Oregon patient safety Commission

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Confusing Labels

The Patient Safety Commission recently received a report from an Oregon hospital about confusion in dosing of a Hepatitis B immunoglobulin. The confusion came from a labeling difference between the box the medication came in, and the vial containing the medication. Adding to the confusion was a label on the side of the vial listing the actual strength of the medication.

Why we are sharing this information: The mis-dosage in this case involved an overdose of immunoglobulin, a medication given monthly to liver transplant patients to protect against Hepatitis B. After their surgeries, liver transplant patients often return to their home communities for continued care, where physicians and pharmacists may be less familiar with the variation in strengths of medications coming from the manufacturer. These variations in the strengths can also occur with other medications derived from plasma proteins, such as those given for hemophilia. While the adverse event described here posed no risk to the patient, the circumstances leading to the error could result in an under-dosing, which would present risks.

What happened: A regular patient came in for her monthly dose of hepatitis B immunoglobulin, required following a liver transplant to decrease the risk of hepatitis. The on-call pharmacist, unaware of a recent change in the supplier of the medication and not present for the staff briefing on the change and its implications for patient safety, entered the drug in to the Pharmacy computer system incorrectly. The dosing of the drug was based on the brown highlighted concentration on the front of the box and vial (> 312 IU/mL).

What the pharmacist did not notice, was the small, non-highlighted text on the side of the vial stating the correct potency (concentration) of 570 IU/mL – written sideways.

In addition, the IV label printed the correct dose (20,000 units), however, the volume (mLs) on the label was incorrect. Upon investigation it was discovered that the new drug was also entered incorrectly in the drug database resulting in an incorrect volume.

The medication was mixed by the IV Technician and checked by another Pharmacist all without noticing the correct vial potency (concentration) on the side of the vial.

The final, and incorrect, infusion the patient received was 33,000 units versus the correct 20,000 units.

Additional Information: Hepatitis B immunoglobulin is used to protect against Hepatitis B in patients who have been exposed to the virus and in liver transplant patients. The process for making the immunoglobulin results in batches of the medication with different strengths. So,

while a manufacturer can assure a minimum strength for all batches, the strengths of each individual batch or lot may be different and is noted in a separate label from the general label on the vials. The manufacture notes the following dose calculation information: *The volume of each 20,000 IU dose should be calculated from the measured potency of the particular lot of HepaGam B as stamped on the vial label.*[2]

Unlike Hepatitis A (previously called infectious hepatitis), the Hepatitis B virus can cause a chronic illness that increases a patient's risk for liver disease and liver cancer. There are several Hepatitis B immunoglobulin products available for patients exposed to Hepatitis B, but currently there is only one that carries the FDA approval for use in liver transplant patients. The new indication is what prompted the change in supplier for the pharmacy in this case. The other immunoglobulins can be and have been used in liver transplant patients, but their use is considered "off-label" because they lack FDA approval for patients who have received liver transplants.

Findings:

- Staff briefings typically do not include resource or on-call pharmacists and pharmacy technicians. Due to sometimes-long absences, email notices are often missed by on-call pharmacists and pharmacy technicians.
- The change in the strength was displayed correctly and clearly in the computer system, but the incorrect volume was missed, which resulted in an inaccurate dose.
- Because the initial basis for the calculating the dose was wrong, the pharmacist's double check of the IV infusion by the pharmacy technician did not pick up the error.
- Because the label on the box of the new immunoglobulin read the same as the previous immunoglobulin, the pharmacists missed the small print off to the side on the box and on the vial itself.

Recommendations:

- Report labeling problems that resulted in the adverse event to USP-ISMP Medication Errors Reporting Program.
- Change computer system to clearly note volume as well as strength.
- Redesign computer generated labels to clearly note volume and strength.
- Add alert to emphasize volume in the computer system.
- Review other similar medications to determine if changes are needed to computer system for other medications.
- Develop procedure for up-dating resource and on-call pharmacists and pharmacy techs when patient safety issues arise.
- Revise "double check" procedures to include independent verification with all high alert medications.

Contact us!

If your hospital has observations, or lessons learned that could improve patient safety, please email or call Leslie Ray at 503.224.9227. In addition, we can connect you to other experts willing to analyze your particular situation. All information is confidential.