Pharma @ the Point-of-Care
William Churchill
Strategic Focus on Improving Medication Safety with Bar Code Verification

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One out of 5 doses of medications are administered erroneously.

Dispensing errors are relatively common in hospital pharmacies given the high volume of medications dispensed.

- More than 160 errors occur per day in a 720-bed hospital (6 million doses/yr).

Many dispensing errors have the potential to harm patients.

- More than 35 errors with potential to harm patients occur per day in a 720-bed hospital.
- Only 1/3 of these serious errors intercepted prior to administration.

Barker et al. Arch Inter Med 2002;162:1804
Bar Code Requirements for Hospitals and Health Systems

- High Quality with limited scan failures
- Reproducible
- Robust capability for storage of a large amount of data
  - Lot number
  - Expiration date
  - Drug name
  - Drug concentration
- Takes up a small amount of space
- Easily readable
GS1 Barcode Standards

DataMatrix

- 2D barcode that holds large amounts of data in a relatively small space
- Used primarily in pharmaceuticals, aerospace, medical device manufacturing, and the U.S. Department of Defense to add visibility to the value chain
- Used for parts that need to be tracked in the manufacturing process because the barcode allows users to encode a variety of information related to the product, such as date or lot number
- Another advantage is their sophisticated error correction algorithm – print quality and contrast are less critical than with traditional barcodes
The Need for Robust Bar Codes in Health System Pharmacies

- Ensure accurate medication preparation, dispensing and administration.
- Supporting robotic medication safety technology.
- Data tracking for lot number and expiration dating in the eMAR and EMR.
  - Blood products (IVIG, Albumin)
The Need for Robust Bar Codes in Health System Pharmacies

- Tracking medications from drug prep through delivery to final bedside administration
- Programming Intelligent Infusion Devices (Smart Pumps)
- Tracking drug recalls
- Identifying and retrieving soon to be outdated medications from storage areas.
Smart Pump Technology and Bar coding

- The Pump Recognizes Drug Name & Concentration in 2D Bar Code
- Calls up correct Drug Library entry
- Critical for PCA !!!
Ian Sheppard
Canadian Pharmaceutical Bar Coding Project

How Will AI Reduce Medication Errors & How We Can Support Application of Global Standards

Global GS1 Healthcare Conference (April 6, 2011)
Medication Errors Do happen ....
Effectiveness of Bar Code (AI) in Safety

System Sources of Errors: Leap LL, Bates, DW. et al, JAMA 1995


<table>
<thead>
<tr>
<th>Category</th>
<th>Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Ordering</td>
<td>32%</td>
</tr>
<tr>
<td>Transcription &amp; Verification</td>
<td>5%</td>
</tr>
<tr>
<td>Pharmacy Dispensing</td>
<td>11%</td>
</tr>
<tr>
<td>RN Dose Administration</td>
<td>32%</td>
</tr>
</tbody>
</table>

Errors from Preventable ADEs
- Errors from Potential ADEs Non-intercepted: 20
- Errors from Potential ADEs Intercepted: 48
- Total Errors: 100

Error %, by Stage
- Physician Ordering: 39
- Transcription: 12
- Pharmacy: 11
- RN Dose Administration: 38

Measured Human Interception Rates
49% of Errors
The Safe Medication Chain
"We learned early in the planning process that “a bar code is not necessarily a barcode,” meaning that just because a product has a barcode on it, the barcode 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.

The Need for National Pharmaceutical Barcoding Standards

Current Medication Practice Situation in Canada, as of 2009 …

Bar codes are not found on all levels of packaging throughout the pharmaceutical supply and dispensing/administration chain. Many primary (e.g. vial) and secondary (outer package) labels do not have a 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 barcodes.

Bar codes, when applied, are different between hospitals and community, and often between healthcare sites.
From This Morning …
Working with all sectors

- **System Acquisition & Human Practice Modification**
- **Promote Aligned Technology & Promote Standardized Data Capture**
- **Application of a Global AIDC Standard to Pharmaceutical Products**
- **Seven Health Sectors: Technical Task Force Collaboration**

1. **Build a Coalition**
2. **Select a Global AIDC Standard**
3. **Align Automated Systems**
4. **Practice Integration**

**Practice Endorsements**
From This Morning ...
A Stepwise Project Roll-out
Progressive Practice Integration: Sector Collaboration

Pharmaceutical Manufacturers
Group Contracting
Institutional Care
Community Care
Technology & Data Providers
Prof. Practice & Health Quality Orgs
Standards Organizations

Revised
Joint Technical Statement
Version II
Compliance Integration: Reward Compliance

Pharmaceutical Manufacturers
Group Contracting
Institutional Care
Community Care
Technology & Data Providers
Prof. Practice & Health Quality Orgs
Standards Organizations

Pharmaceutical Manufacturers

Group Contracting

Align Contracting Criteria

Institutional Care

Read & Comply

Customer Safety Requirements

Award Compliance

Disseminate

Revised
Joint Technical Statement Version II

Prof. Practice & Health Quality Orgs

Endorsements
Progressive Practice Integration: Technology Alignment

Revised Joint Technical Statement Version II

Standard Product Descriptors (ECCnet)

Software Functionality Checklist
Unit of Use, or Unit-dosed?

What we are likely to use within Canada …

Canada is a very small market, and distinctly different than our cousins in the U.S.: population base (1/10th) and geographical population-based challenges.

Canada has federal drug approval and labelling requirements that differ significantly from the U.S., so there is little opportunity to directly move product even just 80 km to the North.

Canada’s health economic model is based on fixed budgets. There is no ability to pass system costs onto a third-party insurer in most cases.

Therefore,
The opportunity for a Pharmaceutical Manufacturer to recover its production-line investment costs is reduced. They may shy away from additional product packaging investments.

Hospital pharmacists are more likely to look toward selective strategically purchasing of unit-of-use products, bulk and consider repackaging in-house.
Unit of Use, or Unit-dosed?

What we are likely to use within Canada...

We fully support commercially-produced unit-of-use labelled by Manufacturers with DataMatrix in theory.

But, due to health budgetary restrictions and reduced manufacturer offerings in Canada, Canadian hospital medication purchases are more likely be from the following categories commercially:

- Bulk tablets to be re-packaged and re-labelled by an automated device
- Unit-of-use volume oral liquids
- Unit-of-use ophthalmic, otic or topical products
- Pre-filled syringes
- Bulk IVs (if dating is acceptable), for unit-dosing by hospitals into patient-specific units
- Possibly, standard doses of routine IV products (e.g. pre-mixed antibiotics)

So, this leads Canada to consider developing in-house (hospital-based) bar coding (AI) standards that are also compliant with global standards, and usable by automated identification systems at all stages of the medication safety chain.
Thank You
Tim Marsh
Pfizer’s Efforts to Improve Patient Safety
Packaging Targeted Patient Safety Strategy

- Leveraging Both Simplicity and Technology
  - From RFID to 2D barcodes to Colours and Fonts

- Multi-faceted Strategy Inclusive of:
  - Product Security
    - Anti-counterfeiting Technologies
    - Serialization Hardware/Software, Processes and More
    - Tamper Evidence
  - Prevention of Medication Errors
    - Barcodes at Unit Dose Level to Enable Point of Care Scanning
    - Trade Dress Designs that Help Human’s as Well
Barcodes for Hospital Unit Dose Packs
Barcodes for Hospital Unit Dose Packs

Define Standard for EU:
- Barcode Symbology
- Data Structures
  - GTIN, Lot Number, Exp Date
    - Value Proposition for Lot and Exp?

Challenges:
- Package Configuration, Installed Print Technology Base, Real Estate Constraints

Expectations:
- First Time Scan Quality
- Do NOT Compromise Human Readability
Hospital Unit Dose – Pfizer Direction

- 2D DataMatrix Barcode
- GTIN
Pfizer New Trade Dress
Compliance with all Relevant National and EMEA Guidelines

Five Different Design Variants to Differentiate Products and Formulations
  — Differentiate Products that are Alphabetically Similar or with Name Similarities - both in Generic and Proprietary Name

Improved Use of Color to Differentiate Strengths
  — Two Colors per Pack
  — Product strength repeated on different faces

Improved Use of Lower and Upper Case

Font Size Minimum of 9 Point *(Sans Serif)*

Critical Information is more Easily Found

Maximise Dispensing Label Area
Need to differentiate *between formulations* (plain and XL) and strengths

Also need to *differentiate from co-prescribed products*

Same design principles apply and same key features but the execution *differentiates products*
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