Barcodes on Unit of Use
Hospitals need medications

- Ready-to-Administer
- In Unit-of-Use
- With Barcode
If not, must go through additional pharmacy processes and manipulated for use

- Compounding
- Reconstitution
- Repackaging
End-point of medication supply chain is the direct administration of a **single dose by a nurse to the patient at the bedside**
What hospitals need

With Barcode

Unique identifier that ensures

- efficiency of distribution and inventory management
- verification of correct medication for patient administration
- tracking and traceability of each dose to the patient in the event of an issue
What is a good barcode?

- Machine readable, every time
- Has clear, crisp print with good contrast
- Can be scanned in any direction
- Is on opaque, non-reflective background
- Is not placed on a curved surface
- Is unique – GS1 compliant
What is a good barcode?

GS1 compliant barcode includes

- Drug identifier (GTIN)
- Variable data – lot number and expiry date
- Application Indicators (AI) to separate different data code functions
Why & How Hospitals use Barcodes
Supply Chain Efficiency

Supply Chain Efficiency

Supply Chain Traceability

Safe Medication Management
Supply Chain Efficiency

Needed to

- Receive product from suppliers
- Do our job efficiently and safely
- Locate drugs in event of a recall
- Track inventory
- Move inventory throughout the hospital
- Reconcile controlled substances (enable auditing and prevent diversion)
Hospitals are under pressure to do more with less

- Medication should be received from manufacturer ready-to-go directly to patient

- Lack of barcoded unit-of-use products has been identified as a factor in not being able to achieve greater verification of medications prior to administration
Moved to active stock

- Barcodes generated on labeler; applied by technician
- Must be verified for accuracy
- Segregated from active stock
- Moved to reprocessing area
- Product with barcode on unit of use
- Product without barcode on unit of use

Supply Chain Efficiency
Impact of additional steps

Introduces risk and inefficiencies

Diverts staff from direct patient care activities
A 350 bed hospital must add barcodes to:

- 30% of products
- 200,000 doses per year
- 200+ FTEs required across Canada
Supply Chain Efficiency

Barcode on box but not on unit of administration

- Injectables (have come a long way)
- Inhalers
- Topical administration
  - Ophthalmic
  - Transdermal patches
  - Cream and ointment tubes
- Suppositories
Ready-to-administer

- Ampoule or vial is not the final product
Supply Chain Efficiency

Not machine readable, every time

**Challenges**

- Multiple barcodes on product, causes disruption in system
- Barcode positioning on curved surface impedes scanner read

**Consequences**

- If barcode quality does not meet hospital needs, they will seek an alternative supplier
- Hospitals may require certificate of readability
Each dose includes all appropriate label information, but no barcode.

If enough room for barcode, hospital staff will add.

Otherwise need to repackage.
• Significant improvement required – currently of no value

• Hospital staff must remove tablets from blister and then repackage, similar to bulk

• NEED – unit dose packaging with barcode on each unit of administration
Oral Solids – Bulk

• Availability of high-tech packaging machines in hospitals allows bulk oral solids to be repackaged into unit dose format with a barcode

• NEED – ensure a readable barcode on the bottle
Supply Chain Efficiency

Narcotic and Controlled Drugs – Unit Dose Pack

• Documentation and reporting requirements
  • Narcotics
  • Controlled Drugs
  • Targeted Substances
• Diversion prevention
• Perpetual inventory
• Strict tracking
Oral Medications that require special handling

- National Institute of Occupational Safety and Health (US) has identified list of antineoplastics and other hazardous substances that require special handling to limit exposure to healthcare workers

- The University of Utah Drug Information Service has published an expanded list of drugs* (hazardous or allergenic) that should not be put in automated machines

- Drugs packaged in automated machines may also lead to cross-contamination risk to patients

*Cytotoxic Hazardous Drugs

Supply Chain Efficiency
Supply Chain Efficiency

Oral Medications that require special handling

- Colleges of Pharmacy in Canada moving to enforce that these products **not be processed** in automated packaging machines (retail + hospital)
- Hospitals must package manually to meet regulatory requirements
- Very labour intensive and must don Personal Protective Equipment (PPE) to mitigate exposure
- Best suited for a supplier manufacturing and packaging facility
Supply Chain Efficiency

External Forces Driving Transformation

- Standards for handling of hazardous products created through NIOSH/The University of Utah Drug Information Service
- Regulators enforcing standards (Colleges across Canada)
- FDA issued the Bar Code Final Rule in February 2004 requiring bar codes on the labels of all human prescription drug products, biological products, and OTC drug products that are commonly used in hospitals and dispensed pursuant to an order
Supply Chain Efficiency

What we need

• commercially available unit dose package
• drugs on NIOSH list packaged in unit dose packages with barcode on each dose
Supply Chain Traceability

Supply Chain Efficiency

Supply Chain Traceability

Safe Medication Management
Suppliers need to Track and Trace


- Securing the drug supply chain against counterfeit drugs through tracking and tracing of every transaction – enabler: barcode or product identifier
- Sunset date for manufacturers – complete supply chain by 2023

Product Identifier
- National Drug Code
- Serial Number
- Lot Number
- Expiration Date
Suppliers need to Track and Trace

- European Union Falsified Medicines Directive – need for security of supply chain based on serialization, product verification at each transaction and compliance reporting;
  - Sunset February 9, 2019
  - Expectations expanding throughout the global supply chain
Counterfeit Version of Drugs Discovered

UK and EU: 2007
- Casodex (for prostate cancer)
- Plavix (for heart disease)
- Zyprexa (for schizophrenia)

US: 2012
- Avastin (for various types of cancer)

Canada (2005)
- Norvasc (for hypertension and angina)
Supply Chain Traceability

- Safeguard “authenticity of health products as they move through the medication use system” — Health Canada
- Based on product verification, product traceability, and automated verification systems

This is a goal for suppliers and all healthcare providers
Supply Chain Traceability

Hospitals also need to Track and Trace

- National Association of Pharmacy Regulatory Authorities (NAPRA) standards of practice – ability to immediately determine which patients received a given drug product.
- Addresses specific public safety issues to trace drugs to rapidly determine which drugs had been dispensed to which patients by:
  - product identifier
  - lot or batch number
  - expiry date
- Serialization is a future need to combat counterfeit drugs.
Supply Chain Traceability

Ideal automated identifier

- **Product Identifier**: e.g. GTIN
- **Variable Data**: Lot or batch # and expiry date
- **Serialization**: Serial number

Yesterday  |  Today  |  Tomorrow
External Forces driving transformation
Supply Chain Traceability

What we need

Ability to “Track and Trace”

• Ready to use product with barcode with variable data and serialization (tomorrow)
• Motives are different
• Enablers are the same
Safe Medication Management

Supply Chain Efficiency

Supply Chain Traceability

Safe Medication Management
Evidence shows that medication errors lead to negative patient outcomes, including death.

In Canada, 24,000 adults die every year from adverse events in acute care settings.¹

Medication errors account for almost half of these.

¹Canadian Adverse Events Study: The incidence of Adverse Events Among Hospital Patients in Canada
Evidence shows barcoding/computerization helps mitigate these occurrences

- Scan verification of medication at the bedside can help reduce patient error in hospitals by up to 41%\(^1\)
- Implementing BCMA in the ED was associated with significant reductions in medication error rate (80% relative rate reduction)
- A study using direct-observation methodology to monitor medication administration before and after the deployment of the EMAR and BCMA systems demonstrated a 54% reduction in medication administration errors following implementation of a multidisciplinary, collaborative approach to medication safety. \(^3\)

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Evidence

38% occur at the point of administration (barcoding can help)

39% of errors occur at the point of prescribing (CPOE* can help)

11% occur at the point of dispensing (barcoding can help)

12% occur at the point of transcription (CPOE* can help)

CLMM requires barcoding on unit of administration


*Computerized Prescriber Order Entry
Evidence is driving the creation of best practices
Safe Medication Management

- Computerized Prescriber Order Entry (CPOE) and Closed Loop Medication Management (CLMM) Systems are fundamental to achieving a high EMRAM score

- Electronic Medical Record Adoption Model (EMRAM) is internationally recognized benchmarking tool which helps improve the quality and safety of patient care

- Is an indicator of the healthcare system’s integration and connectivity

- Highly adopted in U.S., Ontario and British Columbia and increasingly across other provinces in Canada
Safe Medication Management

EMRAM Adoption

Level of eHealth Adoption in Ontario Hospitals vs. US Hospitals - Q4 2015

HIMSS EMRAM℠ STAGE

Adapted from https://www.oha.com/CurrentIssues/keyinitiatives/eHealth/Pages/eHealthAdoptionFindingsandComparisons.aspx
Safe Medication Management

Advocacy for the use of automated barcode technology

Medication bar coding practices significantly reduce serious errors and patient harm, while improving both the patient care environment and electronic health record documentation.
Other standards of practice recommendations to improve patient safety

Accreditation Canada standards
- Standard 18.0 – automated barcode verification help avoid look-alike errors at all points of the medication chain

Canadian Society of Hospital Pharmacists (CSHP) 2015 Targeting Excellence in Pharmacy Practice
- Objective 5.1 Hospitals will use machine readable coding to verify medications before dispensing
- Objective 5.2 Hospitals will use machine readable coding to verify medications before administration to a patient
Hospitals are under pressure to reduce the risk of patient harm

- With automated tracking of inventory, facilitated by a barcode on unit of use, all doses anywhere in the hospital can be retrieved and accounted for
- Reduce risk that a recalled product is administered to a patient
“In the U.S., we could not scan drugs at the point of care until individual packages arrived from the manufacturer with barcodes.”

– Mark Neuenschwander, “Guru of Barcoding”
We are facing external and internal pressures

Barcoding and complete labelling on a ready-to-administer unit dose format is a global need and a necessary state for:

Supply Chain Efficiency
Supply Chain Traceability
Safe Medication Management

We can’t get there without you
We Can Get to a Better State
Let's Transform, Together