Hanna Lin:

Hello. You are listening to a podcast by the Department of Veterans Affairs, Office of Inspector General. My name is Hanna Lin, a health systems specialist with the OIG. Today, I am speaking with Tanya Oberle, a fellow health systems specialist about a healthcare inspection report on deficiencies in pharmacy and nursing processes at the Southeast Louisiana Veterans Health Care System in New Orleans that may have contributed to the death of a patient. Ultimately, the OIG was unable to determine the true cause of death given the patient’s medical history and other mitigating factors; however, several recommendations were brought forward to address policy and process deficiencies identified during the inspection.

Tanya is going to walk us through how the situation developed, the health care system’s response, and the recommendations made to avoid something like this happening again.

Tanya, tell us about the patient and what occurred?

Tanya Oberle:

Hanna, thank you for this opportunity and I hope our listeners gain valuable insight from this discussion. Here, we have a patient with multiple known medical problems including diabetes mellitus, coronary artery bypass surgery, chronic lymphocytic leukemia, and recent unintentional weight loss of more than 40 pounds who had been transferred from the facility’s medicine unit to the intensive care unit or ICU following a code blue.

Hanna Lin:

Can you explain a code blue to our listeners?

Tanya Oberle:

Of course—a code blue is a medical emergency and call for medical personnel and equipment to attempt to resuscitate a patient in cardiac arrest or respiratory failure. And sadly, in this patient’s case, after
another code blue later that morning in the ICU, the patient’s spouse decided against further resuscitation efforts, and the patient died.

After the patient’s death, the VA Police alerted the OIG’s Office of Investigation that the patient’s fentanyl medication, a controlled substance, was lost. However, during the investigation it was determined the fentanyl medication was not lost, but rather mislabeled. The OIG then opened a healthcare inspection to evaluate patient safety concerns, specifically for the improper sending of a medication label and mislabeling of a medication, and failure of the ICU staff to follow medication administration policies and procedures.

Hanna Lin:

Mislabeled medication? Explain to our listeners how this happened?

Tanya Oberle:

In this case, the patient’s treatment included the administration of fentanyl and norepinephrine medication intravenously or by IV. Fentanyl is a synthetic opioid, like morphine but 50 to 100 times stronger, and was being used to sedate the patient, who was on a ventilator. The norepinephrine was helping increase the patient’s heart rate.

After transfer to the ICU, a nurse attempted to document the patient’s medications but was unable to scan the bar code label on the fentanyl IV bag. The ICU contacted the pharmacy and requested a new label. The pharmacy sent a new label for the norepinephrine IV bag not the fentanyl IV bag through the facility’s pneumatic tube system like what banks use for drive-through transactions.

For approximately three hours, the patient received fentanyl although the medication was labeled norepinephrine.

Hanna Lin:

What could happen if you mistook fentanyl for norepinephrine?

Tanya Oberle:

A patient who is given too much fentanyl could experience slowed, shallow, or difficulty breathing, severe sleepiness, or not be able to wake up. An overdose of fentanyl can cause death. Norepinephrine is like adrenaline and is used to treat low blood pressure. These two medications have very different functions, and if you receive them at the wrong dose or if the medication is not given, a patient could experience an adverse event, including death.

Hanna Lin:
Is it routine to send an unaffixed IV medication label?

Tanya Oberle:

No. In fact, the OIG concluded the delivery of an unaffixed label did not comply with VA policy. Many IV medications are mixed or compounded by pharmacists to make a final drug that meets the patient’s individual needs. These medications are called compounded sterile preparations. All compounded sterile preparations, including the patient’s fentanyl, must meet standards set by the United States Pharmacopeia, specifically that all compounded sterile preparations are to be inspected for accuracy of ingredients, packaging, and labeling before they are prepared and delivered. VA requires that a clinical pharmacist prepare and check the contents and label for accuracy and that the label must be directly applied to the medication before delivering it. In this case, sending an unaffixed IV label through the pneumatic tube system was against VHA policy.

Hanna Lin:

Ok, so it’s against policy to send an unaffixed medication label? Why was the label even requested?

Tanya Oberle:

Healthcare facilities deploy technology to manage patient care and stop medication errors. Technology systems like scannable barcodes help ensure accuracy and verify a patient’s medication orders prior to administering.

This patient had an active order for fentanyl and other medications prior to being transferred into the ICU. Upon arrival, the medications were immediately continued; however, the medication orders had not been updated in the system to reflect the patient’s relocation to the ICU. This created a situation where the ICU nurse was unable to successfully scan the medicine, and therefore, requested a new label. Now, staff would later update the system to reflect the patient’s transfer to the ICU but well after the patient was administered mislabeled medication.

This breakdown in process and policy is where the OIG focused its inspection that produced recommendations related to labeling and giving medicine, complying with VA policy on high-risk medications, securing controlled substances, submitting safety reports, deploying the peer review process, and completing an institutional disclosure.

Hanna Lin:

What were some of the deficiencies identified in the inspection that led those recommendations?

Tanya Oberle:
To start, as I’ve previously shared, the sending of the unaffixed label and ICU’s mislabeling of the fentanyl medication did not comply with VA policy. Further, the ICU nursing staff failed to verify the patient’s five rights of medication administration, which are right patient, right dose, right route (how the medication enters the body), right time, and right medication.

The OIG also determined that the ICU nursing staff failed to follow the physician’s orders by administering the fentanyl at a higher rate than was ordered, not adjusting the infusion rate as indicated by the patient’s assessed sedation scale, and not adjusting the norepinephrine infusion rate as ordered by the physician.

Fentanyl and norepinephrine require a double-check by two licensed personnel before the medication can be administered. In addition, fentanyl, which is a high-risk, controlled substance medication, requires a second verifier for rate changes and frequent documentation of a patient’s response.

The OIG found completed documentation for the initial administration and second verification for the norepinephrine. The OIG, however, did not find documentation of the initial administration of fentanyl, second verification for administration of fentanyl, second verification for each fentanyl rate change, or reassessment following rate change to either norepinephrine or fentanyl. The OIG concluded ICU nursing staff did not follow policy, and the lack of complete documentation did not ensure an accurate record of the medications administered.

In addition, the fentanyl bag was not securely attached to the IV pole. Securing the fentanyl in a locked box may have prevented the ICU from placing the norepinephrine label over the fentanyl label.

Also, according to the inspection, a Joint Patient Safety Report was not filed addressing the mislabeling of the fentanyl bag was not filed. In fact, the mislabeling was not discovered until three days after the patient’s death. The OIG concluded that facility staff failed to report the mislabeling as a medication error.

Hanna Lin:

Why is this important?

Tanya Oberle:

Well, had the facility reported it, key clinical staff involved in the mislabeling of the medication would have been included in the peer review, a process of evaluating your colleagues' work in order to ensure that standards of care were met.
Hanna Lin:

Those are serious deficiencies. Was the patient’s family made aware of these issues?

Tanya Oberle:

At the time of the event, the healthcare facility reviewed the case and did not believe an institutional disclosure was warranted as the medication error was not thought to have caused the patient’s death in the medical opinion of the treating team. However, it was later determined that a disclosure would be completed as it is believed the potential was there to cause harm to the patient.

Disclosures inform patients and their families about all clinically significant facts related to the harm caused by VA medical care and options to pursue potential compensation. When institutional disclosures are not completed, patients may inadvertently be denied their rights. A private meeting will be scheduled with the family to discuss the adverse events and inform the family of their rights, including the right to file a tort claim.

Hanna Lin:

What happens next?

Tanya Oberle:

The VA will review the OIG’s recommendations and decide whether to implement them or not. Every 90 days the OIG will follow up with the VA and obtain a current status. The OIG tracks all recommendations to closure.

Hanna Lin:

Tanya, thank you for your time today. This has been a great discussion and I believe it helped our listeners better understand the importance of patient safety and the procedures that medical professionals must follow to ensure patient safety and their rights. If you would like more information about this healthcare inspection, please visit va.gov/oig and enter VA OIG 19-07854-272 in the search box.

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