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ISMP

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

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

Problem: Glucose testing is one of the most frequent point-of-care (POC) tests performed in hospitals.[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

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 due to the way 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 commonly used POC glucometer 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 incorrect administration of insulin (source of photo: VHA[8]).

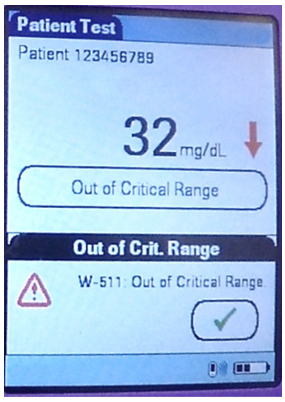

Figure 2. Accu-Chek Inform II glucometer displays the blood glucose as a numeric value, which is the expected format, along with an alarm code of W-511 Out of Critical Range (source of photo: VHA[8]).

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SAFETY briefs

Container label changes for vitamin A, D, and E. You may have noticed changes in the units of measure on the labels of over-the-counter (OTC) fat-soluble vitamins (A, D, and E) from international units (IU) to metric units of measure—micrograms (mcg) or

Figure 1. The vitamin D product from Silarx now has a metric strength (left), not an international unit strength (right). However, the label does not provide an equivalent strength in international units, even on the Supplement Facts label. For clarity, both mcg and units should be listed.

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New FDA/ISMP Fellows

ISMP welcomes two **2018-2019 FDA/ISMP Safe Medication Management Fellows**: **Avani Bhalodia**, PharmD and **Mona Hammam**, PharmD, MS. Avani and Mona will spend 6 months at ISMP and 6 months at the US Food and Drug Administration (FDA). Prior to the Fellowship, Avani was working as a hospital pharmacist at Union Hospital of Cecil County (Elkton, MD) after completing a PGY1 Pharmacy Residency at Jefferson Health (NJ). She received her PharmD from MCPHS University (Boston, MA) in 2014. Mona received her PharmD in 2012 and her MS in Drug Regulatory Affairs in 2018 from Long Island University (Brooklyn, NY). She was working as an emergency department pharmacist at New York Presbyterian Hospital, Weill Cornell Campus (New York, NY) prior to the Fellowship.

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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 configurations violated at least 1 usability principle. However, it was expected that displaying a low blood glucose value as RR LO, with a numeric alarm code (**Figure 1**, page 1), would result in the most treatment errors given that it violated all 7 usability principles, and that displaying a blood glucose as a numeric value, with a numeric alarm code (**Figure 2**, page 1) 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 registered nurses (86%) and licensed practical nurses (14%), 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 in 2 different configurations. The nurses were then asked how they would interpret these results and treat the simulated patients based on their interpretation of the results displayed on the glucometer. 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

When testing for *treatment decision* errors, 1 in 10 nurses misunderstood the abbreviation RR LO and did not choose to administer juice or 50% dextrose to the simulated hypoglycemic patient per policy. 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, misinterpreting the correct meaning of the abbreviation. 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 *interpretation* of the results displayed on the screen, 6-7% of all participants made an error with either configuration. However, most of the nurses who made errors when interpreting the numeric blood glucose value of 32 mg/dL recognized that the value was low and made the correct treatment decision but did not think the value was *critically low*. According to a knowledge survey conducted with the study, 99% of all participants knew that 32 mg/dL was a critically low blood glucose; however, the message "Out of Critical Range" could have been misinterpreted as a message 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 three-quarters required more time to interpret an RR LO reading than a 32 mg/dL reading.

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milligrams (mg). For example, aqueous vitamin D oral drops previously labeled as 400 international units per mL is now labeled as 10 mcg per mL (**Figure 1**, page 1). This change also involves OTC solid dosage forms, but it does not include prescription products such as **AQUASOL A** (water-miscible vitamin A palmitate). These changes are based on a US Food and Drug Administration (FDA) final rule, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels," published in the *Federal Register* on May 27, 2016 (www.ismp.org/ext/112, page 33748). The rule also requires listing the absolute amounts of vitamins and minerals in mg or mcg in addition to the percent daily value (% DV) on the label.

Unfortunately, most healthcare practitioners and consumers are unaware of the change, and the labeling may not be helpful in communicating the change. Only the metric measure may appear on container labels, including the Supplement Facts label (**Figure 1**, page 1), making it difficult to identify the equivalency between the previous measure in international units and the new metric measure. Still, the notice in the *Federal Register* mentions that, "The amount of vitamin D may, but is not required to, be expressed in IUs [*sic*], in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IUs [*sic*] must appear in parentheses after the declaration of the amount of vitamin D in mcg." Note that IU is used here within quotation marks, as it appears in the notice. However, ISMP discourages the use of IU. In our October 18, 2000 newsletter, we mentioned multiple cases in which IU was mistaken as IV. Given that vitamins such as E are available in oily liquids, a wrong route error is possible. Such a mistake could prove harmful, even fatal.

ISMP fully supports including the strength on container labels and Supplement Facts panels in both mcg or mg as well as international units in parentheses to allow for safe transition to metric-only labeling. Incidentally, the labeling changes do not reflect changes in strength. One mcg of vitamin D (cholecalciferol) is equal to 40 international units, so 10 mcg is the same as 400 international units on the new label. We have been in touch with the FDA Center for Food Safety

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The results confirmed that displaying a numeric blood glucose reading eliminated potentially life-threatening treatment 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 showed that nurses were faster at interpreting numeric blood glucose readings compared to out-of-range abbreviations, which can help facilitate rapid treatment decisions for patients experiencing critically high or low blood glucose levels.[8] Although not tested during the 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.

Safe Practice Recommendations: 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 out-of-range abbreviations, obscure alarm codes, and alert language that may appear on the results screen, their intended meaning, and the 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 it contains 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. Contact the manufacturer if necessary, or consider changing to a different manufacturer's glucometer that allows such a configuration. Alert 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 this study during future research and development of POC glucometers. 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, overreliance on memory regarding numeric ranges associated with the abbreviations, and other heuristics associated with usability and effectiveness of the glucometers in guiding treatment decisions should be addressed with future upgrades to the technology.

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and Applied Nutrition (CFSAN) about this situation and encourage the agency to consider a public announcement about the change. Practitioners will most likely still recommend doses in units, and this will be confusing to patients. Thus, we also hope that manufacturers will express the units in parentheses after the metric strength.

HIGH-ALERT

Peel-off label on rocuronium vial leads to confusion. During intubation of a patient in an emergency department, a nurse obtained a vial of rocuronium and noticed that the label listed the concentration as 10 mg/mL. This led to confusion regarding the total amount of drug in the vial until the nurse turned the vial and noticed that the total volume was 5 mL. Upon further inspection, she realized that the manufacturer, X-GEN Pharmaceuticals, had placed a peel-off overlay label on the vial that was intended to be used as a syringe label. Once the label was peeled off, the concentration on the underlying vial label is expressed as 50 mg/5 mL (**Figure 1**). Thankfully, no error was made during preparation of the dose, but it brings to light concerns about the labeling.

Figure 1. Both vials contain 50 mg of rocuronium in 5 mL. The red peel-off label (right) stating 10 mg/mL led to the mistaken belief that only 10 mg was in the 5 mL vial.

This is very similar to the sugammadex (**BRIDION**) vial label issue that was reported in our February 22, 2018 newsletter, which led to a change in the way Merck labeled that product. We do not want to discourage the idea of peel-off labels, but we cannot support such labels when they are affixed in a way that creates safety concerns. Peel-off labels should be included on a separate card or attached in a way that does not cover the required product label, including the total amount of the drug per total volume. We have notified both X-GEN and the US Food and Drug Administration (FDA) regarding the labeling concern. Other rocuronium manufacturers (e.g., Hospira) may have similar labeling, so be sure to inspect your supply to see if that is the case.

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Confusion when thinking about error-prone drug abbreviations

ISMP and the US Food and Drug Administration (FDA) have repeatedly cautioned practitioners about using abbreviations for drug names because they often cause confusion, potentially harmful delays in treatment, and errors. Use of the error-prone abbreviation "tPA" for the tissue plasminogen activator alteplase (**ACTIVASE**) is a prime example. In a recent error described in our July 12, 2018 newsletter (www.ismp.org/node/1179), a verbal request for "tPA" was misheard as "TPN," an abbreviation sometimes used for total parenteral nutrition (properly called parenteral nutrition [PN] today). The confusion led to a delay in therapy, which was detrimental to a stroke patient whose condition quickly deteriorated.

The abbreviation "tPA" has also been confused with "TNK" (www.ismp.org/node/392), a misused abbreviation for **TNKASE** (tenecteplase), and "TXA," an abbreviation for tranexamic acid. Although TNKase is a tissue plasminogen activator, it is not approved to treat ischemic stroke. Tranexamic acid is an antifibrinolytic agent commonly used in patients who are hemorrhaging or at risk of hemorrhage; thus, mix-ups with alteplase have been harmful.

Two recent reports submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP) describing mix-ups between alteplase and tranexamic acid are further evidence that practitioners may still think of these medications by their error-prone abbreviations, "tPA" and "TXA."

The first event involved a patient who received tranexamic acid instead of alteplase. Confusing "tPA" and "TXA" in his mind, a practitioner accidentally removed tranexamic acid instead of alteplase from an automated dispensing cabinet (ADC). The ADC had accidentally been left on critical override from the night before. Thus, the practitioner was able to remove tranexamic acid for the patient even though there was no order for the drug. After the wrong drug was administered, the error was realized. Alteplase was given to the patient, but therapy was delayed.

The second report was a good-catch event. In this case, a prescriber mentally mixed up the abbreviations "tPA" and "TXA" and prescribed tranexamic acid 87.75 mg intravenous (IV) instead of the intended alteplase for a stroke patient. However, because the dose did not seem appropriate for tranexamic acid, a pharmacist contacted the ordering physician for clarification and the order was changed to alteplase.

FDA and ISMP recommend avoiding the use of abbreviations for drug names, including "tPA" and "TXA." Instead, practitioners should refer to medications by their generic and/or brand names only. Make sure drug name abbreviations do not appear in any information technology databases, including order sets and protocols, to avoid perpetuating the use of abbreviations. Alert prescribers to the risk of mental mix-ups between drug name abbreviations, especially "tPA," "TXA," "TNK," and "TPN." Additionally, prescribers should include the drug's indication with orders to further avoid confusion.

Special Announcements

Free ISMP webinar

Join us on **November 15** for a **FREE** webinar, ***ISMP Update on Top Medication Safety Issues from 2018***. This webinar will provide an update on the top medication safety issues from 2018 based on reports to the ISMP National Medication Errors Reporting Program and will include suggested prevention and mitigation strategies. Information will also be provided to bring listeners up-to-date on certain safety standards and product changes that have occurred since the events were first reported. For details, visit: www.ismp.org/node/1168.

Free FDA webinar series

The US Food and Drug Administration's (FDA) Division of Drug Information is presenting the next in a series of **FREE** educational webinars for healthcare professionals, ***FDA Drug Topics: FDA Regulation of Color Additives in Drug Products***, on **November 6**. This webinar will give you an overview of FDA's regulation of color additives in drug products and labeling requirements. You will also learn about the two types of color additives, certified and certification exempt, and how the certification process works. Continuing education (CE) credit is available. For details, visit: www.ismp.org/ext/30, and to register for the program, visit: www.ismp.org/ext/31.

To subscribe: www.ismp.org/node/10

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Join ISMP on Tuesday evening, **December 4, 2018**, at 6:00 p.m. for the **21st Annual Cheers Awards** at **Bowlmor Anaheim** in Anaheim, CA. The gala will celebrate an impressive group of healthcare leaders who are in their own league when it comes to best practices and programs that prevent medication errors and protect patients.

Your donation or attendance at the awards dinner helps bring attention to safety advances and enables ISMP to continue the core of its lifesaving work—preventing medication errors. To make a donation or register for the dinner, please visit: www.ismp.org/cheers-awards.

Keynote Speaker:
Ana McKee, MD,
Executive Vice President and Chief Medical Officer of The Joint Commission

Lifetime Achievement Award Winner:
Timothy S. Lesar, PharmD,
Director of Clinical Services and Pharmacy Residency Director, Albany Medical Center in Albany, NY

ISMP Activities at the 2018 ASHP Midyear Meeting in Anaheim

(all at the Anaheim Convention Center [ACC North] unless otherwise specified)

Workshop

Friday, November 30 & Saturday, December 1: **Medication Safety Intensive,** Maggiano's Little Italy, 3333 Bristol Street, Costa Mesa, CA

Symposia *(preregister at www.ismp.org/ashp-activities)*

Sunday, December 2
Balancing Unpredictable Intravenous Medication Supply with the Demand for Safe Injection Practices
9:00 a.m. – 11:00 a.m.; Doors open at 8:15 a.m.
Room 225

Monday, December 3
Hidden Perioperative Medication Safety Risks: A Time for Pharmacy Involvement
11:30 a.m. – 1:00 p.m.; Doors open at 10:45 a.m.
Room 261

Tuesday, December 4
Transforming Smart Infusion Pump Safety: Are You Ready?
11:30 a.m. – 1:00 p.m.; Doors open at 10:45 a.m.
Room 258

Wednesday, December 5
Addressing Risks Associated with IV Push Medication Use in Adults
11:30 a.m. – 1:00 p.m.; Doors open at 10:45 a.m.
Room 253

Educational Sessions with ISMP Speakers

Sunday, December 2
In Your Spare Time: Addressing Medication Safety Practices Without a Dedicated Medication Safety Practitioner
3:30 p.m. – 4:30 p.m.
Room 210b

Monday, December 3
Three's Good Company: Three Strategies for Improving Safety Through Effective Event Response
4:00 p.m. – 5:15 p.m.
Room 303b

Tuesday, December 4
Strategies to Eliminate Errors in IV Compounding
(Live Webinar)
5:45 a.m. – 7:45 a.m.
Hilton Anaheim

Wednesday, December 5
ISMP Medication Safety Update for 2019
8:00 a.m. – 9:30 a.m.
Room 154

Visit ISMP at www.ismp.org and Exhibit Booth #151