ISMP Medication Error Report Analysis

Pen Device for U-500 Insulin

Tamper-Resistant Seals

Dispelling Myths About ISMP

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These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs. Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below. Errors, close calls, or hazardous conditions may be reported directly to ISMP through the ISMP Web site (www.ismp.org), by calling 800-FAIL-SAFE, or via e-mail at ismpinfo@ismp.org. ISMP guarantees the confidentiality and security of the information received and respects reporters' wishes as to the level of detail included in publications.

PEN DEVICE FOR U-500 INSULIN

The US Food and Drug Administration (FDA) has approved *Humulin R U-500 KwikPen* (insulin human injection) (500 units/mL) in a prefilled pen device. U-500 insulin is indicated for patients with type 1 and type 2 diabetes who need more than 200 units of insulin per day. The U-500 pen holds a 3 mL, 1,500 unit insulin cartridge and is the same size as other Lilly pens, but it dials in 5-unit increments rather than 1-unit increments (**Figure 1**). The device has an aqua pen body to differentiate it from other insulin pens.

Until now, U-500 insulin was only available in a vial; because there is no U-500 syringe, it had to be administered with either a U-100 insulin syringe that required a dose conversion to U-100 markings or a tuberculin (TB) syringe that required conversion to volume markings. The lack of a proper syringe to measure U-500 insulin has frequently led to confusion

about the insulin dose a patient is actually receiving. Most medication errors with *Humulin R U-500* in vials have been due to dosing confusion when the dose was prescribed in units or volume corresponding to the U-100 syringe or TB syringe markings.

When switching to the new pen, dose conversions are no longer needed. Those familiar with the need for dose conversions when using a U-100 syringe may be confused. They need to be aware that the pen's dose window shows the number of units of *Humulin R U-500* to be injected. The pen will then deliver the proper volume that corresponds to the dose. Again, no dose conversion is required. However, keep in mind that patients using U-500 insulin from a vial at home will still communicate their dose in U-100 unit markings or volume, so you will need to verify the dose and syringe or device used at home.

You can find a brief video and more information about the new pen, which will be available in April,

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Figure 1. Lilly will launch a U-500 insulin pen in April.

at www.humulin.com/hcp-u-500.aspx. Note that the 20 mL vial of U-500 insulin will remain available, and the revised U-500 package insert includes the use of both U-500 vials and pens. Therefore, U-100 and TB syringe conversion tables are included, which may give rise to some confusion. These tables are not to be associated with the pen dosage form.

ISMP recommends that hospitals strongly consider using the U-500 pen as a way to eliminate dose conversion problems. This will assist nurses administering U-500 insulin to inpatients and makes sense for patients needing U-500 at home as well. We received an error reported from a long-term care facility where the dose of U-500 was communicated as 20 units (a U-100 syringe had been used), when in fact the dose was actually 100 units. As with any insulin pen, steps should be taken to ensure that it remains patient-specific and is never shared or used with another patient, even if the needle has been changed.

TAMPER-RESISTANT SEALS

A used oxymetazoline nasal spray was inadvertently placed back in storage with unused oxymetazoline nasal sprays. Later, the used product was almost administered to the wrong patient. The error was identified when the patient's physician opened the cap and saw blood residue on the tip of the bottle. It appears that the used spray had been initially opened by twisting off the cap while leaving the tamper-resistant seal in place, then recapping it after use (**Figure 2**). It was restocked in the medication room by a nurse or pharmacy technician who thought the product was unopened.

There is only about a millimeter of tamper-resistant seal that covers the space between the cap and the bottle. Once compromised, the entire seal should be removed; in this case, most of it was allowed to remain. Pharmacy is currently applying their own tamper-resistant stickers to nasal spray bottles, similar to special seals that are often placed on IV container ports, to easily distinguish opened containers from unopened containers and prevent this sort of problem.

The hospital's medication error committee believes that this incident and future incidents could be prevented by improving the product's tamper-resistant seal and how it is placed on containers during the packaging process. The hospital sent a letter to Major Pharmaceuticals, the product manufacturer. ISMP has received similar reports involving ointments and other products where blood-borne pathogens might be transmitted because a used container was mistaken as an unopened container.

We would appreciate hearing your additional suggestions for how to avoid potentially dangerous accidental product reuse. In the meantime, remind staff to completely remove the safety seal when the product is used and to suspect a potential problem if the seal is very loose fitting over the cap, which may happen if only the bottom portion has been removed. We would also like to know what kinds of checks are made when products are returned to unit stock or the pharmacy. Please email us at: isminfo@ism.org.

DISPELLING MYTHS ABOUT ISMP

As we were making plans for 2016, we came across several relatively common but inaccurate beliefs about ISMP that could impact our work. We would like to dispel these myths by providing some general

Figure 2. Tamper-resistant seal appears to be intact. It is not.

information about ISMP. If you still have questions or are confused about our organization, we encourage you to contact us directly (ismpinfo@ismp.org).

Myth 1: ISMP is a regulatory, standards setting, accrediting, or certifying organization.

ISMP works in an expert advisory capacity only, with neither the power to set minimum standards of care nor the authority to certify, regulate, or accredit individuals or organizations based on any standards of care, including those associated with medication safety. While we often support the minimum standards of care required by regulatory, standards setting, accrediting, and certifying agencies, ISMP also attempts to raise the bar by recommending alternative but practical high leverage strategies to improve medication safety. These strategies are based on best practices documented in the literature and learned via ISMP medication error reporting programs, on-site consulting, research, expert consensus building, and advocacy work. ISMP has published guidelines, but not standards, that reflect consensus among key stakeholders associated with medication use. ISMP has also published numerous tools and self-assessments, research findings, targeted medication safety best practices, and various lists (confused drug names, drug pairs with tall-man letters, high-alert medications, and error-prone abbreviations) that best support safe medication practices.

ISMP has no plans to become a regulatory, standards setting, accrediting, or certifying agency, as our sole purpose is to learn about medication errors from involved frontline clinicians so we can help prevent others from making the same errors. We believe that clinicians would be less willing to report hazards, errors, or prevention strategies to ISMP if they thought we could then *require* them to make specific changes they may perceive to be difficult or costly, or if we could impose sanctions or punishment if the specific changes are not implemented. Open reporting begins with trusting that the recipient of the report will not unfairly judge the clinicians involved in the event, dictate a new standard that may not be immediately feasible, and punish individuals or organizations if the standard is not met. Medication error reports are the lifeblood of ISMP, and we will continue to do everything in our power to maintain the trust we have built over the last 45 years with reporters.

Myth 2: ISMP is funded by a government agency and/or the pharmaceutical industry.

ISMP is a wholly independent, nonprofit agency funded via the direct services provided by its

employees, nonrestrictive educational grants, competitive research grants, and charitable donations. We receive no funding from the government or the pharmaceutical industry, with the exception of unrestricted grants intended for a specific project or study. We accept no advertising in ISMP publications, websites, or educational programs, and we will not consider any potential source of funding that might restrict our activities or give the impression that it might influence our work in any way.

Primary sources of funding include ISMP publications, collaborations and consulting work, educational programs, research grants, error analysis, and charitable donations. However, a large portion of our work is related to medication safety advocacy, which generates little to no income. Examples of these advocacy efforts include pro bono participation on international, national, state, and local committees or initiatives, work with consumers and clinicians who seek information about medication safety, and work associated with ISMP's free error-reporting programs.

Myth 3: ISMP operates an external medication error-reporting program similar to mandatory external incident reporting programs.

ISMP operates 3 national, voluntary, medication error-reporting programs: the ISMP National Medication Errors Reporting Program (MERP), the ISMP National Vaccine Errors Reporting Program (VERP), and the ISMP National Consumer Medication Errors Reporting Program. These voluntary reporting programs differ from mandatory external reporting programs in several ways:

- The reports come directly from frontline practitioners and consumers rather than risk, quality, or safety managers.
- The narrative descriptions (and pictures) that accompany the reports offer rich content for learning compared to mandatory reports that often prompt for standard information and a succinct description of the event, but not its causes.
- Communication with the practitioners or consumers who were involved in or detected the event is possible and potentially more helpful than communication with managers screening and completing the mandatory reports.

The reports to ISMP are sent for altruistic reasons—because practitioners want to share information that will benefit others, not because there is a mandate to do so. This information is far more

complete and useful than what is generally captured in a mandatory external incident reporting system. ISMP error reporting programs receive narratives, submitted by reporters, about errors that are unique, actionable, and useful for learning—they want others to understand the risk, learn from the external event, and prevent similar errors.

Unlike mandatory incident reports for which direct contact with the staff involved in the events is essentially impossible, voluntary reports submitted to ISMP flow directly from the field—from physicians, nurses, pharmacists, consumers—to the program. Confidential communication channels with ISMP are direct and stay open, and many ISMP reporters are responsive to follow-up questions from ISMP that support learning.

Myth 4: Medication error reports submitted to ISMP should also be reported to the US Food and Drug Administration (FDA).

ISMP shares all error reports received via our reporting programs with FDA and product manufacturers. What is not shared is the name and contact information of the reporter, location of the event, or any other identifiers unless specific permission has been granted. When ISMP receives a report, a redacted version is shared via a secure portal with ISMP clinical staff responsible for analysis. It is entered into a secure database. If the reporter has identified himself or herself, follow-up questions are typically sent via email if further explanation is necessary for learning. In some cases, an ISMP clinician may talk directly to the reporter to learn more about the hazard or event. ISMP also sends a note via email to reporters to thank them. We also call the pharmaceutical company to discuss any product safety issues.

Once we have received the answers to any follow-up questions, or if there is no response to the questions, ISMP submits all reports to FDA within 1 month of receipt or immediately, as necessary, when the situation is serious and involves a regulated product. We also work with FDA each week and hold formal monthly calls with its Division of Medication Error Prevention and Analysis (DMEPA) to discuss specific events or safety issues that have come to our attention.

Because of the unique and robust relationship ISMP has with FDA, we highly encourage practitioners and consumers to report all medication-related events to ISMP, which are then automatically forwarded to FDA. If the report is sent directly to FDA,

ISMP may miss seeing the full report or miss seeing a very serious event or hazard that requires a rapid response, such as a national alert. Also, we would not be able to follow-up with reporters in a timely manner if questions arise. However, a memorandum of understanding allows FDA to spontaneously forward select but redacted MedWatch (The FDA Safety Information and Adverse Event Reporting Program) reports to ISMP when an important issue arises.

Myth 5: ISMP staff sometimes serve as an expert witness on behalf of defendants or plaintiffs in a civil lawsuit.

Although ISMP staff has occasionally assisted pro bono in the defense of a nurse or pharmacist facing criminal charges or potential action against their licenses after making a medication error, ISMP staff does not serve as expert witnesses in any civil lawsuit that may arise after a harmful medication error. It is not a reluctance to help that informs our policy, but rather an inability to devote time to this service without sacrificing other important functions that better support our mission.

Myth 6: Reporting hazards and errors to ISMP has little value because the organization can do little about practice- or product-related issues.

Although ISMP is a relatively small organization with roughly 30 full-time employees, our influence is deep and our reach is far when it comes to medication error prevention. We review every error report received and use the information to help others prevent errors. For example, since 1996, in direct response to specific hazards reported to ISMP, we have electronically issued more than 30 nationwide hazard alerts (now known as the National Alert Network since 2012) to health care providers. We have conducted dozens of national surveys; created lists of error-prone abbreviations and dose designations, confused drug names, and high-alert medications; and established guidelines for labels, automated dispensing cabinets, smart infusion pumps, standard order sets, timely drug administration, IV sterile compounding, IV push medications, and more. We have promoted learning via clinician and consumer websites, 5 newsletters (acute care, community/ambulatory care, nursing, long-term care, consumer) that reach millions of clinicians or consumers; and published white papers and numerous research projects. These resources have also been used internationally.

Because of error reports submitted to ISMP, thousands of changes have already occurred with US drug product labeling and packaging, FDA regulations and guidances, The Joint Commission and US Pharmacopeial Convention (USP) standards, and practice modifications. These changes began in 1987 when the ISMP founders convened a national committee to establish a federal requirement for potassium chloride for injection to have black caps, closures, and warning statements, and continue to the forthcoming May 1, 2016, move to eliminate ratio expressions on labels of epinephrine and several other medications. The most recent change was formally requested by ISMP via an official petition to USP after receiving a report about a 16-year-old boy who died unnecessarily from an epinephrine injection overdose (www.ismp.org/sc?id=1640). Error reports published in our newsletters have also served as a reputable source of information for health care providers to use as a

risk assessment to guide proactive medication safety efforts—the reports help prevent the same errors in other health care settings.

The impact of some recommended interventions and changes stemming from ISMP reporting programs has been measured and found to improve safety or change risky behaviors; for others, anecdotal evidence suggests that practice and product changes have been implemented, resulting in fewer errors. Although ISMP and the clinician or consumer who reported a specific hazard are rarely recognized as a predecessor to medication safety-related changes stemming from ISMP reports, there is a good chance that, together, we played an important role, even if only to create a persistent impetus to change. The point is, never doubt that your reports of hazards and errors sent to ISMP are powerful drivers of change, in both the US and abroad, and will continue to be a major force in the patient safety movement. ■