MEDICAL PHARMACIES TABLET

Drug information and news for health care providers

March 2014

Narcotics Safety: Focus on HYDROmorphone

In a previous issue of the *Tablet* (December 2013) we reviewed general strategies for the management of high-alert medications. In this issue we focus on narcotics safety—and HYDROmorphone safety in particular. The Required Organizational Practices (ROPs) Handbook as published by Accreditation Canada states that opioids should have limited availability in client service areas and that high-dose formats of opioid products should not be stocked in client service areas. In particular, the following products should not be stocked in client service areas where possible:[1]

- **Fentanyl:** ampoules or vials with total dose greater than 100 mcg per container
- **HYDROmorphone:** ampoules or vials with total dose greater than 2 mg
- **Morphine:** ampoules or vials with total dose greater than 15 mg

Why Focus on HYDROmorphone?

HYDROmorphone is the most common medication associated with harmful medication incidents reported to the Institute for Safe Medication Practices Canada (ISMP). Between January 2000 and September 2013, ISMP Canada received 233 incident reports involving HYDROmorphone that resulted in an outcome of harm or death.

One such incident involved a 69-year-old patient who was given 10 mg of HYDROmorphone IM instead of 10 mg of morphine. HYDROmorphone was mistakenly selected from a narcotics drawer. Contributing to the error were the similarity in names and the identical concentrations of the drugs. Unfortunately, injectable HYDROmorphone 10 mg is equivalent to a dose of approximately 60 mg to 70 mg of morphine. As a consequence, the patient arrested and died despite rescue efforts.[2]

STRATEGIES TO REDUCE RISK OF MIX-UPS

The Institute for Safe Medication Practices has summarized strategies for preventing morphine-hydromorphone mix-ups as follows:[3]

- **Limit access:** Stock amounts of HYDROmorphone should be reduced wherever possible (this strategy should be employed for other high-potency narcotics as well). Floor stock should be eliminated entirely if usage is low.
- **Reduce options:** Avoid stocking morphine and HYDROmorphone in the same strength. Store each medication in a separate individual bin or drawer in the cabinet to help prevent drug selection errors. Recommend strategies that would prevent mix-ups according to protocols used at your particular practice site.
- **Use Tall Man Lettering:** This was the focus of the January 2014 QI but bears repeating here. Use HYDROmorphone when labelling and when entering medication administration records and drug listings. Consider using DILAUDID® (the brand name of HYDROmorphone) as a second name to avoid confusion.
- **Use a double check:** Before administering IV narcotic doses, nurses should be required to perform an independent double check. Facilities can put policies in place to support this process.
- **Ensure that all staff handling medications are educated** to understand the differences between HYDROmorphone and morphine. For example, mistakes have been made in the past because a health professional thought that HYDROmorphone was the generic name for morphine.
- **Educate patients:** Before administering a narcotic to a patient, the health professional should repeat the name of the medication out loud as another source of confirmation.
- **Post equianalgesic** dosing charts in patient care areas and on medication administration records.

Although we have focused on HYDROmorphone in this issue, there are many high-alert medications that require strategies to ensure safe administration to patients. Reporting of medication incidents and near misses is a critically important means of identifying patient care procedures that require modification. MPT

What Is the Difference between Brand Name and Generic Drugs?

Health professionals and patients alike often question the change from a brand name drug to a generic "equivalent," and many are skeptical about just how similar the two versions of the drug are. Following is a brief review of the topic.

A drug formulation is said to be "bioequivalent" to another drug formulation if it has the same bioavailability (i.e., the same rate and extent of drug absorption).[4]

The quality standards for brand name drugs and generic drugs are the same, as the ingredients, manufacturing processes, and facilities for all drugs must meet the federal guidelines for Good Manufacturing Practices.[5] In order to be approved by Health Canada, the generic drug must show that it delivers the same amount of medicinal ingredient at the same rate as the brand name drug in each healthy individual who uses both versions of the drug through studies known as comparative bioavailability studies.[5] Non-medicinal ingredients, such as fillers and ingredients that colour the drug, may be different from those of the brand name product. The generic manufacturer must provide studies showing that the different non-medicinal ingredients have not changed the quality, safety, or effectiveness of the generic drug.

There has been a misconception that generic drug concentrations are allowed to fall within 80% to 125% of the blood concentration of the brand name drug. In actuality, it is the area under the curve (AUC), which is based on a graph of blood concentration versus time, that must fall between 80% and 125% of the brand name formulation. However, the 90% confidence interval of the AUC must also fall within 80% to 125% (the range of measurements within which we are confident that the true result lies). In real terms, studies have found an average variance in area under the curve between the brand name and generic drugs of 3% to 4%.[6]

The bottom line is that clinically important differences have not been reported in well-controlled trials of generic vs. brand name drugs.[6] As mentioned, there are instances where some patients may have allergies or intolerances to fillers or excipients that may include lactose, gluten, sulfites, or tartrazine. Any patient with such intolerances should have these recorded, and ingredients checked when using new drugs or switching brands.

About 75% of the drugs dispensed today are generic, but they represent only about 20% of spending on prescriptions.[7] In today's economy, the savings are important to survival of the healthcare system.

Health Canada has provided an excellent patient-friendly review of this topic in a publication entitled "The Safety and Effectiveness of Generic Drugs." It is available online at http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/med-gen-eng.php. DN

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2. ISMP Canada Safety Bulletin Nov. 4, 2013; 13(10).
3. ISMP Canada Safety Bulletin June 2004; 4(6).
4. Canadian Agency for Drugs and Technologies in Health. Similarities and Differences Between Brand Name and Generic Drugs. Available online at http://www.cadth.ca/media/pdf/Generic_prof_en.pdf. Accessed Feb. 18, 2014.
5. Health Canada. The Safety and Effectiveness of Generic Drugs. Updated April 2012. Available online at http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/med-gen-eng.php. Accessed Mar. 5, 2014.
6. Davit BM, Nwakama PE, Buehler GJ, et al. Comparing generic and innovator drugs: A review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother 2009;43:1583-1597.
7. Kesselheim AS. The backlash against bioequivalence and the interchangeablility of brand-name and generic drugs. CMAJ 2011;183:1350-1351.