually not allowed to leave with an elevated BP. RN1 stated that N2 said to give the Patient clonidine

[80] *Catapres-clonidine Hydrochloride Tablet.*

[81] *Hypoglycemia*. https://www.mayoclinic.org/diseases-conditions/hypoglycemia/symptoms-causes/syc-20373685. (The website was accessed on March 22, 2018.)

[82] ByLaws & Rules of the Medical Staff, Department of Veterans Affairs Medical Center Wilmington, Delaware.

[83] Wilmington VA Medical Center Nursing Policy Memorandum No. A-11, *Validation of Medication and Treatment Orders,* February 27, 2014.

0.1 mg by mouth. RN1 stated that, because the order was a "verbal order," the order was repeated back to Nephrologist 2 for confirmation before RN1 administered the medication.[84]

RN1 documented on the treatment record administering clonidine 0.1 mg by mouth at 3:28 p.m.[85] Nephrologist 2 also documented in the EHR that the Patient received clonidine 0.1 mg but did not enter the order into CPRS before or after RN1 administered the medication.

### *Dialysate Order Change*

OIG staff determined that Unit staff placed the Patient at risk for hyperkalemia when they failed to follow a change to dialysate orders. Approximately two weeks before the Patient's last dialysis treatment, lab results showed that the Patient's serum potassium was elevated. Nephrologist 1 wrote a dialysis change order to a standard bath of 2k (2 potassium), 2ca (2 calcium). The Patient's serum potassium level continued to be elevated. Ten days later, the Unit Nurse Manager wrote a Hemodialysis Interdisciplinary Care Plan Note, "Patient is on a standard bath K+2 [2 potassium] Ca+2 [2 calcium] Bicarb 30 and Na 140." Twelve days after Nephrologist 1 wrote the change order (Day 1 in the context of this report), the Patient was dialyzed with a 3k (3 potassium) dialysate instead of a 2k (2 potassium).

Patients who have ESRD can have chronically elevated potassium, leaving a narrow zone between a safe and dangerously high potassium levels. Dietary noncompliance can also be an issue for ESRD patients with chronically high potassium. Elevated potassium levels can result in cardiac arrhythmias and death. A lower potassium dialysate can protect patients from further potassium elevation.

### *Epogen® Administration Discrepancy*

OIG staff determined that Unit nurses continued to administer Epogen® after a pharmacist discontinued the medication. Chronic kidney disease can lead to low red blood cells also called anemia.[86] Epogen® is a medication used to treat low red blood cells in dialysis patients to decrease the need for a blood transfusion. [87] Epogen® may be prescribed when the hemoglobin

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[84] According to Facility bylaws, a nurse receiving a verbal order must immediately commit it to writing and read it back to the provider to verify the accuracy. The verbal order must then be made available electronically. On the Unit, medications are stored and locked in an OMNICELL, which is stocked by the pharmacy.

[85] RN1 also documented administering clonidine 0.1 mg at 3:44 p.m. in the Patient's EHR. Based on document review and an interview, OIG inspectors determined the EHR entry made by RN1 was incorrect.

[86] *Anemia in Chronic Kidney Disease.* https://www.niddk.nih.gov/health-information/kidney-disease/chronic-kidney-disease-ckd/anemia. (The website was accessed on October 23, 2017.)

[87] FDA Drug Safety Communication: *Modified Dosing Recommendations to Improve the Safe Use of Erythropoiesis-Stimulating Agents (ESAs) in Chronic Kidney Disease*. https://www.fda.gov/Drugs/DrugSafety/ucm259639.htm. (The website was accessed on September 19, 2017.)

(a protein on a red blood cell) level is less than 10 g/dL and the medication generally takes two to six weeks[88] to increase the hemoglobin level.[89]

The Patient's hemoglobin had been consistently above 10 g/dL for six weeks when a pharmacist discontinued the Epogen® order. According to the Patient's treatment record, Epogen® was administered twice after it was discontinued; OIG staff were unable to find an active order for Epogen® for the time frame at issue.[90]

The Food and Drug Administration lists hypertension as one of the major side effects of Epogen® and recommends that a patient's BP be closely monitored.[91] The Food and Drug Administration also reports an increase in the risk of death, heart attack, stroke, and other events in patients with chronic kidney disease/ESRD using Epogen® to reach a hemoglobin level > 11 g/dL.[92]

## Unit Documentation

The OIG determined that Unit nursing documentation inconsistencies placed patients at risk for adverse health outcomes. VHA's Handbook requires that all patient care activities are documented and signed immediately following the care or observation to ensure proper documentation and to make it available to other caregivers.[93] The VHA Handbook states that (1) all clinical staff are required to document in CPRS unless technology is not available for electronic entry, (2) EHR entries must be accurate, and (3) the practitioner who treats the patient is the individual responsible for documenting and authenticating the care provided.

In February 2016, Unit leaders received notification that the dialysis record software program that was being used (FMiS) would no longer be supported by the vendor. According to the Associate Chief Nurse for Acute Care and Surgical Services, guidance received nationally was that each VA could use these options: (1) continue to use the software without vendor support; (2) discontinue FMiS, purchase, and install another third-party software system; or (3) discontinue FMiS and manually document the dialysis treatments. In March 2016, Unit leaders

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[88] *Epogen (Epoetin alfa) for Injection.* https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=10003. (The website was accessed on October 23, 2017.)

[89] FDA Drug Safety Communication: *Modified Dosing Recommendations to Improve the Safe Use of Erythropoiesis-Stimulating Agents (ESAs) in Chronic Kidney Disease.*

[90] The two episodes were approximately one week before and one day before the patient's death.

[91] *Epogen Medication Guide*. https://www.fda.gov/downloads/Drugs/DrugSafety/ucm088591.pdf. (The website was accessed on October 23, 2017.); *Epogen (Epoetin alfa) for Injection*. https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=10003. (The website was accessed on October 23, 2017.)

[92] FDA Drug Safety Communication: *Modified Dosing Recommendations to Improve the Safe Use of Erythropoiesis-Stimulating Agents (ESAs) in Chronic Kidney Disease.*

[93] VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

decided to stop using the FMiS software and converted the recording system to a paper flowsheet in keeping with option 3.

At the time of the OIG site visit in July 2017, Unit nursing staff documented dialysis treatment three ways:

- Treatment record—a preprinted sheet of paper on which staff hand wrote patient information as it occurred. Staff scanned the treatment record into the patient's EHR after completion of dialysis.
- Nursing Note—a CPRS note in the patient's EHR.
- Procedure Report—a CPRS note that contained some information also captured on the treatment record such as pre- and post-dialysis vital signs, medication administration, and the dialysate formula. An assigned Unit nurse transcribed documentation written onto the treatment record to the Procedure Report.

The Facility used the treatment record for documenting treatment performed on a patient during dialysis. The treatment record had

- Limited space for Unit staff to document care,
- Limited space to record vital signs, and
- Limited space to document time, signature, or multiple procedural entries.

The OIG determined that the Unit's nursing documentation processes placed patients at risk for poor quality of care because

- The treatment record did not allow adequate space for thorough documentation and not all areas had space for staff to enter a time and signature for the writer, and
- The process, at the time of the OIG July 2017 review, required that a Unit nurse tasked to transcribe handwritten documentation from the treatment record to the CPRS Procedure Report created duplicate information. This process increased the chance for transcription errors and required the transcribing nurse to document care not personally provided to the patient.

## Examples of Unit Documentation Inconsistencies

The OIG staff found documentation inconsistencies between the Patient's EHR and the treatment record regarding the care received on Day 1.

### *Blood Glucose Result Time*

The documentation in the Patient's treatment record indicated the FSBG was 502 mg/dL at 11:00 a.m. and was 138 mg/dL at 2:39 p.m. According to the Patient's EHR, the FSBG was obtained at 11:38 a.m. and the blood glucose serum lab test result was recorded as 502 mg/dL at 11:40 a.m.

### *Medication Administration*

RN1 documented on the treatment record that clonidine 0.1 mg was given at 3:28 p.m. RN1 also reported during the OIG's onsite interview being the administrator of the clonidine to the Patient. However, at 3:54 p.m. RN2 was the individual who documented as administering the clonidine 0.1 mg in the CPRS Procedure Report.

In addition, RN2 documented on the treatment record administering calcitriol and Epogen® at 1:22 p.m., and regular insulin at 1:50 p.m. However, RN2 documented in the CPRS Procedure Report administering calcitriol, Epogen®, and regular insulin at 1:56 p.m.

## Issue 2: Patient 2's Quality of Care

The OIG did not substantiate that a Unit nurse switched a valve on a dialysis machine in the wrong direction. The OIG substantiated that Unit staff initiated CPR on Patient 2 and identified quality of care concerns related to Unit staff's emergency response on the day in question.

### Dialysis Machine Operation

The OIG determined that the Unit was set up with 10 dialysis machine stations to treat chronic dialysis patients and two portable reverse osmosis dialysis machines used for patients in the intensive care unit.[94]

OIG staff received documentation from a Facility Biomedical Equipment Support Specialist that stated, "I am not aware of any 'valves' on the dialysis machines which can be turned the wrong way." In contrast, the portable reverse osmosis machine contained a valve that if opened during dialysis could eject some of the reverse osmosis water from the sample port. If the valve opens, an alarm signals on the machine and the dialysis machine's product bypasses the patient circuit and the treatment is paused.

The OIG determined that Patient 2 was dialyzed in the Unit and was treated at one of the 10 dialysis machine stations, not with the portable reverse osmosis machine containing a valve.

[94] Reverse osmosis is a process used to purify tap water to use for hemodialysis.

## Emergency Response

The OIG also identified quality of care concerns related to Unit staff's emergency response to Patient 2's respiratory decline. As stated earlier, RN2's documentation in the EHR and treatment record indicated that Patient 2 arrived clammy, diaphoretic, and short of breath from the CLC.

Approximately two hours later, the Unit Nurse Manager became involved when Patient 2 became more distressed. Two staff members could not agree if Patient 2 had a pulse. The RRT was activated. RN2 believed that Patient 2 did not have a pulse and initiated CPR. The Unit Nurse Manager told the OIG that, based on an assessment, Patient 2 registered a blood pressure, was breathing, and did not receive CPR that day.

The presence or absence of a pulse determines the actions of the medical responder(s). If there is no pulse, CPR is initiated; if a pulse is present, the patient is examined for an open airway and breathing and provided medical support in these areas if problems exist.

The RRT and Code Blue teams (responding teams) arrived in the midst of Unit staff's disagreement regarding whether Patient 2 had a pulse. A RRT member assessed Patient 2 for breathing and provided support until the anesthesiologist on the Code Blue team arrived and placed a tube for breathing. However, the OIG found no code sheet documentation that members of the Code Blue team rechecked Patient 2's pulses before continuing CPR and administering epinephrine. Unit staff told OIG staff that the epinephrine used was obtained from the medication room and not the Code cart.[95]

A medical staff member who was not involved with Patient 2's Code Blue documented in the EHR, "[i]t should be noted that the patient's pulses are somewhat difficult to feel even in a normal clinical examination context. It's unclear as to whether [the patient] really did experience pulseless electrical activity." A staff leader at the Facility reviewed Patient 2's CPR event and informed OIG inspectors that Patient 2 was not really pulseless "but had respiratory distress and ended up intubated."

OIG staff reviewed the Facility's Department of VA police report that noted an RRT at 1:21 p.m. The OIG obtained the RRT/Code Blue report sheet for the relevant time frame and Patient 2 was not listed on the document. OIG staff requested the Code Blue sheet documentation for this event, given members of the responding teams documented in the EHR that Patient 2 received treatment during a "Code Blue." Facility leaders were unable to provide a Code Blue sheet on Patient 2 as required by policy. The OIG requested the pharmacy records to review medications or equipment used during Patient 2's Code Blue, and Facility leaders did not produce the pharmacy records. In addition, OIG staff reviewed the Facility Health Care Delivery Council

[95] A code cart contains equipment and medications used to treat a patient in the first 30 minutes of a medical emergency. Crash Cart Supply and Equipment Checklist. https://www.acls.net/acls-crash-cart.htm. (The website was accessed on November 29, 2017.)

meeting minutes for the relevant time frame and found that Patient 2's RRT and/or Code Blue was not documented. According to the Facility's Health Care Delivery Council Charter, one of the Council's primary oversight responsibilities is to review Code Blue and RRT incidents.

OIG staff determined that Patient 2 may not have had pulseless electrical activity requiring CPR and epinephrine. The Unit staff's lack of agreement about the presence of a pulse should have been communicated to the members of the Code Blue team. This admission would have triggered Code Blue team members to confirm the presence of a pulse and thus determine the appropriate treatment for Patient 2.

## Mock Codes

While on-site in July 2017, OIG staff learned that the Facility education staff had not conducted a mock code on the Unit since June 25, 2015.[96] Basic life support training during a mock code enables staff to respond to medical emergencies using CPR.[97] Mock code training employs equipment and a simulation manikin to replicate Code Blue scenarios.[98] The intent of a mock code is to have staff practice skills and build self-confidence in a controlled environment in order to improve patient survival during an actual medical emergency.[99] If any variable, whether a medical skill or non-medical quality, is lacking, the effectiveness of the code team's resuscitation could be hindered. The keys to having a high-performing code team include organization, clearly identified roles, and frequent team mock code practice.[100] Although Patient 2 survived the resuscitation event, the OIG determined that Unit staff would benefit from regular mock code training given the conflicting interviews and EHR documentation concerns surrounding Patient 2's event.

[96] Mock codes are training scenarios for medical staff participating in Code Blues; Basic life support consists of cardiopulmonary resuscitation (CPR) and, when available, defibrillation using automated external defibrillators (AED). https://www.uptodate.com/contents/basic-life-support-bls-in-adults. (The website was accessed on January10, 2018.).

[97] *American Heart Association CPR Guidelines 2015 - Updated 2018.* https://www.cprcertificationonlinehq.com/aha-cpr-guidelines-latest-jan-2014/. (The website was accessed on March 30, 2018.)

[98] *How to Run a Mock Code.* http://www.jumpsimulation.org/research-innovation/our-blog/2016/february/how-to-run-a-mock-code. (The website was accessed on April 20, 2018.)

[99] *Finding the Key to a Better Code: Code Team Restructure to Improve Performance and Outcomes*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4453307/. (The website was accessed on March 30, 2017.)

[100] *Finding the Key to a Better Code: Code Team Restructure to Improve Performance and Outcomes*.

# Issue 3: Additional Concerns

## Dysfunctional Unit Work Environment

Several of the Unit leaders and staff the OIG interviewed expressed a strained relationship between the Unit nurses and nephrologists.

In August 2017, a Nurse Manager from another VA facility (non-Facility Nurse Manager) conducted a review of the Facility's unit nursing practices, processes, and staffing. The non-Facility Nurse Manager documented in a report that, "interviews with [RN3] and the provider revealed a lack of collaboration and trust that is certainly a barrier to creating a cohesive environment in the Dialysis Unit." The non-Facility Nurse Manager also reported that, "the most common theme with every [Unit] staff member that was interviewed was that they do not feel that there is a unified team with the physicians and that they do not feel supported. [Unit] RNs that were interviewed stated that they were not comfortable voicing their opinions or suggestions because they were told they ask too many questions." The non-Facility Nurse Manager documented that the conflict between RN3 and the Unit Medical Director was a barrier and that in order to provide a culture of safety for the other Unit staff, a collaborative and respectful relationship must be created between them.

Facility and Unit leaders and staff were aware that the Unit lacked a cohesive environment and acknowledged that problems had been difficult to resolve. A lack of collaboration within the Unit has the potential to put patients at risk for adverse outcomes.

## Inadequate Facility Event Response

### *Lack of Patient Safety Assessment*

Reporting adverse events and close calls is integral to VHA's approach to patient safety.[101] VHA defines adverse events as "untoward incidents, diagnostic or therapeutic misadventures, iatrogenic injuries,[102] or other occurrences of harm or potential harm directly associated with care or services provided within the jurisdiction of the Veterans Healthcare System."[103] Adverse events may result from acts of commission or omission for example, administration of the wrong

[101] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This VHA Handbook was scheduled for recertification on or before the last working date of March 2016 and has not been recertified.

[102] Iatrogenic injuries are those induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures.

[103] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients:* Corrected copy, October 2, 2012. This VHA Handbook was scheduled for recertification on or before the last working date of October 2017 and has not been recertified.

medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions, or negative outcomes of treatment.[104]

According to VHA policy, some adverse events signal the need for immediate investigation and response, which may result in initiating a Root Cause Analysis (RCA).[105] All adverse events require reporting and documentation in the VHA Patient Safety Information System. The Patient Safety Manager analyzes the information and determines the type of review needed through the Safety Assessment Code (SAC) Matrix scoring process.[106] VHA policy also requires that patient incidents with an actual or potential SAC score of 3 (the scale is 1–3, with 3 being the highest risk) not related to falls, medications, or missing patients, must complete an RCA.[107]

According to the Facility Quality Management Chief, the Patient Safety Manager has presented patient safety training at new employee orientation since January 2015. This training informs employees what an adverse event is and gives them step-by-step instructions for how to report an adverse event or a close call into the Electronic Patient Event Report. The Patient Safety Manager stated that VA staff did not submit an Electronic Patient Event Report related to the circumstances surrounding the Patient's death.[108] Without notification of a possible adverse event, patient safety staff could not conduct an assessment and assign a SAC score. The Patient Safety Manager stated that the Patient's event would have scored a SAC score of 3 and triggered an RCA due to the catastrophic nature.

The Patient was found deceased in his/her own car on VA property approximately 17 hours after dialysis treatment. An RCA may have identified harm or potential harm directly associated with the Patient's care or services provided in the Unit.

### *Need for Disclosure*

VHA facilities must disclose occurrences of adverse events related to patients' clinical care. Disclosure is warranted for "[a]dverse events that cause death or disability, lead to prolonged hospitalization, require life-sustaining intervention or intervention to prevent impairment or damage (or that are reasonably expected to result in death or serious and/or permanent disability), or that are sentinel events."[109]

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[104] VHA Handbook 1050.01.

[105] An RCA is a process for identifying the basis or contributing causal factors that underlie variations in performance associated with adverse events or close calls. VHA Handbook 1050.01.

[106] VHA Handbook 1050.01.

[107] VHA Handbook 1050.01. For more on SAC scores, see https://www.patientsafety.va.gov/professionals/publications/matrix.asp.

[108] The Chief of Police and the Risk Manager reported being at the scene when the Patient was discovered in the car.

[109] VHA Handbook 1004.08.

During the OIG July site visit, it was determined that Facility leaders had not conducted a disclosure. OIG staff recommended that Facility leaders consider whether they had an obligation to disclose to the next of kin the circumstances surrounding the Patient's death including the care received in the Unit to the next of kin. OIG staff were provided documentation that a meeting had taken place between the Facility's Director, Acting Associate Director, Chief of Police and the Patient's son and daughter.

## Unit Staffing

Facility leaders reported that the Unit had staffing challenges and had hired three nurse managers over a 10-month period, all of whom resigned. The staffing challenges identified were multifactorial and included staff burnout, poor Unit culture, and unstable environment, and conflicts between Unit nurses and providers.

A VHA Handbook and Facility procedures require the following positions for a VA Outpatient Dialysis Program: a nurse manager, RNs, LPNs, a program assistant, and an access coordinator.[110] In spring 2017, the Unit had 13 approved support staff positions consisting of one nurse manager, seven RNs, one LPN, and four MITs. The Unit did not have a program assistant position included in the approved staff and the access nurse coordinator position was vacant. On Day 1, two RNs and two MITs were on duty in the Unit.[111]

In late spring 2017, in response to a request to identify the top issues and risks for the Unit from Facility leaders, the Associate Director for Patient Care Services submitted a memorandum to the Acting Facility Director that focused on staffing issues. Staffing was unstable with three RN vacancies and a vacant MIT position. This led to increased overtime and use of non-VA agency staff to maintain a ratio of one RN and one MIT per five patients. Staffing factors contributing to "operational risk" included inadequate recruiting/retention, onboarding processes, and salary structure.

The Associate Director for Patient Care Services told the OIG that the Unit Nurse Manager functioned as a Unit staff nurse at least 50 percent of the time to support staffing (whereas the Nurse Manager reported functioning as a staff nurse at least 80 percent of the time). The Transplant Coordinator was also used as a staff nurse when needed.

[110] VHA Handbook 1042.01, *Criteria and Standards for VA Dialysis Programs*, May 23, 2016.

[111] On the Patient's Day 1, the Unit Nurse Manager was off and not available to provide staffing support. When otherwise available, the Nurse Manager took patient assignments when needed and covered for RNs during their breaks.

A 2011 study reported that Unit staff nurse burnout from excessive workload is a major factor for nurse turnover and quality care.[112] Research also suggests Unit nurses have a higher level of burnout related to perceived high workloads, unsupportive work environments, and lack of confidence in management.[113]

## Unit Policies and Procedures

OIG staff determined that in the absence of stable management, the Unit was not compliant with policies and procedures.

In November 2016, a Chief of Nephrology from another VA facility (non-Facility Nephrologist) was assigned to perform an assessment of the Facility's Unit due to a specific quality indicator that the Facility Unit had not met. The non-Facility Nephrologist met with leaders from the Facility Unit, conducted an assessment of the Unit, and provided a summary and recommendations memorandum to the Facility's COS and Chief of Medicine.

The Facility received six recommendations to address specific unmet VHA Handbook 1042.01 standards and criteria:

1. Implement multidisciplinary patient care plans
2. Implement Quality Assessment and Performance Improvement plan
3. Review dialysis monthly blood work orders
4. Conduct facility dialysis committee meetings
5. Review the dialysis dashboard on a monthly basis
6. Address patient noncompliance with dialysis time

Although OIG staff found that the Facility leaders implemented action plans for the six recommendations, additional concerns related to Unit policies and procedures were identified. The Joint Commission requires leaders to review and approve policies and procedures that guide and support patient care, treatment, and services.[114]

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[112] *Adequacy of Dialysis Clinic Staffing and Quality of Care: A Review of Evidence and Areas of Needed Research.* http://www.ajkd.org/article/S0272-6386(11)00812-2/abstract. (The website was accessed on August 11, 2017.)

[113] *The Work Environment, Nurse Staffing, and Outcomes in Hemodialysis Settings.* https://www.annanurse.org/download/reference/practice/hemoWhitePaper.pdf. (The website was accessed on August 18, 2017.)

[114] The Joint Commission, Hospital Leadership, LD.04.01.07: The hospital has policies and procedures that guide and support patient care, treatment, and services.

The OIG determined that in the absence of a stable Unit nurse manager, new policies had not been developed, and the Unit lacked an adequate organizational structure to ensure that the quality of care provided to dialysis patients met guidelines as outlined in VHA Handbook 1042.01, *Criteria and Standards for VA Dialysis Programs*.

In addition, on Day 1, when the Patient was released after dialysis, Unit nursing staff did not have established criteria to assess a patient for a safe release. Two months following the Patient's death, Facility leaders developed and implemented a Unit discharge policy with criteria to facilitate safe releases.[115] OIG staff found, however, that the policy did not include adequate information for patient assessments and education about medications given during dialysis treatment that were not routinely scheduled.

## Facility VA Police Security

The OIG determined that Facility VA police officers violated policies and procedures by leaving the Patient's car in a visible illegal parking spot for more than 17 hours between Days 1 and 2.

VA Directive sets forth mandatory procedures "for protecting lives and property within VA's jurisdiction."[116] The directive also requires that each VA facility has a sufficient number of police officers "on duty, at all times, necessary to maintain law and order and to concurrently provide protection of persons and property throughout the facility."[117] In addition, Title 38 Code of Federal Regulations prohibits vehicles from being parked in unauthorized locations.[118] The Facility's Chief of Police also had directed police supervisors that "patrol checks (walking or vehicle) will be conducted every hour, by every officer, so long as they are not on another call or doing a report."

Two months prior to OIG's July site visit, a police officer from another VA facility (Independent Officer) issued the Facility's Acting Director an independent fact-finding report about the Patient's death. The Independent Officer assessed the events that occurred from the time Patient 2 exited the Facility until discovery in the vehicle the next morning, specifically focusing on the actions of the Facility's VA police officers.

OIG staff reviewed the legal authorities and guidance, CCTV, and the Independent Officer's report. The review revealed that the VA police officers' actions were not aligned with the requirements governing police actions described above. The CCTV footage showed that the

[115] VA Medical Center Wilmington, DE Nursing Policy A-38, *Discharge Criteria for Hemodialysis patients from the Dialysis Unit following Treatment*, June 2017.

[116] VA Directive 0730, *Security and Law Enforcement*, December 12, 2012, Section 1(a).

[117] VA Directive 0730, Section 2(a)(3); Several Standing Operating Procedures (SOP) are relevant such as: SOP 2-D, Standing Watch Orders; SOP 2-E, Specific Shift Duties and Responsibilities; and SOP 1-J, Vehicle Registration, Parking and Traffic Control.

[118] Title 38 Code of Federal Regulations 1.218, Subparagraph (a) (12), Security and law enforcement at VA facilities.

Patient arrived at the Facility for the dialysis appointment and parked in a valet parking area along the curb, near the east entrance of the Facility. According to the Independent Officer's report, this was an illegal parking space in close proximity to Facility Fire Department Connections and approximately 25 yards from the Facility entrance. The illegal parking space was in a visible area where numerous people walked to enter and leave the Facility.

The CCTV footage showed the Patient exited the Facility late afternoon, entered the vehicle, and remained in the same parking spot for more than 17 hours. On Day 2, a Volunteer Service employee noticed the Patient in the vehicle and notified Facility staff. Staff initiated a Code Blue and the Patient was pronounced dead. The exact time of death is unknown.

# Conclusion

OIG staff were unable to substantiate that the care the Patient received in the Unit on Day 1 contributed to the Patient's death, as the evidence was insufficient to make such a determination. The autopsy performed on Day 3 indicated the Patient had cardiovascular and kidney disease and probably suffered a fatal cardiac arrhythmia. Although unable to determine if the dialysis care contributed to the Patient's death, the OIG identified quality of care concerns related to the Patient's clinical management while in the Unit.

Unit staff failed to obtain the Patient's blood glucose levels prior to starting dialysis as the nephrologist ordered. RN2 reported to OIG staff awareness of the order to test the Patient's levels before the dialysis treatment, but believed it was acceptable to test within one hour of beginning dialysis. OIG staff found no policy or Unit RN direction to support that practice. Unit staff instead obtained the FSBG 38 minutes after starting dialysis and the blood glucose level was critically high.

OIG staff found that Unit nursing staff failed to follow Facility policy requiring STAT urgency when ordering a confirmatory blood glucose lab test after determining the Patient's levels were critically high. Because the lab test turnaround time was one hour and five minutes, generally within the one-hour turnaround time goal of a STAT lab test order, failing to enter the correct lab urgency order in this case may not have delayed the Patient's care. However, failing to enter the correct urgency status to confirm a critically high blood glucose has the potential to negatively affect patient care.

The OIG determined that on Day 1, one of the nephrologists failed to order regular insulin STAT to treat the Patient's critically high blood glucose. During an interview, that nephrologist revealed the expectation was that the regular insulin would be administered "right now" when selecting the NOW order urgency.

The OIG determined because of the combination of the ROUTINE confirmatory blood glucose lab test order and the NOW order for regular insulin, two hours and 12 minutes elapsed between the recognition of the Patient's elevated blood glucose and treatment with insulin. Fifty-three minutes after the insulin was administered, a nurse checked and documented a blood glucose of 138 mg/dL. After injection, regular insulin usually begins lowering blood glucose within 30 minutes, reaches its maximum strength between two to three hours,[119] and is effective for approximately three to six hours. Therefore, the OIG would not expect to see a 364 mg/dL reduction in blood glucose after 53 minutes, but rather a smaller reduction. Unit staff released the Patient from the Unit approximately two hours after staff administered regular insulin; therefore,

[119] *Types of Insulin*. https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/. (The website was accessed on April 17, 2018.)

the regular insulin would have continued to lower the Patient's blood glucose. Staff did not check the Patient's blood glucose prior to release from the Unit.

Unit staff notified a nephrologist of the Patient's post-dialysis elevated blood pressure who gave a verbal order to administer clonidine 0.1 mg. A nurse documented the clonidine as given orally at 3:28 p.m. The OIG determined that the Patient's observation period following the clonidine administration should have been longer than 18 minutes. Unit staff released the Patient with a BP recorded as 183/89 mmHg and a heart rate of 68 bpm. Clonidine acts to lower blood pressure within 30 to 60 minutes with the maximum decrease occurring within two to four hours. The OIG found no documentation in the EHR that Unit staff conducted a full clinical assessment or provided the Patient with instructions regarding the effects of clonidine including drowsiness and a recommendation not to drive. The OIG found that on Day 1, Unit staff failed to clinically assess the Patient prior to release from the Unit after administering regular insulin and clonidine.

In addition to other concerns, the OIG determined that Unit staff placed the Patient at risk for hyperkalemia when they failed to follow a change to dialysate orders. In addition, one of the Patient's medication treatment orders was discontinued but continued to be administered, placing the Patient at risk for hypertension. Further, OIG staff determined the Unit's nursing documentation inconsistencies placed patients at risk for adverse health outcomes.

The OIG did not substantiate that a Unit nurse switched a valve on a dialysis machine in the wrong direction. The OIG learned that the dialysis machines used for Patient 2 did not contain valves that could be turned in the wrong direction.

The OIG substantiated that Unit staff initiated CPR on Patient 2 and identified concerns related to Unit staffs' response to the emergency. The Unit staff could not agree whether Patient 2 had a pulse. Unit staff initiated CPR and activated the Rapid Response and the Code Blue teams. The EHR documentation and information acquired during interviews raised concerns regarding the Unit staff's ability to recognize the need for CPR intervention. The OIG found a lack of required Code Blue documentation and reporting to oversight committees. While on-site in July 2017, OIG staff learned that training staff had not conducted a mock code on the Unit since June 25, 2015.

While reviewing the allegations, the OIG identified additional concerns related to the Unit that included strained relationships between the Unit nurses and nephrologists; failure by Facility leaders and mid-level managers to conduct a root cause analysis of the Patient's incident; delays in disclosing information to the patient's next of kin; staffing challenges; unstable management resulting in lack of effective updated policies; and deficient organizational structure to ensure dialysis patients received care consistent with VHA guidelines.

In addition, on Day 1, when staff released the Patient from the Unit, the nursing staff did not have established criteria to assess a patient for a safe release. Although a policy was developed

two months following the Patient's death. that policy lacked some key criteria identified by OIG staff.

The OIG determined that Facility VA police officers violated policies and procedures by leaving the Patient's car in a visible illegal parking spot for more than 17 hours. VA police officers' actions were not consistent with governing authorities and guidance.

The OIG made 14 recommendations.

## Recommendations 1–14

1. The Wilmington VA Medical Center Director ensures that Hemodialysis Unit providers and staff are educated on laboratory and medication order urgency policy/processes and monitors compliance.

2. The Wilmington VA Medical Center Director ensures that Facility leaders develop and implement a nursing policy that addresses verbal orders and monitors compliance.

3. The Wilmington VA Medical Center Director ensures that Hemodialysis Unit providers receive training on the use of verbal orders including the use of verbal orders only in emergencies within the guidelines presented in the Facility bylaws and monitors compliance.

4. The Wilmington VA Medical Center Director reviews Hemodialysis Unit staff access to and administration of medications to patients who do not have a medication order or the order has expired and takes actions as necessary.

5. The Wilmington VA Medical Center Director ensures that a process is developed to notify Hemodialysis Unit staff of changes in hemodialysis orders and monitors compliance.

6. The Wilmington VA Medical Center Director ensures that the Hemodialysis Unit managers adopt and provide documentation programs that will enable accuracy and efficiency in record keeping and monitors compliance.

7. The Wilmington VA Medical Center Director ensures that the Code Blue members utilize the Code Blue Flow Sheet and that Rapid Response and Code Blue events are documented and presented monthly to the Facility's Health Care Delivery Council.

8. The Wilmington VA Medical Center Director ensures that the Education Department conducts unannounced mock code training twice a year in the Hemodialysis Unit with debriefings and monitors improvement and compliance.

9. The Wilmington VA Medical Center Director resolves the conflict between Hemodialysis Unit staff to provide a work place environment where staff collaborates to reduce the risk of adverse patient outcomes.

10. The Wilmington VA Medical Center Director evaluates the Facility's education and training program to ensure that Safety Assessment Code assignments and Root Cause Analyses are

conducted in accordance with Veterans Health Administration Handbook 1050.01, *National Patient Safety Improvement*.

11. The Wilmington VA Medical Center Director continues efforts to recruit and hire for Hemodialysis Unit staff vacancies, and ensures that, until optimal staffing is achieved, alternate methods are consistently available to meet patient care needs.

12. The Wilmington VA Medical Center Director ensures that the Chief of Medicine establishes a safe discharge process for hemodialysis patients including those who receive not routinely scheduled medications during hemodialysis and monitors compliance.

13. The Wilmington VA Medical Center Director ensures Facility policies are consistent with Veterans Health Administration Handbook 1042.01, *Criteria and Standards for VA Dialysis Programs,* and Hemodialysis Unit providers and staff adhere to the policies.

14**.** The Wilmington VA Medical Center Director ensures that the Facility Police Department act in alignment with VA Directive 0730 and Title 38 Code of Federal Regulations and takes actions as appropriate.

# Appendix A: Unannounced Second Site Visit to Wilmington VAMC

The OIG conducted a teleconference with Facility leaders on September 7, 2017, to discuss specific findings from the July 11 through July 13, 2017, OIG site visit. The Facility Director informed OIG inspectors that since the initial OIG visit, Facility managers developed a workgroup to improve Unit compliance with VHA Handbook 1042.01; enhanced Unit staffing and leaders; improved interdisciplinary documentation and communication; upgraded equipment; and made improvements to the environment of care. On that same day, OIG inspectors received an email from the Facility Director with action plans that were implemented (see Table 4).

On November 1, 2017, OIG inspectors conducted an unannounced second site visit to the Facility to evaluate whether the action plans had been implemented. OIG staff interviewed the Facility Director, COS, Associate Director for Patient Care Services, two members of the Unit workgroup, Acting Unit Medical Director, Unit pharmacist, a nephrologist, and the Unit Nurse Manager.

Table 4 shows the implementation status for each action item.

**Table 4: Summary of Action Plan Follow-Up for the Unit**

| Action Item | Implemented Yes/No | Comments |
|---|---|---|
| Decrease Unit patient census from 36 to 13. | Yes | Unit patient census was decreased from 36 to 16. |
| Operate Unit Monday, Wednesday, and Friday. | Yes | None. |
| Initiate and work on Unit program enhancement and modernization efforts on Tuesday and Thursday. | Yes | Nephrologist 1 told the OIG team that the Unit policies were being reviewed to see what was wrong. |
| Nephrologist 1 will provide Unit leadership in an acting role. | Yes | The Facility Director, Nephrologist 1, and Unit Nurse Manager acknowledged that Nephrologist 1 was the Acting Unit Medical Director. |
| Nephrologist 2 will coordinate the care for 23 patients who will receive dialysis in the community. | Yes | Nephrologist 2 was responsible for the placement of the 20 patients in Non-VA care. |
| Nephrologist 1 and Nephrologist 2 will remain on the Unit workgroup and assist with upgrades needed to promote safe and effective patient care. | Yes | None. |
| Associate Chief Nurse will ensure resources are available to meet patient care needs and lead recruitment effort for a new experienced Unit Nurse Manager. | Yes | Facility Leaders told the OIG team that the Unit Nurse Manager submitted resignation papers; but later rescinded them. |
| Unit workgroup will meet weekly and progress reports presented monthly to the Executive Leadership Board meetings. | No | The OIG interviewed two Unit workgroup members who indicated that the workgroup only met once since October 1, 2017; they did not state why weekly meetings were not held. |

*Source: VA OIG Analysis of Interviews*

Although, Facility leaders implemented action plans for improvement, the Facility COS stated that teamwork in the Unit continued to be an issue. The Facility Associate Director for Patient Care Services told the OIG that there continued to be a conflict between RN3 and the nephrologists.

The Acting Unit Medical Director stated that there was also a conflict between a pharmacist and RN 3. The pharmacist stated that there had not been any changes on the Unit since the OIG last visit except that there were fewer dialysis patients.

# Appendix B: VISN Director Comments

**Department of Veterans Affairs Memorandum**

Date: August 24, 2018

From: Director, VA Healthcare VISN 4 (10N4)

Subj: Healthcare Inspection—Quality of Care Concerns in the Hemodialysis Unit at the Wilmington VA Medical Center, Delaware

To: Director, San Diego Regional Office of Healthcare Inspections (54SD)

Director, Management Review Service (VHA 10E1D MRS Action)

I have reviewed the responses provided by the Wilmington VA Medical Center, Wilmington, Delaware. I am submitting to your office as requested. I concur with their responses.

(Original signed by:)

MICHAEL D. ADELMAN, M.D.

# Appendix C: Facility Director Comments

**Department of Veterans Affairs Memorandum**

Date: August 24, 2018

From: Director, Wilmington VA Medical Center, DE (460/00)

Subj: Healthcare Inspection—Quality of Care Concerns in the Hemodialysis Unit at the Wilmington VA Medical Center, Wilmington, Delaware

To: Director, VA Healthcare VISN 4 (10N4)

1. I have reviewed and concur with14 of the 14 recommendations from the Office of Inspector General's (OIG), pertaining to the Draft Report received August 10, 2018, Quality of Care Concerns in the Hemodialysis Unit at the Wilmington VA Medical Center. The medical center has made substantial progress and has implemented new practices to promote quality of care and ensure the safety of patients and staff. Leadership continues to monitor and asses the action plans to achieve compliance in accordance with the recommendations.

*(Original signed by:)*

Vincent Kane

Director

## Comments to OIG's Report[120]

## Recommendation 1

The Wilmington VA Medical Center Director ensures that Hemodialysis Unit providers and staff are educated on laboratory and medication order urgency policy/processes and monitor compliance.

Concur.

Target date for completion: July 31, 2018

### Director Comments

Since my appointment in May 2017 as the Medical Center Director I have prioritized putting Veterans first, improving employee satisfaction and fostering a culture of safety and excellence Along with other leadership and staff we have increased our focus on training. We are in the process of recruiting a new Chief of Staff and a new, experienced nurse executive has been selected. A primary focus for them is updating policies and ensuring that staff are properly oriented to the policies and that they are compliant with them. The following procedures are being put in place to improve safety and quality of care:

a. 100% of Dialysis Medical Staff will receive education on laboratory order urgency categories

b. 100% of Dialysis Medical Staff will receive education on medication order urgency categories

c. 100% of Dialysis Nursing Staff will receive education on laboratory order urgency categories

d. 100% of Dialysis Nursing Staff will receive education on medication order urgency categories

## Recommendation 2

The Wilmington VA Medical Center Director ensures that Facility leaders develop and implement a nursing policy that addresses verbal orders and monitors compliance.

Concur.

[120] The OIG confirmed that the Facility assigned the following terms to the acronyms used in the Facility Director's Comments: BCMA – bar code medication administration; HD – hemodialysis, JPRS – Joint Patient Safety Reporting System; N – Numerator; PSM – Patient Safety Manager; SME- subject matter expert; and SOP – Standard Operating Procedure.

Target date for completion: July 31, 2018

### Director Comments

The following actions are being implemented and compliance monitored:

a. Nursing Processes for verbal orders will be written and posted as signed policy/procedure

b. 90% of verbal orders accepted for treatment of patients will be entered in emergent scenarios for three consecutive months.

## Recommendation 3

The Wilmington VA Medical Center Director ensures that Hemodialysis Unit providers receive training on the use of verbal orders including the use of verbal orders only in emergencies within the guidelines presented in the Facility bylaws and monitors compliance.

Concur.

Target date for completion: October 31, 2018

### Director Comments

The following actions are being implemented and compliance monitored:

a. 100% of HD providers will received training on the use of verbal orders in accordance with the Medical Center By-Laws

b. 90% of verbal orders accepted for treatment of patients will be entered in emergent scenarios for three consecutive months.

## Recommendation 4

The Wilmington VA Medical Center Director reviews Hemodialysis Unit staff access to and administration of medications to patients who do not have a medication order or the order has expired and takes action as necessary.

Concur.

Target date for completion: October 31, 2018

### Director Comments

## The following actions are being implemented and compliance monitored:

a. Implement BCMA Clinic Orders in the dialysis unit for all medication administration - *Completed*

b. Dialysis Unit will meet the National Benchmarks for medication scanning compliance for three consecutive months at 97%

## Recommendation 5

The Wilmington VA Medical Center Director ensures that a process is developed to notify Hemodialysis Unit staff of changes in hemodialysis orders and monitors compliance.

Concur.

Target date for completion: October 31, 2018

### Director Comments

The following actions are being implemented and compliance monitored:

a. Hemodialysis orders will print to a designated printer in the hemodialysis unit to alert hemodialysis staff of new orders. – *Complete*

b**.** 90% of STAT orders will be reviewed and verified in CPRS within one hour of entry compliance for three consecutive months at 90%

## Recommendation 6

The Wilmington VA Medical Center Director ensures that the Hemodialysis Unit managers adopt and provide documentation programs that will enable accuracy and efficiency in record keeping and monitors compliance.

Concur.

Target date for completion: FY19 (pending procurement)

### Director Comments

The following actions are being implemented and compliance monitored:

a. We will do 50 chart audits a month for 90% Compliance for three consecutive months

b. Dialysis Leadership evaluated and selected a dialysis software package that will streamline and approve the accuracy of the patient record

c. Education for 100% of staff will co-inside with Software implementation

d. Equipment purchase request will be completed and submitted

## Recommendation 7

The Wilmington VA Medical Center Director ensures that the Code Blue members utilize the Code Blue Flow Sheet, and that Rapid Response and Code Blue events are documented and presented monthly to the Facility's Health Care Delivery Council.

Concur.

Target date for completion: July 31, 2018 and ongoing reporting

### Director Comments

The following actions are being implemented and compliance monitored:

a. Process for code blue and RRT documentation will be updated to ensure timely and accurate completion and follow up

b. 100% of Code Blue Responses will have completed documentation

c. 100% of RRT Responses will have completed documentation

d. 100% of Code Blue and RRT Responses will be reviewed in Health Care Delivery Council and reflected in the minutes

## Recommendation 8

The Wilmington VA Medical Center Director ensures that the Education Department conducts unannounced mock code training twice a year in the Hemodialysis Unit with debriefings and monitors improvement and compliance.

Concur.

Target date for completion: July 31, 2018

### Director Comments

The Dialysis Unit will have a minimum of 2 Mock Code Exercises each FY. - *This training has been completed for FY18.*

## Recommendation 9

The Wilmington VA Medical Center Director resolves the conflict between Hemodialysis Unit staff to provide a work place environment where staff collaborates to reduce the risk of adverse patient outcomes.

Concur.

Target date for completion: July 31, 2018 and ongoing

### Director Comments

This has been a priority for the new Wilmington VAMC leadership team. The facility has recruited a new Associate Director for Patient Care Services, and a new Associate Chief Nurse providing leadership to the nurse manager and the entire HD team. We are recruiting for a new Chief of Staff; we have established service meetings and a comprehensive multidisciplinary team to address Veteran care needs, identify barriers to quality and to work in a respectful and collaborative manner to improve Veteran care, Veteran outcomes and employee effectiveness. In September of 2017 we reduced the census, adjusted the HD scheduling to 3 days a week to give staff the opportunity to update policies, participate in training and work on building better team cohesiveness. Nursing staff has established a daily huddle. Medical Center leadership and nursing leadership have been conducting "rounds" to get periodic updates from staff on progress as well as continued challenges. A specialist from our Quality Management Department is working closely with the nurse manager and staff to review data and help the team with process improvement priorities. We are currently recruiting for a full-time nephrologist and a final determination of the medical leadership for the HD unit will be made upon selection of a candidate. We have additional outside nursing and SME in HD scheduled to visit and review the program and provide recommendations on how we can continuously improve care and communications. Lastly, we have engaged the National Office for Organizational Development to work with us in fostering an environment of civility, respect and engagement.

a. EEO Diversity and Inclusion Manager is conducting team building conflict resolution and communication enhancement sessions with the dialysis staff.

b. Team Building sessions are being conducted for Nursing Staff

c. Team Building sessions are being conducted for Dialysis Medical Staff

d. Team Building sessions are being conducted for all Dialysis staff

e. Dialysis Team will identify three new goals for FY19 to improve staff satisfaction and Veteran satisfaction

## Recommendation 10

The Wilmington VA Medical Center Director evaluates the Facility's education and training program to ensure that Safety Assessment Code assignments and Root Cause Analyses are conducted in accordance with Veterans Health Administration Handbook 1050.01, *National Patient Safety Improvement*.

Concur.

Target date for completion: N/A

### Director Comments

Wilmington VAMC has procedures in place to evaluate training and compliance with Veterans Health Administration Handbook 1050.01, *National Patient Safety Improvement*. With respect to this OIG report a root cause analysis was not conducted because there was an active criminal investigation open for possible wrong doing related to death by suicide and possible homicide. VHA Directive 1050.01 VHA National Patient Safety Improvement Handbook advises that Root Cause Analyses should be halted if criminal acts or wrong doing is suspected. It was possible to initiate an RCA in August; however, several reviews were already in process that were addressing documentation, updating policies, leadership and improving practices to create a safer and more respectful environment of care. Our reviews did indicate there were both systemic and performance components and both were being addressed by active work groups and leadership. A clinical quality review was completed and subsequent clinical external peer reviews for both providers and nursing staff were initiated to evaluate the clinical quality of care by clinicians with comparable education, training, experience, licensure, and privileges/scope of practice as defined in VHA Directive 2010-025 Peer Review for Quality Management. Recommendations from the peer reviews were then addressed appropriately. For the Veteran's death, the Patient Safety Manager was actively engaged throughout the process however an ePIR (electronic Patient Incident Report) for the event was not submitted. Going forward all patient, visitor, and staff safety event will be entered into the new JPRS and SAC scores will be assigned.

The following actions will be implemented to monitor compliance.

a. 100% of staff will be training in the use of JPRS and events to be entered

b. PSM will be trained in JPRS and SAC scoring

c. All patient safety events are reported to the Director in "Morning Report" meeting

## Recommendation 11

The Wilmington VA Medical Center Director continues efforts to recruit and hire for Hemodialysis Unit staff vacancies, and ensures that, until optimal staffing is achieved, alternate methods are consistently available to meet patient care needs.

Concur.

Target date for completion: October 9, 2017

### Director Comments

We have achieved and sustained optimal staffing since October 9, 2017 when we reduced the dialysis unit census from 36 to 16. We are currently recruiting for a medical staff assistant and

for a nephrologist. Census will be maintained at a maximum of 20 until we have adequate space along with staff to insure high quality clinical care for this medically complex population. Staffing methodology is in progress utilizing available evidence/recognized nephrology nursing and medical organization recommendations.

The following actions will be implemented to monitor compliance:

a. Monitor monthly census for 3 months of 90% compliance

b. Monitor total monthly overtime for 3 months for 90% compliance in improved staff utilization

## Recommendation 12

The Wilmington VA Medical Center Director ensures that the Chief of Medicine establishes a safe discharge process for hemodialysis patients including those who receive not routinely scheduled medications during hemodialysis and monitors compliance.

Concur.

Target date for completion: October 31, 2018

### Director Comments

The following actions have been implemented and monitoring for compliance:

a. A SOP defining discharge criteria for hemodialysis patients from the dialysis unit following treatment was developed, approved, and implemented inclusive of training staff. – *Complete.*

b. 90% of dialysis discharges will be completed within the criteria established in the Dialysis Discharge SOP (N=50 discharges/month) until compliance is met for 3 consecutive months.

## Recommendation 13

The Wilmington VA Medical Center Director ensures Facility policies are consistent with Veterans Health Administration Handbook 1042.01, *Criteria and Standards for VA Dialysis Programs*, and Hemodialysis Unit providers and staff adhere to the policies.

Concur.

Target date for completion: October 31, 2018

### Director Comments

The interim dialysis program medical director, in conjunction with the dialysis nurse manager, established new and updated existing comprehensive policies and procedures for the dialysis

program service that are consistent with Veterans Health Administration Handbook 1042.0. These policies and procedures were subsequently sent to external expert for review of appropriate and accurate content.

The following actions will be implemented to monitor compliance:

a. 100% of Dialysis Medical Staff will receive education on new policies and documented.

b. 100% of Dialysis Medical Staff will receive education on updated policy and documented.

c. 100% of Dialysis Nursing Staff will receive education on new policies and documented.

d. 100% of Dialysis Nursing Staff will receive education on updated policy and documented

## Recommendation 14

The Wilmington VA Medical Center Director ensures that the Facility Police Department act in alignment with VA Directive 0730 and Title 38 Code of Federal Regulations and takes actions as appropriate.

Concur.

Target date for completion: October 31, 2018

### Director Comments

The facility has reviewed the findings of the OIG recommendations and facilities policies. We have implemented the following:

a. Create tracking tool to monitor daily rounds. – *Completed.*

b. Monitor for 3 months of 90% compliance

c. Train 100% of staff on VA Dir. 0730 and Title 38 Code Federal Regulations. – *Complete*.

# OIG Contact and Staff Acknowledgments

| | |
|---|---|
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