ISMP Canada

Pharmaceutical bar coding: Moving forward in Canada

By Ian Sheppard, BSc (Pharm), Sylvia Hyland, BScPhm, MHSc (Bioethics), Pierrette Leonard, APR, FCPRS, and Christine Koczmara, RN, BSc

Abstract

The purpose of this article is to provide an update on the status of automated identification (e.g., bar coding) of pharmaceutical products manufactured for distribution within Canada.

Analyses of medication incidents, such as the inadvertent administration of hydromorphone instead of morphine, (ISMP Canada, 2004; ISMP Canada, 2006) have led to recommendations that health care facilities strategically plan for implementation of advanced technologies such as bar coding at the point of care, prescriber order entry, and electronic medication administration records. The use of bar coding, the most widely recognized machine-readable identifier in a point-of-care scanning system (ASHP, 2004; Neuenschwander et al., 2003), combined with a computerized medication product database, allows health care professionals to verify that the right drug, in the right dose, and by the right route of administration is being given to the right patient at the right time (FDA, 2004). Bar coding, when integrated with enabling advanced technologies, can serve as an automated independent double check. Numerous articles and other sources of information highlight the benefits, as well as the challenges with automated identification systems such as bar coding (AHRQ, 2008; Cochran, Jones, Brockman, Skinner, & Hicks, 2007; Cohen, 2007; Koppel, Wetterneck, Telles, & Karsh, 2008; Neuenschwander et al., 2003; Poon et al., 2006; Wright, & Katz, 2005).

Fundamental to the ability to implement widespread automated identification of medications at every step of the medication use process, including point of care verification and smart pump programming, is the development of a pan-Canadian health sector agreement on the coding of pharmaceutical products manufactured and distributed for use in Canada. The achievement of such an agreement creates a foundation upon which further sophisticated identification of medications and patients can occur. The purpose of this article is to provide critical care practitioners with an update on the status of automated identification (e.g., bar coding) of pharmaceutical products in Canada.

Background

Bar coding is well established in industries outside of the health care sector and is now used in some health care-related industries, such as in retail pharmacy to enhance both efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain efficiency. The exterior package labels of most prescription medications for sale in Canada include an identifying bar code. However, the same does not hold true for the inner labels on unit-of-use packaging, such as ampoules, vials, and blister packs. As a result, Canadian facilities that have begun to implement bar coding systems have had to generate and print their own bar code labels for application to ampoules, vials, and blister packs, as well as for their own pharmacy-prepared products.

In Canada, there are currently no regulations for the bar coding of medications from pharmaceutical manufacturers, whereas in the U.S., the Food and Drug Administration requires that manufacturers include a bar code for all medications used in hospitals (FDA, 2004; FDA, 2006). Recently, several pharmaceutical manufacturers have demonstrated leadership by adding bar code identification to their products' inner labels. As stated by the National Coordinating Council for Medication Error Reporting and Prevention, "Before healthcare practitioners and organizations can benefit from machine-readable codes, the codes must be physically present in a standard format on unit-of-use medication packaging" (NCC MERP, 2001, p. 3).

There have been no formally recognized Canadian standards for bar coding specifically developed for medications. However, a number of related initiatives are underway. For example, the Public Health Agency of Canada is taking steps to develop a consensus on standards for bar coding of vaccines (Public Health Agency of Canada, 2007). By collectively confirming a national standard for coding pharmaceuticals distributed in Canada, an essential foundation can be created for downstream patient safety and efficiency benefits. Practices in which patient safety could be positively improved are many. They include the stocking of patient care areas and automated drug cabinets, essential product identification in high-risk compounding processes performed by both pharmacy and critical care nursing staff and, importantly, bedside (or "point-of-care") verification of the medications administered to patients.

A national collaborative effort: The Canadian Pharmaceutical Bar Coding Project

In early 2008, a national stakeholder invitational roundtable, co-chaired by ISMP Canada and the Canadian Patient Safety Institute (CPSI), was convened in Ottawa to discuss and seek pharmaceutical manufacturer consensus on voluntary guidelines for the use of bar codes to label medications at the unit-of-use packaging level. Prior to the roundtable, a document was prepared and circulated to stimulate discussion on how pharmaceutical manufacturers can best meet the needs of Canadian health service organizations seeking to improve patient safety by using automated identification technologies in medication dispensing and administration systems (ISMP Canada, 2008). During the meeting, there was overall agreement that a national standard is urgently needed for bar coding of pharmaceutical products (ISMP Canada & CPSI, 2008).

Pursuant to the roundtable, a multiphase project plan for pharmaceutical bar coding in Canada was prepared and approved. The project is being guided by a national implementation advisory committee, co-chaired by ISMP Canada and CPSI and currently comprises representatives from multiple organizations and associations, including (in alphabetical order): Canada Health Infoway, Canada's Research-Based Pharmaceutical Companies, Canadian Association of Chain Drug Stores, Canadian Association for Pharmacy Distribution Management, Canadian Generic Pharmaceutical Association, Canadian Society of

Hospital Pharmacists, Group Purchasing Organization Alliance (currently includes Approvisionnement-Montréal, Health*PRO*, and Medbuy), and the Public Health Agency of Canada. This project is financially supported by grants from both public and private organizations who are acknowledged on the ISMP Canada website and documents.

In follow-up to the first meeting of the implementation advisory committee earlier this year, ISMP Canada and CPSI jointly endorsed the adoption of the GS1 global standard for automated identification (e.g., bar coding) of pharmaceutical products in Canada. Going forward, work with stakeholders will aim to ensure that the Canadian standard continues to evolve so that user requirements for implementing bar coding within the health care system are fully identified and met across all health care sectors. A 34-member technical task force with representation from pharmaceutical manufacturers, supply chain organizations, health and information technology providers, retail pharmacy, institutional pharmacy, and health standards organizations met in May 2009 to review the technical requirements of pharmaceutical bar coding for health care. The technical task force will define the requirements of Canadian health care constituents in the following areas: bar code components and symbology, required database elements, medications to be included, and packaging levels and bar code placement. The technical task force will also provide recommendations to the national implementation committee on a pan-Canadian implementation and sustainability plan.

By proactively and cooperatively reaching agreement on the standards to be implemented, the health care system can move toward the implementation of integrated bar coding safety checks during medication-use processes such as compounding, dispensing, and administration, while maintaining enhanced efficiencies along the entire medication supply chain. This national collaborative effort is envisioned to have multiple phases, during which strategic alliances will be further developed. Additional project information and updates are available from ISMP Canada (http://www.ismp-canada.org/barcoding/). Project updates will also be available from CPSI (www.patientsafetyinstitute.ca).

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The Canadian Patient Safety Institute (CPSI) is a not-for-profit corporation, operating collaboratively with health professionals and organizations, regulatory bodies and governments to build and advance a safer health care system for Canada. CPSI performs coordinating and leadership roles across health sectors and systems, promotes leading practices and raises awareness about patient safety by working in collaboration with partners, patients, their families and the general public. For more information, visit www.patientsafetyinstitute.ca.

ISMP Canada gratefully acknowledges the valuable lessons learned and information reported by professionals in the Canadian health care community that can then be shared to enhance medication system safety. All ISMP Canada Safety bulletins are available from http://www.ismp-canada.org/ISMPCSafetyBulletins.htm.

ISMP Canada is an independent national not-for-profit organization committed to the advancement of medication safety in all health care settings. ISMP Canada maintains a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Our collaborative goal is implementation of preventive strategies and system safeguards to decrease the risk for error-induced injury.

ISMP Canada is a key partner in the Canadian Medication Incident Reporting and Prevention System (CMIRPS). 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 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.

About the authors

Ian Sheppard, BSc (Pharm), is the project leader for the Canadian pharmaceutical bar coding project. He is also the Assistant Pharmacy Director at B.C. Children's and B.C. Women's Hospitals. E-mail isheppard@ismp-canada.org

Sylvia Hyland, BScPhm, MHSc (Bioethics), is Vice-President and Chief Operating Officer of the Institute for Safe Medication Practices Canada (ISMP Canada), Toronto, Ontario, and is co-chair for the Canadian pharmaceutical bar coding project. E-mail shyland@ismp-canada.org

Pierrette Leonard, APR, FCPRS, is the Canadian Patient Safety Institute (CPSI) Senior Advisor for National Partners of CPSI in Ottawa, and is co-chair for the Canadian pharmaceutical bar coding project. E-mail pleonard@cpsi-icsp.ca

Christine Koczmara, RN, BSc, is a Senior Medication Safety Analyst with the Institute for Safe Medication Practices Canada (ISMP Canada). She also holds a casual position as a bedside nurse in an intensive care unit (ICU). E-mail ckoczmara@ismp-canada.org

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