

Pharmaceutical Bar Coding: National Recommendations

In a May 2009 ISMP Canada Safety Bulletin¹, a national collaboration of organizations from 6 healthcare sectors was announced to oversee the development of a pan-Canadian strategy for the use of commercial pharmaceutical bar codes. Automated Identification and Data Capture (AIDC) technology, of which bar coding forms a part, has been identified as a critical component of future medication process technologies expected to lead to more efficient and safer medication systems for Canadians.

This bulletin provides an update on this national initiative. It highlights the release of pan-Canadian guidelines for bar codes to be placed on commercial pharmaceutical product labels and the application of this technology to practices across all health sectors.

Background

Medication errors causing adverse events have been widely acknowledged as a significant problem in healthcare.^{2,3} Although studies vary in the reported rates of adverse events caused by medication errors, there is strong agreement that patient harm caused by such events is unacceptably high, especially considering their mostly preventable nature.

In the literature, errors have been described as occurring at different stages of the medication-use process, such as prescribing, order transcription and verification, dispensing, and administration,⁴ but in reality, errors can occur even before the medication is prescribed. Figure 1 describes the medication flow chain, showing stages that occur even before the traditional “first step” of prescribing. The chain begins with the pharmaceutical manufacturer that produces the medication and designs its labelling and packaging. Then, whether viewed from an institutional or a community perspective, the medication chain proceeds down a series of steps, culminating in administration of the dose to the patient. Success depends

on many factors, including accuracy, efficiency, and documentation. At any given point in the chain, there is a risk that a medication error will occur.

Bar coding, or AIDC more generally, can reduce the potential for inadvertent error at every step of the medication flow chain, while maintaining efficiency of handling and accuracy and timeliness of documentation.⁵⁻⁸

The Project

Following a national stakeholder roundtable in 2008, the Canadian Pharmaceutical Bar Coding Project was initiated, with co-facilitation by ISMP Canada and the Canadian Patient Safety Institute. A meeting of the project’s national advisory committee of leading organizations was held in 2009, followed by the establishment of a technical task force. This task force, consisting of more than 40 representatives from the 6 healthcare sectors, was given the mandate to define the necessary technical requirements and to provide input into an implementation and sustainability plan. Later that same year, the GS1 global AIDC standard was endorsed as the recommended national AIDC standard for pharmaceutical bar coding of commercial pharmaceutical products across all health sectors in Canada.

Establishment of the pan-Canadian standard will allow critical changes to medication systems to proceed in concert, which will lead to innovative automated methods of identifying pharmaceutical products and performing calculations, as well as novel patient bedside systems and forms of documentation. Canadians can now reasonably expect safer medication systems in the years to come.

Joint Technical Statements

In January 2010, the project released its first joint technical statement (JTS version I), which presented guidelines for the use of commercial pharmaceutical bar codes within Canada. The document, entitled *Joint Technical Statement*



Figure 1 – The medication flow chain

on *Pharmaceutical Automated Identification and Database Requirements* reviewed the following issues:

- common national standard for automated identification
- required content of bar codes
- defined packaging levels and placement of bar codes
- common Canadian pharmaceutical product registry
- allowable bar code symbologies
- expectations of professional practice organizations and end users
- timeline for adoption

The 2010 JTS recommended use of the GS1 global unique product identifier or Global Trade Item Number (GTIN). In Canada, the globally unique pharmaceutical GTIN is linked to the Health Canada Drug Identification Number (DIN), for cross-referencing purposes. The JTS recommended that pharmaceutical manufacturers comply with the guidelines by **December 2012**. The document also identified future needs, such as the need to establish related recommendations for the following aspects of bar coding:

- a common pharmaceutical product data registry
- additional bar code labelling guidelines
- smaller bar code symbologies for “reduced-space pharmaceuticals”
- aligned software safety functionality checklists for automated (bar code) systems used within healthcare practices

In February 2012, the new JTS (version II) was released, containing technical updates on many key issues, such as the following:

- identification of the GS1 Canada database (ECCnet Registry) as the primary source of standardized pharmaceutical product data for commercial pharmaceuticals in Canada, with alignment with the Health Canada Drug Product Database through a GTIN/DIN cross-linkage
- requirement for pharmaceutical manufacturers to include additional product data elements (e.g., expiry date and lot number) within the single GS1 bar code by December 2017
- promotion of the more compact 2-dimensional bar code, GS1 DataMatrix (or any other form approved by GS1 global), for small package labels
- need to allow for staged transition, in the community pharmacy setting, from the current use of the Universal Product Code (UPC) to more sophisticated bar code symbologies capable of carrying additional data elements

Two supplements were included with JTS version II:

- Supplement A: Guidance for Placement of Bar Codes on Pharmaceutical Labels for Primary Packaging
- Supplement B: Minimum Software Safety Functionality Checklist

The project and its recommendations continue to receive endorsements from leading Canadian organizations, including:

- BC Patient Safety and Quality Council
- Canadian Anesthesiologists’ Society
- Canadian Healthcare Association
- Canadian Medical Association
- Canadian Medical and Biological Engineering Society
- Canadian Nurses Association
- Canadian Society of Hospital Pharmacists
- Health Council of Canada
- Health Quality Council of Alberta
- Healthcare Insurance Reciprocal of Canada
- HealthPRO Procurement Services Inc
- Manitoba Institute for Patient Safety
- Medbuy Corporation
- Ontario Hospital Association
- Vancouver Island Health Authority

Next Phase

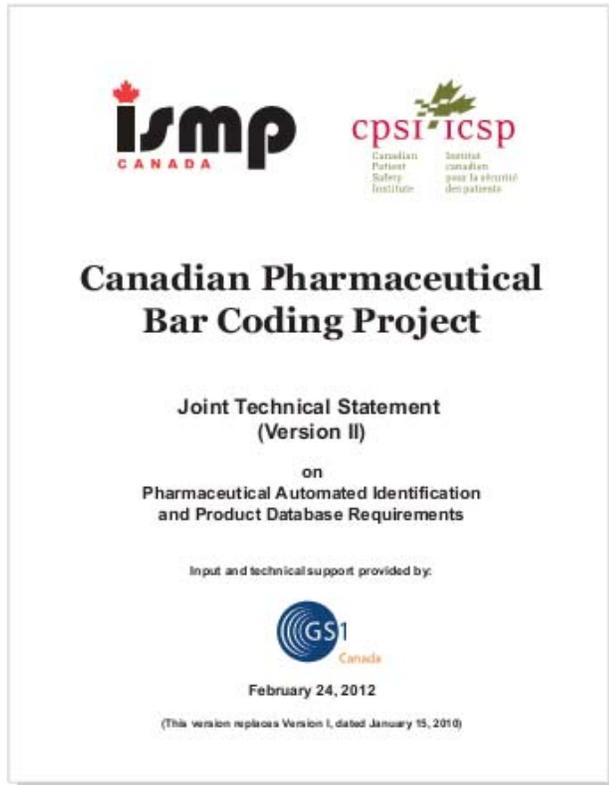
The project team will continue to work with community and institutional practitioners and their practice organizations to promote enhanced understanding, acquisition, and implementation of automated practices using bar coding, where readiness exists.

The following activities are planned for 2012 to 2013:

- national end-user readiness survey
- bar code implementation kit
 - Bar Coding Principles Made Easy
 - The Argument for Bar Code System Acquisition
 - implementation guide for institutions

Impact of National Standards for Automated Identification of Pharmaceuticals

The issuance of collaborative national recommendations for pharmaceutical bar coding, built on a common national AIDC standard, is foundational. It provides a pathway for coordinated and systematic growth of innovative medication technologies and practices that use “machine-readable code” (bar codes or radio frequency identification chips) across Canadian healthcare sectors, as promoted by the Canadian Society of Hospital Pharmacists in its CSHP 2015 objectives.⁹ In turn, improvements in medication safety for all Canadians can be expected.



Canadian Pharmaceutical Bar Coding Project

Find out more about the project and who is endorsing standardized pharmaceutical bar coding practices:

ismp-canada.org/barcoding



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Learn More about the National Bar Coding Initiative

The work related to the Canadian Pharmaceutical Bar Coding Project can be found on the ISMP Canada website, with documents available for viewing or download.

- Joint technical statement (version II, 2012), available from: <http://www.ismpcanada.org/barcoding/download/JTSv2/JTSv2.pdf>
- Joint technical statement, Supplement A: Guidance for Placement of Bar Codes on Pharmaceutical Labels for Primary Packaging, available from: <http://www.ismp-canada.org/barcoding/download/JTSv2/SupplA-LabelingGuidelines.pdf>
- Joint technical statement, Supplement B: Minimum Software Safety Functionality Checklist, available from: <http://www.ismpcanada.org/barcoding/download/JTSv2/SupplB-MinFunctionality.pdf>
- Project website, including endorsements from leading Canadian organizations, available from: <http://www.ismp-canada.org/barcoding/index.htm>

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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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