The Canadian Pharmaceutical Bar Code Project: Pharmaceutical Bar Coding to Improve Patient Safety & Rising Above the Bar: A Canadian Success Story – North York General Hospital

*Presentation for the* Global Healthcare Conference, June 2010
*By Doris Nessim, Director of Pharmacy, North York General Hospital*
Presentation Objectives

To Describe:

1. The need for bar code medication administration (BCMA) - internal and external patient safety drivers
3. The Need for a National Strategy - The Canadian Bar Coding Project
4. Future Direction in Canada
Why Implement Bar Code Medication Administration (BCMA)?

… there is a need for enhancing patient safety related to medication use in hospitals

The Canadian Adverse Events Study
Drs. Ross Baker and Peter Norton, Lead investigators, CMAJ, May/04
Errors at each stage of the Medication Use Process

“Human errors do not occur in isolation but when humans confront systems and processes whose design either invites, or at least does not prevent it.”*


Ref.: Leape et al. JAMA July 5, 1995
Errors at each stage of the Medication Use Process

only 2% of errors that originate at the patient’s bedside are captured, making the administration phase of medication delivery the most hazardous phase nurses have no safety net
North York General Hospital Profile

General Site
- 454 Acute Beds
- 34 Mental Health & Rehab
- ~100,000 ED visits/year
- ~30,000 inpatient cases/year
- ~1000 medical staff
- ~3200 staff

Branson Site
- Rapid Care Clinic
  - Provides urgent care to community
  - ~30,000 urgent care visits/year
  - Centre of Excellence

Seniors Health Center
- 192 bed LTC Ambulatory Geriatric

Philips House Outpatient
- Pediatric speech & language services
NYGH’s Electronic Medical Record Strategy

External Drivers:
Federal Electronic Health Record Strategy:

Patient Safety:
Federal Government – EHR:
“Canada needs electronic health records. They will help our health providers to be more efficient, improve the quality of care provided and reduce the chance of medication errors.”
The Honourable James Flaherty, Minister of Finance, 2007 Federal Budget Speech

Internal Drivers:
NYGH Electronic Medical Record Strategic Themes:

- Quality & Patient Safety
- Clinical Process Improvement
- Comprehensive EMR (alignment with Ministry of Health/LHIN/eHealth/ Infoway)
- Empower People
- Create & Share Knowledge and Innovation
- High Performing IT Systems
The Learning Organization Systems Leverage Model

- Shared Vision
- Dialogue & Reflection
- Options
- Leverage
- Feedback

Shared Reality

Assumptions

Gap
Why Implement BCMA?

**Impact:**
Reduce medication errors – dispensing and administration errors
Increase staff productivity and workflow
Improve overall operational efficiencies and quality of care
Enable data collection and feedback
Enable standardization across the system
North York General Hospital Strategy Map

Our Mission
A community teaching hospital in a continuum of health care, providing compassionate and quality care to diverse communities in North Toronto and beyond.

Our Evolving Vision: Community of Success: Serving with Kindness
- Each role is essential
- A well designed, safe workplace makes it easy to do the right things right
- System relationships achieve improved care for populations, patients and their families
- Everyone is a leader achieving quality outcomes and in leveraging resources
- People celebrate with others the joy and success of their work

Operational & Clinical Excellence
- Provide outstanding patient and family experience
- Recognized for outstanding and responsive care and service by NYGH staff, volunteers and physicians
- Achieve excellence in quality care and contribute to system sustainability through inquiry, innovation & learning
- Foster and value educational expertise, innovation and research
- Align our clinical programs and physical facilities to be responsive to community and stakeholder needs

Patient & Community Perspective
- Recognized as an ultra safe organization
- North York General Hospital Strategy Map

Learning & Innovation
- Access to the highest quality and safest care for patients
- Recognized as an ultra safe organization
- Foster and value educational expertise, innovation and research
- Develop healthcare and academic leaders

Community Integration & System Priorities
- Enhance access to support system priorities
- Improve quality and efficiency through integration of services
- Align our clinical programs and physical facilities to be responsive to community and stakeholder needs

Quality & Safety
- Implement evidence based leadership practices related to patient and family experience
- Leverage actions that will create a highly reliable or ultra safe organization
- Achieve excellence in quality care and contribute to system sustainability through inquiry, innovation & learning
- Foster and value educational expertise, innovation and research

Outcomes
- To deliver the best evidence based processes
- That meet our patients needs

Core Processes Perspective
- Enable competencies to support organizational objectives
- Continue to foster a culture of a learning organization
- Support existing processes through information technology, tools and systems
- Provide business intelligence capabilities to support processes and outcomes

Resource Management Perspective
- Cultivate engaged, aligned and dedicated employees, volunteers and physicians
- Nurture and develop leadership talent
- Provide business intelligence capabilities to support processes and outcomes
- Leverage revenue opportunities from non-traditional and special areas

Enablers
- Listening to appreciate diversity
- Learning through dialogue and reflection
- Serving patients, families and others with kindness

Our Values

April 2010

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NYGH’s Electronic Medical Record Strategy

Phase I
- **Positive Patient Identification** (barcoded wristband): July/07
- **Hospital-wide Electronic Scheduling**: April/08
- **Electronic Interprofessional Documentation**: June/08

Phase II
- **CPOE**: ~200 Order Sets - using Cerner Knowledge Catalog clinical decision support (Zynx)
- **Medication Integration Process**: eMAR, electronic Medication Reconciliation, ADE alerts, Dose Range Management, Rx Writer, and Depart Process
- **Addition**: Bar Code Medication Administration (BCMA) and the Medication Use Process
Future Process

Physician enters order in eCare

Orders reviewed by pharmacy and nursing

Barcoded medication sent from pharmacy to unit

Nurse scans patient and medication, confirms “5Rs”

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BACKGROUND: U.S. Experience

• The Joint Commission: National Patient Safety Goals
  • To implement bar coding that would help *identify patients* and *match them to their medications and treatments*.

• Barcoded NDC - required by the FDA since April 2004 with compliance required by April 2006

• Implementation experience suggests that readability, user prepared products, partial doses, backorders, devices, workflow, and workarounds continue to be issues.
Barcode Standards

Background: Canada

Canada currently has no Federal mandate for regulating barcode medication requirements.

Barcode medications provide an opportunity to improve patient safety and efficiency in the medication distribution system.

Canadian Hospitals that seek to take advantage of the opportunities are forced to determine the priority, strategy, and capital to undertake the barcoding internally.
Determined **bar code content, data format, and symbology** requirements and developed ‘selection criteria’:

- Formed basis for functionality specifications for new automation; determined functionality with existing automation

Created a **flow chart identifying touch points** in the medication use system where bar codes are needed to assure safe medication administration

**Tested compliance** with electronically readable ID symbology and location using Cerner CareMobile

**Developed an implementation plan**, identifying and securing equipment, resources, and timeline aligned with CPOE and eMAR implementation
NYGH – Pharmacy

Design considerations for assuring medication safety with bar code medication implementation with various forms of pharmacy automation

• Hours of Service Pharmacy Services NOT 24 x 7
• Medication Formulary: 2200 medications
• Approximately 3 M doses/year (po and IV)
• % of Commercially Available Medications in Unit Dose / ‘single unit of use’ packaging
• % of medications with ‘UPC’ codes
• Compatibility with automated medication cabinets
• Capital & Resource Requirements & Plan:
  • Automated medication prepackaging system
  • ‘Bar code medication station’ (new capital)
• Pharmacy Resource Requirements
NYGH – Pharmacy
Design Considerations:
Bar Code Content, Data Format & Symbology

• Established Bar Code Characteristic:
  static and unique

• Bar Code Content:
  Options:
  – Drug Identification Number (DIN)
  – Universal Product Code (UPC)
  – Cerner Item_ID Number
  – Cerner Dispense_ID Number

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Drug Identification Number (DIN)

PROS

• Unique for each medication strength/concentration

• Assigned by Health Canada (National registry)

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Drug Identification Number (DIN)

CONS

• Not barcoded by the manufacturer
• Not unique for different bottle package sizes or volume sizes

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UPC

PROS

Assigned by the manufacturer

- Unique for each medication strength, bottle/volume size
- Barcoded by the manufacturer; do not need to add a barcode for hospital use

Copyright: North York General Hospital, Pharmacy Services. Use only with permission.
CONS

• Most UPC codes are printed on the external package, not on the container itself
• Different data formats of UPC code (GS1 or HIBCC)
• Can be assigned by the manufacturer based on different batches
NYGH – Pharmacy
Design Considerations:
Bar Code Content, *Data Format* & Symbology

- Standards are the foundation for clear, understandable exchanges between companies in an increasingly globalised economy. (GS1)

- Two standards for data format in health care:
  - Global Standard (GS) 1 using the GTIN
    - Compatible with Cerner functionality and devices (CareMobile)
  - Health Information Business Communications Council (HIBCC)
NYGH – Pharmacy
Design Considerations:
Bar Code Content, Data Format & Symbology

• Bar Code Symbology selected:
NYGH – Pharmacy Medication Bar Code Implementation

Prepackager
Create bar code for unit dose oral full or split tablets

Bar coding station
Create barcode for injectables, topicals, inhalers

Bubble (Medidose) packaging
Create barcode for oral solid (cytotoxic) and oral liquid
Keys to Success
Beyond Bar Code Medication: System Improvements – Building Capacity

Successful and **sustainable** realization is based on strong inter-relationships and collaboration requiring:

- **culture transformation**
- **executive** leadership and support
- **human factors** thinking,
- enabling **technologies**.
The Canadian Pharmaceutical Bar Code Project

Pharmaceutical Bar Coding to Improve Patient Safety

GS1 Canada Board

Referencing Presentation by: Ian Sheppard, Project Manager,
The Canadian Pharmaceutical Bar Coding Project
The exact rate of Adverse Drug Events is uncertain, as is the number of related deaths or significant injury per admission. Equally, the proportion of ADE caused by human (system) error is not precisely known. Yet, we can reasonably conclude:

- The number of ADEs is unacceptably high (3-6% of admissions to hospitals).
- Serious patient injury in 20-30% of events. Death in approximately 1%. (Estimated 700 deaths annually in Canada.)
- Many ADEs are caused by human error; the majority at the point of administration.
- Approximately 30-40% of ADEs are preventable, and the more serious the ADE, the more likely the event was preventable.
The Need for National Pharmaceutical Barcoding Standards: Lack Standardization

“We learned early in the planning process that “a bar code is not necessarily a bar code,” meaning that just because a product has a bar code on it, the bar code will not necessarily be usable in a BCMA system.

The lack of a standard barcode format is a significant hurdle …”

Improved control of medication use with an integrated bar-code-packaging and distribution system.
Bar codes are not found on all levels of packaging. Many primary (e.g. vial) and secondary (outer package) labels lack bar codes.

There is no standard for the type of bar code to use, nor the required information within the code itself. Reader/scanners and software cannot be seamlessly written to read the codes.

There is no national standard for the rules regarding how to assign an identification number, which is used continuously through the medication chain, and at every package level, or a common product descriptor database connected to the bar codes.

Bar codes, when applied, are different between hospitals and community, and often between healthcare sites.
The Canadian Pharmaceutical Bar Code Project
Project Overview
A National Collaboration between six healthcare sectors.
A two-year project comprised of 3 phases.

Major Objectives:
To develop a pan-Canadian strategy for bar coding of commercial pharmaceutical products.

To develop a common product database for standardized product data

To facilitate clinical information systems development which utilizes automated identification and data capture at each point of the medication chain

To create a national environment for automated identification (and data capture) implementation within each identified healthcare sector.
Collaborating Organizations
## Project Outputs: Phases II and III

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>Phase I</td>
<td>Needs Assessment for Automated Identification and Data Capture National Consensus on Pharmaceutical Bar-Coding Initiative Convened the Canadian Bar Coding Project</td>
<td>Completed June 2008</td>
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<tr>
<td>Phase II</td>
<td>Development and Approval of National Bar-Code Standards</td>
<td>Completed Dec 2009</td>
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<tr>
<td>Phase III</td>
<td>Dissemination and Stakeholder Engagement Phases</td>
<td>Jan 2010 - Sep 2010</td>
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<td>Current Phase</td>
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<tr>
<td>Phase IV</td>
<td>Implementation of Variable Bar-code Elements (Out of Scope)</td>
<td>Out of Scope of Two-Year Project</td>
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<tr>
<td>Phase V</td>
<td>Post-Implementation Interventional Change (Out of Scope)</td>
<td>Out of Scope of Two-Year Project</td>
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</table>
GS1 Global Standard Endorsement: A Global Automated Identification Standard

Canadian Pharmaceutical Bar Coding Project Endorsement Statement
April 27, 2009

The Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI), following broad consultation, jointly endorse the adoption of the GS1 global standard for automated identification (e.g., bar coding) of pharmaceutical products in Canada. Going forward, ISMP Canada and CPSI will work with stakeholders to ensure that the Canadian standard continues to evolve so that user requirements for implementing bar coding for enhanced safety of medication use within the healthcare system are fully identified and met across all healthcare sectors.

The Canadian Pharmaceutical Bar Coding Project is a unique opportunity for all stakeholders of the Canadian medication system to collaborate nationally and internationally, from industry to healthcare providers, on a comprehensive strategy for enhanced medication use to improve patient safety.
GS1 Canada’s Healthcare Pharmacy Sector Board ultimately seeks to ensure that Canada’s pharmacy sector trading partners are able to fully operate in an increasingly e-driven global supply chain reality.

Through collaboration with sector representatives, as well as government and key healthcare stakeholders, the Board identifies opportunities to leverage global standards-based solutions and transferable adoption models that support a safe and sustainable healthcare delivery system across Canada.
The Joint Technical (Task Force) Statement (Phase II)

Section 1: Pharmaceuticals to be Encoded

Section 2: Common National Standard

Section 3: Content of the Bar Codes

Section 4: Pharmaceutical Packaging Levels and Placement of Bar Codes
The Joint Technical Statement
(Phase II)

Section 5: Common Canadian Pharmaceutical Product Registry (CCPPR)

Section 6: Bar Code Symbology

Section 7: Expectations of Professional Practice Organizations and End-Users

Section 8: Timeline Adoption of Standard by each Health Sector (Pharmaceuticals Dec 2012)
Other Health Jurisdictions Undertaking barcoding for either Medical/Surgical or Pharmaceutical products:

- US FDA
- UK NHS
- Canada
- Australia
- New Zealand
- France
- Brazil
- India
- China and Hong Kong
- Turkey
- Columbia
- Japan
- Council of Europe
- Chile

Many are based on GS1 global standards.
How will the standardized bar coding of commercial pharmaceuticals integrate into professional practices?

-Phase 3: Sustainability strategies for engaging stakeholders
Healthcare IT solution providers
Healthcare end users
Cost effectiveness models for averting adverse events
Practice Implementation
The Medication Chain
Evidence of Effectiveness of Bar Coding (AI) on Patient Safety and Return on Investment
Effectiveness of Bar Code on Medication Safety ... (‘Toolkit’)

Effect of Bar-Code Technology on the Safety of Medication Administration

Summary: Using a bar coded eMAR
Brigham Young, Boston
* 41.4% reduction in dose administration and order transcriptions, excluding potential timing errors.
* A 27.3% reduction in dose timing errors.

Conclusion:
* Use of bar-code eMARs reduced the rate of errors and adverse drug events in order transcription and medication administration.
* Bar-code eMAR is an important intervention to improve medication safety.
Future Canadian Bar Code Project Phases and Initiatives
The Dissemination and Stakeholder Engagement Strategy
(Phase III – Integration with practice and implementation)

Three Tiers of Communications, then….

**Step 1:** Manufacturer Engagement

**Step 2:** Health Technology Provider Engagement

**Step 3:** End-User Practice Engagement

**Step 4:** Community/Retail Engagement
The Dissemination and Stakeholder Engagement Strategy
Inter-relationships of Key Organizations
Practice Endorsements (Phase III)

2010 TerraPharma WayPaver Award (U.S.)
2010 and Future Potential Project Phases

Canadian Pharmaceutical Bar Coding Project: Phase III/IV Documents 2010 to 2011

<table>
<thead>
<tr>
<th>Process</th>
<th>Implementation Committee Final Approval</th>
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<tbody>
<tr>
<td>Pharmaceutical Manufacturer Adoption</td>
<td>End User (Clinical) Adoption Begins</td>
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<tr>
<td>Database Work Group</td>
<td>Technical Task Force</td>
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<tr>
<td>&quot;Product Database Selected&quot;</td>
<td>&quot;Variable Data&quot;</td>
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<td>&quot;Product Data Transfer&quot;</td>
<td>January 2011 Meeting</td>
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<tr>
<td>Minimum Software Functionality</td>
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<td>Joint Technical Statement Version 1</td>
<td>Joint Technical Statement Version 2</td>
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<td>15 January 2010</td>
<td>February 2011</td>
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- Database: Out-of-scope Proposed Activity
- Database: Identified using unspent Original Project Budget
- Database: Identified 2010 Activity

- Commercial Labeling Proposal
- Commercial Labeling Small Volume Parenterals (SVP)
- Commercial Labeling Small Volume Parenterals (SVP)

- In-house Labeling Proposal
- In-house Labeling - Re-packaging - Patient Specific
- In-house Labeling - Re-packaging - Patient Specific
We Are Very Happy with the Association with GS1 Canada and are Seeking a Continuation of the Special Project Partnership with GS1 Canada, the “engine of integration”

<table>
<thead>
<tr>
<th>Medication Management Standard</th>
<th>GS1 Support</th>
<th>ISMP</th>
<th>Project</th>
<th>Discussion</th>
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<td>Joint Technical Statement Version 2</td>
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<td>Summer Fall 2010</td>
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<tr>
<td>Database Work Group: Data Transfer Issues</td>
<td>✓</td>
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<td>Summer 2010</td>
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<tr>
<td>Develop Minimum Software Requirements for EAR</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>January 2011</td>
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<tr>
<td>Facilitate JTS Review and Amendments (Version II)</td>
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**Implementation Readiness**

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<tr>
<th>Implementation Kit:</th>
<th>GS1 Support</th>
<th>ISMP</th>
<th>Project</th>
<th>Discussion</th>
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<tr>
<td>IK: Value RCI Statement</td>
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<td>Spring/Early Summer 2010</td>
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<td>IK: Barcoding Training Module for Clinical End Users</td>
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<td>Fall 2010</td>
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<tr>
<td>IK: Bar Coding Implementation Guide</td>
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<td>Fall 2010</td>
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**State of Readiness Assessment**

- Pharmaceutical Sector: ✓ Initial: Early Summer 2010
- Health Technology Providers: ✓ Initial: Early Summer 2010
- Hospitals and Retail: ✓ Summer 2010
- End-user and Practice Knowledge Dissemination: ✓ Duration 2010
- International communications: ✓ Duration 2010/2011

**Labelling and Packaging**

- Commercial Packaging and Labelling Guidelines: ✓ Possible Health Canada collaborative: Fall 2010
- In-house Bar Code and Labelling Guidelines: ✓ ✓ Fall 2010
So, from a ‘client’s’ perspective, Collaboration:
Inspite of the absence of a National Mandate….
Canada now has a National Bar Code Strategy..
Thank You!

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