



A Review of National Pharmaceutical Bar Coding Practice Integration

The Canadian Pharmaceutical Bar Coding Project

November 22, 2012



***Canadian Institute for Health Information:
System Performance is the Real Problem***

If we wish to reach a standard of performance quality that prevails in other industries there will be a need to transform the healthcare system from a “cottage industry” to one in which quality is taken seriously.

~ Dr. John Millar, Vice-President (2000)

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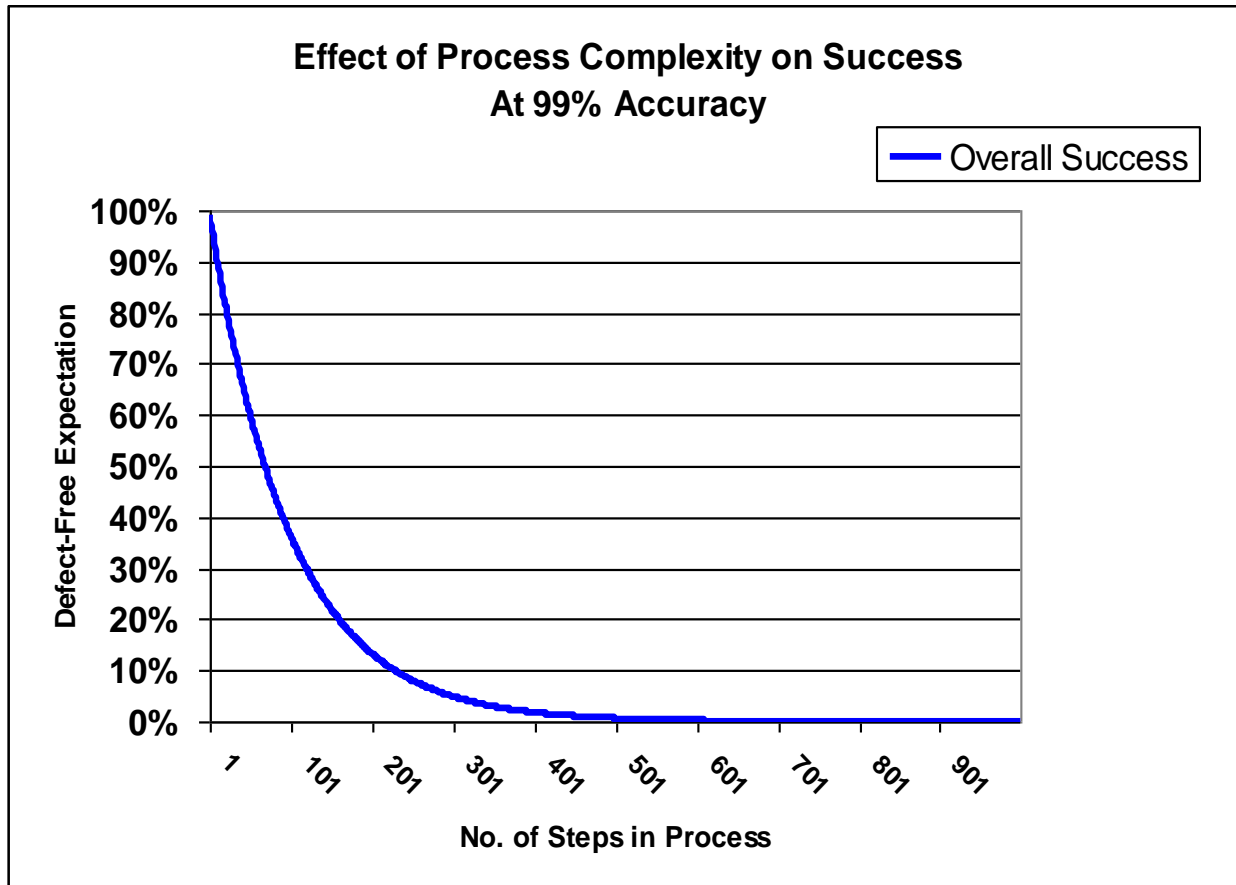


Bar Coding and Medication Safety: *A Systems Perspective*

The Weary Paradigm

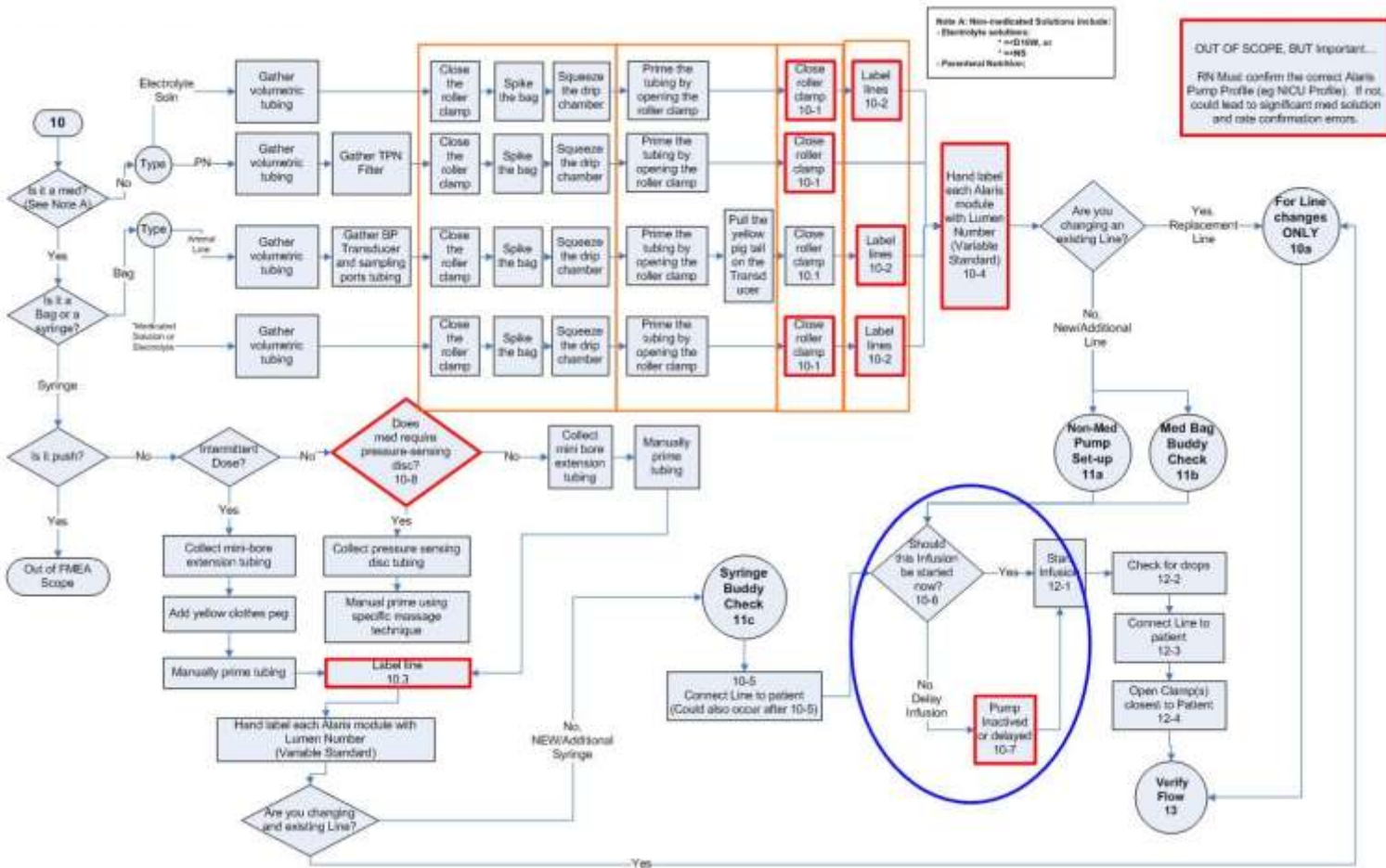


Chances of Success...Complexity of Process



When we analyze our systems

What do we find?



How does a busy healthcare worker succeed in complex environments ?

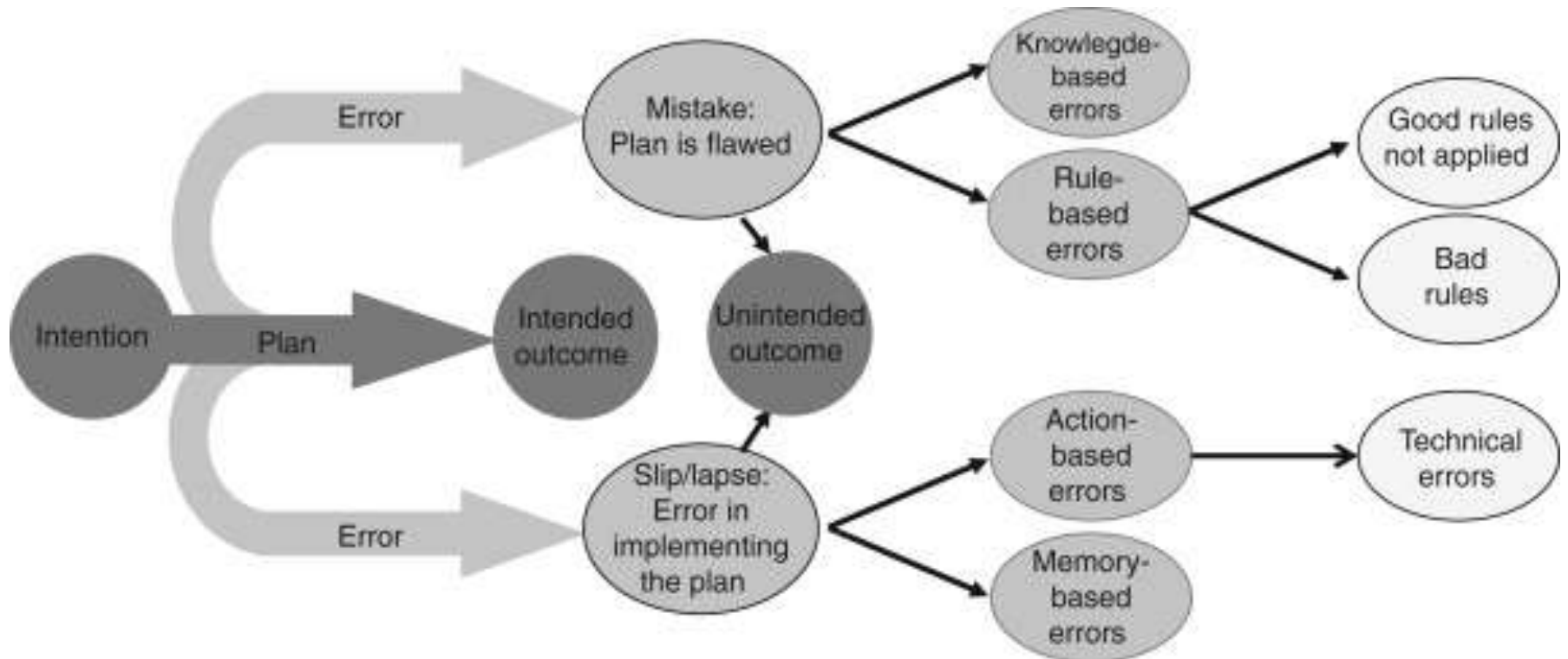


... or this ...



Figure 7. Look-Alike Packaging in LDPE Ampuls. From left, Naropin injection, cromolyn for inhalation, and ipratropium bromide for inhalation. Image provided courtesy of ISMP.

Human Fallibility





Alyssa Shinn
Zinc Overdose



Keith and Kaylynn Garcia
Heparin Overdose



Jasmine Gant
Bupivacaine IV



The Faces of Medication Errors

Approximately 7,000 deaths occur each year and medication errors occur in just about 1 of every 5 doses given in hospitals. (The Prescription, 2005)

Quaid twins
Heparin Overdose



D'myia Nelson



Emmery Miller



Courtesy: Rick Osteen, Vanderbilt Univ Med Ctr



And what about them?

The Rights of the Second Victim

If the first victims are the patients and their families who are harmed, then the second victims are the caregivers and staff who sustain psychological harm ...

~ Charles R. Denham, MD

How Large is the Adverse Drug Event Problem?

- The number of Adverse Drug Events (ADEs) is unacceptably high (**3-6% of admissions to hospitals**).
- Medication errors reported in a 2007 CIHI report:
 - **10% Canadian patients** report experiencing a medication error in the previous two year period. (Commonwealth Fund Health Policy Survey, 2005)
 - “Medication safety has become an area of increasing awareness.”
- Of reported ADEs:
 - Serious patient injury or deaths, results in **20-30%** of events.
 - The more serious the ADE, the more likely the event was preventable.
 - Overall **30-40% of ADEs are preventable medication errors**.
 - Many ADEs are caused by **human error**.
 - **Errors occur at each stage** of the medication process

How Large is the Adverse Drug Event Problem?

- Varying reports of error rates in residential and nursing homes also.
- UK NHS (Wales NHS Trust review)
 - UK study (2009) 8.4% of administered doses; 22% of patients affected in trial
 - Dutch study (2009) 21.2% of doses (including timing errors)
 - US (Geriatric Psychiatric) (2007): 25.9% of doses
- Institute of Medicine: Chasm Report (2007):
 - Cooper (1984): 6% of doses
 - Baker (1982): 12.2% of doses
 - **Baker (2002) 14.7% of doses (excluding timing errors) (20.6% including timing)**
 - Baldwin (1992): 20% of doses
- Prospective Study: Gurwitz (2005): 0.1 ADE per patient month: 46% at dose administration, and 42% were preventable ADEs.

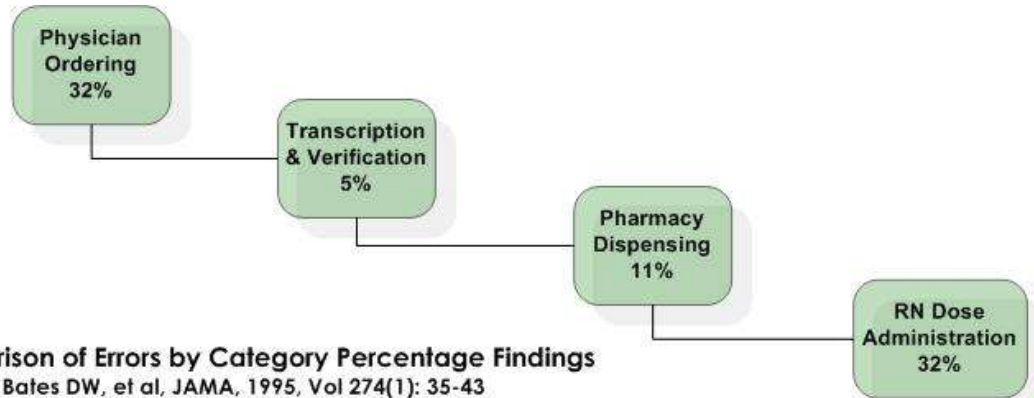
How Large is the Adverse Drug Event Problem?

“If the findings of these two well-designed [Gurwitz] studies are applied to all U.S. nursing homes, between 24 and 100 ADEs occur annually in the average 100 bed nursing home. Between 350,000 and 1.9 million ADEs occur each year [U.S.], about 40-50% of which are preventable.

“Of the estimated 20-000-86,000 fatal or life-threatening ADEs, about 70-80% are preventable.”

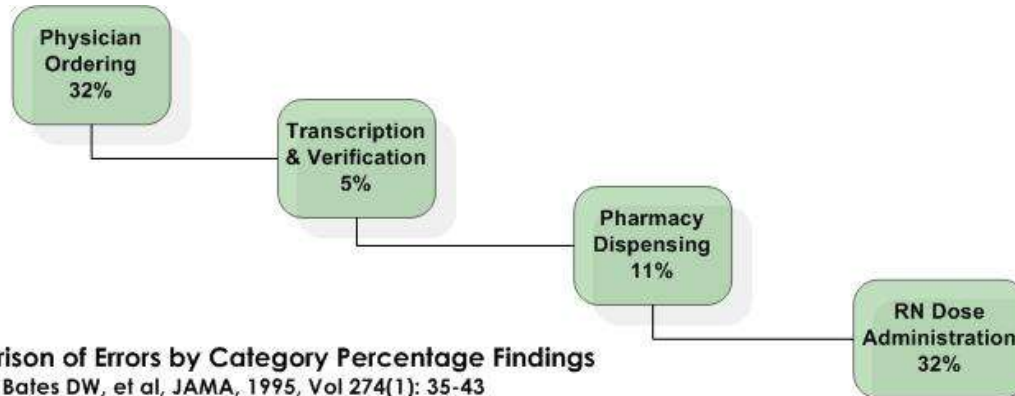
*Institute of Medicine
Preventing Medication Errors
Quality Chasm Series Report
2007*

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)

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

	Physician Ordering	Transcription	Pharmacy	RN Dose Administration
Errors from Preventable ADEs	32	5	11	32
Errors from Potential ADEs Non-intercepted	20	63	55	67
Errors from Potential ADEs Intercepted	48	33	34	2
Total Errors	100	100	100	100
Error %, by Stage	39	12	11	38

Measured Human Interception Rates (indicated by red circles around the 'Errors from Potential ADEs Intercepted' row)

49% of Errors (indicated by an arrow pointing to the total error counts)

Rank order of Errors in Residential and Nursing Homes

Of all errors:

- *Timing of Dose: up to 50%*
- *Omission of dose 30-40%*
(staff forgetfulness, patient sleeping, refused medication)
- *Wrong Dose: 10-25%*
- *Wrong Route: 2-3%*
- *Wrong form: 0.4-5%*

System Modification Approaches:

In rank order of effectiveness

1. Forced function
2. Automation, computerization
3. Protocols and pre-printed orders
4. Checklists
5. Rules and double-checking
6. Education
7. Information

Human



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Effectiveness of Bar Code Scanning (AI) in Medication Safety ?

Effectiveness of Bar Coding (AI) in Safety

In Pharmacy Practice Environments

- A **96% reduction in pharmacy dispensing errors**. And a 75% reduction in urgent stock-outs, and a **7% increase in inventory turns**

Ragan, R, Am J Health-Syst Pharm 2005; 62: 1075-9

- A **63% reduction pharmacy dispensing**. Study shows a return of Investment of approximately 1 year.

Maviglia SM, Churchill, Wm et al. *Arch Intern Med*. 2007; 167: 788-794

Effectiveness of Bar Coding (AI) in Safety

At the patient bedside

- A **54% reduction in dose administration errors with bar coding** with Electronic Medication Records.

Paoletti R et al. *American Journal of Health-Systems Pharmacists*. 2007; 64(5): 536-543

- A **41.4 % reduction in dose administration** and order transcriptions, excluding potential timing errors. A **27.3% reduction** in dose timing errors.

Barcode technology is an integral piece of safe medication management systems like Electronic Health Records (EHR) and medication reconciliation.

Poon EG, et al. *New England Journal of Medicine* 2010; 362:1698-707

- A **47% reduction in dose administration errors in a neonatal ICU.**

The Journal of Pediatrics 2009; Volume 154, Issue 3, Pages 363-368.e1

Endorsements of Bar Coding for Patient Safety:

UK NHS Department of Health: Coding for Success, 2007

U.S. Food and Drug Administration 2009

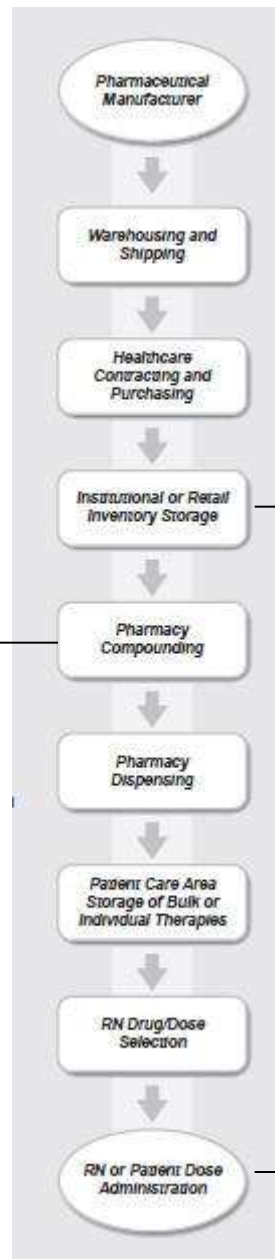
National Coordinating Council for Medication Error Reporting and Prevention, 2007 (U.S.)

American Society of Health-Systems Pharmacists 2009

Australia: Therapeutics Goods Committee, Dept of Health and Ageing, Australian Government, 2008

European Association of Hospital Pharmacists 2010

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.

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Canadian Health Organization Endorsements

 <p>Canadian Anesthesiologists' Society</p> <p>Endorsement</p>	 <p>Canadian Association of Paediatric Health Centres</p> <p>Endorsement</p>	 <p>Canadian Healthcare Association</p> <p>Endorsement</p>	 <p>Canadian Society of Hospital Pharmacists</p> <p>Endorsement</p>	 <p>2010 BPOC Way Paver Award</p> <p>Award</p>	 <p>BC Patient Safety and Quality Council</p> <p>Endorsement</p>
 <p>Canadian Medical Association</p> <p>Endorsement</p>	 <p>Canadian Medical and Biological Engineering Society</p> <p>Endorsement</p>	 <p>Canadian Nurses Association</p> <p>Endorsement</p>	 <p>Health Quality Council of Alberta</p> <p>Endorsement</p>	 <p>Manitoba Institute for Patient Safety</p> <p>Endorsement</p>	 <p>Vancouver Island Health Authority</p> <p>Endorsement</p>
 <p>Health Council of Canada</p> <p>Endorsement</p>	 <p>Healthcare Insurance Reciprocal of Canada</p> <p>Newsletter</p>	 <p>HealthPRO</p> <p>Endorsement</p>	 <p>Medbuy</p> <p>Endorsement</p>	 <p>Ontario Hospital Association</p> <p>Endorsement</p>	

Project Overview

A National Collaboration between six healthcare sectors. A two-year project comprised of 3 phases.

Major Objectives:

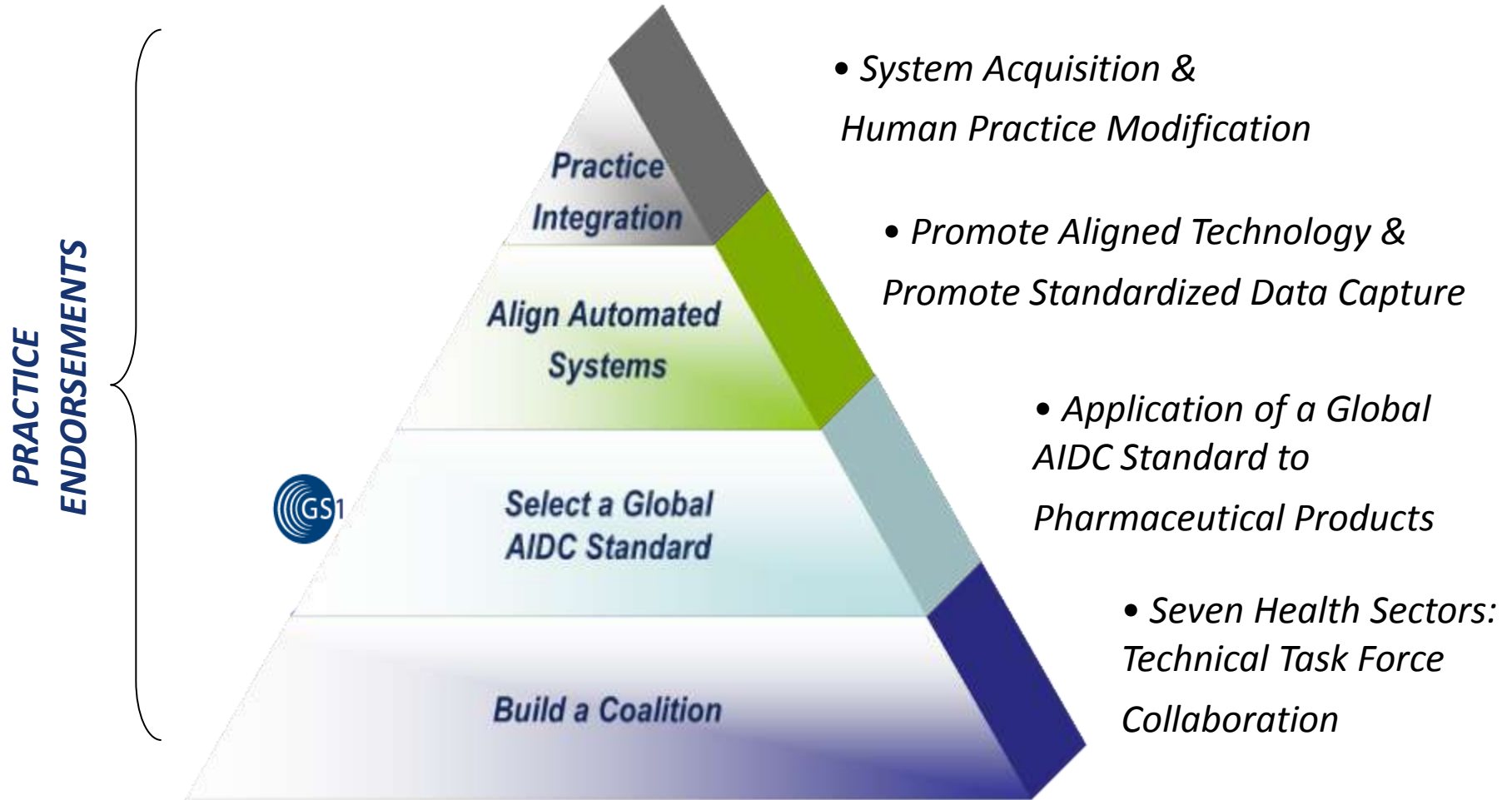
To develop a pan-Canadian strategy for bar coding of commercial pharmaceutical products.

To select a common product database for standardized product data

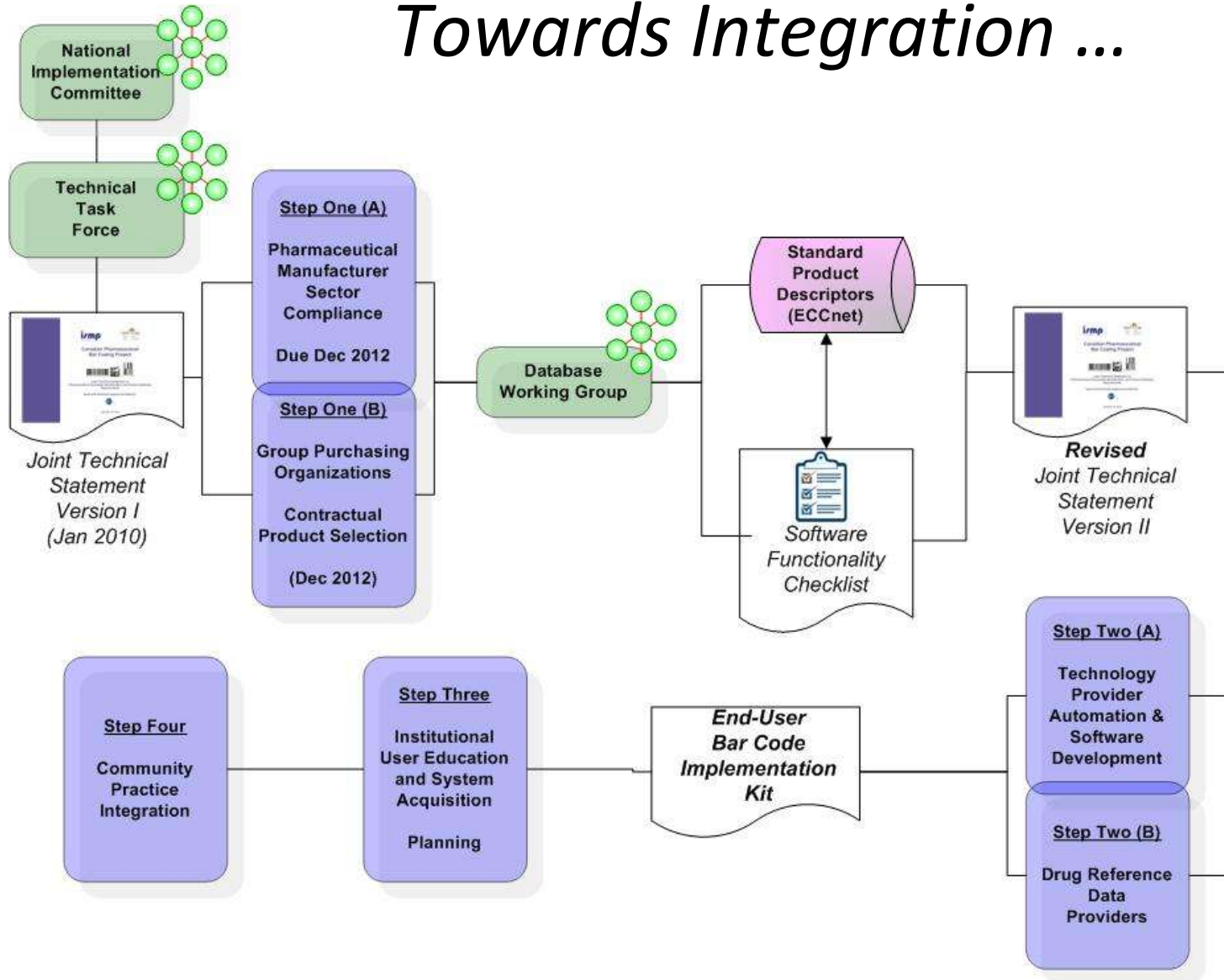
To encourage clinical information systems development which utilizes automated identification and data capture at each point of the medication chain

To create a national environment for automated identification implementation within each identified healthcare sector.

Progressive Practice Integration



Towards Integration ...



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The Joint Technical Statement (2012)

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

Section 5: A Common Canadian Pharmaceutical Product Registry (ECCnet Registry)

Section 6: Bar Code Symbology

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

Section 8: Timeline for Adoption



[Click here for Joint Technical Statement \(2012: version II\) Download](#)

Statement Sections

Joint Technical Statement on
Pharmaceutical Automated Identification
and Database Requirements

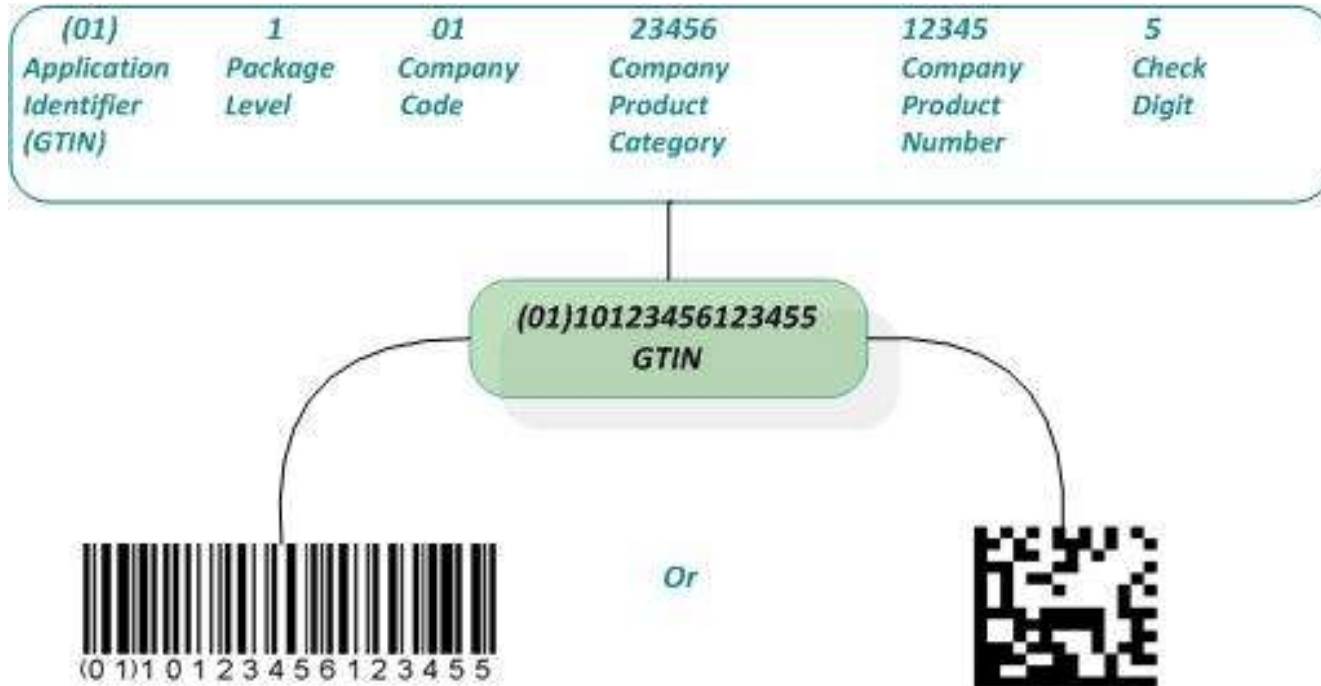
Main Statement

Section 3: Content of Bar Codes

- * Required: GTIN, up to 14 character (December 1, 2012)
- * Required: Lot number (December 1, 2017)
- * Required: Expiry Date (December 1, 2017)

- * Optional: Serial Numbers (To be reviewed in 2013)

Practice Integration ...



Statement Sections

Joint Technical Statement on
Pharmaceutical Automated Identification
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Main Statement

Section 6: Bar Code Symbolologies and Uses

- * As above. GS1-Canada approved symbolologies
 - preference for GS1 DataMatrix (2D) for smaller items
- * Camera-ready scanners should be bought by health sectors (1D and 2D)

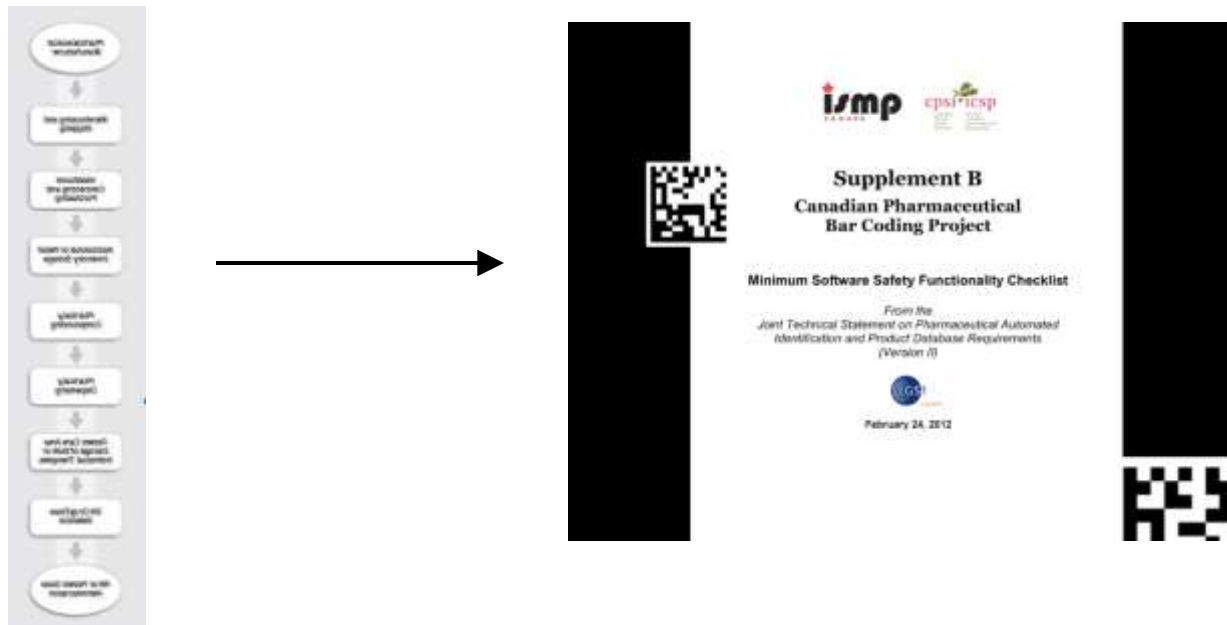


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Supplement B: Minimum Safety Software Functionality

* A list of technology bar code functionality (checklist) for technology providers (developers) and End Users (customers).



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How do we differentiate very different things that look-alike at a glance?



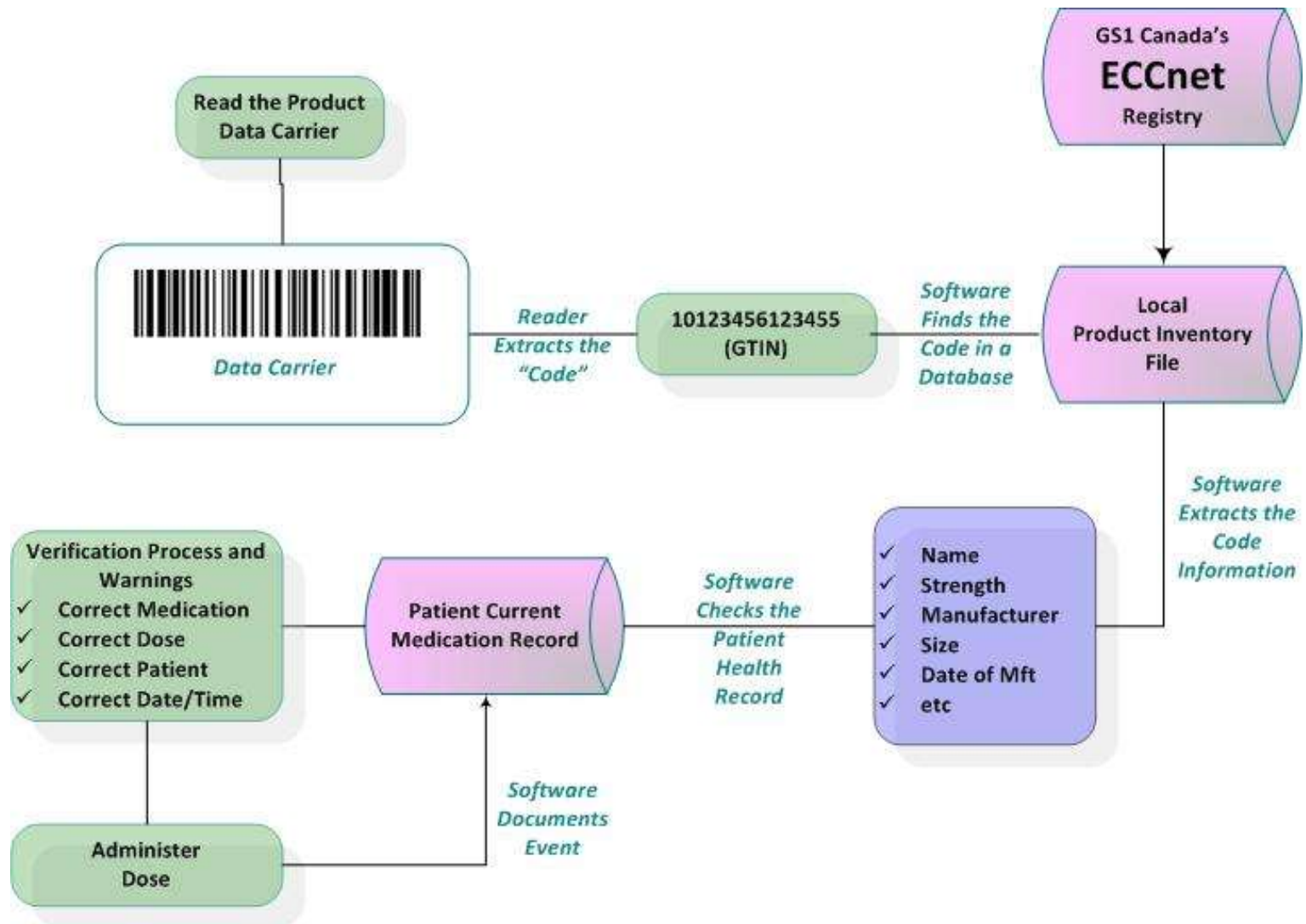
How do we move from this....



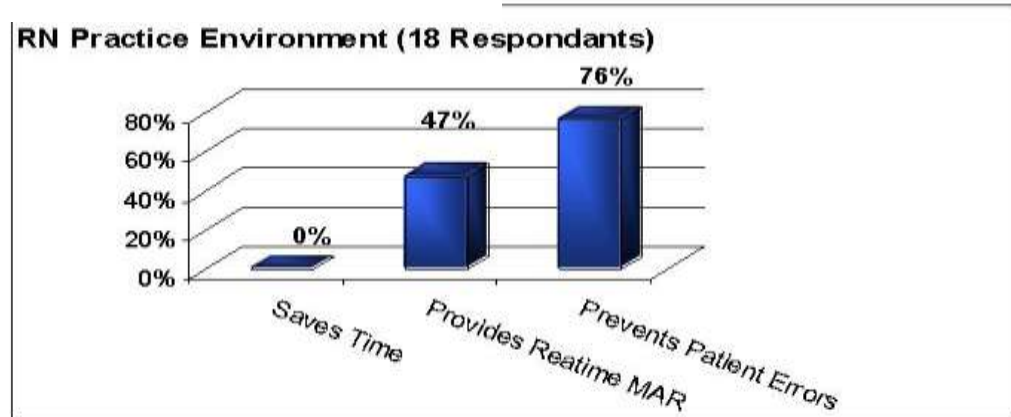
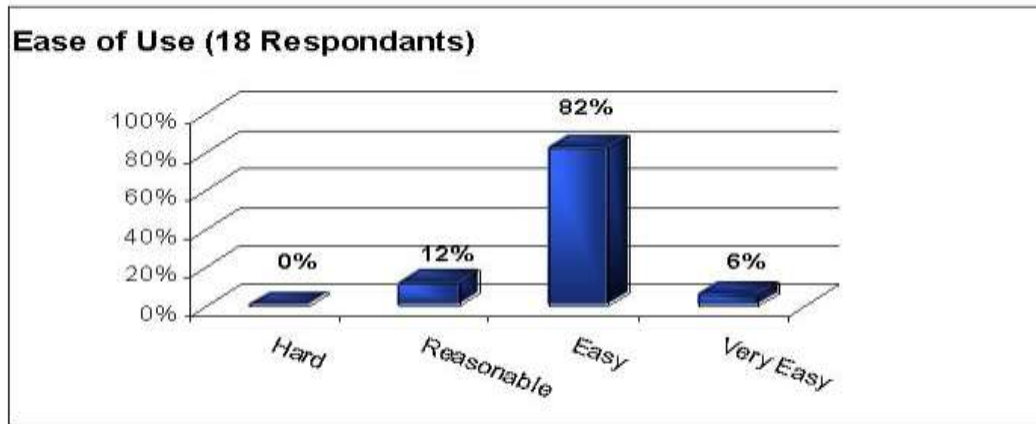
... to this ...



Practice Integration ...

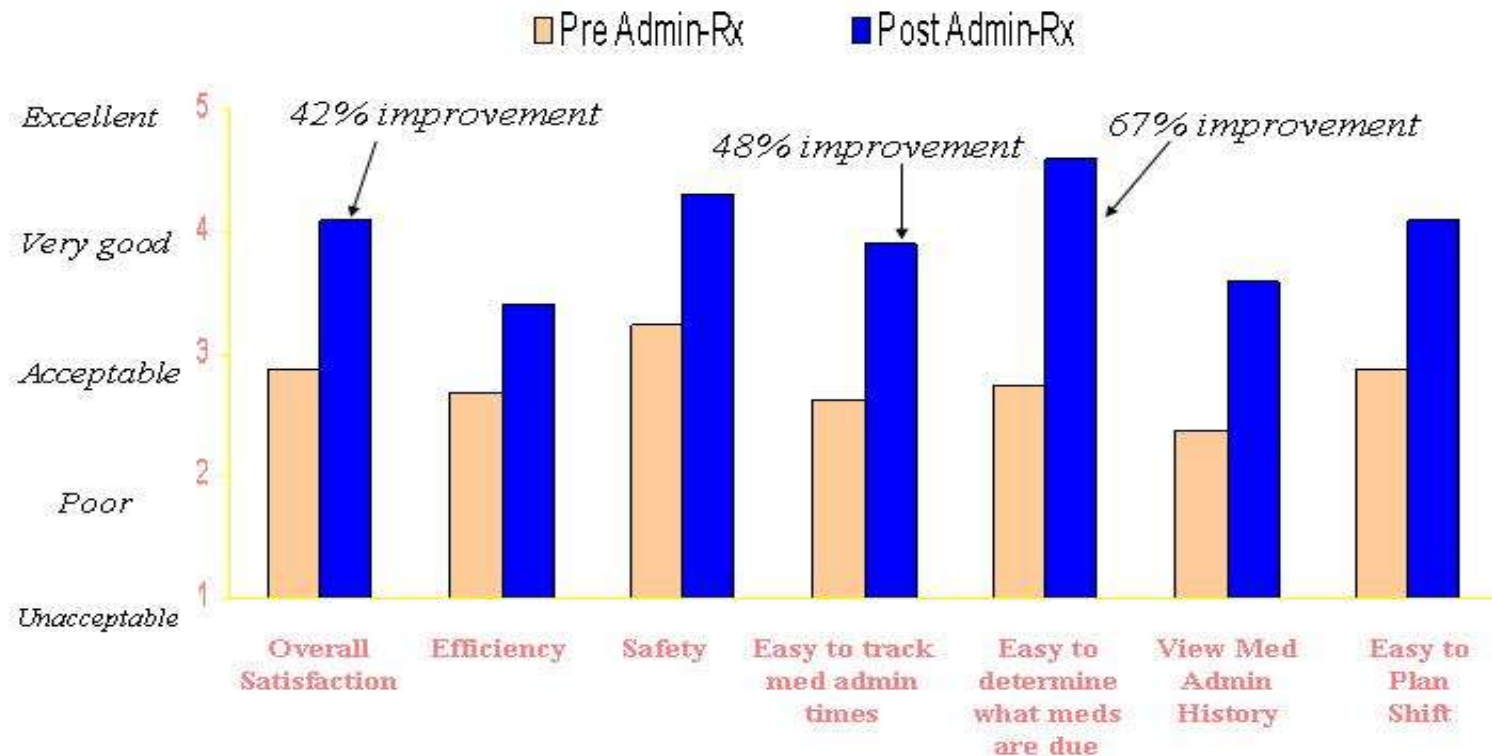


C&W Bedside Dose Verification Trial 2006



Practice Integration ...

UWHC Pre versus Post-Bar Code Scanning: Nursing Satisfaction



Supporting the National Bar Coding Initiative ...

1. Consider adding your endorsement to the ISMP Canada/CPSI national initiative agency support.
2. Discuss bar coding with your Facility's Practice Leader(s), and your affiliated national practice organization(s).
3. Meet with your Facility decision-makers to discuss bar coded medication systems, and how they might be included in your 5 year strategic plan.
4. Discuss with your external Pharmacy Provider. Discuss either a pharmacy-provided system, or integration of pharmacy dose bar codes with your own Facility's Electronic Health Record system.



Thank you!

Canadian Pharmaceutical Bar Coding Project




Version two of the **Joint Technical Statement along with two supplements are now available at:**

www.ismp-canada.org/barcoding/download/JTSv2/JTSv2.pdf

The joint technical statement is a national consensus which consolidates not only pharmaceutical manufacturer needs and efforts in bar coding, but also the development of aligned automated (software) systems, standard medication product data descriptors and, most importantly, the continued effort to integrate these improvements into safer medication practices within both institutional and community patient care.

The national initiative on automated identification of medications is made possible through the collaborative contributions of many stakeholders from six healthcare sectors.

Find out more about the project and who is endorsing standardized pharmaceutical bar coding practices: ismp-canada.org/barcoding.




ismp CANADA **cpsi icsp**
Canadian Pharmaceutical Institute Canadian Institute for Patient Safety

Canadian Pharmaceutical Bar Coding Project

Joint Technical Statement (Version II)

on
Pharmaceutical Automated Identification and Product Database Requirements

Input and technical support provided by:



February 24, 2012
(This version replaces Version I, dated January 15, 2011)

VERSION 2

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