

# Nurse AdviseERR®

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 hospitals.<sup>1</sup> 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<sup>2</sup> and a failure to positively identify patients prior to testing.<sup>3</sup> 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.<sup>3</sup> Other factors that can affect POC glucose test results include hematocrit, ascorbic acid levels,<sup>4</sup> and other sugars such as maltose,<sup>5</sup> including maltose-containing medications or parenteral solutions.<sup>6,7</sup>

### VHA Study

In a more recent study conducted by the Veterans Health Administration (VHA),<sup>8</sup> 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.



**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<sup>8</sup>).

These events involved mistakes in interpreting patients’ blood glucose levels due to the way the results were displayed on some glucometer screens, including **ACCUCHEK Inform** (no longer available from the manufacturer) and **ACCUCHEK 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



**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<sup>8</sup>).

when CR LO was misinterpreted as a high blood glucose reading, and insulin was incorrectly administered to the patient.<sup>9</sup> 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.<sup>10,11</sup> Insulin was incorrectly administered to both patients, one of whom died. In the fatal event, the practitioner expected a numeric blood

continued on page 2 — **Glucometers** >

## 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.<sup>8</sup>
- Configure the critical results to display as a numeric value to prevent the display of CR LO or CR HI abbreviations.<sup>8</sup> (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
- continued on page 2—**check it out** >

> **Glucometers** — continued from page 1

sugar value to appear on the results screen, so the numeric portion of the alarm code, W-510 (**Figure 1**, on page 1), was presumed to be the patient's blood glucose value.<sup>11</sup>

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.<sup>8</sup>

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**, on 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**, on 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

continued on page 3 — **Glucometers** >

> **check it out** continued from page 1

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. Future upgrades to the technology should address the 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.

**SAFETY wires**

**Give thought to how “thousand” and “million” are expressed.** When looking at wholesaler (AmerisourceBergen) listings for **RETACRIT** (epoetin alfa-epbx), a biosimilar to **EPOGEN** and **PROCRIT** (epoetin alfa), a pharmacist noticed that the strengths were listed differently. The Procrit vial containing 20,000 units was listed as “20K UN/ML,” while the Retacrit vial containing 10,000 units was listed as “10M UN/ML.” While it is safest to avoid abbreviations for thousand, the failure to use a standard abbreviation adds to the risk of confusion. The letter M has often been used for millions (or MU for “million units”), and the letter K (kilo) is a popular abbreviation for thousand (as in a 10K race). However, M is the Roman numeral for 1,000, and it has been used at times, as it was here with Retacrit, to represent thousand. Although highly unlikely to be misunderstood in the case of epoetin, use of the abbreviation in another situation could potentially lead to a 1,000-fold error. We hope that AmerisourceBergen avoids using these abbreviations (or if the company continues the unsafe practice of abbreviating “thousand,” to standardize to K). It is difficult to control what wholesalers

continued on page 3 — **SAFETY wires** >

> **Glucometers** — continued from page 2

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.

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.<sup>8</sup> 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.

To avoid misinterpretation of blood glucose results on POC testing glucometers and incorrect treatment decisions, consider the recommendations listed in the **check it out!** column, starting in the right column on page 1.

**References**

- 1) Shaw JLV. Practical challenges related to point of care testing. *Pract Lab Med*. 2016;4(1):22–9.
- 2) O’Kane MJ, McManus P, McGowan N, Lynch PL. Quality error rates in point-of-care testing. *Clin Chem*. 2011;57(9):1267-71.
- 3) Cantero M, Redondo M, Martin E, Callejón G, Hortas ML. Use of quality indicators to compare point-of-care testing errors in a neonatal unit and errors in a STAT central laboratory. *Clin Chem Lab Med*. 2015;53(2):239-47.
- 4) Heinemann L. Quality of glucose measurement with blood glucose meters at the point-of-care: relevance of interfering factors. *Diabetes Technol Ther*. 2010;12(11):847-57.
- 5) Schleis TG. Interference of maltose, icodextrin, galactose, or xylose with some blood glucose monitoring systems. *Pharmacotherapy*. 2007;27(9):1313-21.
- 6) ISMP. FDA Advise-ERR. Prevent dangerous drug-device interaction causing falsely elevated glucose levels. *ISMP Medication Safety Alert!* 2008;13(12):1-3.
- 7) ISMP. Be aware of false glucose results with point-of-care testing. *ISMP Medication Safety Alert!* 2005;10(18):1-3.
- 8) Estock JL, Pham IT, Curinga HK, et al. Reducing treatment errors through point-of-care glucometer configuration. *Jt Comm J Qual Patient Saf*. 2018;000:1-12.
- 9) FDA. MAUDE adverse event report: Roche Diagnostics Accu-Chek Inform meter blood glucose monitoring device. April 29, 2010. [www.ismp.org/ext/109](http://www.ismp.org/ext/109)
- 10) FDA. MAUDE adverse event report: Roche Diagnostics Accu-Chek Inform II test strips blood glucose monitoring test strips. November 3, 2015. [www.ismp.org/ext/110](http://www.ismp.org/ext/110)
- 11) FDA. MAUDE adverse event report: Roche Diagnostics Accu-Chek Inform meter blood glucose monitoring device. January 17, 2016. [www.ismp.org/ext/111](http://www.ismp.org/ext/111)

## what’s in a Name?

### The “-oxacin” drug name stem

The suffix “-oxacin” refers to an antibacterial class of drugs called fluoroquinolones.<sup>1,2</sup> These medications prevent and treat bacterial infections by interfering with DNA formation in bacterial cells.<sup>2,3,4</sup> They should not be used for viral infections.<sup>3,4</sup> Fluoroquinolones first appeared on the market in the 1980s, with ciprofloxacin soon becoming the most commonly used antibiotic worldwide.<sup>5</sup> This happened because ciprofloxacin was available orally and could be used to treat serious gram-negative infections with pathogens such as *Pseudomonas*. Since ciprofloxacin was developed, other “-oxacins” (i.e., gemifloxacin, levoFLOxacin, moxifloxacin), with a broader spectrum of activity against gram-positive, gram-negative, and atypical bacteria, have become available.<sup>6</sup> These three other “-oxacins” are also known as respiratory fluoroquinolones because of their

continued on page 4 — **what’s in a Name ?** >

> **SAFETY wires** continued from page 2

do—we have even seen MM used to abbreviate million (1,000 x 1,000)—but again, everyone may not understand the meaning of these abbreviations.

In healthcare facilities, instead of using these abbreviations in computer listings, we believe that expressing large doses using words or numbers is safest (ISMP. A million abbreviations. *ISMP Medication Safety Alert! Nurse AdviseERR*. 2007; 5[9]:2). When deciding between words and numbers, consider that the words “million” and “thousand” carry nearly the same number of characters as its corresponding number but are less prone to confusion. This is because the words “million” and “thousand” exhibit different and more distinguishable characters, while 100,000/1,000,000 or 100000/1000000 are very similar, especially when commas are omitted or misplaced. As ISMP advisor Dr. John Senders, a human factors engineer and psychologist, points out, if all doses were written as a word, the occasional dropped or deformed character would still result in interpreting the correct meaning. For example, “one undred thousand” would still be understood as 100,000; however, a dropped zero in 100,000 would change the number to 10,000. If doses in the thousands or millions are expressed as numbers (some situations may require numbers for dose calculations or electronic alerts), properly spaced commas (e.g., 5,000) are necessary to ensure understanding.



**Phenylephrine overdose.** A patient in the post-anesthesia care unit (PACU) was supposed to receive 100 mcg of phenylephrine for acute hypotension. A nurse assisting in PACU retrieved a 503B outsourced prefilled phenylephrine syringe (QuVa Pharma) and gave it to the patient’s nurse. (503B compounding pharmacies are external pharmacies that prepare large batches of certain medications for hospitals to purchase and use within their facility.) The drug was packaged in a 10 mL syringe labeled as “PHENYLephrine HCl 100 mcg/mL (1 mg/10 mL)” (Figure 1, page 4). The total dose and total volume in the syringe appear in parentheses following the per mL concentration, which is the

continued on page 4 — **SAFETY wires** >

what's in a *Name?* continued from page 3

effectiveness against common bacteria associated with community-acquired pneumonia and their ability to penetrate the lung tissue.

Fluoroquinolones and combination products that contain fluoroquinolones can be administered by a variety of routes and are available in multiple formulations (Table 1). Oral formulations should be given at least 2 hours before or 6 hours after antacids and other drugs that contain calcium, aluminum, magnesium, iron, or zinc because these can reduce the absorption of “-oxacins” if given at the same time.<sup>2,5</sup>

**Table 1.** List of available fluoroquinolone and fluoroquinolone combination products in the US

Generic Name	Brand Name	Formulations
besifloxacin	<b>BESIVANCE</b>	ophthalmic suspension
ciprofloxacin	<b>CIPRO, CIPRO in D5W, CIPRO XR, CILOXAN, CETRAXAL, OTIPRIO</b>	intravenous solution, oral suspension, oral tablet, oral extended-release tablet, ophthalmic solution, ophthalmic ointment, otic solution, intratympanic suspension
ciprofloxacin/dexamethasone	<b>CIPRODEX</b>	otic suspension
ciprofloxacin/fluocinolone	<b>OTOVEL</b>	otic solution
ciprofloxacin/hydrocortisone	<b>CIPRO HC</b>	otic suspension
delafloxacin	<b>BAXDELA</b>	intravenous solution, oral tablet
gatifloxacin	<b>ZYMAXID</b>	ophthalmic solution
levo <b>FLOX</b> acin	No brand name available	intravenous solution, oral solution, oral tablet, ophthalmic solution (generic only)
moxifloxacin	<b>AVELOX, MOXEZA, VIGAMOX</b>	intravenous solution, oral tablet, ophthalmic solution
ofloxacin	<b>OCUFLOX, FLOXIN OTIC</b>	oral tablet (generic only), ophthalmic solution, otic solution

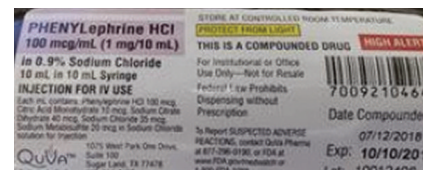
Common side effects of systemic fluoroquinolone antibiotics (i.e., oral and injectable formulations) are headache, dizziness, nausea, and diarrhea, including *Clostridium difficile*.<sup>2,3,5</sup> In July 2016, the US Food and Drug Administration (FDA) updated the Boxed Warning for systemic “-oxacins” to include the risk of serious, irreversible adverse effects, including peripheral neuropathy, tendon rupture, tendonitis, and exacerbation of myasthenia gravis.<sup>3</sup> Because of these serious adverse effects, fluoroquinolones should only be prescribed for those who do not have alternative treatment options when used for uncomplicated urinary tract infection (UTI), acute bacterial sinusitis, and acute bacterial exacerbation of chronic bronchitis.

In July 2018, FDA further strengthened warnings across the entire class of systemic fluoroquinolones to include mental health side effects (e.g., agitation, memory impairment, delirium, nervousness) and hypoglycemia that could lead to coma.<sup>4</sup> Patients, especially those with diabetes and the elderly, should be counseled about the signs and symptoms of hypoglycemia and how to treat it. Patients should also be aware of the risk of psychiatric side effects that could develop after only one dose and should inform their healthcare provider as soon as possible about any of the above effects or changes in thinking, mood, or behavior.

continued on page 5 — what's in a *Name?* >

> **SAFETY**wires continued from page 3

exact opposite of how the strength and total volume appear on commercial products. The patient's nurse administered the entire volume in the syringe, 10 mL (1,000 mcg), resulting in a 10-fold overdose. The patient's blood pressure rose for about 10 minutes but then, fortunately, returned to within normal limits.



**Figure 1.** This syringe contains 1 mg (1,000 mcg) of phenylephrine in 10 mL but was thought to hold just 100 mcg. This QuVa Pharma label does not comply with USP <7>.

The US Food and Drug Administration (FDA) requires commercial manufacturers to follow USP <7>, which states that product labels must first list the total amount of drug per total volume (i.e., 1000 mcg/10 mL) in the container, followed by the strength per mL (i.e., 100 mcg/mL) enclosed in parentheses. As a result, most practitioners expect a product's strength to be expressed this way. However, as we have pointed out repeatedly, 503B out-sourcers are not required to follow USP <7> labeling requirements. This situation has led to medication errors and overdoses when the amount per mL was mistaken as the total amount in the container. With the latest error, the difference between the expected and actual concentration expression was a factor.



**Figure 2.** QuVa Pharma has begun to revise its syringe labels to comply with USP <7>, including this phenylephrine syringe label.

This error is similar to an event described in our December 2018 newsletter in which a patient received a 5-fold overdose of ketamine due to the labeling on a 503B compounded ketamine syringe. The good news is that QuVa Pharma has begun to revise its syringe labels to comply with USP <7> (Figure 2). Once again, we call upon the US Food and Drug Administration (FDA) to provide labeling and packaging continued on page 5 — **SAFETY**wires >

## what's in a Name? continued from page 4

After review of reports submitted to FDA and 4 published observational studies that showed an increased risk of aortic aneurysm or dissection with fluoroquinolone use, FDA issued yet another warning in December 2018.<sup>7</sup> Although these conditions are rare, they can lead to dangerous bleeding or even death. Healthcare professionals should avoid prescribing fluoroquinolones to patients with a history of blockages or aneurysms of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes (i.e., Marfan syndrome, Ehlers-Danlos syndrome), and the elderly.

### References

- 1) World Health Organization. Guidance on the use of International Nonproprietary Names (INNs) for pharmaceutical substances. Switzerland: 2017:22. [www.ismp.org/ext/26](http://www.ismp.org/ext/26)
- 2) Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed September 25, 2018.
- 3) US Food and Drug Administration (FDA). FDA drug safety communication: FDA updates warnings for oral and injectable fluoroquinolone antibiotics due to disabling side effects. May 12, 2016. [www.ismp.org/ext/147](http://www.ismp.org/ext/147)
- 4) US Food and Drug Administration (FDA). FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes. July 10, 2018. [www.ismp.org/ext/148](http://www.ismp.org/ext/148)
- 5) King DE, Malone R, Lilley SH. New classification and update on the quinolone antibiotics. *Am Fam Physician*. 2000;61(9):2741-8.
- 6) Wispelwey B, Schafer KR. Fluoroquinolones in the management of community-acquired pneumonia in primary care. *Expert Rev Anti Infect Ther*. 2010;8(11):1259-71.
- 7) US Food and Drug Administration (FDA). FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients. December 20, 2018. [www.ismp.org/ext/149](http://www.ismp.org/ext/149)

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**Editors:** Ann Shastay, MSN, RN, AOCN; Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon); Russell Jenkins, MD; Ronald S. Litman, DO. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org); Tel: 215-947-7797; Fax: 215-914-1492.

## > SAFETYwires continued from page 4

guidance to all outsourcing pharmacies, and to require them to follow USP <7> so every prefilled syringe is labeled in the same, safe manner.



**FDA cautions on misuse of pen needles.** An FDA communication published at the end of September ([www.ismp.org/ext/105](http://www.ismp.org/ext/105)) cautioned pen (e.g., insulin and **EPINEPHrine**) users and clinicians about the misuse of pen needles by patients. This was also the subject of a National Alert Network (NAN) communication by ISMP, the American Society of Health-System Pharmacists (ASHP), and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) on October 12, 2017 ([www.ismp.org/node/44](http://www.ismp.org/node/44)).

*Standard* pen needles have an outer cover and a removable inner needle cover, which both need to be manually removed before an injection. *Safety* pen needles have an outer cover that is removed, and an inner needle shield that is not removed before an injection. Most hospitals use *safety* pen needles to protect staff from needlesticks. So, hospital staff may teach patients to self-inject a medication using a *safety* needle. Patients who later purchase *standard* pen needles may not know to remove both the outer and inner covers. If the inner cover is left on, the needle will not enter the skin at the time of administration. Although some medication may leak out from the inner cover, the problem may not be realized. In such cases, the patient will not receive any of the medication.

The FDA communication lists recommendations for both patients using pens and providers who care for or treat patients. FDA also asked needle manufacturers to review educational materials to assess the need for updates to clearly explain how to use the pen needle safely. In addition, FDA requested that *standard* pen needle manufacturers consider adding a warning in the labeling regarding the need to remove both the outer cover and the inner needle cover before use.