Pharmaceutical Bar Coding to Improve Patient Safety:

Options for Technical Standards in the Canadian Environment

Proceedings of a Stakeholder Invitational Roundtable

Facilitated and recorded by Karen Graham of Panacea Canada Inc: January 2008
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A Key Partner in the Canadian Medication Incident Reporting and Prevention System
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Executive Summary

On January 24, 2008, a stakeholder invitational roundtable, co chaired by the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI), was convened in Ottawa, Ontario, to discuss and seek consensus on voluntary guidelines for pharmaceutical manufacturers related to the use of bar codes for labelling medications at the unit-dose (or unit-of-use) packaging level. The 40 participants who attended represented a variety of organizations and interests. They worked in discussion groups to explore various aspects of bar coding for pharmaceutical labels, including the products to be bar coded; packaging and placement of bar codes; and the content, format, and symbology of the bar codes themselves. Before the roundtable, ISMP Canada circulated a discussion paper outlining a proposed approach for each of these aspects.

Products to be Bar Coded
For discussion purposes, ISMP Canada proposed that bar code guidelines apply to all prescription drugs intended for human consumption (except for investigational new drugs and radiopharmaceuticals) and any nonprescription drugs commonly ordered for and administered to hospital inpatients. Roundtable participants agreed in principle that all prescription and nonprescription drugs should be bar coded. They pointed to the need for clear definitions of and evidence-based rationales for exemptions. Given limited resources, participants suggested that it might be necessary to focus on higher-risk items initially.

Packaging and Placement of Bar Codes
For discussion purposes, ISMP Canada proposed that bar codes appear on both exterior and interior packaging, as well as on individual blister card bubbles, vials, ampoules, and small bottles. During the roundtable, there was agreement in principle that bar codes should appear on each level of packaging. Participants suggested that the compliance of pharmaceutical manufacturers with bar coding guidelines could be driven forward by buying groups, with stepwise implementation of bar coding guidelines. Next steps should include an implementation timeline and work plan.

Content of Bar Codes
For discussion purposes, ISMP Canada proposed that the following information elements be encoded in the bar code: drug product name, drug strength and form, manufacturer, package size, lot number, and expiry date. Participants agreed that all of this information should be included eventually but recommended a progressive approach, starting with a minimum requirement for a simple identifier (linear bar code without variable data such as expiry date and lot number) and increasing the requirements to incorporate a two-dimensional composite as technology and readiness evolve.

Participants suggested that Canada start by taking the same approach as that of the US Food and Drug Administration (FDA), whereby all proposed information except lot number and expiry date would be encoded in the bar codes from the outset, with a specified timeframe for the addition of lot number and expiry date. Participants stressed the need for a single, centrally accessible, up-to-date database for bar codes.

It was suggested that agreement be reached within 6 months on the information to be contained in the bar code (i.e., coding methodology and required data elements), followed by implementation of the bar codes themselves within an acceptable time frame.

Format of Bar Codes
For discussion purposes, ISMP Canada proposed that standards developed by either GS1 Healthcare (GS1) or Health Industry Business Communications Council (HIBCC) be deemed acceptable.

Participants stressed that there should be a single source of data that could be linked with several types of bar codes and that the data set should be easily accessible. Ideally, the database would be centrally maintained by an unbiased source, with endorsement by healthcare associations, standards-setting organizations, and regulators. It was agreed that further consultation is needed before a particular format is selected, and that, in light of global production of pharmaceuticals, this choice may not be within the control of Canadian stakeholders.

Symbology for Bar Codes

For discussion purposes, ISMP Canada proposed that the guidelines recommend two-dimensional (data matrix) symbology, but participants did not agree with this proposal. Instead, they recommended that linear bar coding be the minimum requirement, with recognition that although this form is acceptable today, it may not necessarily be suitable in the future. Nonetheless, they also suggested that the two-dimensional matrix format be allowed where manufacturer readiness exists. Participants recommended that hospitals start by obtaining camera readers to accommodate the development of bar codes. They further suggested that bar coding standards be set so that they are "enabling" and that a hierarchy-of-products approach be considered, in recognition that the lot number and expiry date are of more importance on certain products.

General Comments and Next Steps

There was overall agreement that a standard is urgently needed for bar coding of pharmaceutical products in Canada. It was noted that in the absence of national standards, manufacturers will move forward on their own, which could result in disparate systems, and that the time to begin is now. A standardized methodology, work plan, and implementation timelines must be developed.

Roundtable participants proposed that the next steps include one more meeting of the planning committee to review the roundtable results. The proceedings document was circulated to participants for feedback, and a follow-up document is to be prepared to reflect areas of consensus and aspects where standards might evolve (for example, identification of what is most important and most practical now and directions for future enhancements). Consideration will be given to the potential need for a document outlining "best practices," which would include details to assist in implementation.

Additional steps will be developed in consultation with stakeholders.

Introduction

On January 24, 2008, a one-day invitational stakeholder roundtable was held to discuss the topic of bar coding for pharmaceuticals in the Canadian setting. The 40 participants who attended represented a variety of organizations, professions, and interests; they included advocates for patient safety; hospital and community pharmacists; nurses; representatives of the pharmaceutical industry, including brand and generic manufacturers and the biotechnology sector; health system organizations; regulators; policy experts; standards-setting agencies; and experts in bar code technology. A list of the participants appears in **Appendix A**, and the agenda is presented in **Appendix B**. A discussion paper (available from: http://www.ismp-canada.org/publications.htm), developed by the Institute for Safe Medication Practices Canada (ISMP Canada) with assistance from Barbara Wells of BA Wells Healthcare Inc. and circulated to stakeholders before the event, guided discussion during the roundtable event. The roundtable itself was designed by a planning group (members listed in **Appendix C**).

The purpose of the roundtable was to discuss and seek stakeholder consensus on voluntary guidelines for pharmaceutical manufacturers related to the use of bar codes for labelling medications at the unit-dose (or unit-of-use) packaging level.

Objectives of the Roundtable

The following specific objectives were affirmed by the Roundtable Planning Committee during a teleconference held on August 22, 2007:

- Acknowledge the scope and repercussions of medication errors in Canada and recognize how bar coding can reduce errors (this combined goal was accomplished through the various speakers' presentations).
- Review the facts and options (these were presented in the discussion paper circulated in advance and were reiterated in various speakers' presentations).
- Reach consensus on the following aspects of pharmaceutical label bar coding:
    - products to be bar coded
    - packaging and placement of bar codes
    - content of bar codes
    - format of bar codes
    - symbology
- Identify challenges and barriers to implementing the aspects listed above, along with options for solving these problems.
- Reach consensus on next steps, champions, and timelines for action.

Following a series of presentations (see **Appendix D**), participants worked together in five discussion groups to identify areas of consensus, barriers and challenges and potential solutions, for each of the five aspects listed above. These discussions were guided by four focus questions:

1. Is there agreement with what ISMP Canada has proposed?
2. If not, what is the specific nature of the disagreement?
3. What are the barriers and challenges to implementation?
4. What solution(s) does the group recommend?

Each group summarized its deliberations, and a closing plenary discussion yielded consensus in a number of areas. A summary of the plenary discussion is presented in the following pages.

1. Products to be Bar Coded

For discussion purposes, ISMP Canada proposed that bar coding guidelines apply to

- *all prescription drugs for human consumption (except for investigational new drugs and radiopharmaceuticals)*
- *any nonprescription drugs commonly ordered for and administered to hospital inpatients.*

Agreement with ISMP Canada's proposal

- In principle, all prescription and nonprescription drugs should be bar coded.

Discussion points

- A rationale is needed for the proposed exclusions. For example, there is some commonality with the approach of the Food and Drug Administration (FDA) (i.e., radiopharmaceuticals), but there are also some differences.
- Bar coding should be examined and considered in contexts beyond the acute care environment, across the continuum of care, including community, home care, and nursing homes.
- There is a need to ensure that the exceptions are clearly and comprehensively defined.
- Bar coding of inner labels for nonprescription drugs poses a particular set of challenges.

Barriers and challenges to implementation

- It will be a challenge to examine the applicability of bar coding to healthcare environments other than acute care; nonetheless, there is a need to define the business case for community-based pharmacy and extended care.
- A cost analysis will be needed to ensure that bar coding is feasible for industry.
- The size of the Canadian market and the potentially increased costs for nonprescription drugs must be considered.
- Certain types of automation in the hospital setting (e.g., automated unit-dose packaging and dispensing machines) are designed for use with bulk supplies, with the bar code being added at the time of packaging in the hospital.

Possible solution(s)

- Develop clear definitions of exceptions.
- Provide evidence-based rationale for exceptions, starting with the exemptions outlined by the FDA.
- Given limited resources, it may be necessary to focus on higher-risk items.

2. Packaging and Placement of Bar Codes

For discussion purposes, ISMP Canada proposed that bar codes appear on both exterior and interior packaging, as well as on individual blister card bubbles, vials, ampoules, and small bottles.

Agreement with ISMP Canada's proposal

- In principle, bar codes should appear on each level of packaging.

Discussion points

- Exceptions to the general practice remain to be identified.
- The timeframe for implementation must be identified. For example, the FDA had a 2-year window for implementation.
- For blister packs, there will be issues related to size and other labelling requirements (e.g., DIN [Drug Identification Number], bilingual wording).
- The technology is available to put bar codes on blister packaging, but there are larger issues related to manufacturing, regulation, and size of the market.
- Sometimes, there may be no choice about placement of a bar code (e.g., a 1 mL vial is very small).
- What will be the driving force for the bar coding initiative?
    - Will manufacturers feel it is important to add bar codes if 60% of hospitals do not use them and purchasers do not require them?
    - Accreditation standards could be set for any point of contact (bedside, stocking, purchasing), but this will be difficult to enforce if manufacturers are not providing bar codes.
    - Systematic implementation of bar codes will be needed, regardless of accreditation standards.

Barriers and challenges to implementation

- Leadership is needed to drive bar coding forward.
- Manufacturers may require Health Canada's guidance to meet labelling requirements

Possible solution(s)

- Drive the initiative forward through the buying groups or through requirements for bar coded products.
- Focus should be on the weakest area of hospital care (i.e., the area with the most intense risk), and bar coding should be implemented in a stepwise fashion.
- A UK study[1] that examined optimal label design for patient safety including placement of a bar code on the label, could be helpful and should be reviewed.
- It will be necessary to determine the time to implementation and to create a work plan.

[1] National Health Service, National Patient Safety Agency. *Design for patient safety: a guide to the graphic design of medication packaging*. 2nd ed. Place of publication: NHS; 2007.

3. Content of Bar Codes

For discussion purposes, ISMP Canada proposed that the following information elements be encoded in the bar code:

Drug product name	*Drug strength and form*	*Manufacturer*
Package size	*Lot number*	*Expiry date*

Agreement with ISMP Canada's proposal

- All of the proposed information elements should be included, eventually. A progressive, tiered approach was proposed, starting with a minimum requirement for a simple, unique product identifier (linear bar code without variable data) and increasing the requirements to incorporate a two-dimensional composite as technology and readiness evolve.

Discussion points

- A single, unique international product identifier code must be established and maintained for each Canadian drug product.
- It will be important to have a background database, linked to the unique identifiers, so that detailed information for each product can be maintained and, through the database, expanded in the future to include new information elements.
- The FDA could not identify evidence to support requirements to include lot number and expiry date.
- Lot number and expiry date (variable data) could be added as a later requirement.
- In Canada, 23,000 pharmaceuticals and 700 biologics are currently available.
- The time required to obtain regulatory approval through Health Canada is approximately 18 months; voluntary participation would be easier to achieve but harder to "enforce".

Barriers and challenges to implementation

- Effective database maintenance is critical to the success of bar coding:
    - Ideally, Health Canada would maintain the database.
    - If Health Canada is not ready to maintain the database, then it would be the responsibility of the supplier or an independent body (GS1, HIBCC, other).
- Including lot numbers and expiry dates in bar codes poses specific challenges to manufacturers:
    - Once a timeframe has been defined, manufacturers could request that equipment manufacturers make the necessary adjustments.
    - If lot numbers and expiry dates are included, the bar codes must be printed at the time the label is affixed to the product. This is inconsistent with current practice and, in the opinion of some, is not achievable.
    - The size of the Canadian market must be considered in a global context. Specifically, how will multinational companies justify the expense of bar coding in a single market? Lot numbers and expiry dates are very difficult to add in the context of global manufacturing processes. Additional costs are due to greater labour needs and slower line speed. Therefore, global trends can be expected to drive Canadian decisions.
    - A business case will be needed for each piece of information to be added to the bar code.
- The timeframe for implementation presents challenges: What is realistic? What is "soon"? As an example, the timeframe for bar coding of vaccines is 5 years after standards are set. Two years is not a long time for manufacturers to effect changes to manufacturing lines, label filing, etc.
- Voluntary guidelines may not result in the desired change, particularly for singe-source items.

Possible solution(s)

- Start by taking the same approach as that of the FDA, whereby all proposed information except lot number and expiry date would be included initially, with a specified timeframe for the addition of lot number and expiry date.
- Start implementation of bar coding with those drugs that present the highest potential risk, e.g., injectables.
- Maintain one database, linked to the unique identifiers, such that scanning a bar code would provide local access to several data elements, including the minimum required elements outlined above, and possibly an expanded list as future requirements are agreed.
- Within 6 months, reach agreement on the information to be contained in the bar code (i.e., coding methodology and required data elements), and then implement the codes themselves in an acceptable time frame.

4. Format of Bar Codes

For discussion purposes, ISMP Canada proposed that standards developed by either GS1 Healthcare (GS1) or Health Industry Business Communications Council (HIBCC) be deemed acceptable.

Agreement with ISMP Canada's proposal

- There should be a single source of data or a single database that can be linked with several types of bar codes.
- Ideally, the database will be centrally maintained by an unbiased, validated source and will be endorsed by healthcare associations, standards-setting organizations, and regulators (e.g., Canadian Standards Association, Health Canada, ISMP Canada, Canadian Pharmacists Association, Canadian Society of Hospital Pharmacists, Canadian Nurses Association, Canadian Medical Association).
- At this stage, there is no recommendation for one format over another; further consultation is needed in this area.
- Global production means that the format may be decided elsewhere.

Discussion points

- Approximately 90% of all outer packaging for pharmaceuticals currently has some sort of bar code, which should eventually migrate to also adding a bar code to the inner packaging (with a consistent format across levels of packaging for each individual product), but the structure of the bar code itself may differ depending on placement.
- Approximately 90% of outer packaging uses GS1 format (exact percentage has not been verified).
- As standards evolve, stakeholder consultation will be necessary.
- Harmonization of standards with those in other countries would be ideal.

Barriers and challenges to implementation

- Availability of a single database that can accommodate various types of data and bar codes is uncertain.
- The format must be adoptable for pharmacy use, to allow unit-dose products to be repackaged or dispensed in house from original packages (e.g., 0.08 mL in a syringe prepared from a vial in a pediatric setting).
- It is uncertain how compounded products will be handled.

Possible solution(s)

- The data set must be easily accessible by all users.

5. Symbology of Bar Codes

For discussion purposes, ISMP Canada proposed that the guidelines recommend two-dimensional (data matrix) symbology.

Agreement with ISMP Canada's proposal

- There was no agreement on this aspect.
- Linear bar coding was recommended as the minimum requirement, with recognition that although this form is acceptable today, it may not necessarily be suitable in the future.
- Use of the two-dimensional matrix format should be allowed where manufacturer readiness exists.
- Hospitals, when starting implementation, should obtain camera readers to accommodate the development of bar codes.

Discussion points

- Discussion of symbology is taking place at a global level.
- The United States has recommended linear bar codes, which are easier and faster to implement. Canadians should learn what they can from the US experience.
- The proposed UK standard is similar to the two-dimensional data matrix technology proposed by ISMP Canada.
- The United Kingdom and the European Union advocate linear bar codes on outer packaging, with two-dimensional matrix coding for expiry date and lot number on the inner package (as recommended by the UK National Health Service).
- Inclusion of expiry date and lot number in bar codes, for all drugs, is not reasonable at this point; requiring their inclusion would delay implementation of bar coding.
- In addition to the import of drug products to Canada, Canadian manufacturers also export products globally.
- In situations where a unique identifier with variable data is needed (e.g., vaccines) two-dimensional bar coding should be used.
- In Canada, drugs do not have a unique identifying number like the NDC code used in the United States (the DIN is not a unique identifier for drug products).

Barriers and challenges to implementation

- Graduated implementation of specific products (e.g., injectables, specific types of high-risk products) may be needed.
- Wireless scanning does not interfere with hospital equipment, but there may be software issues when two scanning devices are operated in close proximity.
- Research is needed to determine if product integrity is compromised by repeated exposure to scanning.

Possible solutions

- Set standards that are "enabling."
- Use a hierarchy-of-products approach, in recognition that the lot number and expiry date are of more importance on certain products.

General Comments

- There was overall agreement that a standard is urgently needed for bar coding of pharmaceutical products in Canada.
- The global movement of products presents a potential challenge with respect to a uniquely Canadian solution, and the global direction of developments in the area of bar coding will help drive changes in bar coding practice within Canada.
- Pan-Canadian requirements for bar coding must be defined, but Canadians must also look to global solutions, including the ongoing work of an international standards working group (in which Canada Health Infoway is involved).
- The needs of healthcare providers in remote areas, where appropriate technology may not be available, must be considered.
- In the absence of national standards, manufacturers will move forward on their own, which could result in disparate systems.
- The time to begin is now; specifically, a work plan and implementation timelines must be developed.
- Health Canada, through its progressive licensing framework, will examine requirements for labelling, and bar coding may fit in with this process. Cost-recovery regulations are also being reviewed.
- Health Canada operates within a framework that allows for stakeholder input.
- Regulatory changes require at least 18 months to take effect, and the Blueprint for Renewal is the current priority.
- Consensus on a voluntary strategy will stimulate action more quickly; significant improvements are possible.

Next Steps

- The planning committee met one more time to review the results of the roundtable.
- The proceedings document was circulated to participants for feedback.
- A follow-up document is to be prepared to reflect areas of consensus and aspects where standards might evolve (for example, identification of what is most important and most practical now, with direction for future enhancements).
- Consideration will be given to the potential need for a document outlining “best practices,” which would include details to assist implementation.
- Additional steps will be developed in consultation with the stakeholders.

Appendix A – Participants

Table One	Table Four
Jeff Leger, Apotex, Inc	**Mark Ferdinand,** Rx&D, Canada's Research-Based Pharmaceutical Companies
Garry Cruikshank, Canada Health Infoway	**Sylvia Hyland,** Institute for Safe Medication Practices Canada
Heather Tyrrell, Canadian Association of Chain Drug Stores	**Mary Burkhardt,** Speaker (keynote)
Elaine Orrbine, Canadian Association of Paediatric Health Centres	**George DeAngelis,** AstraZeneca Canada Inc
Phil Hassen, Canadian Patient Safety Institute	**Régis Vaillancourt,** Planning Committee (member)
Jessica Peters, Canadian Council on Health Services Accreditation (now Accreditation Canada)	**Philip Hoy,** Pharmaceutical Partners of Canada
Luna Al-Khalili, Health Canada – Marketed Health Products Directorate	**Lisa Belzak,** Public Health Agency of Canada
Lisa D. Clarke, Hospira Healthcare Corporation	**Lisa Ashley,** Canadian Nurses Association
Table Two	**Table Five**
Alicia Gatt, Baxter Corporation	**Julie Tam,** Canadian Generic Pharmaceutical Association
Pierrette Leonard, Canadian Patient Safety Institute	**Patricia MacGregor,** Canadian Society of Hospital Pharmacists
David Crosbie, Canadian Pharmacists Association	**Lynn M. Brodsky,** Health Canada – Therapeutic Products Directorate
Nigel Wood, GS1 Canada	**Luis Figarella,** Health Industry Business Communications Council
Allen J. Vaida, Institute for Safe Medication Practices (US)	**Kathy Boyle,** HealthPRO Procurement Services Inc
Liette Champagne, Sandoz Canada Inc	**David U,** Institute for Safe Medication Practices Canada
Esther Fung, Speaker	**Robert White,** Non-prescription Drug Manufacturers Association of Canada
	Ludwik Fedorko, Physician
Table Three	
Louis Lamarche, BIOTECanada	**Orvie Dingwall,** Observer Canadian Patient Safety Institute
Meera Makim, Health Canada – Biologics and Genetic Therapies Directorate	**Tara Harris,** Observer Public Health Agency of Canada
Ron Swartz, Medbuy Corporation**Meera Makim,** Health Canada – Biologics and Genetic Therapies Directorate	**Bonnie Salsman,** Observer Institute for Safe Medication Practices Canada
Rob VanExan, Sanofi-Pasteur**Ron Swartz,** Medbuy Corporation	
Ian Sheppard, Speaker**Rob VanExan,** Sanofi-Pasteur	
David T. Windross, Novopharm Limited **Ian Sheppard,** Speaker	
Scott Ginther, Health Quality Council of Alberta **David T. Windross,** Novopharm Limited	
Scott Ginther, Health Quality Council of Alberta	

Appendix B – Roundtable Agenda

Pharmaceutical Bar Coding to Improve Patient Safety:
Options for Technical Standards in the Canadian Environment
Stakeholder Invitational Roundtable
Crowne Plaza Hotel, Ottawa - Thursday, January 24, 2008

0830 – 0845 **Welcome –Cosponsors, Facilitator**

0845 – 0905 **Keynote presentation**
Mary Burkhardt, Medication Safety Specialist

0905 – 1120 **Setting the scene – short presentations**

1. Public Health Agency of Canada's work on vaccine bar coding
   - *Tara Harris, PHAC*

2. Perspectives of the standards setters
   - *Nigel Wood, GS1 Canada*
   - *Luis Figarella, HIBBC*

3. Perspectives of the manufacturers
   - *Liette Champagne, Sandoz*
   - *Rob VanExan, Sanofi-Pasteur*

4. Perspectives of the end users
   - *Marie Segars, McLeod Medical Centre, Florence, NC (via teleconference)*
   - *Ian Sheppard, Children's and Women's Health Centre of B.C.*
   - *Esther Fung, University Health Network (Toronto)*

5. The US experience: perspectives of the Food and Drug Administration
   - *Phil Chao, FDA (via teleconference)*

1120 – 1140 **Formation of working groups and facilitators' instructions to groups**

1140 – 1300 **Working lunch and small group discussions**
- Review guideline components:
  - Products to be bar coded
  - Packaging and placement
  - Content
  - Format
  - Symbology
- Reach consensus on preferred options
- Identify any barriers for reaching consensus

1300 – 1400 **Report back to plenary**

1415 – 1530 **Plenary consensus discussion**

1530 – 1545 **Next steps**

1545 – 1600 **Closing remarks**

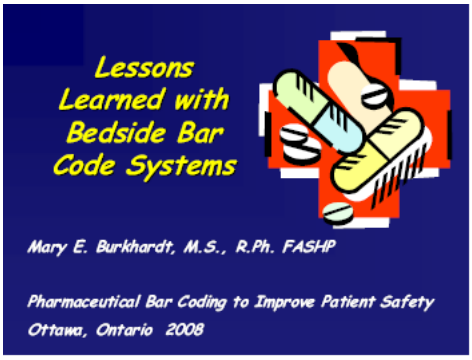
Appendix C – Pharmaceutical Bar Code Roundtable Planning Committee

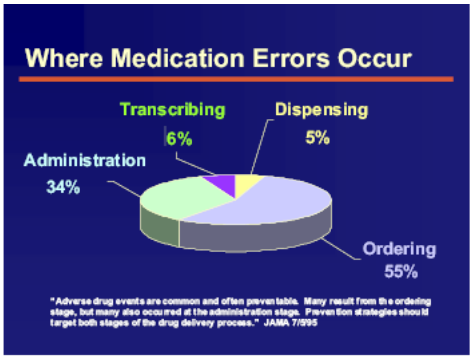
- Sylvia Hyland, ISMP Canada (Co chair)
- Pierrette Leonard, Canadian Patient Safety Institute (Co chair)

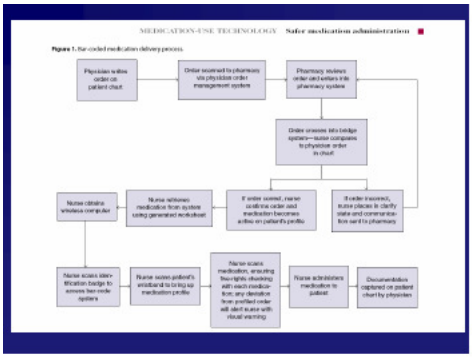
- Lisa Belzak, Public Health Agency of Canada
- Pat Carruthers-Czyzewski, Sintera
- Mark Ferdinand, Rx & D, Canada's Research-Based Pharmaceutical Companies
- Graeme Fraser, BioTECH Canada
- Tara Harris, Public Health Agency of Canada
- Hélène Perrier, Sintera
- Julie Tam, Canadian Generic Pharmaceutical Association
- Régis Vaillancourt, Children's Hospital of Eastern Ontario
- Margaret Zimmerman, (Health Canada)

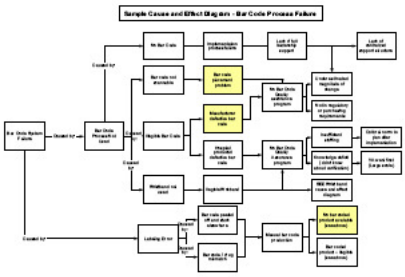
Appendix D –Short Presentations

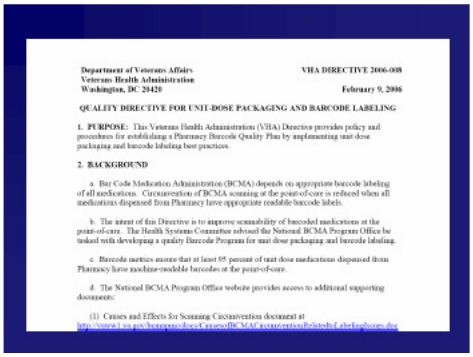
Lessons Learned with Bedside Bar Code Systems
Presented By Mary Burkhardt

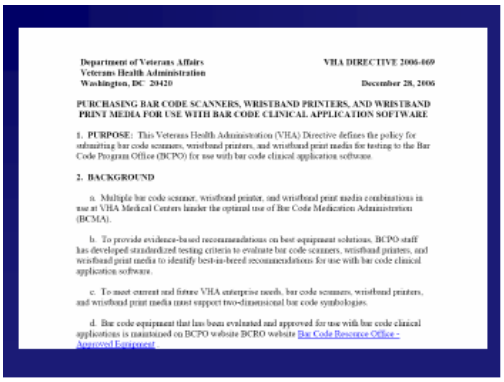












Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 2006-069

December 28, 2006

PURCHASING BAR CODE SCANNERS, WRISTBAND PRINTERS, AND WRISTBAND PRINT MEDIA FOR USE WITH BAR CODE CLINICAL APPLICATION SOFTWARE

1. **PURPOSE:** This Veterans Health Administration (VHA) Directive defines the policy for submitting bar code scanners, wristband printers, and wristband print media for testing to the Bar Code Program Office (BCPO) for use with bar code clinical application software.

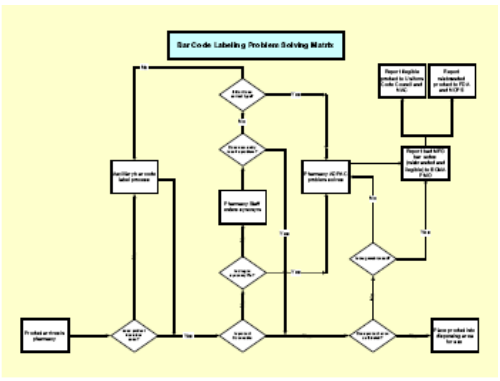
2. **BACKGROUND**

a. Multiple bar code scanner, wristband printer, and wristband print media combinations in use at VHA Medical Centers hinder the optimal use of Bar Code Medication Administration (BCMA).

b. To provide evidence-based recommendations on best equipment solutions, BCPO staff has developed standardized testing criteria to evaluate bar code scanners, wristband printers, and wristband print media to identify best-in-breed recommendations for use with bar code clinical application software.

c. To meet current and future VHA enterprise needs, bar code scanners, wristband printers, and wristband print media must support two-dimensional bar code symbologies.

d. Bar code equipment that has been evaluated and approved for use with bar code clinical applications is maintained on BCPO website BCRO website Bar Code Resource Office - Approved Equipment



Through the retrospectoscope

- Implement quality programs sooner
  - Verification at healthcare facilities AND manufacturers and labelers (closed loop)
  - Right grade, right label (some misbranded @ labelers)
  - ANSI / ISO – recommend to verify at regular print intervals
  - Manage the print and packaging materials (durable, good contrast, flat and not shiny)
- Attach bar codes to the IMMEDIATE container to assure bar code is not discarded in preparation

Through the retrospectoscope

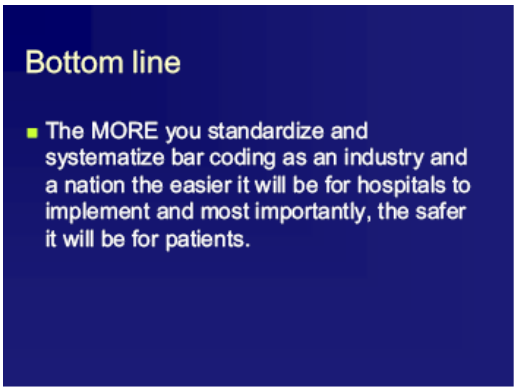
- Do better job of placement
  - Ointment tubes with bar code at end – lose access to bar code when tube is rolled up
- After label application (flat labels scan fine but when applied to round containers don't all scan)
- Insist on standardization
  - Management of various numbering systems and symbologies is untenable
  - Think GLOBALLY, but act locally
- Watch your users USE your products
- Solicit feedback and make improvements as you go (VA has sent HUNDREDS of letters to FDA, contracting office and GS1 about bad bar codes)
- American Society of Health-System Pharmacists has a "report bad bar codes" website

Through the retrospectoscope

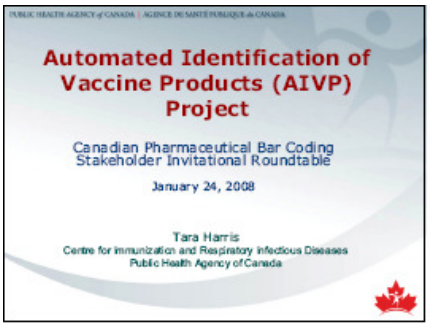
- Include bar codes on components and kit, both
- Bar code diluents as diluents, not the active drug (glucagon kit mistake)
- Not multiple bar codes on one product – nurse won't know which one to scan
- Avoid use of internal inventory tracking numbers – confuses staff at bedside

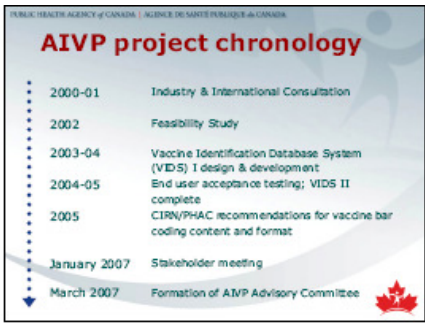
Your job, Mr. Phelps.....should you choose to accept it.....

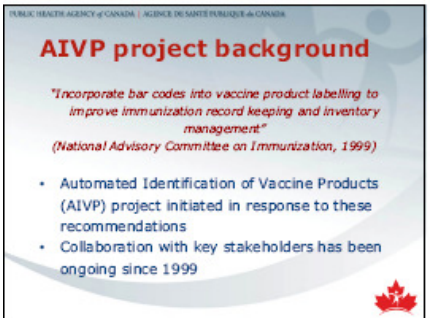
...is to work with healthcare organizations to eliminate the barriers to safely implementing bedside bar code systems

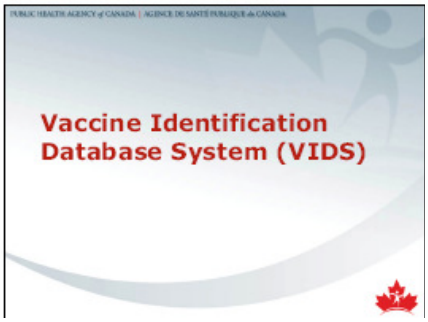

Bottom line
The MORE you standardize and systematize bar coding as an industry and a nation the easier it will be for hospitals to implement and most importantly, the safer it will be for patients.

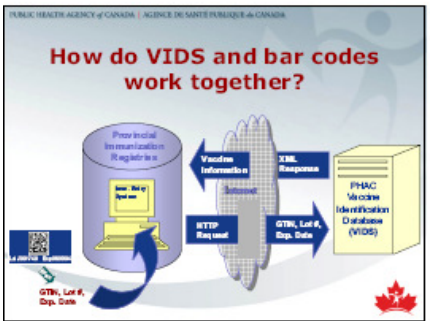
Automated Identification of Vaccine Products (AIVP) Project
Presented by Tara Harris





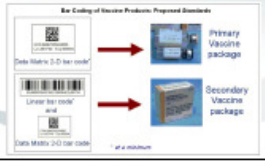






AIVP recommendations

1. Bar code content
Encode GTIN, lot# and exp. date on both the 1° & 2° packages
2. Bar code specification
Use the GS1-128 Code Structure to encode the data into the bar
3. Bar code symbology
Use Data Matrix (2-D) bar code on 1° packages and linear (1-D) bar code, at the minimum, on 2° packages



Collaboration

AIVP recommendations (cont.)

4. Peel-off / detachable labels

Two peel-off labels, with bar code[a] & human readable information[b], to be provided for each unit dose of vaccine enclosed in a secondary vaccine package

Peel-off labels should be affixed to primary package and should not obscure the information on the package.

Stakeholder Meeting (Jan. 2007)

Outcomes:
- Seven main priorities were identified:
  - development of a strategic plan
  - analysis of costs
  - identification of further research priorities
  - manufacturing issues
  - harmonization of standards
  - assessment on the state of readiness
  - the Vaccine Identification Database System (VIDS)
- Formation of an Advisory Committee recommended

AIVP Advisory Committee

- Formed in March 2007

Mandate:
- To provide leadership, overall guidance, direction, advice and support for the development and the implementation of vaccine bar codes in Canada and contribute to the development of global standards for bar coding of vaccines.

Membership:
- PHAC / Industry co-chairs
- Cross-sectional representation from the regulator, immunization-specific FPT groups, industry, end-users and standards-setting organizations

Lessons Learned

- Contribute to and promote the adoption of global standards
- Collaborate and align with international partners
- Engage all stakeholders across the supply chain, including the regulator, industry and both private and public end users
- Maintain interest and momentum through ongoing and regular communication with stakeholders

Automated Identification of Vaccine Products (AIVP) Strategic Plan (2007-2012)

Vision:
Improve the efficiency and effectiveness of immunization provision and safety of vaccine use in Canada through the automated identification of vaccine products by 2012.

Goals:
1. Engage key stakeholders to facilitate broad-based support for AIVP
2. Assemble a comprehensive collection of information about AIVP and its implementation
3. Facilitate the voluntary implementation of bar codes on vaccine products that meet Canadian requirements and international standards
4. Implement VIDS to be the national online database containing comprehensive information on all vaccines licensed for use in Canada and support auto-population of immunization registries and / or other information systems using vaccine bar codes
5. Facilitate the configuration of immunization information management systems to accept bar codes that meet international standards and automatically population vaccine specific fields through electronic messaging with VIDS
6. Support the use of bar codes in the immunization practice of individual providers and immunization programs

Key Contacts

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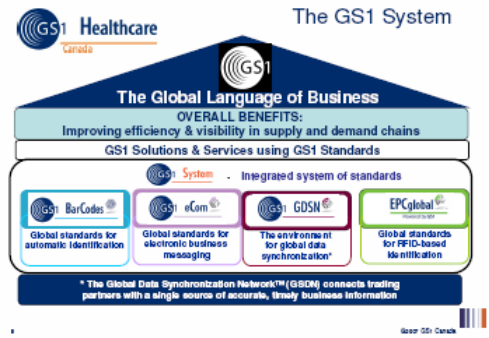
Standards and Patient Safety
Presented by Nigel Wood



GS1 Healthcare User Group: *Areas of focus*

Prevention of Medical Errors
Encoding of the unit dose or unit of use package to enable automated verification to ensure right dose, for the right patient at the right time. Encoding of the unit of use package to enable automated verification to ensure the right device for the right patient.

Product Authentication
Utilizing a GS1 data structure, enable authentication of individual packages, cases or pallets.

Tracking and Tracing
Utilizing a GS1 data structure, work with supply chain trading partners to enable an electronic pedigree for individual packages such that in the event of a counterfeiting incident, tracing of the suspect product can occur.

Increase Total Supply Chain Efficiency
Through greater visibility, accuracy and velocity.

Supporting Healthcare

- **GS1 Healthcare Canada** - to lead the healthcare industry to the effective utilization and development of global standards to enable efficiencies and improve patient safety
- **GS1 Canada and CareNET Services Inc.** - sign strategic alliance to enhance and increase the adoption of global supply chain and e-commerce standards and practices to improve safety and efficiency within the Canadian healthcare community
- Over **430 Canadian hospitals** are now members of GS1 Canada

GS1 Global Standards in Healthcare

- Over 90% of Canada's pharmaceutical and OTC products carry a GS1 bar code
  - Global focus on unit dose level
- In August 2006, the world's leading medical device and pharmaceutical companies adopted GS1 as the sole system of standards in healthcare

Global Healthcare Members

Pharmaceutical Manufacturers
- Alcon Laboratories
- Amgen
- Astra Zeneca
- Baxter
- Bekring
- Boehringer Ingelheim
- B Braun
- Cephalon
- GSK
- Johnson & Johnson Pharma
- Meerkap Pharma
- Merck
- Merck Germany
- Novartis
- Pfizer
- Procter & Gamble
- Roche Diagnostics
- Sanofi Aventis
- Schering Plough
- Wyeth

Manufacturer Medical Devices
- 3M
- Associated B Braun
- Alcon Laboratories
- Baxter
- BD
- Boston Scientific
- B Braun
- Cloth
- DePuy (J&J)
- Edwards Lifescience
- Medtronic
- Johnson & Johnson MD
- Kimberley Clark
- Medtronic
- Olympus Medical Systems
- Pall Medical
- Smiths Medical
- St. Jude
- Terumo
- Tyco Healthcare

Hospitals/GPO
- Comparato University Hospital Group
- Mariahospital Name
- Toronto
- Nation
- Premier
- University Hospital of Dijon
- University Hospital of Lyon
- And further 15 French University hospitals
- University Hospital of Leeds
- University Hospital of Geneva
- Chelsea & Westminster NHS Hospital, London
- Tokyo Medical University
- Mount Sinai Medical Center
- Mayo Clinic

Transport & Logistics
- Exel
- Alerado

Retail
- Wal*Mart Stores Inc
- Sobeys Pharmacy Group

Associations
- U.S. Association of Medical Device Manufacturers (AdvaMed)
- European Associations of Medical Device Manufacturers and National Associations (Eucomed)
- European Generic Medicines Association (EGA)
- International Hospital Federation (IHF)
- European Association of Full-line Wholesalers (GIRP)
- American Nurse Association (ANA)
- HLT

Regulatory Bodies
- Public Health Agency of Canada (PHAC)
- US Food & Drug Administration (FDA)
- Ministry of Health New Zealand
- Ministry of Health UK
- NEHTA Australia
- Ministry of Health Serbia
- Ministry of Health Japan

...and more!

Why Use Global Supply Chain Standards in Healthcare?

Because of the global nature of the healthcare industry today, as well as the worldwide threats of medical errors, counterfeiting and diversion, **country-by-country work is neither sufficient nor effective.**

Global standards shared across the healthcare industry are key to identifying and authenticating products.

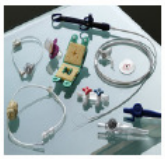
Canada is an Import Nation

Why Did They Choose GS1?

The GS1 System of Standards is:

- **Open** – Non-propriety system open to all industries
- **Global** – The standards development and maintenance process is global
- **Cross Sector** – The same system and rules are applied across various sectors
- **Represents both Bar Coding and EPC/RFID**

Carriers in Auto-ID Work team: Carrier



Carrier Business Requirements have been gathered, vetted, approved and forwarded to the application standards work group

Specific carrier production details are being collected. They are line speeds when applying the AIDC carriers, panel size and substrate material

These details will be finalized in Granada

Goal: Determine the global healthcare sector's requirements for the business requirements for the selection and placement of carriers (bar codes and RFID tags) on parts and packages for all healthcare products

AIDC Standards for product marking/labelling

Work Team: Application Standards

All data requirements have been mapped to the part marking and packaging level for the healthcare products

Preparations for development of the application standard have started

Development of the application standards will start in January

First area of development will be Rx Pharma

Patient Identification

Inconsistencies and inefficiencies in how patients are identified in the process of receiving healthcare puts the patient at risk and impacts patient safety.

Several studies and reports from around the world have clearly illustrated this problem.

A global solution has not yet been reached.

Five "Rights" of Patient Safety & GS1 Solutions

Right Patient
- Global Service Relation Number (GSRN)

Right Drug
- Global Trade Item Number (GTIN)

Right Dosage
- Global Trade Item Number (GTIN)

Right Time
- Bedside scanning

Right Route
- Bedside scanning

GS1 Identification Numbers are:

Unique: every variant of an item is allocated a separate unique number

Non-significant: they identify an item but contain no information about it

International: GS1 identification numbers are unique across all countries and all sectors

Secure: GS1 numbers are fixed length, numeric and include a standard check digit

Recognized: Endorsed by ISO standards (ISO/IEC 15459)
- ISO standards cover regional and local standards
  - ANSI *American National Standards Institute*
  - CEN *European Standards Organisation*
  - BSI *British Standards Institute*

What do GS1 Identification Numbers identify?

Trade items: Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced **or** ordered **or** invoiced at any point in the supply chain

Logistic units: An item of any composition established for transport **and/or** storage which needs to be managed though the supply chain

Locations: Physical, functional or legal entities requiring a permanent identification (company, warehouse, hospital, ward...)

Assets: e.g. Surgical Instruments, container, crates

Service Relationships: Patients Identification number

ISMP Recommendation #1

Products to be bar coded
All prescription drugs for humans, with the exception of drug samples, investigational new drugs, prescription drugs sold directly to patients and radio pharmaceuticals.

GS1 Canada comments
GS1 Canada supports the recommendations and suggests that excluded products be considered in secondary efforts to ensure full traceability of all drugs entering the healthcare supply chain.

ISMP Recommendation #2

Packaging and Placement of the bar codes.
Bar codes be included on both exterior and interior packaging as well as on individual blister card bubbles, vials and small bottles.

GS1 Canada comments
Industry solution required consistent with global efforts.
Number assignment at the dispensing level required

ISMP Recommendation #3

Content of the bar code

The following elements be encoded in the bar code

Drug product code
Drug strength, form
Manufacturer
Package size
Lot number
Expiry date

GS1 Canada comments

Product identifier should be the GTIN, Lot #, Expiry date. All other attributes should be accessible from appropriate data base.

GS1 Healthcare Canada

Unique GTIN at every level

GTIN Allocation Rules for Healthcare

GS1 Healthcare Canada

GS1 Healthcare Canada

ISMP Recommendation #4

Format

Data format standards developed by HIBCC and GS1 be deemed acceptable.

GS1 Healthcare Canada

GS1 Canada comments

Canada has an established standard for pharmaceuticals in Canada the GTIN

Open Standard

Global

Cross Sector

GS1 Healthcare Canada

ECRx Bar Code Audit Results

Summary:

At the request of the ECRx Enabler Committee, the Electronic Commerce Council of Canada conducted a warehouse barcode audit in order to determine the industry compliance rate to the ECRx U.P.C. code timelines.

Medis Health and Pharmaceutical Services Inc. (Brampton Facility) now McKesson was chosen for the audit.

SKUs Tested	10,865	
SKUs Bar Coded	9,989	91.73%
SKUs Not Bar Coded	876	8.07%

GS1 Healthcare Canada

ECRx Bar Code Audit Results

Detail:

The audit checked for the presence of a U.P.C. (or EAN), if the bar code scanned, and tested for compliance to certain UCC/EAN U.P.C. standards (size and location). In addition the audit also noted the printing technology used and general category of the product.

	OTC	RX	Combined Subsequences	Total
SKUs	4932	4505	364	
Barcoded	95.54%	87.92%	87.09%	
Not Barcode	3.46%	12.08%	12.92%	
Type of Barcode				
U.P.C. A (12-digit)	97.24%	99.39%	99.00%	98.28%
U.P.C. E (8-digit)	2.39%	0.17%	1.10%	1.30%
EAN (13-digit)	0.37%	0.54%	0.00%	0.90%
Barcode Location				
Correct	97.04%	98.59%	92.31%	99.15%
Incorrect	2.96%	1.41%	7.69%	85.00%
Barcode Size				
Correct	72.14%	55.06%	57.97%	64.74%
Incorrect	27.86%	44.94%	7.69%	35.26%
Printing Technology				
Pre-printed	98.60%	99.02%	100.00%	98.80%
Ink Jet	0.14%	0.46%	0.00%	0.30%
Thermal Transfer	1.26%	0.53%	0.00%	0.90%

GS1 Healthcare Canada

Stakeholders & Regulatory Bodies

- Public Health Agency of Canada - GS1 to develop implementation guidelines for bar coding vaccines and biologics
- Department of Health UK – recommends the GS1 System of standards and membership in the Healthcare User Group - Coding for Success Report
- The Council of Europe's Expert Group on Safe Medication Practices – makes recommendation to use the GS1 System
- International Hospital Federation - joined forces with GS1 to promote the development and adoption of global supply chain standards in hospitals.
- HL7 Global and GS1 - sign Memorandum of Understanding
- ISBT and GS1 – sign Memorandum of Understanding
- Government of Australia's National E-Health Transition Authority – national medical product catalogue hosted by GS1 Australia using the GS1 Global Trade Item Number (GTIN)
- US Healthcare Standards Coalition – endorses GS1's Global Location Number (GLN) for organization identification and its Global Trade Item Number (GTIN) for product identification standards.

GS1 Healthcare Canada

Some highlights throughout the world

April 2007: The Council of Europe's Expert Group on Safe Medication Practices issues strong recommendation to use GS1 System

Sept 2007: The New Zealand Medication Safety Project is an initiative of the New Zealand Ministry of Health to reduce medication errors using GS1 system.

Sept 2007: GS1 Healthcare and ICCBBA (Blood standards) join forces to advance global standards.

June 2007: GS1 and HL7 (patient records) join forces to ensure GS1 standards are reflected in HL7 standards.

March 2007: The UK Dept of Health issues guidelines confirming support of GS1 standards.

March 2007: IHF joins GS1 effort to include patient safety.

Oct 2007: Turkish Dept of Health requires GTIN on all medical devices.

Some highlights throughout the world

In Japan required for drugs and medical devices

In Spain requested by Regional Healthcare Service Area of Andalucia

In France big initiative of university hospitals in e-commerce, move from CIP code to GS1 standard in 2007.

In Germany study demonstrated ROI of e-commerce – study regarding ROI of scanning in hospitals underway

In Australia successful Central Medicines Drug Repository project, will be replicated in other countries (Hong Kong, New Zealand)

In Netherlands migration to GS1 on initiative of whole supply chain

In US GLN registry is taking off

In Brazil organized common action with industry, government and hospitals

ISMP Recommendation #5

Use of 2-D (data matrix) symbology

GS1 Canada comments

GS1 Data Matrix and GS1 Data Bar are viable options

Data Matrix

Data Matrix is very small and two dimensional - can store up to 2000 characters and holds additional information

Pilots forming in Europe for Animal Health – IFAH (International Federation for Animal Health) is endorsing GS1 standards for traceability

Will be mandatory in France from 2007 onwards

(17) 050101 (10) ABC123

(01) 04012345678901

GS1 DataBar & Composite

The linear component carries the GTIN (identification) and the 2D component attribute data such as expiration date and lot number.

GS1 DataBar & Composite

DataBar-14 Composite product identification

Expiration Date

Lot number

(17) xxxxxx(10) xxxxxxxxxxxxxxxx etc..

(01) xxxxxxxxxxxxx

GTIN

It's a Global Effort

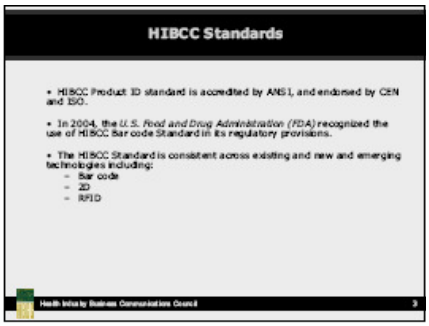
Proud Host

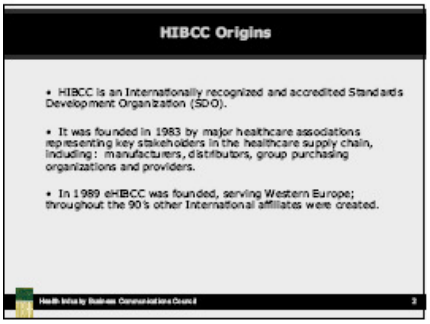
June 16 – 18, 2008 - King Edward Hotel, Toronto

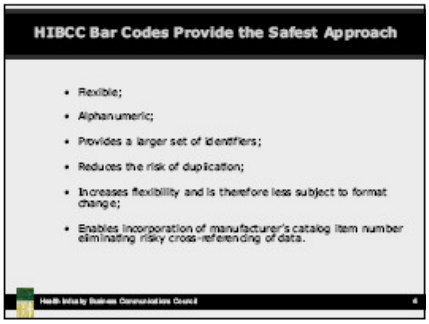
Join Us!
GS1 Healthcare Canada Official Launch

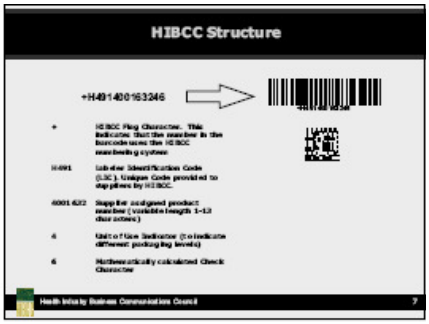

GS1 Healthcare
Canada
285238 529846
Questions?
Contact:
Alicia Duval, Vice President Healthcare, GS1 Canada
alicia.duval@gs1ca.org

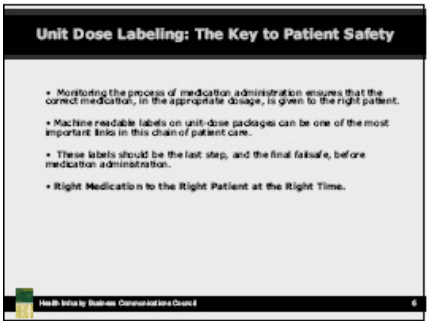
Use of HIBCC Standards in Pharmaceutical Bar Coding
Presented by Luis Figarella

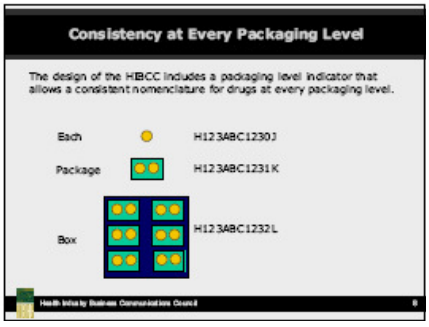












HIBCC Secondary Data

- HIBCC Standards also include control data for capturing:
  - Expiry Date Information
  - Lot/Batch Numbers
- For small packages, we can put all of this on a Data Matrix.

Safety feature unique to the HIBC design

* HIBCC believes that crucial secondary data is essential for product traceability, particularly for dangerous drugs.

Concluding Remarks

- HIBCC Product ID Standard is a globally accepted standard, accredited by ANSI and endorsed by CEN and ISO.
- FDA rule for bar coding allows manufacturers to choose between the HIBC and GS1 product ID formats.
- There is no downside to supporting the HIBCC Standard – but there are significant benefits to be gained.

Contacting HIBCC

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(01) 602.381.1093 (fax)
info@hibcc.org (e-mail)

Please visit www.hibcc.org

Sandoz unit-of-use Bar Coding
Presented by Liette Champagne

SANDOZ

Sandoz Unit-of-use Bar Coding

Liette Champagne, B. Pharm., D.P.H.
Professional Relations Manager, Hospital Division
Sandoz Canada

Canadian Pharmaceutical Bar Code Initiative Roundtable Ottawa, January 24th, 2008

Linear Bar Codes

- Four linear bar codes (developed by GS1) using the GTIN:

1- EAN/UPC
2- ITF-14
3- UCC/EAN-128
4- Reduced Space Symbology (RSS) or GS1 DataBar

- Content of the bar codes:

NDC or DIN
Manufacturer
Drug Name,
Drug Strength, Form and Format
Lot number and Expiry date

SANDOZ

When, Why and What

March 2003:

FDA requires linear bar codes on all drug and blood products to improve patient safety.

November 2003:

Sandoz takes the decision to have a linear bar code on all injectable product labels (Canadian and US markets).

SANDOZ

RSS Symbology or GS1 DataBar

RSS Limited

- Possible to print in a very small space (1mL ampoule label)
- Encodes 14 digits of numerical data (GTIN)
- 12.9mm of free space is needed on the label artwork to allow for barcode and lot/expiry information to be printed.
- 14-digit GTIN supplied to label printer, who then generates the RSS code from software, and applies it to the printed labels

SANDOZ

RSS Limited or GS1 DataBar

(01) 1 0057513080705

SANDOZ

The GTIN composition

The GTIN 14 digits is created as followed:

1- One digit to indicate a packaging level (0 or 1)

2- Twelve digits are for the GS1 Company Prefix and the Item Reference number

3- A calculated Check Digit

The check digit is calculated by a software called « GS1 Check Digit Calculator » available on GS1 website:

http://www.uc-council.org/ean_ucc_system/education_support/cdc.html

SANDOZ

Global Trade Item Numbers (GTIN)

The GTIN is the globally unique GS1 identification number used to identify trade items worldwide (products and services) that are sold, delivered, warehoused and invoiced.

Each level of packaging of the same product must have a unique GTIN.

Many of Sandoz' products have five levels of packaging, for example:

1 mL ampoule
Box of 10 ampoules
Inner pack of 10 boxes of 10 ampoules
Case (shipper) of 8 inner packs
Pallet of 132 cases

SANDOZ

The remaining twelve digits

1- The GS1 Company Prefix

Unique number licensed to a company/organization by GS1.
Sandoz' GS1 Company Prefix is 057513

2- The Item Reference Number

Each product must have its own Item Reference Number.

SANDOZ

Item Reference Number

US market:

FDA requires that the bar code contains the National Drug Code (NDC).

The NDC is a 10-digit number which is specific to the manufacturer, formulation and format of a drug.

Sandoz FDA labeller code is 54643.

When used in a bar code, the NDC code is always prefixed by the number 3, which indicates to the scanner that the FDA assigned the labeller code and not the GS1 organization.

SANDOZ

Item Reference Number

Canadian market:

The use of the Drug Identification Number (DIN):

It is a number assigned sequentially and has no particular meaning (no labeller code or item reference number).

The DIN is specific to the manufacturer and formulation but not the format of a drug.

Sandoz uses its internal product code which is specific to the formulation and the format.

SANDOZ

US unit-of-use bar code

(01) 1 0354643582001

SANDOZ

Canadian unit-of-use bar code

(01) 1 00575130807 0 5

SANDOZ

Conclusion

Linear bar coding is proven, established, easy to use, inexpensive and offers many possibilities.

SANDOZ

Canadian Vaccine Bar Coding Initiative Vaccine Industry Committee Presented by Rob VanExan

BIOTECanada

Canada's voice for biotechnology
Le porte-parole canadien de la biotechnologie

Canadian Vaccine Bar Coding Initiative
Vaccine Industry Committee
January 24, 2008
Ottawa

Vaccines Distribution in Canada

F/P/T=14

Federal + 10 Provinces + 3 Territories

- 85% to 90% of vaccines are purchased and distributed by provincial and territorial governments
- 10% to 15% of vaccines are sold through the private sector (wholesale distribution or direct to physician) – usually travel vaccines, some flu vaccine, pre-exposure rabies vaccine etc.
- They are usually administered by public health practitioners or by physicians (requires health care professional to inject)
- They are usually administered in a physician's office or at a public health clinic.

What are Vaccines

Biologicals....not Pharmaceuticals

- Preparations of antigenic components derived from or related to a pathogen
- Stimulating an immune response and conferring active protective immunity to the recipient:
  - ✓ Induce humoral response – neutralizing antibody
  - ✓ Induce cell mediated immune response
- Induce protective effect through one to three doses
- Dose is generally very small (in range of ug to mg in 0.5-1.0ml volume)
- Immunity lasts for a long time (1 yr to lifetime)
- It takes 12 to 24 months to manufacture vaccines
- It takes 2 years to validate changes to vaccine fill & pack lines
- Vaccine enterprise is global – 5 companies manufacture 85% of all vaccines

Vaccine Bar Codes: Current Status

Canada and the Global Perspective

- Canada represents 1.9% of the vaccine market
- Canada has a unique reason for bar coding – Immunization registries and inventory management.
- Patient safety subsequently added as a potential benefit.
- Counterfeiting – Product Pedigree (serialization) may be also be introduced in Canadian legislation.
- The Canadian vaccine bar code initiative does not apply to other biological therapies and pharmaceuticals.
- Canada is more advanced than most other countries in their pursuit of vaccine bar coding (the only public health agency represented on HUG)
- Industry is working on global standards for vaccine bar codes. All VIC members are represented on HUG.

AIVP Proposed Standards (con't)

4. Peel-off/Detachable Labels:
   - Two peel-off labels, with bar code[6] & human readable information[7], to be provided for each unit dose of vaccine enclosed in a secondary vaccine package.
   - Peel-off labels should be affixed to primary package and should not obscure the information on the package.

- *6. Bar code content – GTIN, Expiry Date and Lot #*
- *7. Human readable information – Vaccine Trade Name, GTIN, Expiry Date and Lot #*

AIVP Proposed Standards

1. **Bar Code Content:**
   – Encoded the following data into bar codes on both the primary & the secondary vaccine packages:
   - GTIN (GS1-14[1]) + Expiry Date + Lot #
2. **Bar Code Specification:**
   – Use the GS1-128 Code Structure to encode the data into the bar.
   Example:
   40697 17700 0322 060904 J001740
   GTIN + Expiry Date + Lot #
3. **Bar Coding Symbology:**
   – Use Data Matrix (2-D) bar code on primary vaccine packages;
   – Use Linear (1-D) bar code, at the minimum, on secondary vaccine packages; optionally with a Data Matrix.

GS1-14 – previously EAN/UCC-14, 14-digit GTIN number consisting of a packaging indicator, a company reference (company id + product id) and a check digit value.

Current Labelling Technology

Variable Data Issues

- Non variable data is information that does not change from lot to lot
  - Manufacturer name
  - Product name
  - DIN number
  - GTIN
  - Dose volume
  - Bar codes that contain no variable data
- Non Variable data can be pre-printed on labels prior to the labels being put on vials.
- Variable data is information that changes from lot to lot
  - lot #
  - expiry date
  - serial number
  - Bar codes containing variable data or mixed variable and non variable data
- Variable data must be printed on line as the labels are being put on vials at a speed of 200 to 600 vials per minute
- The data (including bar codes) must also be read on line to confirm that each vial actually says what it is supposed to say.

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Potential Impact on Vaccines Supply

Definitive impacts

- Label space – vaccine vials and syringes are very small
- Reduction of line speed when change implemented
  - ✓ Labeller speed depends on volume of data to print on each label
  - ✓ After discussion with machine vendors, that impact can be illustrated as indicated in table below using a 400 container / min theoretical machine with laser

Data to be added to the label		
Type	Total # characters	approx. Machine Speed
2Dmatrix barcode (GTIN+Batch+exp)	36	400 containers/min
4 lines of codes (batch/exp/exp/exp)	40	400 containers/min
2D matrix + 4 lines of codes	76	300 containers/min
2x2D matrix + 4 lines of codes	112	200 containers/min

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Variable Data: Production Issues

- Current Status
- All vaccines labels currently contain variable data
  - ✓ Human readable lot #
  - ✓ Human readable expiry date
- These are printed on line and read on line to validate the information
- Impact of adding additional variable data and variable data bar codes
- Impact of more Variable Data
  - ✓ Line Speed
  1. Line speed is reduced as more human readable data is applied on line
  2. Line speed is reduced as variable data bar codes are added to the label
  3. The more data embedded in the bar code, the larger the bar code and the slower the line speed
  - ✓ Space
  1. Any additional data must fit on the current label without removing information that is already there.
  2. Vaccine labels are very small and space is extremely limited
     - Label size: 1.8 x 4.7 cm
     - Print size – at the limits of readability

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Comparison of on line print requirements

Elements of the proposed Cdn standard	Current Single label No detachable	Proposed Cdn Standard Double detachable	Possible Amendment to Cdn Standard Double Detachable
Vaccine Trade Name - Preprinted	Yes	Exp Date Not needed on detachable labels	Yes On each label piece
Lot # (Human Readable)	Printonce Read once	Print 3 times Read 3 times	Print 3 times Read 3 times
Expiry Date (Human Readable)	Printonce Read once	Print 3 times Read 3 times	Printonce Read once
GTIN # (Human Readable)		GTIN (human readable) Not needed on detachable labels	
2D bar code Lot # Exp		Bar code on one detachable label for Doctor records	Print 1 times Read 1 times
Total information printed	2 Printreads	10 Printreads	5 Printreads

Issues: Line speed Label space

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Other Technical Issues

- **Multidose Vials:**
- There is no technology to permit adding 20 detachable labels with variable data to a 10 dose vial.
- If this causes a shift in demand from 10 dose vials to single dose presentations, then industry production capacity will be negatively affected at least in the short run.
- **Small volume specialized products:**
- Yellow Fever – low volume, freeze dried, shipped on dry ice etc.

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Options

- Use US standard
- Develop Global Standard
  - Develop one set of data variables for vaccines which addresses needs of all stakeholders

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Options and Lead Times

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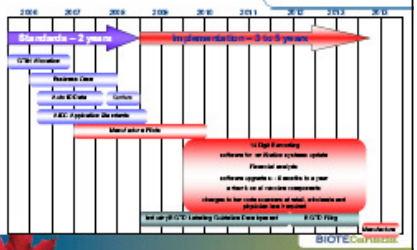
Time line to introduce bar coding in Canada



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Next Steps
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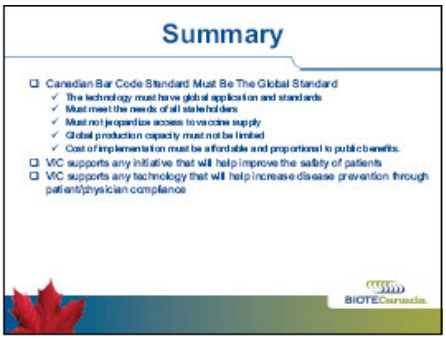
Summary
Canadian Bar Code Standard Must Be The Global Standard
The technology must have global application and standards
Must meet the needs of all stakeholders
Must not jeopardize access to vaccine supply
Global production capacity must not be limited
Cost of implementation must be affordable and proportional to public benefits.
VIC supports any initiative that will help improve the safety of patients
VIC supports any technology that will help increase disease prevention through patient/physician compliance
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Next Steps
Vaccine Manufacturers:
Global Standards – continue to work with HUG
Develop individual company business plans
Technology testing to secure line speeds when HUG standards are proposed
Establish needs of all stakeholders from national and global perspective.
Pilot projects in the field.
PHAC/ISMP:
Cost effectiveness studies
Stakeholder evaluation (doctors, nurses, pharmacists, hospitals etc.)
Implementation plans
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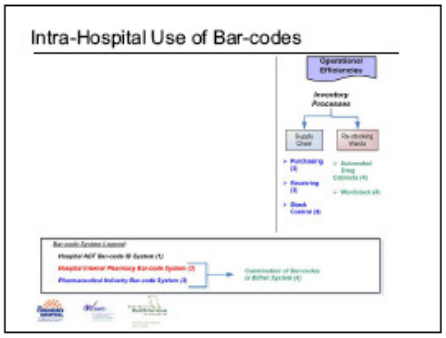
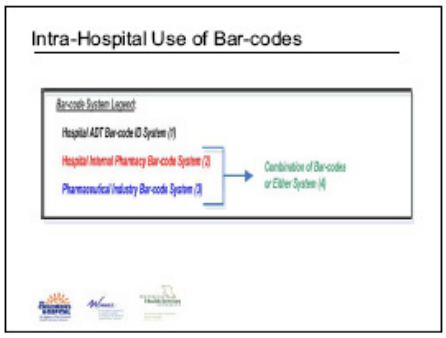
Bar Code and Patient Safety, A Health Institution Perspective
Presented by Ian Sheppard

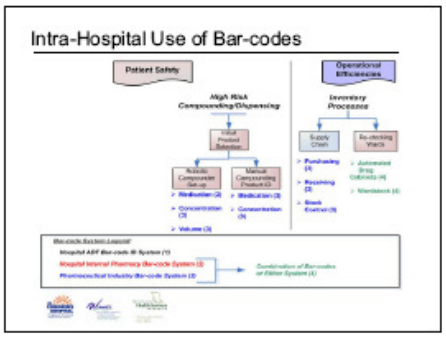
Children's and Women's Health Centre of British Columbia

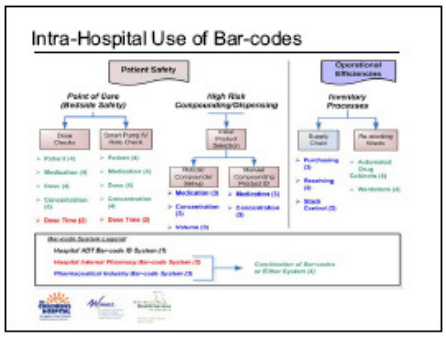
Bar-code and Patient Safety:
A Health Institution Perspective

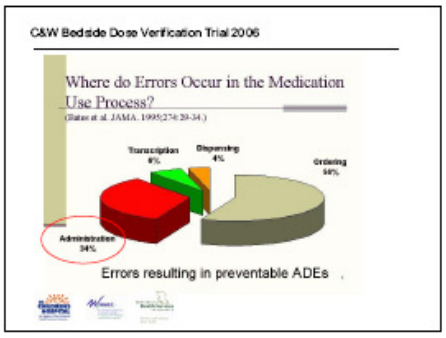
Stakeholder Invitational Roundtable, Ottawa, January 24, 2008

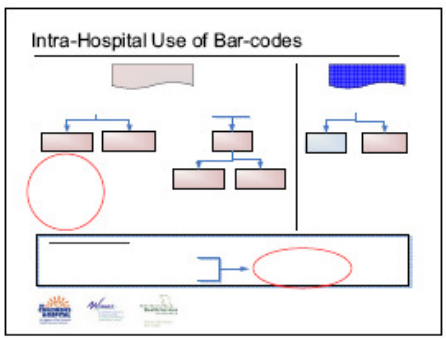


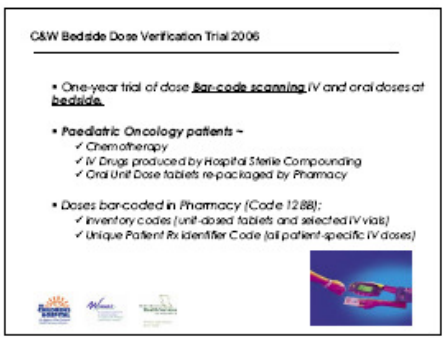












C&W Bedside Dose Verification Trial 2006

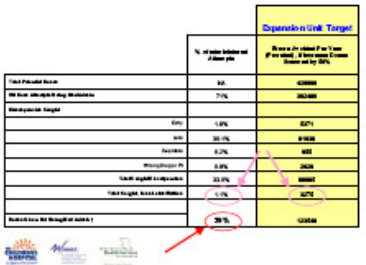
Due to incompatibility of industry Bar-code Systems we were not able to incorporate:

- ✓ Vials or ampoules
- ✓ Unit dosed tablets
- ✓ IV bags

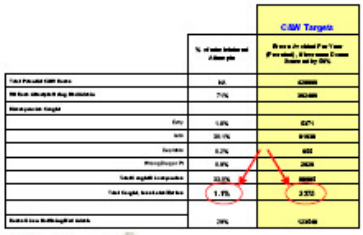
These excluded dose formats were administered unchecked by bar-code scanning by RNs.

(29% of all doses Excluded due to missing industry codes)

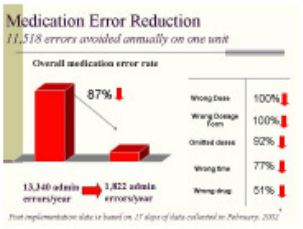
C&W Bedside Dose Verification Trial 2006: Results



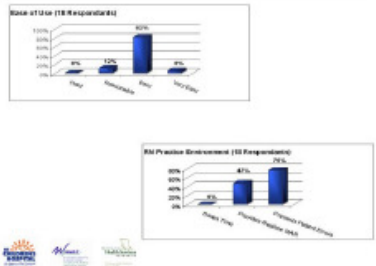
C&W Bedside Dose Verification Trial 2006: Extrapolated Results



C&W Bedside Dose Verification Trial 2006: UWHC

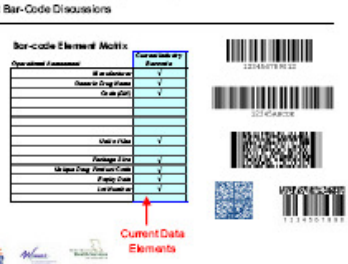


C&W Bedside Dose Verification Trial 2006



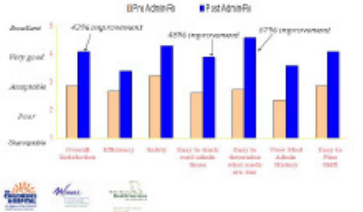
Alignment of Industry and Operational Needs

Current Bar-Code Discussions



C&W Bedside Dose Verification Trial 2006

UWHC Pre versus Post-Bar Code Scanning: Nursing Satisfaction



Alignment of Industry and Operational Needs

Additional Fields for Bedside Use

But, what bar-code method could:

A) Fit the extra logical fields now required?

B) Be expandable for future functional evolution?

C) Simple to expand without massive industry labeling changes?

Alignment of Industry and Operational Needs

DIN+Plus Database Matrix

Bar-code Element Matrix

Additional Safety Data Elements

Alignment of Industry and Operational Needs

Canadian DIN+Plus Concept ....

- A simplified unique code that most readers can interpret
- Linear Code would contain minimal data:

DIN number + Pkg Volume + Expiry Date + Lot Number

- Health Canada maintains a simple DIN+Plus database upon awarding NOC, except current lot numbers or expiry dates.

Alignment of Industry and Operational Needs

An observation....

We may have two options to consider, using the same required fields ....

Option #1: Integrated Data Code:

Choose a symbology with possible problems with future safety data expansion.

or

Option #2: A Simplified National Bar-code ... A DIN+Plus concept:

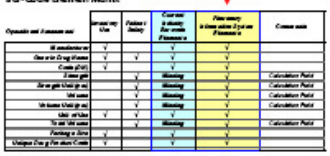
A unique "Key bar-code" linked to simple safety database matrix maintained by Health Canada. The FDA (NDC) approach

Alignment of Industry and Operational Needs

DIN+Plus Database Matrix

DIN+Plus Provides Access to Additional fields

Bar-code Element Matrix



Alignment of Industry and Operational Needs

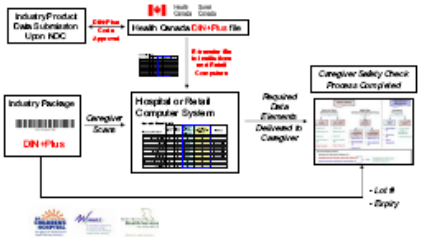
DIN+Plus at the Patient Interface ....

- Institutions' computers receive updated DIN+Plus data by electronic file download into their corporate (Regional or LHIN) information system(s).
- Each individual caregiver scans the simplified DIN+Plus bar-code, and the local information system provides:
  - Required database fields from the DIN-Plus data cube, based on function being performed
  - Expiry Date of product (always)
  - Lot number (if functionally required)

Thank you!

Alignment of Industry and Operational Needs

DIN+Plus Overview....



Canadian Pharmaceutical Bar Coding to Improve Patient Safety
Presented by Esther Fung

UHN Anesthesiologist – a single clinician for drug administration without any independent double check

- Prescribes the medication
- Obtains the stock from the OR room 's anesthesia drug trays
- Admixes and repackages into pre-loaded syringes
- Re-labels the drug on syringes
- Dispenses the medication from the pre-loaded stock (a pile of syringes)
- Administers via injection or infusion

Requirement for Pharmaceutical Bar Coding From Our Pilot

Essential

- Drug Name
- Drug Concentration
- Drug format and size
- Manufacturer

Nice to have

- Lot numbers
- Expiry date


CCHSA Patient Safety Goals

Required Organizational Practices and Evidence of Compliance

PATIENT SAFETY AREA A: MEDICATION USE

PATIENT SAFETY AREA B: INFECTION CONTROL

Bar Coding Requirement

- Do what is feasible NOW (immediate goal is to save lives)

  Legislate to put essential requirement on bar code
  - -Sandoz
  - -Pharmaceutical Partner Canada
- Plan what can be achieved for the next step

  Put all nice to have features on bar code

Canadian Pharmaceutical Bar Coding to Improve Patient Safety

Roundtable Discussion

Perspective of End Users

University Health Network Experience

Esther Fung MSc Phm, Rph and Ludwik Fedorko MD, PhD

Focus of UHN Experience

Direct Patient Care at point of administration

- Dispensing, Admixing
- Administration

Poster presentation : "Point of Care Medication Bar Coding Pilot in Hospital Operating Room", 4 Dec2007, ASHP Clinical Meeting, Las Vegas

Point of Use for Pharmaceutical Bar Coding:

- Supply Chain Management
  - -purchasing and receiving
  - -inventory management
- Direct Patient Care
  - -Prescribing
  - -Dispensing, Admixing and Prepackaging
  - -Administration

Reality: Drug errors are common in anesthesia and acute care areas

- System driven
- Caused by the workflow requirements
- Lack of redundant checks and balances
- Often serious and potentially lethal
- Disproportionate representation in legal settlements
- Assumption of guilt is a common perception

FDA's Bar Code Rule, Principle Themes and Issues Presented by Phil Chao

FDA's Bar Code Rule

Principal Themes and Issues

January 24, 2008

The Rule's Origins

- May, 2001 – Secretary Thompson, in an appearance before a Senate committee, notes that technology, such as bar codes, could help save lives and money
- July, 2001 – the American Society for Health System Pharmacists asks Secretary Thompson to have FDA "develop regulations that mandate that drug manufacturers provide a standardized machine-readable code (bar coding) on all drug containers...."

The Rule's Origins (cont.)

- In late 2001, HHS directs FDA to begin working on a bar code proposal
- FDA begins researching the issues and visits the Veterans Administration hospital in Washington, DC. The VA has a bar code system in place
- July 26, 2002 – as public interest grows, FDA holds a public meeting to discuss bar code issues. Nearly 400 people attend.

The Proposal

- Published on March 14, 2003
- Would apply to manufacturers, repackers, relabelers, private label distributors, and blood establishments
- Would apply to prescription drugs (except samples), OTC drugs commonly used in hospitals and dispensed pursuant to an order, blood, and blood components

The Proposal (continued)

- For drugs:
  - Would require a linear bar code that meets UCC (now known as GS-1) standards
  - Would require the bar code to contain, at a minimum, the drug's NDC number

Main Issues: Should the Rule Specify a Technology?

- Many comments, particularly from industry and automatic identification interests, *opposed* the use of linear bar codes. However, the comments failed to agree on any particular alternative. Some endorsed 2-D symbologies, whereas others would let firms choose any technology, regardless of whether hospitals would be able to read that technology.
- The tension, therefore, was between predictability for end users and innovation by manufacturers/others.
- Some comments argued against UCC standards.

The Proposal (continued)

- For blood and blood components:
  - Would require "machine-readable information" approved for use by CBER. The last approved version is ISBT 128.
  - Would encode, at a minimum, the facility identifier, lot number relating to the donor, product code, and donor's ABO and Rh.

Technology – Pros and Cons

- **Linear Bar Codes**
  - Pros: simple; easy to use; proven technology; low costs to users
  - Cons: limited opportunity for innovation; limited data encoding capabilities
- **Non-Linear Codes**
  - Pros: can encode more data; some may even identify individual products; greater potential for innovation
  - Cons: uncertain impact on device functions; some technologies have not matured; costs

Final Rule Position on Technology

- Final rule requires a linear bar code, but allows use of UCC/EAN or HIBCC standards.
- FDA noted other technology issues, such as possible electromagnetic interference with other medical devices inside a hospital and higher read/error rates compared to linear bar codes.

Final Rule Position on Data Encoded

- NDC number must be encoded.
- Lot number and expiration date information is not required, but FDA will not object if a firm voluntarily encodes such information.
- FDA suggested that hospitals consider equipment purchases carefully if they choose to buy drugs with lot number and expiration date information encoded.
- For blood and blood components, the machine-readable information contains, at a minimum:
  - A unique facility identifier
  - Lot number relating to the donor
  - Product code, and
  - ABO and Rh of the donor

Main Issues: What Information Should Be Encoded?

- Nearly all comments agreed on encoding the NDC number.
- Many comments continued to advocate encoding lot number and expiration date information, but failed to provide data to show that the benefits of encoding such information exceeded the costs.

Main Issues: Should FDA Allow Exemptions?

- Most comments seeking an exemption focused on specific drugs or types of drugs.
- Public health groups and health professionals opposed exemptions, but industry groups favored specific and general exemptions.
- No comments addressed FDA's concerns regarding a general exemption provision (how to ensure that such a provision is not abused).

Final Rule Position on Exemptions

- Individual exemptions granted for allergenic extracts, intrauterine contraceptive devices, medical gases, radiopharmaceuticals, low-density polyethylene form fill and seal containers, and prescription drugs sold directly to patients.
- General exemption provision created, but it would only apply if:
  - Compliance would adversely affect the drug's safety, effectiveness, purity, or potency or would not be technologically feasible or
  - An alternative regulatory program or method of product use makes the bar code unnecessary

Final Rule Position re: OTC Drugs

The final rule:

- Retains the construct of "OTC drugs commonly used in hospitals and dispensed pursuant to an order." The alternatives were either overly inclusive or offered no advantage over the rule.
- Rejects case-by-case review of OTC drugs.
- Allows firms to make bar-coded and non-bar-coded OTC package lines.

Main Issues: Which Over-the-Counter Drugs Are Covered?

- Most comments would refer to "non-prescription drugs used therapeutically pursuant to a prescriber's order."
- Other comments sought case-by-case review of OTC drugs, either on an individual drug or class basis.
- Some comments sought exclusion of all or most OTC drugs, even if those drugs were sold to hospitals.

Summary of Principal Changes in the Final Rule

- Exemptions granted for allergenic extracts, intrauterine contraceptive devices regulated as drugs, medical gases, radiopharmaceuticals, low-density polyethylene form fill and seal containers, and prescription drugs sold directly to patients
- HIBCC standards allowed in addition to UCC/EAN
- General exemption provision created


Post-Rule Issues/Experiences
• Hospital adoption of bar code systems – anecdotal evidence of significant benefit to hospitals adopting bar code systems; conflicting data on percentage of hospitals adopting such systems
• Industry compliance – most firms complied easily, but some were slow to comply or claimed exemptions
• Bar code quality issues – poor quality bar codes, multiple bar codes, inadequate reporting
• Technology/automatic identification issues – RFID, 2-D, "no standard" - continued tension between predictability for purchasers vs. innovation