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ISMP

Long-Term Care Advise ERR™

Educating the Healthcare Community About Safe Medication Practices

Errors due to the presentation of results on Accu-Chek Inform II and possibly other glucometers

Glucose testing is one of the most frequent point-of-care (POC) tests performed in healthcare facilities.[1] While POC glucose testing offers immediate results that can be used to make important clinical decisions about the treatment of hypo- or hyperglycemia, errors can occur at any point in the testing process. For example, earlier studies have found that the most common types of errors associated with POC glucose testing are related to delays in testing due to the unavailability of trained staff[2] and a failure to positively identify patients prior to testing.[3] In the latter case, a study in a neonatal unit showed that staff failed to confirm two patient identifiers for 45% of the POC tests performed.[3] Other factors that can affect POC glucose test results include hematocrit, ascorbic acid levels,[4] and other sugars such as maltose,[5] including maltose-containing medications or parenteral solutions.[6,7]

VHA Study on Misinterpretation of Glucose Display Results

In a more recent study conducted by the Veterans Health Administration (VHA),[8] a different type of error was described. The study was conducted in response to multiple adverse events reported to the US Food and Drug Administration (FDA) since 2010. These events involved mistakes in interpreting patients' blood glucose levels in relation to how the results were displayed on some glucometer screens, including **ACCU-CHEK Inform** (no longer available from the manufacturer) and **ACCU-CHEK Inform II** (Roche Diagnostics), a POC glucometer commonly used by the VHA. In the events reported to FDA, practitioners misinterpreted the results on the glucometers when the blood glucose was displayed using an out-of-range abbreviation, such as RR LO (out of reportable range; low limit) or CR LO (out of critical range; low limit), and/or when numeric alarm codes (e.g., W-510) were displayed in a pop-up message. One error occurred when CR LO was misinterpreted as a high blood glucose reading, and insulin was incorrectly administered to the patient.[9] Two other events occurring within 3 months of each other involved the abbreviation RR LO, which was also misinterpreted as a high blood glucose reading.[10,11] Insulin was incorrectly administered to both patients, one of whom died. In the fatal event, the practitioner expected a numeric blood sugar value to appear on the results screen, so the numeric portion of the alarm code, W-510 (**Figure 1**), was presumed to be the patient's blood glucose value.[11]

Figure 1. Accu-Chek Inform II glucometer displays the blood glucose with an abbreviation, RR LO (out of reportable range; low limit) and an alarm code, W-510 Out of Reportable Range, below the abbreviation. The "510" in the alarm code has been mistaken as the blood glucose value, leading to the incorrect administration of insulin (source of photo: VHA[8]).

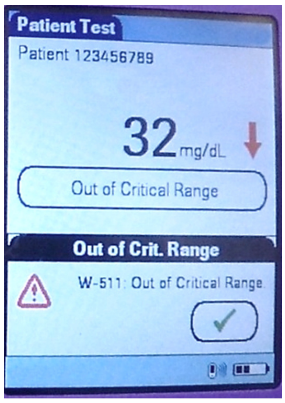

Figure 2. Accu-Chek Inform II glucometer displays the blood glucose as a numeric value, which is the expected format, along with an alarm code of W-511 Out of Critical Range (source of photo: VHA[8]).

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check it out

To avoid misinterpretation of blood glucose results on POC testing glucometers and incorrect treatment decisions, consider the following recommendations:

If you use Accu-Chek Inform II glucometers

- Set the reportable range to match the entire measurement range of the device (10 mg/dL to 600 mg/dL) to prevent the display of RR LO or RR HI abbreviations.[8]
- Configure the critical results to display as a numeric value to prevent the display of CR LO or CR HI abbreviations.[8] (This setting and the one above match the default configurations documented by the manufacturer.)
- During educational programs and simulation training, include a description of hypo- and hyperglycemia values, out-of-range abbreviations, obscure alarm codes, and alert language that may appear on the results screen, their intended meaning, and the associated risk of confusion.

If you use another type of glucometer

- Evaluate the display of blood glucose results on glucometers used in the facility to determine if they contain potentially confusing language, terminology, alarm codes, or abbreviations. Whenever possible, configure glucometers to display the actual numeric blood glucose value rather than out-of-range codes and confusing alarm messages. If necessary, contact the manufacturer, or consider changing to a different manufacturer's glucometer that allows such a configuration. Alert and educate

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The Accu-Chek Inform II can display critical blood glucose levels 6 different ways depending on glucometer configuration. For example, for a blood glucose value of 32 mg/dL, 4 of the 6 configurations will display an out-of-range abbreviation (CR LO or RR LO)—2 of which will include a numeric alarm code. **Figure 1** (page 1) provides an example of 1 of these 4 configurations, RR LO with alarm code W-510. Two of the 6 configurations will display a numeric blood glucose value (e.g., 32 mg/dL), 1 of which will include a numeric alarm code. **Figure 2** (page 1) provides an example of 1 of these 2 configurations with alarm code W-511. Thus, the VHA conducted a study to determine the safest way to configure the Accu-Chek Inform II glucometers that would lead to the fewest treatment errors.[8]

The 6 different ways of displaying blood glucose results were first evaluated against 7 usability principles related to language, expectations, error codes, memory load, word meanings, terminology, and abbreviations. All 6 configurations violated at least 1 usability principle. It was thought a low blood glucose value displayed as RR LO, along with a numeric alarm code (**Figure 1**), would result in the most treatment errors given that it violated all 7 usability principles; whereas a blood glucose displayed as a numeric value, along with a numeric alarm code (**Figure 2**), would result in fewer treatment errors, as it violated only 3 usability principles. Thus, these 2 configurations were tested.

Using a computer-based simulation at two different Veterans Affairs (VA) medical centers, a total of 66 nurses (86% were registered nurses and 14% were licensed practical nurses), who were trained and experienced with using the Accu-Chek Inform II, were provided with clinical scenarios of hospitalized patients with diabetes. For each scenario, blood glucose values were displayed using the 2 identified configurations. The nurses were then asked how they would interpret these results displayed on the glucometer and, based on this interpretation, how they would treat the simulated patients. Although technicians and nursing assistants are also common users of the glucometers, they were not included as participants in the study because interpretation of the results and treatment decisions were outside their scope of practice. Most of the participating nurses used the Accu-Chek Inform II glucometers daily, although only half of the nurses received prior education regarding the meaning of RR LO.

Study Results

Testing for *treatment decision* errors revealed 1 in 10 nurses misunderstood the abbreviation RR LO and failed to follow policy when they chose not to administer juice or 50% dextrose to the simulated hypoglycemic patient. In fact, almost half of the nurses who misinterpreted the RR LO abbreviation chose to administer additional insulin to the simulated patient. Furthermore, some of the nurses (6.7%) who had prior training and exposure to the RR LO reading made a treatment decision error. None of the nurses made a treatment decision mistake when the glucometer displayed the numeric blood glucose value (32 mg/dL) instead of the abbreviation.

When evaluating the nurses' *interpretation* of the results displayed on the screen, 6-7% of all participants made an error with either configuration. Of the nurses who interpreted the numeric blood glucose value incorrectly, most recognized the 32 mg/dL value was low and made the correct treatment decision; however, they did not think the value was *critically low*. According to a knowledge survey conducted within the study, 99% of all participants knew 32 mg/dL was a critically low blood glucose. Nonetheless, the message "Out of Critical Range" could have been misinterpreted to mean that the value was **not** *critically low*. Most of the nurses who misinterpreted the RR LO abbreviation decided that it was a *critically high* blood glucose value because they misinterpreted the pop-up message "W-510" as a high blood sugar value. For participants who correctly interpreted both configurations, more than 75% required more time to interpret an RR LO reading than a 32 mg/dL reading.

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staff to the meaning of any alarm codes and warning messages if they must be displayed on the screen, particularly if they include numeric values.

Manufacturers and FDA

- Strongly consider the findings from the VHA study during future research and development of POC glucometers. In future upgrades, manufacturers should address the problematic heuristics associated with usability and effectiveness of the glucometers in guiding treatment decisions, including confusing language, obscure alarm codes that appear on results screens, unexpected presentation of blood glucose results as out-of-range abbreviations rather than numeric values, and over-reliance on memory regarding numeric ranges associated with the abbreviations.

SAFETY wires

Inconsistent levETIRAcetam unit dose liquid labeling. An issue we first reported in our May 2016 newsletter is back—inconsistency in the way the concentration of a drug is expressed on oral unit dose cups. The 5 mL oral levETIRAcetam solution packaged by American Health Packaging and some other companies list the drug concentration as 100 mg/mL rather than 500 mg/5 mL, as Pharmaceutical Associates and other companies do (**Figure 1**). A typical dose for initial treatment in adults is 500 mg BID. Given that this is a unit dose cup, practitioners are used to seeing the total amount of drug per total volume, "500 mg/5 mL," on cup labels. Those who fail to notice the words, "Delivers 5 mL," below

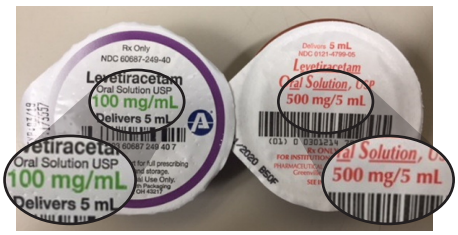

Figure 1. Oral unit dose cups of levETIRAcetam from different manufacturers do not present the concentration in a standardized format.

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Conclusion

The VHA study results confirmed that the display of a numeric blood glucose value eliminated potentially life-threatening treatment decision errors caused by confusing abbreviations. The results also suggest that prior training can help but cannot eliminate the risk of errors when out-of-range abbreviations are displayed. The study also revealed that nurses were faster at interpreting numeric blood glucose readings compared to out-of-range abbreviations, which can facilitate rapid treatment decisions for patients experiencing critically high or low blood glucose levels.[8] Although not tested in the VHA study, mistakes are also possible when the abbreviations RR HI (out of reportable range; high limit) and CR HI (out of critical range; high limit) appear on the glucometer.

To help prevent errors related to misinterpreting blood glucose results, consider the recommendations in the **check *it* out!** column, starting on page 1 in the right column.

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what's in a *Name?*

The "-sartan" name stem for ARBs

The suffix "-sartan" is a drug name stem used for angiotensin II receptor blockers (ARBs).[1] ARBs are prescription medications primarily used to treat hypertension. Some are also approved to treat heart failure or diabetic nephropathy.[2] Dosing of these agents is typically once daily, although some are occasionally dosed twice daily.[3]

There are 8 approved "-sartan" medications available in the US,[4] all available only as oral tablets. Combination products are also available in which an ARB is combined with another antihypertensive agent, most often hydro**CHLORO**thiazide (a diuretic), am**LODIP**ine (a calcium channel blocker), or both (**Table 1**, page 4).[4-6] A combination ARB product that contains hydro**CHLORO**thiazide can often be recognized by its brand name because it has the modifier "HCT" (e.g., **BENICAR HCT**, contains olmesartan [**BENICAR**] and hydro**CHLORO**thiazide). While not all combination "-sartan" products that contain hydro**CHLORO**thiazide use the HCT modifier (e.g., **HYZAAR**, contains losartan [**COZAAR**] and hydro**CHLORO**thiazide), the HCT modifier can be helpful in properly identifying most of the antihypertensive agents during medication reconciliation.

Of note, "-sartans" should never be combined with the direct renin inhibitor aliskiren (**TEKTURNA**) for residents with diabetes mellitus, and use should be avoided with angiotensin converting enzyme (ACE) inhibitors (e.g., lisinopril [**ZESTRIL**], enalapril [**VASOTEC**],

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"100 mg/mL" might assume they need to give 5 cups for a single 500 mg dose, leading to an overdose. Because healthcare facilities and pharmacies must often purchase alternative products during shortages, the US Food and Drug Administration (FDA) should not allow situations like this to exist. We recommend purchasing products that only list the amount of drug per container volume (500 mg/5 mL) or affixing an auxiliary label to clarify the container's total dose. We have notified FDA and American Health Packaging about the above concern.

Don't "hold" onto that patch! We recently received a report about a nurse who began feeling weak, lethargic, and dizzy while at work. She also had other vague symptoms that led her coworkers to believe she was having a stroke! They rushed her to an emergency department (ED) to be evaluated so she could be treated quickly if, in fact, she was having a stroke. While assessing her, the ED staff discovered that during her shift, she had removed a transdermal scopolamine patch from a resident. However, she did not discard it right away because the resident had other immediate needs. So, she held onto the patch, which got stuck to her skin, causing the scopolamine to absorb into her body. Enough of the drug must have been absorbed to cause these symptoms. The nurse was monitored for a few hours until the symptoms resolved.

Vaccine error potential with new herpes zoster vaccine. **SHINGRIX** (zoster vaccine recombinant, adjuvanted), referred to as "RZV" by the Centers for Disease Control and Prevention (CDC), was approved for use by the US Food and Drug Administration (FDA) in October 2017 to protect against shingles and postherpetic neuralgia (PHN), pain from shingles. For over a decade, the medical community has been accustomed to the storage and administration requirements of Merck's **ZOSTAVAX** (zoster vaccine live, or ZVL), the only herpes zoster vaccine on the market before Shingrix. But Shingrix and Zostavax have different storage require-

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benazepril [**LOTENSIN**]) due to an increased risk of hyperkalemia, hypotension, and nephrotoxic effects.[4] Caution should be used if residents are taking potassium supplements or medications that increase blood potassium levels, such as spironolactone and trimethoprim.

Residents who are prescribed "-sartans" should have routine monitoring of electrolytes (particularly potassium), kidney function, blood pressure, and be assessed for signs of swelling associated with angioedema. Residents may experience headache and dizziness, especially postural hypotension. Unlike ACE inhibitors, the risk of developing a cough is minimal.[5]

Table 1. List of available ARBs in the US including combination products (all are oral tablets)

Generic Name	Brand Name	Combination Medications[6]
azilsartan	Edarbi	azilsartan/chlorthalidone (Edarbyclor)
candesartan	Atacand	candesartan/hydro**CHLORO**thiazide (Atacand HCT)
eprosartan	N/A	eprosartan/hydro**CHLORO**thiazide
irbesartan	Avapro	irbesartan/hydro**CHLORO**thiazide (Avalide)
losartan	Cozaar	losartan/hydro**CHLORO**thiazide (Hyzaar)
olmesartan	Benicar	olmesartan/hydro**CHLORO**thiazide (Benicar HCT) olmesartan/am**LODIP**ine (Azor) olmesartan/am**LODIP**ine/hydro**CHLORO**thiazide (Tribenzor)
telmisartan	Micardis	telmesartan/hydro**CHLORO**thiazide (Micardis HCT) telmesartan/am**LODIP**ine (Twynsta)
valsartan	Diovan	valsartan/hydro**CHLORO**thiazide (Diovan HCT) valsartan/am**LODIP**ine (Exforge) valsartan/am**LODIP**ine/hydro**CHLORO**thiazide (Exforge HCT) valsartan/sacubitril (Entresto) valsartan/nebivolol (Byvalson)

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ments, components/diluents, and routes of administration.

GlaxoSmithKline, the manufacturer of Shingrix, has received a small number of error reports involving differences between the vaccines. Both components of the Shingrix vaccine need to be stored under refrigeration, both before and after reconstitution (see package insert for details). If either component is improperly stored in a freezer, they must be discarded. The storage requirements for Zostavax differ; the lyophilized vaccine (attenuated varicella-zoster virus) needs to be stored in a freezer, and the Merck-supplied sterile water diluent can be stored in a refrigerator or at room temperature. The product components are not interchangeable. A system needs to be employed to ensure the Shingrix lyophilized component and adjuvant suspension vials are stored with one another to reduce the risk of using a diluent from another vaccine. Finally, Shingrix is given intramuscularly, and Zostavax is given subcutaneously.

Please pass on this information to providers who manage vaccine programs or administer vaccines in your organization. Early this year, the CDC Advisory Committee on Immunization Practices published recommendations for use of herpes zoster vaccines in *Morbidity and Mortality Weekly Report (MMWR)* January 26, 2018; 67(3);103–8 (www.ismp.org/ext/120). The American Pharmacists Association (APhA) also has a table describing the differences, which can be used as a reference: www.ismp.org/ext/25.

FREE nursing CE credit available. ISMP is offering 1 hour of nursing continuing education (CE) credit covering the six issues of Long-Term Care Advise-ERR published in 2018. To obtain credit, nurses must read the prior issues and answer questions posted on our website. The CE test is now available covering the January-December 2018 issues. To obtain CE credit, visit: www.ismp.org/nursing-ce.

Special Recognition...Our 2018 Long-Term Care AdviseERR Clinical Advisory Board

Production of this peer-reviewed newsletter would not be possible without the assistance of a reliable and talented clinical advisory board. As 2018 nears an end, we want to thank each of the following members of the advisory board for their dedication to making this newsletter a valuable medication safety resource for clinicians.

Happy Holidays

from the staff and trustees at the Institute for Safe Medication Practices. We wish you joy, health, and happiness this holiday season!