Dilantin: Pharmacy/nurse errors lead to fatal ADE

**Snapshot:** Make sure that Dilantin is prepared in your pharmacy, that the drug’s concentration and administration rate are standardized, and that nurses check physician orders before administering it. You otherwise may face the same problems Alameda (Calif.) County Medical Center did: a patient fatality, a state fine, numerous potential RFIs, and embarrassing publicity. Below:

- Specific pharmacy and nursing errors at the hospital, the hospital’s corrections and lessons learned.
- Read the actual Statement of Deficiencies and Plan of Correction.

Dilantin is a high-alert drug rife with ADE potential. Failure to perform first-dose review, prepare the drug in the pharmacy, or administer it according to a doctor’s order may lead to patient death, government fines and potential RFIs, as Alameda (Calif.) County Medical Center’s Highland Hospital, 236 beds) recently found out.

A patient at the hospital died Oct. 7, 2009 after a nurse administered 1 gram of Dilantin by intravenous push within 5 minutes. The drug “should have been given slowly over an hour as ordered by the physician,” according to the California Dept. of Public Health Statement of Deficiencies. The Immediate Jeopardy condition cost the medical center $75,000 in an administrative fine “noncompliance with licensing requirements (that) has caused, or was likely to cause, serious injury or death to patients.”

**Here’s what happened**

A patient with a history of hypertension and end stage renal disease, identified by the state as Patient 14, was admitted to the hospital Oct. 5 for sudden shortness of breath and chest pain. While undergoing hemodialysis two days later, the patient experienced seizures, high blood pressure and lung congestion that required intubation and a transfer to the ICU. A physician’s order specifically stated to “give 1 gm (gram) Dilantin over 1 hr (hour). IV (into the blood through a vein access), don’t push quickly,” the Statement of Deficiencies says.

The nurse pushed the full 1 gram dose into the patient’s vein in 5 minutes.

Six minutes after the Dilantin was given, the Statement continues, “Code Blue was called in the intensive care unit” because the patient developed bradychardia (heart rate less than 60 per minute) with PEA (pulse less electrical activity of the heart). The resuscitation efforts failed….there was no heart activity. Patient 14 died at 10:24 p.m.”

**Lessons learned and best practices**

Aside from the fact that a drug intended to be administered over one hour was instead administered in five minutes, multiple errors occurred during this incident, as the Statement of Deficiencies points out and medication safety and accreditation experts tell the Medication Safety Roundtable. Some of these are likely RFIs. Best practices ould have been used to avoid most. Here is a rundown:

- **Mix all compounded IVs, high-risk drugs in particular, in the pharmacy.** Failure to do so is a violation of Joint Commission standard MM.05.01.07, EP 1 (A pharmacist, or pharmacy staff under the supervision of a pharmacist, compunds or admixes all compounded sterile preparations except in urgent situations...). The hospital pharmacy instead had instructed the nurse to mix four ampoules of Dilantin 250 mg in a 250 ml bag of saline.

  "If the pharmacy is open 24 hours, Dilantin should only be stocked in the pharmacy and the pharmacy should prepare all IV Dilantin solutions," says Phil Klein, managing consultant, Pharmacy Healthcare Solutions, Solano Beach, Calif. "If the pharmacy is not open 24 hours, the pharmacist should be called in to mix the drug or if that is not possible, the drug should be stocked in the afterhours storage locations with the appropriate instructions, labels, auxiliary labels, dates and IV bags, and prepared the order be double checked by the nurse supervisor and..."
labels, drug and IV bag, and require the order be double-checked by the nurse supervisor and
the nurse.”

- **Perform first-order review.** This basic medication safety requirement can be found in Joint
Commission standard MM.05.01.01, EP1 (a pharmacist reviews all medication orders or
prescriptions). “It was identified that the order written... was not reviewed by pharmacy...,” the
medical center says in its Plan of Correction. The Statement of Deficiencies notes that “during an
interview on 11/19/09 at 9:30 a.m., the Director of Pharmacy acknowledged that Dilantin order
for Patient 14 was not reviewed in advance of administration as required by the [hospital's own]
current policy and procedure on medication administration. There was no evidence that the
pharmacy received and reviewed the scanned physician’s order for Dilantin....”

- **Review and follow the medication order.** The nurse who administered the Dilantin “failed
to review and follow the physician’s order to give Dilantin over an hour,” the Statement of
Deficiencies says. This is a violation of MM.05.01.07 (Medications are prepared and administered
in accordance with the orders of a licensed independent practitioner responsible for the
patient’s care...).

- **Standardize drug concentration and administration rate.** This should be true for all IV drugs,
not just Dilantin, says Klein, who adds that “their concentration, total volume and rate of
administration should be readily available for reference on the patient care units.” Failure to
standardize drug concentrations violates MM.02.01.01, EP 6 (The hospital standardizes and
limits the number of drug concentrations available to meet patient care needs).

“There should be a hospital-approved list, through the P&T committee, that identifies the IV
medications acceptable for use in the hospital, who is authorized to administer them, the
dilation that is required, the rate at which it can be administered, and any other cautions,” says
Patricia Kienle, director of accreditation and medication safety for Cardinal Health. She adds that
dissemination of the information “cannot be a stealth process” and should be formalized into
policy that is regularly updated, with the date of the last update visible.

In the case at Alameda County Medical Center, the Statement of Deficiencies shows confusion
between the nurse and the pharmacist involved as to how the Dilantin was to have been
administered, each providing the state surveyor with a different version of what happened. The
nurse told the surveyor “she called the pharmacy and requested the pharmacy to mix Dilantin ....
the pharmacist instructed her to get ampoules of Dilantin 250 mg from the Pyxis and give the
medication IV, without any recommendation on how to give it.”

‘It shouldn’t have happened. I shouldn’t have listened to the pharmacist, and it didn’t sound
right to give four vials IV push. I should have refused,’” the nurse, who the medical center says
has since been placed on Do Not Return, told the surveyor.

The pharmacist told the surveyor the she instructed the nurse to mix the four Dilantin ampoules
in a 250 mg. bag of saline and use a 22 micron filter when administering it. The pharmacist,
however, “failed to indicate the rate of administration,” the Statement of Deficiencies says.

Calls to the hospital’s chief quality officer, director of pharmacy, and the office of the director of nursing
from The Roundtable were not returned.

Corrective actions

Among the steps Alameda County Medical Center’s says it will take to correct the deficiencies are the
following:

- Add Dilantin to its high-risk medication policy and re-educate nurses.
- All Dilantin will now be mixed in the pharmacy.
- Remove Dilantin from Pyxis ADCs, since it will now always be prepared in the pharmacy.
- Ensure that pharmacy will review Dilantin orders before administration.
- The pharmacy will label Dilantin with the drug name, dose, route and administration rate
- ICU will conduct 12-hour chart checks for nursing to check all medication administration records
  (MAR) for complete drug information, including drug, dose, route and rate of administration, as
  well as compare the MAR to the physician’s orders. Nursing will review 30 charts each month to
do the same.

**Joint Commission compliance:** Proper selection, preparation, review and administration of
Dilantin address Joint Commission standards MM.02.01.01, EP 6 (The hospital standardizes and
limits the number of drug concentrations available to meet patient care needs);
MM.05.01.01, EP1 (a pharmacist reviews all medication orders or prescriptions); and
MM.05.01.07 (Medications are prepared and administered in accordance with the orders of a
licensed independent practitioner responsible for the patient’s care...), in particular EP 1 (A
pharmacist, or pharmacy staff under the supervision of a pharmacist, compunds or admixes
all compounded sterile preparations except in urgent situations...).
For more best practices on preparation of medications, visit the Preparing & Dispensing library.

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