The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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Administration of Product-Specific Diluent without Medication

ISMP Canada has received reports of incidents involving the medication glucagon, as well as incidents involving the vaccine for measles, mumps, and rubella (MMR), in which *only the product-specific diluent* was administered. The reporters asked that this information be shared to raise awareness of this medication safety issue.

Background

Some parenteral medications are manufactured in a ready-to-use liquid format, whereas others are supplied in a powder format and must be reconstituted with a diluent before administration. Most medications that are supplied in a powder format can be reconstituted with any of the generic diluents typically available where injectable medications are stocked. However, some of these medications require reconstitution with a product-specific diluent.

Medication Incidents

The following incidents involving medications for reconstitution with product-specific diluent are examples of those that have been reported to ISMP Canada.

Glucagon

Three separate incidents have been reported in which the product-specific diluent was administered on its own, instead of the glucagon powder being reconstituted with the diluent before administration. In one case, patient harm resulted.

In 2 of the incident reports, concern was expressed that the lyophilized glucagon powder was provided in a vial stored within a separate compartment in the box (Figure 1). In these instances, the identified underlying cause of administering only the diluent was lack of visibility of the vial containing the lyophilized medication powder. The legibility and clarity of the labelling of the product-specific diluent was also identified as a concern.

Measles, Mumps, and Rubella (MMR) Vaccine

- One clinic reported that in a total of 4 cases, it was likely that only the diluent had been administered, instead of the diluent combined with the MMR vaccine. The error was identified when additional vaccines were received into stock, and the existing stock was counted; the count revealed that there were 4 more vials containing MMR powder than the number of vials of diluent. Staff at the clinic reviewed hundreds of charts but were unable to identify which patients might have received only the diluent. The reporter thought it unlikely that the missing diluent vials had been broken and discarded, as clinic staff were unable to deliberately break any test vials. The clinic took steps to ensure that all new staff were appropriately educated about the problem. In addition, several strategies were employed in an effort to prevent recurrence, such as taping together the outer multivial boxes containing diluent and vaccine, using auxiliary labels on the outer packaging, and using the other brand of the MMR vaccine. However, the error continued to recur.
- A consumer reported an incident in which she took her child to a physician's office for vaccinations. About an hour after returning home, the consumer received a call from the physician's office asking her to return with the child. Staff in the physician's office had determined that the MMR vaccine powder had not been mixed with the diluent, and the child had therefore received only the product-specific diluent.
- A new family practice resident contacted a pharmacist shortly after administering what was assumed to be the

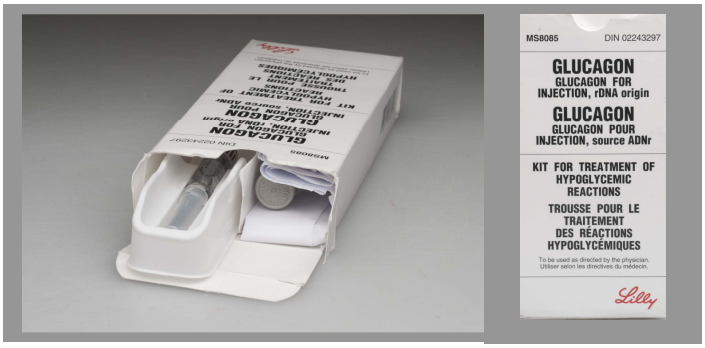

Figure 1: An example of the labelling and packaging for glucagon, in which the medication powder is provided in a vial and the product-specific diluent in a prefilled syringe. The 2 items are packaged in separate compartments within the same box. The full product monograph[1] is also included in the box, in the same compartment as the vial of medication, and it may obscure the vial.

MMR vaccine to a patient. In follow-up, the pharmacist determined that the resident had administered only the product-specific diluent, not the MMR vaccine powder reconstituted with the diluent. Fortunately, quick identification of the error meant that the patient received the MMR vaccine before leaving the clinic.

Two MMR vaccine products are available in Canada (M-M-R II[2] and Priorix[3]), and for both products, the vaccine and product-specific diluent are packaged separately (see example in Figure 2). Healthcare professionals reporting these incidents have commented to ISMP Canada that there are opportunities for improving the presentation of critical information on the diluent label and also for enhancing the packaging of these products.

Figure 2: An example of the packaging for an MMR vaccine (M-M-R II). The box on the left contains 10 vials of MMR vaccine in powder form. The box on the right contains 10 vials of product-specific diluent, intended for use with the vials of vaccine on the left. The front panel of the box containing the diluent (at right) lists the names of the vaccine products with which it can be mixed and their drug identification numbers.

Discussion

Failure to deliver an intended dose of glucagon to an individual who is experiencing a severe hypoglycemic reaction can have serious consequences, including unconsciousness and seizures.[4]

Failure to deliver an intended vaccine has consequences that cannot immediately be identified, leaving the patient at a potentially increased risk of acquiring an infectious disease against which the patient and others believed the patient was protected. At this time there have been no reports of patients acquiring infectious diseases in circumstances where they believed they had received an MMR vaccine but in fact had not.

One manufacturer of glucagon also supplies the drug in a kit format (Figure 3). Once the package is opened, the vial containing the medication, the prefilled syringe containing the product-specific diluent, and the pertinent instructions for administration are all visible. A similar plastic case for the Eli Lilly Canada brand of glucagon powder and diluent is also available, by request, from the manufacturer.

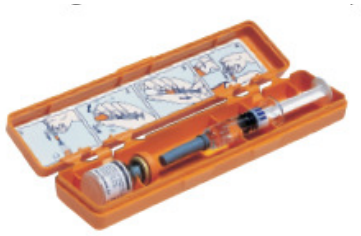

Figure 3: Glucagon kit (GlucaGen® HypoKit) from Novo Nordisk Canada Inc. Once the kit is opened, the medication in its vial, the product-specific diluent in its syringe, and the administration instructions are all visible.

"If multiple people make the same mistake, then that should tell us something about the nature of the mistake being made: its cause probably isn't individual but systemic."[5] The term "human factors" refers to the study of the "interrelationships among humans, the tools they use, and the environments in which they work."[6] Human factors principles can be used to design systems for optimal human performance. "How a medication is packaged, stocked, dispensed, and administered; its colour and shape; and how it works with other components or parts of the system, including the various technologies—all these elements can be engineered for safety."[7]

ISMP Canada has notified the manufacturers of glucagon and MMR vaccines with the intent of initiating discussions about opportunities for improved labelling and packaging — a key strategy for minimizing the risk of error.

The incidents highlighted in this safety bulletin raise awareness of the risk of administering the product-specific diluent on its own, instead of using the diluent to reconstitute the medication.

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ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

Medication Incidents (including near misses) can be reported to ISMP Canada:
(i) through the website: http://www.ismp-canada.org/err_report.htm or (ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.
ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

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