

Concerned Reporting: Mix-ups Between Bisoprolol and Bisacodyl

ISMP Canada received a near-miss incident report involving a mix-up between bisoprolol and bisacodyl. Briefly, the report described how bisacodyl had been used to fill a pediatric patient's prescription for bisoprolol to be taken daily. The error occurred on 2 separate occasions, and in both instances a pharmacist identified the error before the medication left the pharmacy. Staff at the facility reviewed the incident and identified the look-alike nature of this drug-name pair as a key contributing factor. Because this mix-up could cause severe patient harm, ISMP Canada was contacted. This concerned reporting by a practitioner (the voluntary reporting of an incident to assist in identifying new or undetected safety issues^{*}) prompted an aggregate analysis of similar incident reports received by ISMP Canada. This bulletin shares the findings of the aggregate analysis, including specific points within the medication-use process where this and other look-alike/sound-alike drug names may increase the potential for errors to reach patients.

Background

Bisoprolol is a beta-blocker approved for the treatment of mild to moderate hypertension.¹ It may also be given to patients with stable angina pectoris or heart failure.¹ Bisoprolol is available as 5 mg and 10 mg tablets, and effective doses for the various indications range from 2.5 mg to 20 mg daily.^{1,2}

Bisacodyl is a stimulant laxative available in a 5 mg enteric-coated tablet and as 5 mg and 10 mg suppositories. The usual dosage for the treatment of constipation in adults and older children (over 12 years of age) ranges from 5 mg to 10 mg daily.³

The potential harm from mix-ups with this drug pair is clinically significant. Hypotension or bradycardia can result if bisoprolol is received in error. Conversely, if bisacodyl is received in error, it can cause gastrointestinal upset; but importantly, the omission of bisoprolol in error can lead to untreated or rebound hypertension, rebound tachycardia or arrhythmias, or myocardial infarction.^{1,2}

Method of Analysis and Overview of Findings

Information was extracted from all voluntary reports submitted to ISMP Canada's medication incident database from August 1, 2000, to February 1, 2012. Of the 88,703 incidents submitted during that period, a total of 32 incidents involved a mix-up between bisoprolol and bisacodyl[†]. These 32 reports had been submitted by practitioners working in a variety of settings, including hospitals, long-term care facilities, and community pharmacies. The incidents involved pediatric patients, adults, and older adults. None of the incidents led to severe harm or death.

The 32 incidents reviewed were categorized according to themes based on the stages of the medication-use system (Figure 1). Incidents within each theme were further evaluated to identify key subthemes (Figure 1). The following report presents the findings of a qualitative analysis, along with incident examples, comments, and recommendations.

Findings of the Qualitative Analysis

Theme: Prescribing/Ordering

Subtheme: Verbal Orders

Incident example: A staff member from a retirement home contacted a patient's pharmacy to report that bisoprolol 2.5 mg had been ordered upon the patient's discharge after a recent hospital stay. The pharmacist receiving the order understood that the prescription was for bisacodyl 2.5 mg and repeated this back to the caller, who confirmed the

[†]A data search conducted on July 5, 2012 of the Canadian Institute for Health Information's National System for Incident Reporting database for the period 2008–2012 revealed fewer than 5 reports of mix-ups between bisoprolol and bisacodyl that were not included in the aggregate analysis.

^{*}This definition was adapted from a published discussion about pharmacovigilance and the reporting of adverse drug reactions.⁴ In their discussion, Härmark and van Grootheest⁴ suggested that "concerned reporting" would be a better term to describe the reporting systems commonly referred to as "spontaneous reporting", because the individuals who provide such reports are often highly selective in what they convey. Edwards⁵ first introduced the idea of concerned reporting when he described spontaneous reports from healthcare professionals as genuine concerns about a drug and a suspected harmful reaction. The term "concerned reporting" also captures the essence and value of voluntary medication incident reporting programs. The reporting of harmful or potentially harmful medication incidents by individual practitioners or by consumers can assist in detecting safety issues.

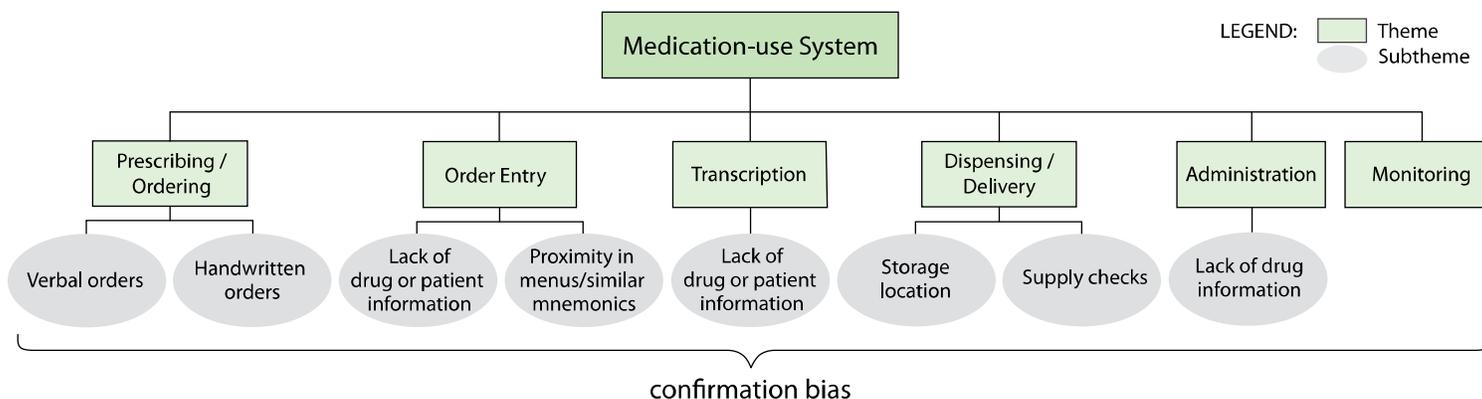


Figure 1. Themes (stages of the medication-use system) and subthemes identified in an aggregate analysis of mix-ups involving bisoprolol and bisacodyl reported to ISMP Canada, 2000–2012.

information, although it was incorrect. Bisacodyl was dispensed. Fortunately, the pharmacist followed up shortly after dispensing the medication, as the dose was unusual. The error was identified, and the patient missed only one dose of bisoprolol (and received only one dose of bisacodyl).

Comment: Medications with look-alike/sound-alike names are subject to mix-ups when information is conveyed verbally. The recommended practice of having the recipient repeat back the drug name and directions is not always enough to prevent an error, and it may also be necessary to spell out the drug name.

Subtheme: Handwritten Orders

The risk of mix-ups with look-alike/sound-alike drug-name pairs also increases if handwritten orders are not completely legible, if typical dosages overlap, or if the indication for the drug is unknown by the professionals expected to provide or administer the medication.

Theme: Order Entry

Subtheme: Lack of Drug or Patient Information

Incident example: A patient’s profile in the pharmacy included an order for bisoprolol to be given as needed, instead of bisacodyl, which was the prescribed drug.

Comment: Several of the incidents reviewed in this analysis involved situations in which an unusual dose (e.g., bisacodyl 2.5 mg or 7.5 mg po) or an unusual frequency (e.g., bisoprolol on an “as needed” [prn] basis) had been entered into the pharmacy system. Bisacodyl is available as a 5 mg enteric-coated tablet and should not be split (e.g., to create a 2.5 mg dose), as the uncoated tablet may cause gastric upset and will not dissolve in the intestine to provide the desired action. Similarly, when bisoprolol is used for one of the usual indications described above, it must be given on a scheduled basis, not a prn basis.

Subtheme: Proximity of Names in Selection Menus / Similar Mnemonics

Incident examples:

- An order for bisacodyl 5 mg po/pr daily was written and entered as bisoprolol 5 mg po daily and bisacodyl 5 mg pr daily.
- The medication bisoprolol 5 mg was ordered, but the prescription was entered as bisacodyl 5 mg. Later, the prescription was filled with bisoprolol tablets (the correct medication) incorrectly labelled as bisacodyl.

Comment: Because the drug names “bisacodyl” and “bisoprolol” share the same first 3 letters, these 2 drugs may appear in close proximity in drop-down computerized selection menus. In some hospitals, depending on the institutional formulary, they may actually appear consecutively. Cues may or may not be present to alert healthcare professionals to the potential for a mix-up. Additionally, similarities in terms of both name and tablet strength of the 2 products can create potential problems with the use of drug mnemonic codes (used in some pharmacies). For example, “BIS5T” could be interpreted as “bisacodyl 5 mg tablet” or “bisoprolol 5 mg tablet”.

Theme: Transcription

Subtheme: Lack of Drug or Patient Information

Incident example: When preparing a patient for transfer, a nurse noticed an unusual order for bisoprolol 10 mg nightly as needed. Upon further investigation, it was noted that the intended order for bisacodyl 10 mg nightly as needed had been transcribed incorrectly.

Comment: This example represents 1 of 2 incidents in which a healthcare professional (a nurse and a pharmacist, respectively) noticed the unusual use of bisoprolol on a prn basis. As a result, a transcription error was caught. In some

hospitals, nonclinical staff who have little or no knowledge about medications or underlying patient conditions may transcribe or input handwritten orders into a patient's medication administration record (MAR). Any medication transcribed onto the MAR must make clinical sense, and checking for clinical suitability is an additional safeguard toward ensuring that the drug name, as well as the dose, the route, and the frequency of the medication, is correctly communicated.

Theme: Dispensing/Delivery

Subtheme: Storage Location

Incident example: In a community pharmacy, bisoprolol 5 mg tablets were dispensed to a patient instead of bisacodyl 5 mg tablets. The error was discovered when the pharmacist was returning the stock bottles to the shelf and realized that although a prescription had been prepared from the stock bottle of bisoprolol, no bisoprolol prescriptions had recently been processed by the pharmacy.

Comment: Because both "bisoprolol" and "bisacodyl" begin with the letters "bis", these medications may be stored side by side in both community and hospital dispensaries. Cues may or may not be present to alert healthcare professionals to the potential for a mix-up. In this particular incident, the medications had been obtained from the same generic manufacturer. In such circumstances, the potential for a mix-up may be increased if the labelling and packaging are similar, and also because the drugs' brand names have the same prefix (the abbreviated manufacturer's name) followed by the name "bisoprolol" or "bisacodyl".

Subtheme: Supply Checks

Incident example: The hospital night cupboard was found to contain bisacodyl 5 mg tablets where bisoprolol 5 mg tablets should have been stocked.

Comment: Night cupboards are used in hospitals to provide access to certain required medications after regular pharmacy hours. A similar "emergency supply" system may be in place in long-term care facilities. One concern is that night cupboards (or other stock supplies) may lack a check process to be followed during filling of the stock supply by pharmacy staff.

Theme: Administration

Subtheme: Lack of Drug Information

Incident example: A patient's MAR was misinterpreted, and bisacodyl 2.5 mg was given to the patient to take orally instead of bisoprolol 2.5 mg.

Comment: Administration (or self-administration) is the last stage in the medication-use process where an error can be caught before reaching the patient. Fortunately, many errors are caught by healthcare practitioners during administration (or by informed patients before or during

self-administration). However, some errors, such as the incident described above, can be missed at this stage. Confirmation bias can play a role. For example, errors can occur when medications ordered are not consistently provided as patient-specific items but rather require selection from stock; in this situation, confirmation bias leads the healthcare professional to select the better-known and readily available drug in stock, particularly if no information is available to prevent incorrect selection. Errors can also occur if patients or caregivers are not given appropriate information and are not engaged in the process.

Recurrent Subthemes across Stages of Medication Use

Confirmation Bias

Confirmation bias is the tendency to see what you expect to see or what you are familiar with. Confirmation bias can occur during any stage of the medication-use process and may be exacerbated when look-alike/sound-alike drug names are involved. In cases where there is no obvious additional information to contradict the bias (e.g., information about the condition for which the medication is being prescribed), the error is likely to go unnoticed by the healthcare professional. When a new drug with a name that looks or sounds similar to the name of another agent reaches the market or is added to a hospital's formulary, confirmation bias commonly contributes to look-alike/sound-alike mix-ups, as individuals usually "see" the medication name with which they are most familiar. For example, the report that prompted this aggregate analysis identified that bisacodyl is commonly used for pediatric patients, whereas bisoprolol is not.

Involvement of Patients and Caregivers

Many of the incidents reviewed also demonstrate the value of including the patient and/or caregiver in the medication-use process whenever possible. Informed patients and caregivers have an important role in the safe use of medications. They can and do identify errors before the wrong medication is taken or administered. The important role that healthcare practitioners can play in facilitating and supporting patient and caregiver involvement, especially by providing drug information and encouraging communication, should never be underestimated.

Recommendations

The drug name and dose similarities of bisoprolol and bisacodyl are contributing factors that can manifest themselves differently within each stage of the medication-use process. The following recommendations, categorized according to the various stages of the medication-use process, are suggested to reduce the potential for errors with bisoprolol and bisacodyl and may also be more generally applicable to other pairs of look-alike/sound-alike drug names.

Prescribing

- Include the indication for the medication when possible.⁶
- When the brand name provides a means of differentiation, use both the generic name and the brand name of the drug.^{6,7}
- Use computer-generated prescriptions, such as preprinted order sets, if possible. If prescriptions are handwritten, use printing rather than cursive writing to assist with legibility.⁷
- Ensure that the patient and/or the caregiver understands why the medication has been prescribed (the indication) and how to properly use the medication. It is also helpful to verify that the patient or caregiver can read the prescription.⁶
- If an order must be conveyed verbally, spell out the name of the drug.^{6,8}

Order Entry

- Review options for enhancing how information appears in pharmacy and prescriber order entry systems. Examples include using both the generic and brand names in the drug library and including the indication (or prompting the inclusion of an indication) in order entry systems.
- If computer mnemonics are used for certain drugs, ensure that the mnemonic for any particular drug is clearly distinguished from and does not look or sound the same as the mnemonic for any other drug (e.g., use sufficient characters to differentiate the drug names).⁹
- Review mnemonic codes to ensure that no codes link to unintended drug products.¹⁰

Transcribing

- Plan for and work toward systems that eliminate the need for transcription (e.g., integrate prescriber order entry with electronic MAR system).
- Ensure that one or more healthcare professionals with knowledge of the medications and the patient's clinical condition (e.g., nurse or pharmacist) review newly transcribed orders before they are implemented.
- Include redundant information on the MAR (e.g., indication for medication), to provide cues that will reduce the potential for confirmation bias.

Dispensing and Delivery

- Review pharmacy storage areas to determine if look-alike/sound-alike products are stored in close proximity. Consider the following strategies to enhance differentiation:
 - Purchase look-alike/sound-alike products from different manufacturers.
 - Place warning labels on look-alike/sound-alike products and/or in their storage areas (regardless of whether they are stored separately or in close proximity).^{6,11}
- Engage in dialogue with the patient and/or the caregiver as a way to detect potential errors. For example, as an additional check before providing a medication, ask the patient to state the reason why the medication was prescribed.^{6,10}
- Because technologies such as night cupboards and other stock supplies bypass the pharmacy's usual safety checks for patient-specific dispensed medications, ensure that medications for these devices include safety checks.
- Consider use of bar-coding technology to allow for automated and independent checks during the dispensing process (as well as other processes).

Administration

- When feasible, communicate with the patient and/or the caregiver about the medication that is to be administered. This gives the patient or caregiver an opportunity to speak up if the medication is not one that he or she was expecting.¹²

Conclusion

It has been estimated that about 25% of medication errors can be attributed to similarities in drug names.^{6,13} In a 2008 analysis, the United States Pharmacopeia identified 1,470 drug names involved in look-alike/sound-alike medication errors and over 3,000 pairs of drug names (both proprietary and generic) that could potentially be mixed up.^{8,14}

It is hoped that this bulletin will serve to remind all healthcare professionals of the risk for error with look-alike /

sound-alike drug names, including human limitations such as confirmation bias. Awareness is a first step. The analysis and system recommendations provided in this bulletin are intended to guide review of local processes and ultimately to reduce the potential for harmful mix-ups between bisoprolol and bisacodyl (and between other look-alike/sound-alike drug-name pairs) at each stage of the medication-use process.

Sharing SafeMedicationUse.ca Learning—A Sip of Water May Not Always be Enough

ISMP Canada reminds healthcare practitioners that certain oral medications require administration with an adequate quantity of water or other appropriate fluid. This is an important consideration when administering medications with the potential to cause esophageal or gastric irritation or ulcers. Dosing schedules or routes of administration may require adjustment in advance of procedures that require withholding of food and water or for patients who will be lying down for an extended period. A SafeMedicationUse.ca newsletter on this topic is available at the following link: http://www.safemedicationuse.ca/newsletter/newsletter_water.html

Version II of the Medication Safety Self-Assessment for Long-Term Care Now Available

The *Medication Safety Self-Assessment for Long-Term Care (MSSA-LTC) Version II* is now available for use by long-term care facilities. This self-assessment tool was revised this year under the guidance of a working group of long-term care representatives. Version II contains additional self-assessment items and new appendices to provide guidance to users, including how to interpret and present the findings of a medication safety self-assessment.

The MSSA-LTC Version II is now available to users upon request, and uploading of results to the ISMP Canada website can begin October 1, 2012. Data entry for assessments based on Version I of this MSSA must be completed by September 30, 2012. Historical data for assessments already completed will remain within the database, allowing users to continue to track and compare their results each time they complete the MSSA.

If you have questions or need additional information, please contact ISMP Canada by e-mail mssa@ismp-canada.org or by phone 416-733-3131 x236, or check online at <http://www.ismp-canada.org/lmssa/index.php>

References

1. Bisoprolol. In: Repchinsky C, editor-in-chief. Compendium of pharmaceuticals and specialties. Ottawa (ON): Canadian Pharmacists Association; 2012. p. 443-444.
2. DRUGDEX evaluations: bisoprolol. In: Micromedex healthcare series [Internet database]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; updated periodically [cited 2012 Jul 2]. Available from: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionID/pf.LoginAction>
3. Dulcolax product monograph. Burlington (ON): Boehringer Ingelheim Canada Ltd; 2010 Jul 9 [cited 2012 Aug 12]. Obtained through Health Canada Drug Product Database; search term "bisoprolol" as active ingredient, available from: <http://webprod3.hc-sc.gc.ca/dpd-bdpp/start-debuter.do?lang=eng>
4. Härmark L, van Grootheest AC. Pharmacovigilance: methods, recent developments and future perspectives. Eur J Clin Pharmacol. 2008;64(8):743-752.
5. Edwards IR. Spontaneous reporting—of what? Clinical concerns about drugs. Br J Clin Pharmacol. 1999;48(2):138-141.

6. What are look-alike sound-alike (LA/SA) health product names? Ottawa (ON): Health Canada; modified 2009 Nov 9 [cited 2012 Jul 2]. Available from: <http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/fs-if/2003-lasa-pspcs/index-eng.php>
7. WHO Collaborating Centre for Patient Safety Solutions. Look-alike, sound-alike medication names. Geneva (Switzerland): World Health Organization; 2007 May [cited 2012 Jul 9]. Vol. 1, solution 1 of Patient Safety Solutions. Available from: <http://gis.emro.who.int/HealthSystemObservatory/PDF/Patient%20Safety/PS-Solution1.pdf>
8. Thompson CA. USP says thousands of drug names look or sound alike. *Am J Health Syst Pharm*. 2008;65(5):386-388.
9. U D. Medication safety alerts: double-checking: does it work? *Can J Hosp Pharm*. 2003 [cited 2012 Jul 6];56(3):167-169. Available from: <http://www.ismp-canada.org/download/cjhp/cjhp0306.pdf>
10. Improving medication safety in the community: assessing risk and opportunities for change. Horsham (PA): Institute for Safe Medication Practices. 2009 [cited 2012 Jul 3]. Available from: <http://141.109.38.4/resources/ISMP-US%20Assess%20Err%20Manual.pdf>
11. Emmerton LM, Rizk MFS. Look-alike and sound-alike medicines: risks and “solutions”. *Int J Clin Pharm*. 2012;34(1):4-8.
12. Consumer reports submitted to SafeMedicationUse.ca provide insights into opportunities to enhance safety. *ISMP Can Saf Bull*. 2011 Dec 21 [cited 2012 Jul 30];11(8):1-4. Available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2011-08-Consumer_Reports_Submitted_to_SafeMedicationUse.pdf
13. Chadwick M. Look-alike sound-alike health product names. Health Canada workshop; 2003] Oct 20 [cited 2012 Jul 9]; Gatineau (QC). Available from: http://www.hc-sc.gc.ca/dhp-mps/brgtherap/proj/alike-semblable/sum-res_consult_workshop-atelier-eng.php
14. Hicks RW, Becker SC, Cousins DD, editors. MEDMARX data report. A report on the relationship of drug names and medication errors in response to the Institute of Medicine’s call for action. Findings 2003–2006 and trends 2002–2006. Rockville (MD): US Pharmacopeia, Center for the Advancement of Patient Safety; 2008 [cited 2012 Jul 9]. Available from: <http://www.scribd.com/doc/26028426/MedMarx-Report-2008>

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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.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System