Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

Volume 19 • Issue 9 • November 28, 2019

Dose Confusion When Switching between Insulin Delivery Devices

- *Determine a patient's insulin usage by confirming the type(s) of insulin, the concentration(s), the dose(s) in terms of units, and the delivery method or device used to administer each dose (i.e., syringe, insulin pen, or pump).*
- *Encourage patients to always describe their insulin dose in terms of units whenever they are asked for this information.*
- *Encourage patients who are switching insulin products to record and closely monitor their blood glucose after the change, and to contact their primary care practitioner if there is an unexpected result.*
- *When obtaining medication from Health Canada's Special Access Programme, advocate for community pharmacies to be kept in the communication loop.*

Insulin products are supplied predominantly as solutions with a standard concentration of 100 units/mL. However, several high-concentration products (i.e., with concentration above 100 units/mL) are available for patients who require relatively high doses because of significant insulin resistance.[1,2] These high-concentration products are often provided in product-specific injection delivery devices. Failure to consider the differences among insulin products, including the insulin concentration and the delivery device, can lead to serious dosing errors.[1] ISMP Canada received a report of a dosing error with a high-concentration insulin product, which resulted in an emergency department visit. This bulletin highlights the factors that potentially contributed to the error and recommends a systems approach to reduce the likelihood of recurrence.

INCIDENT DESCRIPTION

A patient was switched from Humulin R 500 units/mL (regular insulin provided in a multi-dose vial and obtained through Health Canada's Special Access Programme [SAP]) to Entuzity KwikPen 500 units/mL (regular insulin provided in a prefilled pen and obtained through the community pharmacy) when the latter became available on the Canadian market. When writing the prescription for the Entuzity KwikPen, the physician asked the patient what dose of Humulin R was being administered. The patient reported that the dose was measured as 30 units on the syringe.

The physician wrote the prescription for Entuzity KwikPen 30 units twice daily, and the patient then filled the prescription at the community pharmacy. The patient declined pharmacist counselling at the time the prescription was dispensed, indicating familiarity with the use of high-concentration regular insulin. However, after using the Entuzity KwikPen product for more than a week, the patient experienced hyperglycemia and had to be treated in hospital. After discharge, the patient returned to the community pharmacy to ask the pharmacist how the hyperglycemia could have occurred.

BACKGROUND

Specially marked syringes are available for patients to measure the insulin dose when withdrawing solution from a vial; U-100 syringes are intended for use with 100 units/mL insulin solution and U-500 syringes for the 500 units/mL product. The calibration markings on each syringe will indicate the number of units of insulin being measured *only* if used with the corresponding concentration of insulin.

Several high-concentration insulin products are currently available in Canada (Table 1) and each product is marketed in its own prefilled injection delivery device (known as an insulin pen). At the time of this incident, the Humulin R 500 units/mL product was available in multi-dose vials through the SAP, but was discontinued by the manufacturer and replaced with the Entuzity KwikPen, a prefilled pen device containing regular insulin 500 units/mL.

DISCUSSION

In the incident described above, the patient returned to the pharmacy to ask whether the community pharmacist could determine and explain why hyperglycemia occurred. After questioning the patient further about insulin use, the pharmacist identified that the patient had been withdrawing insulin from the Humulin R 500 units/mL vial using a U-100 syringe and measuring the dose to the 30-unit calibration marking. Therefore, the patient's actual dose of insulin was 150 units. When the patient responded to the physician's question about the dose of Humulin R 500 units/mL, the patient's answer referred to the 30-unit marking on the U-100 syringe, not the actual insulin dose of 150 units. The patient experienced hyperglycemia because the 30-unit Entuzity KwikPen dose that the physician had prescribed was too low, as it was only one-fifth of the patient's previous insulin dose.

Several factors contributed to the under-dosing error described in this bulletin:

- There was miscommunication regarding the patient's insulin dose. Patients who are receiving insulin may only know their insulin dose by the unit markings on a syringe (if withdrawing from a vial) or by the number of clicks to be dialed (if using a pen device). These measurement indicators may not correspond to the actual number of units of insulin being administered. In this incident, failure to clarify the delivery device (i.e., the U-100 syringe) that the patient was using for the high-concentration product led to the prescribing, dispensing, and administration of an insulin dose that was one-fifth of the intended dose.

- Ideally, a patient who is withdrawing a dose from a vial containing 500 units/mL insulin solution would use a U-500 syringe, such that the syringe markings would accurately reflect the number of units being administered. In this incident, however, the patient had been measuring and administering the Humulin R 500 units/mL product with a U-100 syringe, possibly because U-100 syringes are more commonly available than U-500 syringes or

Table 1.
Prefilled injection delivery devices (insulin pens) for high-concentration insulin products currently available in Canada

Product Name	Type of Insulin	Insulin Concentration
Entuzity KwikPen	Insulin human, biosynthetic (regular insulin)	500 units/mL
Humalog KwikPen	Insulin lispro	200 units/mL
Toujeo SoloStar	Insulin glargine	300 units/mL
Tresiba FlexTouch	Insulin degludec	200 units/mL

because the patient was unaware of the existence of U-500 syringes. Consequently, when asked about the insulin dose, the patient would have had to perform a dose conversion calculation to correctly report the number of units of insulin measured in the U-100 syringe.

The calibration markings on an insulin syringe will indicate the number of units of insulin being measured only if used with the corresponding concentration of insulin.

- High-concentration insulin products are not as commonly prescribed and dispensed as the standard-concentration products, resulting in a lack of familiarity by health care practitioners[3] with the indications and/or doses of the high-concentration products. This knowledge gap may have contributed to the failure to recognize that the prescribed insulin dose with the Entuzity KwikPen was low. The most common reason for switching from 100 units/mL insulin to a high-concentration product is to enable a high dose to be delivered in a lower volume; however, 30 units is not considered a high dose and should therefore have been questioned at the time of prescribing and dispensing.

- The patient's vials of Humulin R 500 units/mL were ordered and received through the SAP. Under the SAP, the prescriber may order, receive, and store the medication, leaving the patient's community pharmacy out of the communication loop.[4] As a result, staff in the community pharmacy were not aware that the patient had been using Humulin R 500 units/mL. This communication gap can occur with any SAP product, and therefore the recommendations below may apply to all SAP products.

- The patient declined counselling by the community pharmacist because the change in delivery device was not recognized to be particularly significant, and the patient was comfortable with the use of high-concentration insulin. However, patient counselling, including demonstrating and confirming the appropriate use of an insulin delivery device, is an opportunity for pharmacy practitioners to help prevent dosing and administration errors. In this case, the opportunity was missed because the pharmacist was unaware that the patient was switching to a different insulin delivery device.

RECOMMENDATIONS

Prescribers

- Determine a patient's insulin usage by confirming the type(s) of insulin, the concentration(s), the dose(s) in terms of units, and the delivery method or device used to administer each dose (i.e., syringe, insulin pen, or pump). Encourage patients to bring all of their medications to each appointment to confirm these details.
- Express the dose of insulin in terms of units both when communicating with patients and when writing prescriptions; this can only be done if the concentration of insulin and the delivery device have been confirmed.
- Develop a mechanism to communicate with the patient's pharmacy about any medications for which prescribing or dispensing bypasses the patient's pharmacy (e.g., SAP products, investigational drugs, prescriber samples).

Pharmacists and Pharmacy Technicians

- Ensure that standardized processes for collecting a patient's best possible medication history include questions about medications that might bypass traditional pharmacy dispensing (e.g., SAP products, investigational drugs, prescriber samples).
- Before dispensing a prescription for insulin, confirm with the patient the type and concentration of insulin, the expected dose in terms of units, and the delivery method or device.
- Discuss with the patient every new or changed insulin prescription; emphasize that close monitoring of blood glucose is especially important when switching insulin products and that the primary care practitioner must be contacted if there is an unexpected result.

Health Canada

- Consider advising prescribers to inform the patient and the patient's community pharmacy about any use of an SAP medication (e.g., on the form used for making an SAP request).

CONCLUSION

Dosing errors with high-concentration insulin products and related insulin delivery devices are preventable. All health care practitioners involved in prescribing, dispensing, monitoring, or providing education about insulin use should be aware of the need to determine the type and concentration of insulin, the insulin dose in terms of units, and the delivery device when communicating with and educating patients and others in the circle of care.

ACKNOWLEDGEMENTS

ISMP Canada gratefully acknowledges expert review of this bulletin by the following individuals (in alphabetical order):

Gagandeep Gill RN CDE CPT, Member of the Board of Directors, Stop Diabetes Foundation; Lisa Rutherford BSP PharmD CDE, Clinical Pharmacist, Enhanced Health & Diabetes Centre, Prince Albert, SK; Lindsay Yoo BSc BScPhm RPh CDE BCGP PharmD, Pharmacist, LMC Pharmacy.

References

1. Lamos EM, Younk LM, Davis SN. Concentrated insulins: the new basal insulins. Ther Clin Risk Manag. 2016;12:389-400.
2. Reid TS, Schafer F, Brusko C. Higher concentration insulins: an overview of clinical considerations. Postgrad Med. 2017;129(5):554-562.
3. U-500 insulin errors. Horsham (PA): Institute for Safe Medication Practices; 2019 [cited 2018 Nov 27]. Available from: http://www.consumermedsafety.org/insulin-safety-center/item/499
4. Special Access Programme – drugs. Ottawa (ON): Health Canada; 2018 [cited 2019 Nov 21]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs/special-access-programme-drugs-1.html

Communication about Special Access Programme Medications

Health Canada's Special Access Programme (SAP) provides access to nonmarketed medications for prescribers who are treating patients with serious or life-threatening conditions, when conventional therapies are not an option.[1] To access medications through the SAP, the prescriber must first complete the SAP request form (available at the Health Canada website)[2] and then send the completed form by fax to the SAP for review. If approved, the medication is supplied directly from the manufacturer to one of the following distribution points: the requesting prescriber's office, an inpatient hospital pharmacy, a radiopharmacy (i.e., a pharmacy that prepares radioactive pharmaceuticals), or a blood bank.

Unlike medications dispensed from a community pharmacy, medications procured through the SAP—whether for a patient residing in the community or a patient transitioning to or from a health care facility—often bypass the usual chains of communication. In the incident described earlier in this issue of the ISMP Canada Safety Bulletin, information about a medication that was authorized and provided through the SAP was not made available to the patient's community pharmacy. As a result, key information that the pharmacist would have used to assess the appropriateness of the medication that replaced the patient's SAP medication, bypassed a key stakeholder in medication safety.

Recommendations

The following recommendations are offered to improve communication about SAP medications:

- *Health Canada:* Consider advising prescribers to inform the patient and the patient's community pharmacy about any use of an SAP medication (e.g., on the form used for making an SAP request).
- *Prescriber:* Consider informing each patient's community pharmacy of medications received through the SAP. Encourage patients to inform their pharmacist of any medications that are being supplied through the SAP.
- *All health care providers:* When gathering information from patients, always ask about medications procured from sources other than the pharmacy, such as physician samples, investigational medications, or SAP drugs, as shown in the "Best Possible Medication History Interview Guide".[3] Enter any SAP medications used in the patient's profile to allow for clinical software checks, where available.

Health Canada recently held an open consultation concerning draft guidance about the SAP for industry and practitioners;[4] the review of feedback received during that consultation is in progress. The incident reported in this issue and the recommendations presented have been shared with Health Canada to support improved communication about SAP products.

References

1. Special Access Programme - drugs. Ottawa (ON): Government of Canada; 2018 Jul 5 [cited 2019 May 21]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs/special-access-programme-drugs-1.html
2. Health Canada's Special Access Programme (SAP) instructions for making a special access request form A. Ottawa (ON): Health Canada; 2008 Jan [cited 2019 May 21]. Available from: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sapf1_pasf1-eng.pdf
3. Best possible medication history interview guide. Toronto (ON) and Edmonton (AB): ISMP Canada and Safer Healthcare Now; [cited 2019 May 21]. Available from: https://www.ismp-canada.org/download/MedRec/SHN_medcard_09_EN.pdf
4. Consultation - draft guidance document for industry and practitioners on the Special Access Program (SAP) for drugs. Ottawa (ON): Health Canada; 2019 Aug 2 [cited 2019 Nov 18]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/drug-products/draft-guidance-industry-practitioners-special-access-program.html

This segment of the bulletin describes a recent SafeMedicationUse.ca publication from ISMP Canada's Consumer Program.

June 2019 - Newsletter:

How to Safely Transfer Your Prescriptions

SafeMedicationUse.ca received a report from a patient who moved from one province to another. She asked that her prescriptions be transferred to her new pharmacy. After receiving the transferred prescriptions, the new pharmacy mistakenly filled a medication that had been stopped by the patient's doctor more than a month earlier.

Several recommendations were shared with patients to minimize the risk of error when transferring prescriptions from one pharmacy to another. These recommendations included updating their medication list with the prescriber and pharmacist prior to the transfer as well as requesting a medication review with the new pharmacy.

Tips for Practitioners

Prescribers

- If the patient is moving to a new area and has a stable, long-term medication regimen, consider writing prescriptions with enough repeats to last a full year. This will give the patient time to find a new family doctor.

Original Pharmacy

- Update the patient's profile before transferring prescriptions to the new pharmacy. This process may include "inactivating" or "discontinuing" prescriptions for medications that the patient is no longer taking.
- Before the transfer of prescriptions, for each medication verify the name, strength, and directions for use with the patient. This step will help to ensure that only current information is transferred.

New Pharmacy

- After the transfer of prescriptions has been completed, for each medication confirm the name, strength, and directions for use with the new patient, using an up-to-date list provided by the patient as a resource. Work with the patient and/or previous providers to resolve any discrepancies identified.
- Once the prescriptions have been transferred, conduct a thorough medication review with the patient. This is an important first step in understanding your new patient's health needs.

For more information, read the full consumer newsletter:
https://safemedicationuse.ca/newsletter/rxtransfer.html

CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

Système canadien de déclaration et de prévention des incidents médicamenteux

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

HIROC

The Healthcare Insurance Reciprocal of Canada (HIROC) provides support for the bulletin and is a member owned expert provider of professional and general liability coverage and risk management support.

ISMP CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Report Medication Incidents

(Including near misses)

Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

ISMP Canada strives to ensure confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications. Medication Safety bulletins contribute to Global Patient Safety Alerts.

Stay Informed

To receive ISMP Canada Safety Bulletins and Newsletters visit:

www.ismp-canada.org/stayinformed/

This bulletin shares information about safe medication practices, is noncommercial, and is therefore exempt from Canadian anti-spam legislation.

Contact Us

Email: cmirps@ismpcanada.ca
Phone: 1-866-544-7672