



Pharma @ the Point-of-Care





William Churchill





Strategic Focus on Improving Medication Safety with Bar Code Verification



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Focus on Safe Medication Administration

- 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.



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- Identifying and retrieving soon to be outdated medications from storage areas.



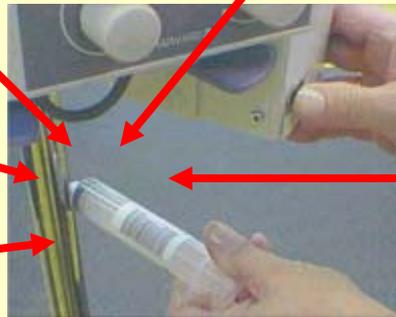


Smart Pump Technology and Bar coding



SIGMAWORLD PUMP
(available August 2003)

- Five IV Pump Categories In One Box (VP, Antibiotic, PC, Epidural, Syringe)
- Choice Of 3 Drug Error Prevention (DEP) Systems (Manual, Built In Bar Code Reader, FDA Bar Code Reader)
- PC Pharmacy Worksheet Drug Library
- 500 Drug Entries
- Wireless Drug Library Updates With FDA
- 1/2 The Size Of Other IV Pumps
- 55H x 35W x 1.5D
- Use Any Brand Standard IV Set
- Wireless
- No Power Cord Required
- Used Software Upgrades
- Lowest Cost DEP Pump



BAR CODE LABEL CONTENT per HIBCC labeling standard

MASSACHUSETTS GENERAL HOSPITAL
hydroMORPHONE 0.5 mg/mL

Total Amount hydroMORPHONE: 25 mg
0.9% Sodium Chloride 50 mL Bag

EXP 09/30/2007 **FOR IV USE ONLY**
LOT# 0102000@00 **Preservative Free**
CV# 20005122 **Latex Free**
RN/Hang Date/Time _____ NDC# 2420030103

Ameridose
Framingham, MA

hydroMORPHONE 0.5 mg/mL

- 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)

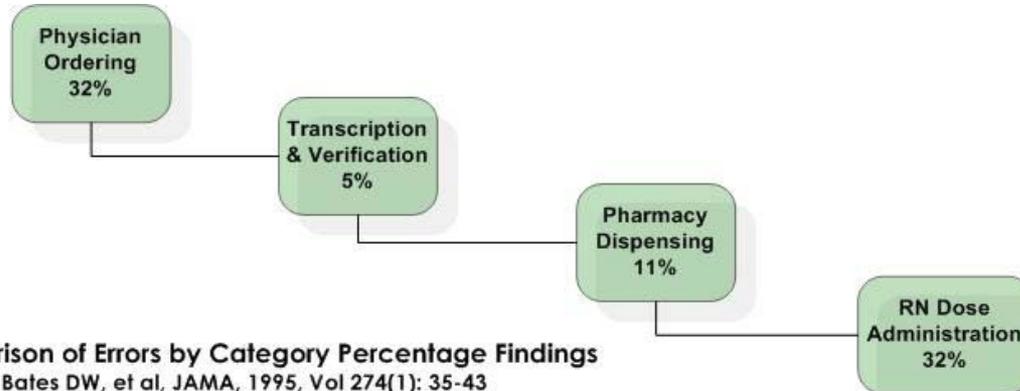


Medication Errors Do happen

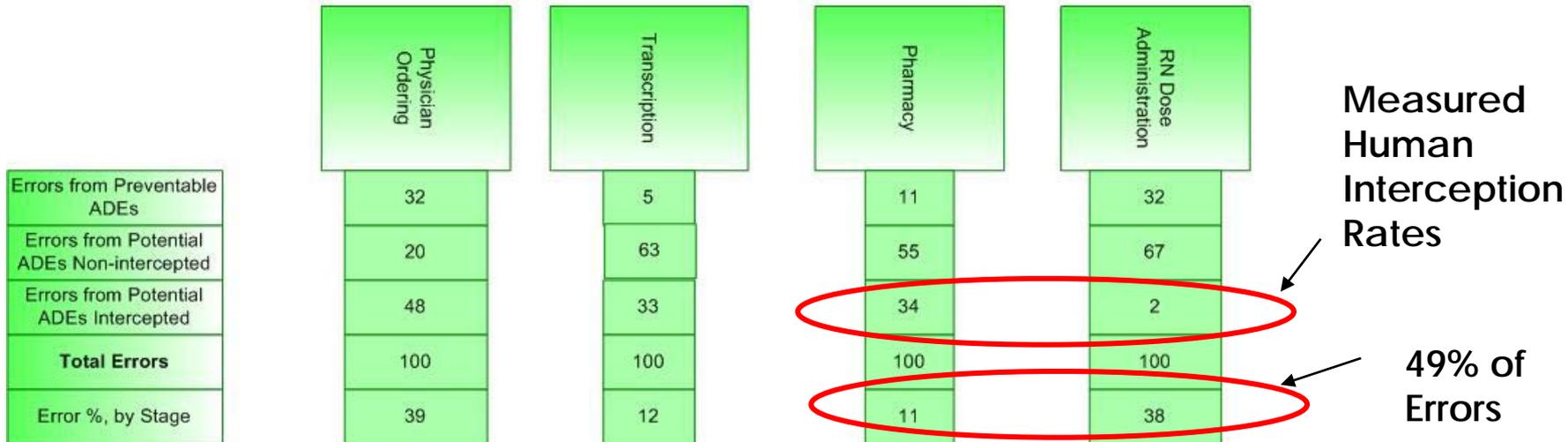


Effectiveness of Bar Code (AI) in Safety

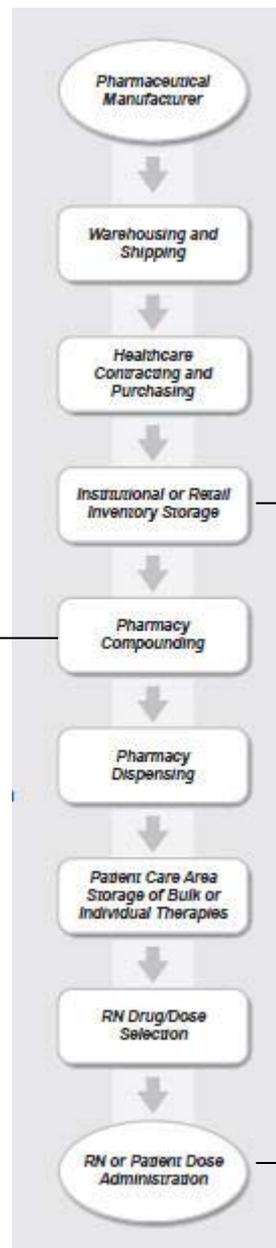
System Sources of Errors: Leap LL, Bates, DW. et al, JAMA 1995



Comparison of Errors by Category Percentage Findings
(Leape L, Bates DW, et al, JAMA, 1995, Vol 274(1): 35-43)



The Safe Medication Chain



The Need for National Pharmaceutical Barcoding Standards

“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.

Am J Health-Syst Pharm. 2005; 62: 1075-9

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.

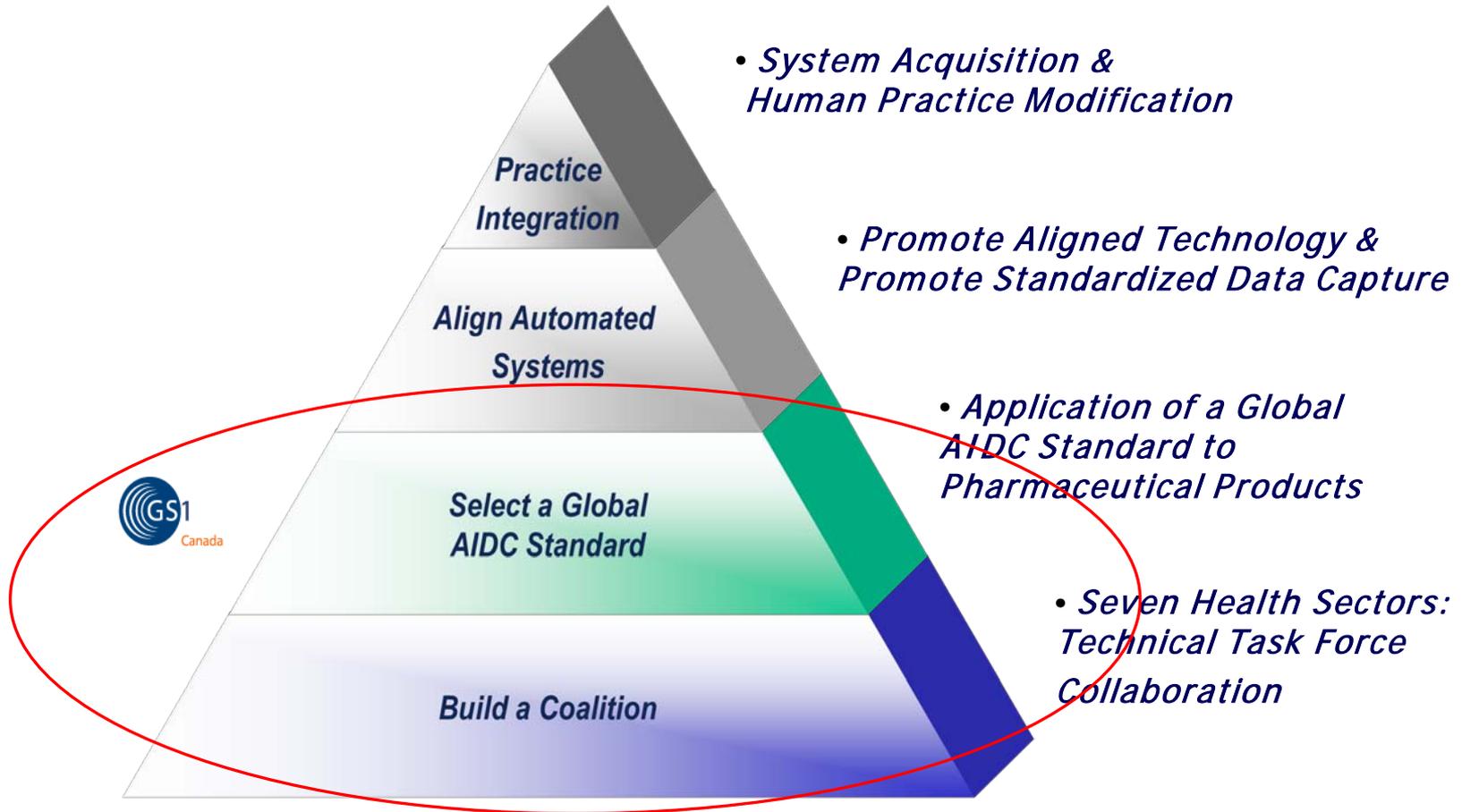
There is no standard for the type of bar code to use, nor the required information within the code itself. Reader/scanners and software cannot be seamlessly written to read the codes.

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 bar codes.

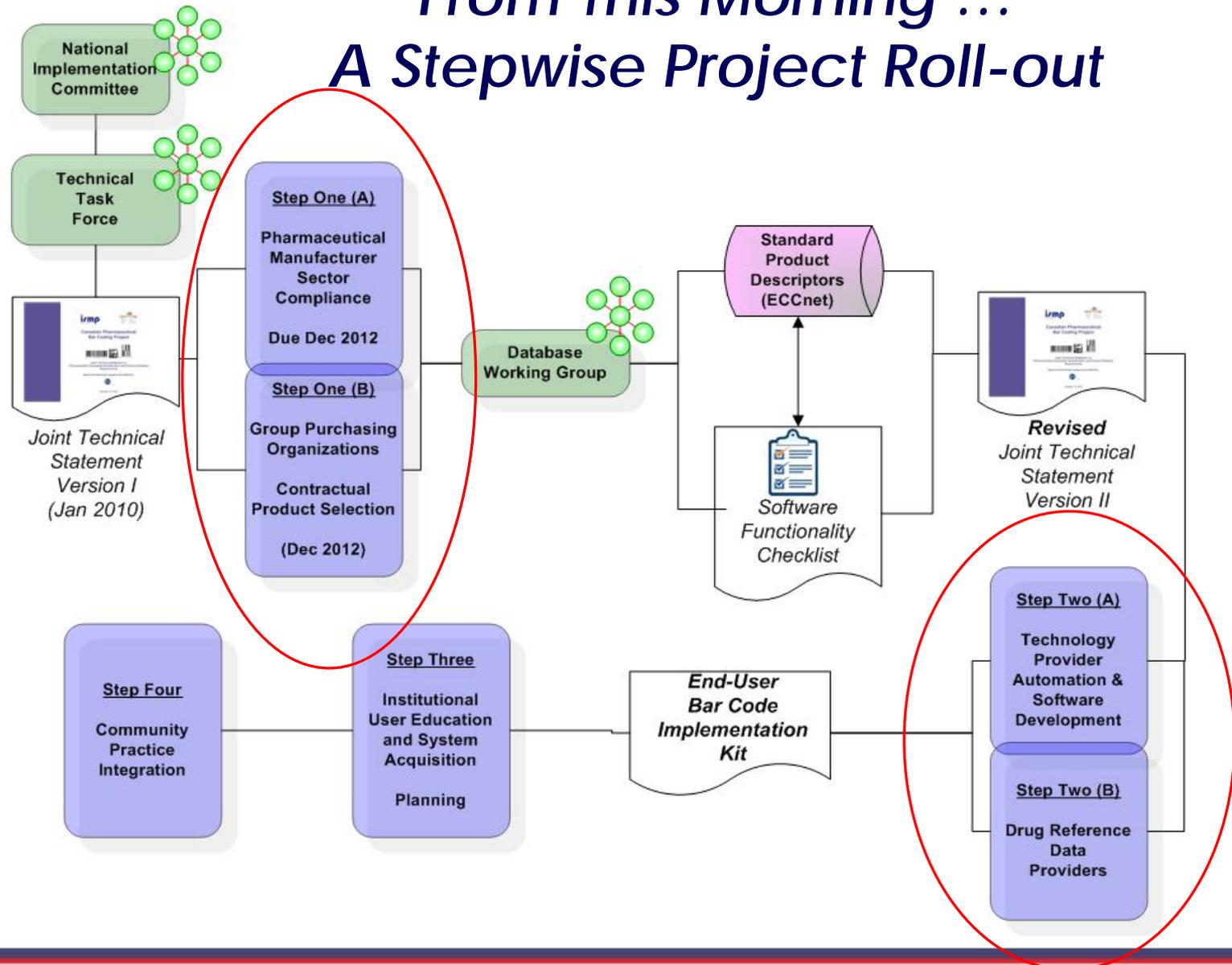
Bar codes, when applied, are different between hospitals and community, and often between healthcare sites.

From This Morning ... Working with all sectors

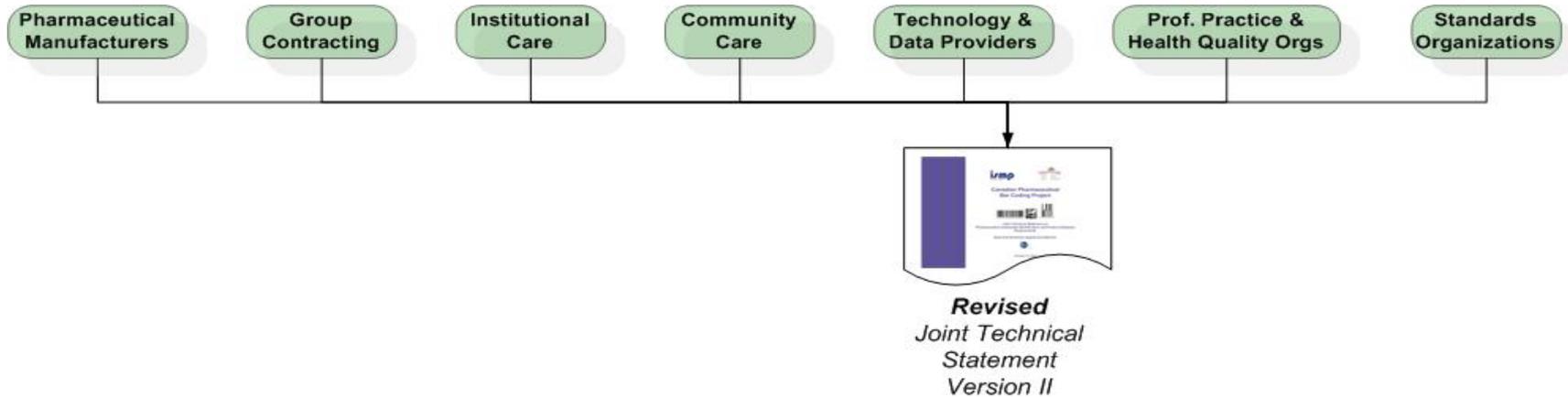
PRACTICE
ENDORSEMENTS



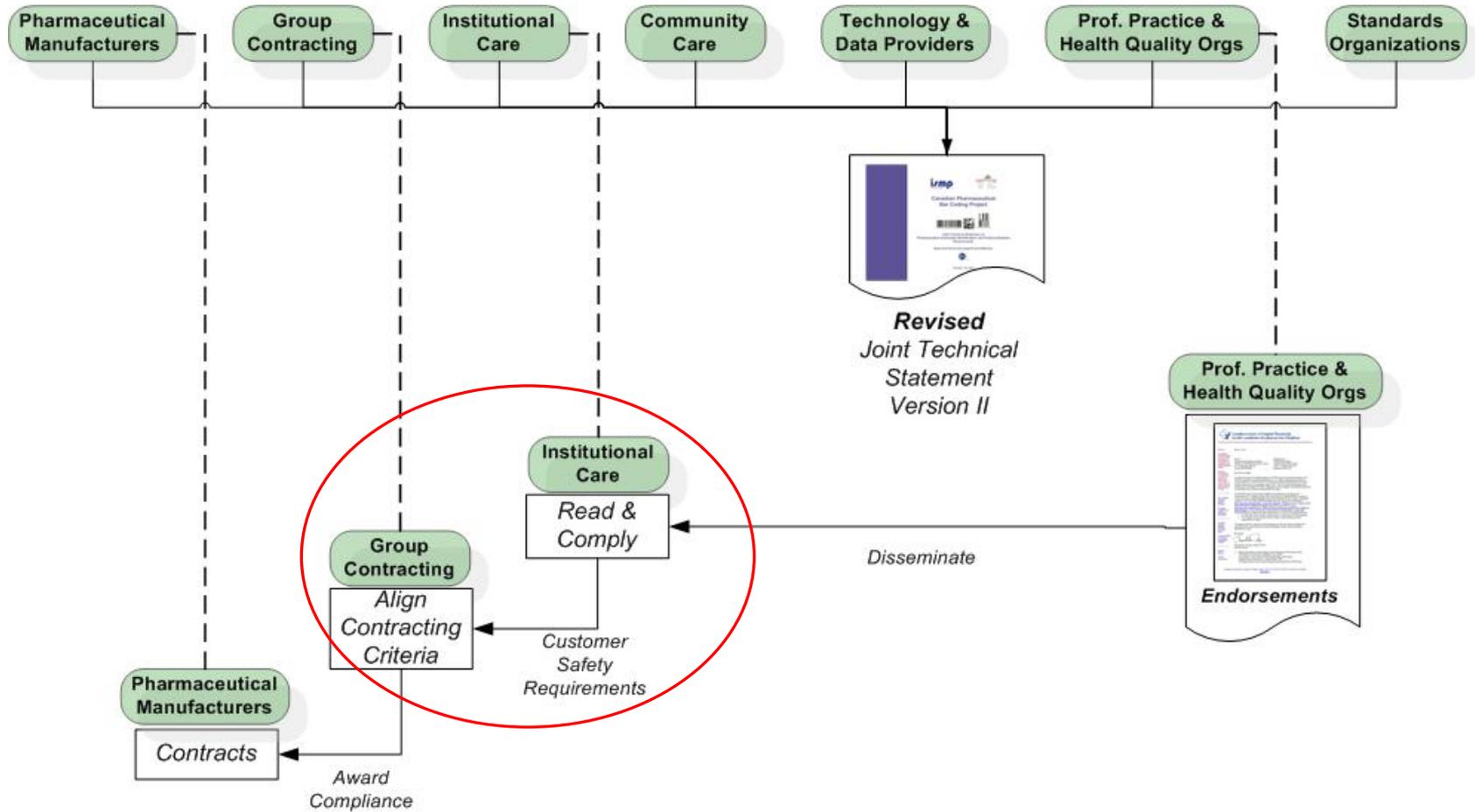
From This Morning ... A Stepwise Project Roll-out



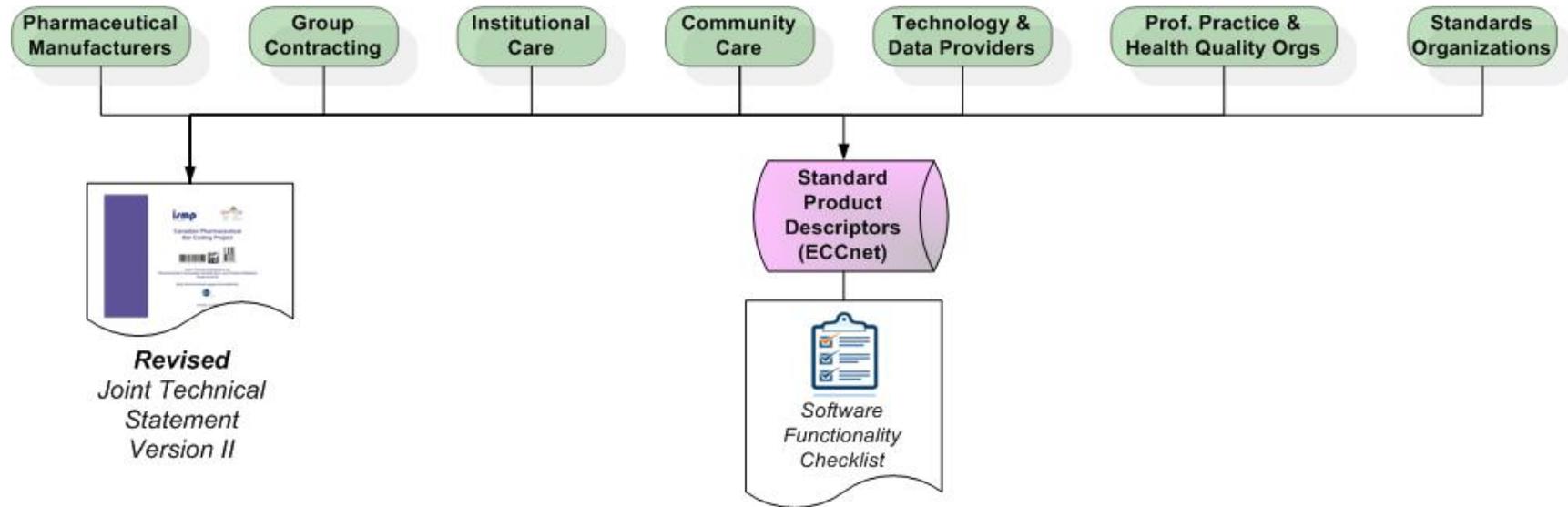
Progressive Practice Integration: Sector Collaboration



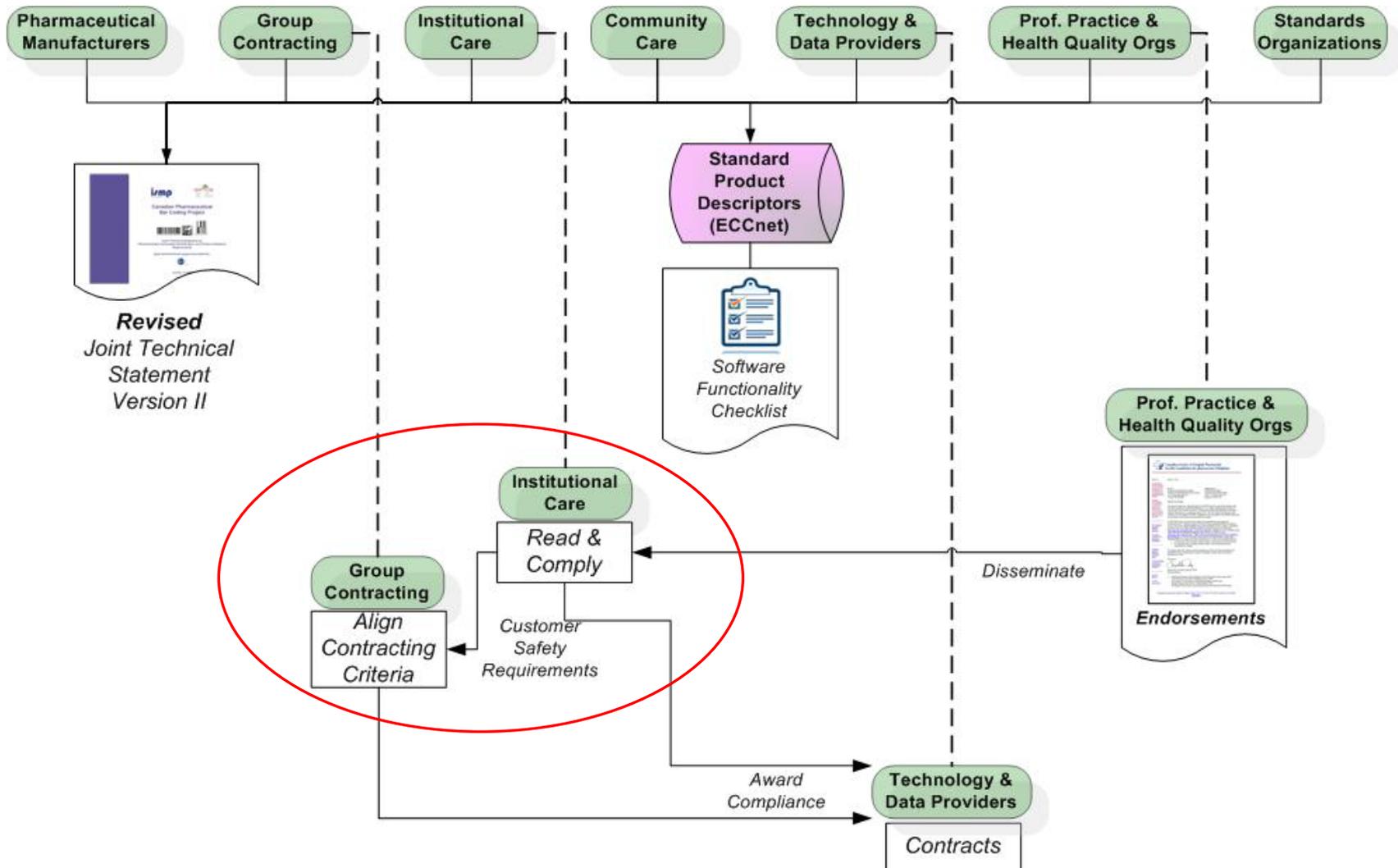
Compliance Integration: Reward Compliance



Progressive Practice Integration: Technology Alignment



Compliance Integration: Technology Rewards



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, 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



Pfizer 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

Pfizer 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





Pfizer New Trade Dress

Pfizer 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



Pfizer Design Variants



Pfizer Current vs. New



- 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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