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
Revised with input from attendees: April 2008
Edited for Internet Release: June 2008
Contents

Executive Summary ..............................................................................................................................................4
Introduction ...........................................................................................................................................................6
Objectives of the Roundtable ..............................................................................................................................6
1. Products to be Bar Coded ................................................................................................................................7
2. Packaging and Placement of Bar Codes ........................................................................................................8
3. Content of Bar Codes .......................................................................................................................................9
4. Format of Bar Codes ......................................................................................................................................11
5. Symbology of Bar Codes ...............................................................................................................................12
General Comments .............................................................................................................................................13
Next Steps ...........................................................................................................................................................13
Appendix A – Participants .................................................................................................................................14
Appendix B – Roundtable Agenda ....................................................................................................................15
Appendix C – Pharmaceutical Bar Code Roundtable Planning Committee ...................................................16
Appendix D – Short Presentations ...................................................................................................................17

Lessons Learned with Bedside Bar Code Systems, Presented By Mary Burkhardt ........................................17
Automated Identification of Vaccine Products (AIVP) Project, Presented by Tara Harris ................................20
Standards and Patient Safety, Presented by Nigel Wood ................................................................................22
Use of HIBCC Standards in Pharmaceutical Bar Coding, Presented by Luis Figarella ...............................28
Sandoz unit-of-use Bar Coding, Presented by Liette Champagne .................................................................30
Canadian Vaccine Bar Coding Initiative Vaccine Industry Committee, Presented by Rob VanExan ..........32
Bar Code and Patient Safety, A Health Institution Perspective, Presented by Ian Sheppard .........................35
Canadian Pharmaceutical Bar Coding to Improve Patient Safety, Presented by Esther Fung ....................38
FDA’s Bar Code Rule, Principle Themes and Issues, Presented by Phil Chao ..............................................39
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.

---

3. Content of Bar Codes

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

<table>
<thead>
<tr>
<th>Drug product name</th>
<th>Drug strength and form</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Package size</td>
<td>Lot number</td>
<td>Expiry date</td>
</tr>
</tbody>
</table>

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 single-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 timeframe.
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>
<thead>
<tr>
<th>Table One</th>
<th>Table Four</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Jeff Leger</strong>, Apotex, Inc</td>
<td><strong>Mark Ferdinand</strong>, Rx&amp;D, Canada’s Research-Based Pharmaceutical Companies</td>
</tr>
<tr>
<td><strong>Garry Cruikshank</strong>, Canada Health Infoway</td>
<td><strong>Sylvia Hyland</strong>, Institute for Safe Medication Practices Canada</td>
</tr>
<tr>
<td><strong>Heather Tyrrell</strong>, Canadian Association of Chain Drug Stores</td>
<td><strong>Mary Burkhardt</strong>, Speaker (keynote)</td>
</tr>
<tr>
<td><strong>Elaine Orrbine</strong>, Canadian Association of Paediatric Health Centres</td>
<td><strong>George DeAngelis</strong>, AstraZeneca Canada Inc</td>
</tr>
<tr>
<td><strong>Phil Hassen</strong>, Canadian Patient Safety Institute</td>
<td><strong>Régis Vaillancourt</strong>, Planning Committee (member)</td>
</tr>
<tr>
<td><strong>Jessica Peters</strong>, Canadian Council on Health Services Accreditation (now Accreditation Canada)</td>
<td><strong>Philip Hoy</strong>, Pharmaceutical Partners of Canada</td>
</tr>
<tr>
<td><strong>Luna Al-Khalili</strong>, Health Canada – Marketed Health Products Directorate</td>
<td><strong>Lisa Belzak</strong>, Public Health Agency of Canada</td>
</tr>
<tr>
<td><strong>Lisa D. Clarke</strong>, Hospira Healthcare Corporation</td>
<td><strong>Lisa Ashley</strong>, Canadian Nurses Association</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table Two</th>
<th>Table Five</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alicia Gatt</strong>, Baxter Corporation</td>
<td><strong>Julie Tam</strong>, Canadian Generic Pharmaceutical Association</td>
</tr>
<tr>
<td><strong>Pierrette Leonard</strong>, Canadian Patient Safety Institute</td>
<td><strong>Patricia MacGregor</strong>, Canadian Society of Hospital Pharmacists</td>
</tr>
<tr>
<td><strong>David Crosbie</strong>, Canadian Pharmacists Association</td>
<td><strong>Lynn M. Brodsky</strong>, Health Canada – Therapeutic Products Directorate</td>
</tr>
<tr>
<td><strong>Nigel Wood</strong>, GS1 Canada</td>
<td><strong>Luis Figarella</strong>, Health Industry Business Communications Council</td>
</tr>
<tr>
<td><strong>Allen J. Vaida</strong>, Institute for Safe Medication Practices (US)</td>
<td><strong>Kathy Boyle</strong>, HealthPRO Procurement Services Inc</td>
</tr>
<tr>
<td><strong>Liette Champagne</strong>, Sandoz Canada Inc</td>
<td><strong>David U</strong>, Institute for Safe Medication Practices Canada</td>
</tr>
<tr>
<td><strong>Esther Fung</strong>, Speaker</td>
<td><strong>Robert White</strong>, Non-prescription Drug Manufacturers Association of Canada</td>
</tr>
<tr>
<td></td>
<td><strong>Ludwik Fedorko</strong>, Physician</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table Three</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Louis Lamarche</strong>, BIOTECanada</td>
<td><strong>Orvie Dingwall</strong>, Observer Canadian Patient Safety Institute</td>
</tr>
<tr>
<td><strong>Meera Makim</strong>, Health Canada – Biologics and Genetic Therapies Directorate</td>
<td><strong>Tara Harris</strong>, Observer Public Health Agency of Canada</td>
</tr>
<tr>
<td><strong>Rob VanExan</strong>, Sanofi-Pasteur<strong>Ron Swartz</strong>, Medbuy Corporation</td>
<td></td>
</tr>
<tr>
<td><strong>Ian Sheppard</strong>, Speaker<strong>Rob VanExan</strong>, Sanofi-Pasteur</td>
<td></td>
</tr>
<tr>
<td><strong>David T. Windross</strong>, Novopharm Limited<strong>Ian Sheppard</strong>, Speaker</td>
<td></td>
</tr>
<tr>
<td><strong>Scott Ginther</strong>, Health Quality Council of Alberta <strong>David T. Windross</strong>, Novopharm Limited</td>
<td></td>
</tr>
<tr>
<td><strong>Scott Ginther</strong>, Health Quality Council of Alberta</td>
<td></td>
</tr>
</tbody>
</table>
## 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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>0830 – 0845</td>
<td>Welcome –Cosponsors, Facilitator</td>
</tr>
</tbody>
</table>
| 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

Improving the bar-coded medication administration system at the Department of Veterans Affairs

The interdependent processes in medication-use systems typify the situation where the risk of failure increases with the task’s complexity.

- Collaborative breakthrough series – 30 hospital teams and subject matter experts over 18 months with 1 year follow up

Lessons Learned with Bedside Bar Code Systems

Where Medication Errors Occur

<table>
<thead>
<tr>
<th>Type of Activity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcribing</td>
<td>6%</td>
</tr>
<tr>
<td>Dispensing</td>
<td>5%</td>
</tr>
<tr>
<td>Administration</td>
<td>34%</td>
</tr>
<tr>
<td>Ordering</td>
<td>55%</td>
</tr>
</tbody>
</table>

Lessons Learned with Bedside Bar Code Systems

Can you say, “tightly coupled processes”?

Source: Medication Safety Alert 2009 INтипаша the Medication Practice

Lessons Learned with Bedside Bar Code Systems

Source: Medication Safety Alert 2009 INтипаша the Medication Practice

Lessons Learned with Bedside Bar Code Systems

Lessons Learned with Bedside Bar Code Systems

Lessons Learned with Bedside Bar Code Systems
Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment

Proceedings of a Stakeholder Invitational Roundtable

Page 18 of 41
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 project chronology
- 2000-01: Industry & International Consultation
- 2002: Feasibility Study
- 2003-04: Vaccine Identification Database System (VIDS) 1 design & development
- 2004-05: End user acceptance testing; VIDS II concept
- 2005: CBER/PHAC recommendations for vaccine bar-coding content and format
- January 2007: Interim user meeting
- March 2007: Formation of AIVP Advisory Committee

AIVP project background
- "Automated bar codes into vaccine products leading to improved immunization record keeping and inventory management" (National Advisory Committee on Immunization, 1998)
- Automated Identification of Vaccine Products (AIVP) project initiated in response to these recommendations
- Collaboration with key stakeholders has been ongoing since 1999

Vaccine Identification Database System (VIDS)

Standards development

How do VIDS and bar codes work together?

AIVP standards development process
- Recommendations developed by PHAC and the Canadian Immunizations Registry Network
- First proposed in fall of 2004 to industry, Health Canada, and other stakeholders
- Recommendations address bar-code content, specification, symbology, and the use of peel-off/attachable labels
- Draft recommendations have been used to conduct Canadian requirements to global standards development
- Recommendations will be finalized following cost-benefit analysis and further consultation with stakeholders
AIVP recommendations

1. Bar code content
   - Include patient name, id and age on both the 1st & 2nd packages
   - Include patient name and id on the 1st package
   - Include patient name and id on the 2nd package

2. Bar code standardization
   - Use the GS1-128 Code structure to encode the data into the bar code
   - Use EAN-13 bar code in 1st package and linear (1-D) bar code in the minibags on 2nd packages

3. Two-part bar code
   - Store bar code information on both the 1st & 2nd packages

4. Pull-off / detachable labels
   - Two pull-off labels, with bar code & patient information, should be provided for each with clear indication of vaccine and dose
   - Pull-off labels should be affixed to primary package and should not obscure the information on the package.

AIVP Advisory Committee

- Formed in March 2007
- Membership:
  - PHAC/Health Canada
  - CDNA/Canadian Drug Information Network
  - Immunization programs with stakeholders and the health care system
  - Representation from various provinces and territories

Lessons Learned

- Contributed to and promoted the adoption of global standards
- Collaborated and aligned with international partners
- Engaged all stakeholders across the supply chain, including the regulatory, industry and both private and public end users
- Maintained interest and momentum through ongoing and regular communication with stakeholders

Key Contacts

Lisa Belzak
AIVP Advisory Committee Federal co-chair
lisa.belson@phac-acsc.gc.ca
613-948-8980

Tara Harris
AIVP Project Manager
tara.harris@phac-acsc.gc.ca
416-205-0137

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 of the state of the art
- Use Vaccine Identification Database Service (VIDS)
- Formation of an Advisory Committee recommended

Strategic Plan (2007-2012)

- Aligns with global initiatives to improve patient safety
- Aims to improve the efficiency and effectiveness of vaccine vaccination programs and pooling of resources in Canada through the active participation of industry, government, and stakeholders

- Priorities:
  1. National standards and guidelines for the implementation of AIVP
  2. Development of an international standard for vaccine identification
  3. Development of an international standard for vaccine identification
  4. Development of an international standard for vaccine identification
  5. Development of an international standard for vaccine identification
  6. Development of an international standard for vaccine identification
  7. Development of an international standard for vaccine identification
  8. Development of an international standard for vaccine identification

Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment
Proceedings of a Stakeholder Invitational Roundtable
Standards and Patient Safety
Presented by Nigel Wood

GS1: An Integrated Organization
A fully integrated, global organization
- 30 years of experience
- 106 GS1 Member Organizations (MOS) representing all points in the supply chain
- Over 1 million companies doing business across 146 countries
- Approximately 200,000 staff worldwide
- Over 20 sectors including consumer goods, foodservice, healthcare, transportation and logistics
- Over 5 billion transactions a day

GS1 is the most widely used supply chain standards system in the world.

The GS1 System
The Global Language of Business

OVERALL BENEFITS:
- Improving efficiency, profitability, and customer service
- GS1 Solutions & Services using GS1 Standards

The GS1 System is an integrated system of standards

- GS1 keys:
  - GTIN
  - GLN
  - SSCC
  - GS1 128
  - Data Matrix
  - GPAI
  - GS1N
  - GDTI
  - EPC

GS1 standards are used across industry

- Healthcare
- Food & Beverage
- Retail
- Finance
- Manufacturing
- Construction
- Industrial
- Transportation
- Government

GS1 Healthcare Canada

What is GS1 Canada?
- Not-for-profit, industry-led organization that promotes and maintains global standards for the identification of goods, locations and related e-commerce communication
- Mission: To be a leader in establishing, promoting, and facilitating the implementation of global multi-industry standards for collaborative commerce
- Canada’s voice in the development and maintenance of global collaborative commerce standards
- A GS1 Member Organization

106 GS1 Member Organizations
146 countries served
Local services, global reach

Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment
Proceedings of a Stakeholder Invitational Roundtable
Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment

Proceedings of a Stakeholder Invitational Roundtable

Page 23 of 41
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.

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
- Scalable: GS1 numbers are flexible and can include a standard check digit
- Recognised: endorsed by ISO standards (ISO/IEC 15456)
  - ISO standards cover regional and local standards
  - ANSI American National Standards Institute
  - CEN European Standards Organisation
  - BSI British Standards Institute

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
  - Batch code scanning
- Right Route
  - Batch code scanning

What do GS1 Identification Numbers identify?

- Trade items: Any item (product or service) upon which there is a need to attach predefined information that may be printed or included 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 through the supply chain
- Locations: Physical, functional or legal entities requiring a permanent identification (company, warehouse, hospital, ward...)
- Assets: e.g. Surgical instruments, containers, 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, investigational new 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 the accessibility of all drugs entering the healthcare supply chain.

ISMP Recommendation #2

Packaging and placement of the bar codes. Bar codes should be included on both exterior and interior packaging as well as on individual blister card, 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 strengths, terms
- Manufacture
- 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.
Unique GTIN at every level

GTIN Allocation Rules for Healthcare

GS1 Canada comments
Canada has an established standard for pharmaceuticals in Canada and the GTIN
Open Standard
Global
Cross Sector

ECRx Bar Code Audit Results

Summary:
At the request of the ECRx Enable Committee, the Electronic Commerce Council of Canada conducted a warehouse-barcode audit in order to determine the industry confidence level in the ECRx U.P.C. code timelines.

Media Health and Pharmaceutical Services Inc. (Brampton Facility)
Role: McKesson was chosen for the audit.

<table>
<thead>
<tr>
<th>SKUs Tested</th>
<th>10,065</th>
</tr>
</thead>
<tbody>
<tr>
<td>SKUs Bar Coded</td>
<td>9,881</td>
</tr>
<tr>
<td>SKUs Not Bar Coded</td>
<td>874</td>
</tr>
</tbody>
</table>

ECCRx Bar Code Audit Results Details:
The audit checked for the presence of a U.P.C. for ECRx. If the bar code scanned, and tested for compliance to the UCC/EDIFACT U.P.C. standards (size and location). In addition, the audit also noted the printing technology used and the general category of the product.

<table>
<thead>
<tr>
<th>Country</th>
<th>Type &amp; Location</th>
<th>Details</th>
<th>Present &amp; Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Type &amp; Address</td>
<td>Present &amp; Correct</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Address only</td>
<td>Present &amp; Correct</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Name only</td>
<td>Present &amp; Correct</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Name &amp; Address</td>
<td>Present &amp; Correct</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Some highlights throughout the world
April 2007: The Canadian Standards Association on EHR and ISM
talks about the future of EHR and ISM.

Stakeholders & Regulatory Bodies
- Public Health Agency of Canada - G11 licensing, implementation guidelines for bar coding association and NGOs
- Department of Health and Social Services: the use of the GS1 System of standards and services is a policy adoption in the Health Care User Group - Partner in Success Report
- The Council of Canadian各省的Expert Group on ISM
- The Canadian Standards Association - ISM guidelines, implementation guidelines and services
- International Hospital Federation - joint work with GS1 to promote the development and adoption of global supply chain standards in healthcare
- HIT in Egypt and other African countries
- ISBT and GS1 - sign Memorandum of Understanding
- Government of Australia - National Health Information Standards Authority - local endorsement of GS1 as the ISM standard
- Government of New Zealand - Health "Doing Business Together" initiative
- Australian Healthcare Standards Council - endorsement of GS1 as the national standard for inter-operability standards
- ISBT and GS1 - joint work on bar coding for patients
- GS1 in Canada - Canadian standard for pharmaceuticals

Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment
Proceedings of a Stakeholder Invitational Roundtable
Page 25 of 41
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: initiative of nearly 200 hospitals in e-commerce, move from QR code to GS1 standard in 2007
- In Germany: study demonstrated ROI of e-commerce – study regarding ROI of improving hospitals ordering
- In Australia: successful Central Medicines Drug Registry project, will be replicated in other countries (Hong Kong, New Zealand)
- In Netherlands: migration to GS1 on initiative of wholesale supply chain
- In US: GS1 registry is taking off
- In England: regarded 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.

Pilot 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.

**GS1 DataBar & Composite**

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

**It’s a Global Effort**

**Proud Host**

June 18 – 19, 2008 - King Edward Hotel, Toronto

Join Us!

GS1 Healthcare Canada Official Launch
Use of HIBCC Standards in Pharmaceutical Bar Coding
Presented by Luis Figarella

HIBCC Standards
- HIBCC (Health Industry Business Communications Council) is an international trade association that provides technical standards for the healthcare industry.
- HIBCC standards are widely used in the healthcare industry for bar coding and patient safety.

HIBCC Origins
- HIBCC was founded in 1992 by the Healthcare Information and Management Systems Society (HIMSS) and the National Healthcare Information Corporation (NHIC).
- The primary goal of HIBCC is to develop and maintain technical standards for the healthcare industry.

The HIBCC Standard is Flexible for Global Use
- HIBCC standards are designed to be flexible and can be adapted to meet the needs of different healthcare organizations.
- HIBCC standards are used worldwide and have been implemented by over 1,000 companies.

Unit Dose Labeling: The Key to Patient Safety
- Unit dose labeling is a process of providing medication in individual units that are ready for administration.
- This process helps to reduce medication errors and improve patient safety.

Consistency at Every Packaging Level
- Consistency at every packaging level ensures that the medication is correctly labeled and easily identifiable.
- This helps to prevent medication errors and improve patient safety.

Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment
Proceedings of a Stakeholder Invitational Roundtable
Page 28 of 41
Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment
Proceedings of a Stakeholder Invitational Roundtable

**HRBC Secondary Data**

- HRBC Standards also include control data for authentication:
  - Source Data Information
  - Source Data Reference
- For small packages, we can print all of this on a data matrix.

**HRBC believes that a minimal secondary data is essential for
providing traceability, particularly for dangerous drugs.**

**Concluding Remarks**

- HRBC Core is standard is a globally adopted standard,
  mandated by the FDA and endorsed by CSPA and SCC.
- FDA rule for bar coding allows manufacturers to choose between
  the HRBC and other product ID formats.
- There is no downside to supporting the HRBC Standard — but
  there are significant benefits to be gained.
**Sandoz unit-of-use Bar Coding**

**Presented by Liette Champagne**

---

### Linear Bar Codes

- Four linear bar codes (developed by GS1) using the GTIN:
  1. S/N
  2. IFU
  3. JCG001
  4. Revised Space Synology (RSS bar GS1 DataBar)

- Content of the bar codes:
  - UDC or SN
  - Manufacturer
  - Drug Name
  - Drug Strength, Form and Normal
  - Lot number and Expiry date

---

### RSS Synology or GS1 DataBar

- RSS Limited
  - Packed in a very small space (100, ampoule label)
  - Includes 14 digits of numerical data (GTIN)
  - 12.5cm of the space is reserved on the label area to allow for barcode and label text information to be printed.
  - 16 digit GTIN supplied to label printer, who then generates the RSS code using software, and applies it to the printed label.

---

### The GTIN composition

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, found at the GS1 website:
   - [http://www.gs1connect.epson.uea.ac.uk/systeem/extra/mathcrash.html](http://www.gs1connect.epson.uea.ac.uk/systeem/extra/mathcrash.html)

---

### The remaining twelve digits

1. The GS1 Company Prefix
   - Unique number licensed to a company/organisation by GS1
   - Sandoz’ GS1 Company Prefix is 937992
2. The Item Reference Number
   - Each product requires its own Item Reference number.

---

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:
- first, ampoule
- box of 10 ampoules
- inner pack of 10 boxes of 10 ampoules
- case (2000) of 20 inner packs
- pallet of 80 cases
Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment
Proceedings of a Stakeholder Invitational Roundtable

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 labeler code is 05643.

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

**Canadian market:**

The use of the Drug Identification Number (DIN) is a number assigned sequentially and has no particular meaning (no labeler 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.

US unit-of-use bar code

(01) 1 0354643582001

Canadian unit-of-use bar code

(01) 1 005751308070 5

Conclusion

Linear bar coding is proven, established, easy to use, inexpensive and offers many possibilities.
Canadian Vaccine Bar Coding Initiative Vaccine Industry Committee

Presented by Rob VanExan

Vaccines Distribution in Canada

What are Vaccines

Biologicals and Pharmaceuticals

What are Vaccines

Vaccine Bar Codes: Current Status

AIIVP Proposed Standards (cont)

AIIVP Proposed Standards

Current Labelling Technology
Variable Data Issues

- Non-removable data on containers may change from batch to batch
- Physical Volatility
  - Product size
  - Printers can vary
  - Data can fade
- Non-volatile data
  - Designates
  - Bar codes are scanned
- Some containers do not require bar coding
- Less than 100% of containers are bar coded
- Reliably reads database, varies by container
- Small volume of pharmaceuticals

Variable Data: Production Issues

- Current Status
  - Bar coding is currently used in variable data
  - Data is difficult to maintain
  - Current software used
  - Variances in production data due to various factors
  - Bar coding currently used on containers
  - Impact on various Variable Data
    - In some cases, non-volatile data is used
    - Current systems do not work as intended
- Implications
  - Increased reliability of data
  - Reduced variability in production data
  - More consistent data
- Other Technical Issues
  - Multiverse Vision
    - There is no technology to permit adding 3D data to variable data
    - More cases in demand
  - Smaller volumes
    - Reduced production capability
    - Smaller volumes in demand

Potential Impact on Vaccine Supply

- Definite impacts
  - Label size and variable data are very small
  - A label size can be determined on each label
  - Software used for bar coding
  - Reduced production capacity
  - Label size
  - Impact on vaccine supply

Comparison of Online Print Requirements

| Elements of the expected Ongoing
| | | System Strategy
| | | Proposed System
| | | Online Print Requirements
| | | Current System
| | | Available Online
| | | Proposed System
| | | Available Online

Options and Lead Times

Overview of the timeline to introduce bar coding in Canada

- Options
  - Lean standards
  - Competitive standards
  - Develop a bar coding strategy for vaccines
  - Reduce the use of non-volatile data for vaccines

Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment
Proceedings of a Stakeholder Invitational Roundtable
Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment

Proceedings of a Stakeholder Invitational Roundtable

Page 34 of 41
Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment
Proceedings of a Stakeholder Invitational Roundtable

Page 36 of 41
Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment

Proceedings of a Stakeholder Invitational Roundtable

Alignment of Industry and Operational Needs

DIN+Plus at the Patient Interface...

- Institutions, computer systems, receive updated DIN+Plus data by electronic file downloaded into their respective (Regional or LHIN) information systems.
- Each individual product carries the simplified DIN+Plus barcodes, and the local information system provides:
  - Required data set fields from the DIN+Plus data to be:
  - Expiry Date of product (reference)
  - Lot number (function if required)

Thank you!
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 tray
- Administers and recap packages into pre-loaded syringes
- Realizes the drug on syringe
- 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
  - Expire date

Bar Coding Requirement
- Do what is feasible NOW (Immediate goal is to save lives)

Lagelate 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

Focus of UHN Experience
Direct Patient Care at point of administration
- Dispensing, Admining
- Administration

Point of Use for Pharmaceutical Bar Coding:
- Supply Chain Management
  - Purchasing and receiving
  - Inventory management
- Direct Patient Care
  - Prescribing
  - Dispensing, Admining and Preparing
- 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

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, D.C. 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, repackagers, wholesalers, 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 academic identification-interest, opposed the use of linear bar codes.
  - However, the comments failed to agree on an particular alternative. Some advocated 2-D barcodes, whereas others voiced that linear bar codes may cause any technology, regardless of whether it would be used for design or international information exchange.
  - The consensus, therefore, was the need for a technology that meets the administrative, logistical, and technical needs.

The Proposal (continued)

- For blood and blood components:
  - Would require "machine-readable information" approved for use by CBRP.
  - The last approved version is EBT1 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
  - Pro: simpler, easier to use; proven technology; lower costs for users
  - Con: limited opportunity for improvement; limited code encoding capabilities

- Non-Linear Codes
  - Pro: can encode more data accurately even in the presence of individual products; greater potential for innovation
  - Con: uncertain benefits compared to linear bar codes
Final Rule Position on Technology

- Final rule requires a linear bar code, but allows use of UCC/EAN or HIBC standards.
- FDA noted other technology issues, such as possible electromagnetic interference with other medical devices inside a hospital, and higher readerror 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 advised pharma companies to consider equipment purchases carefully if they choose to buy drugs with lot number and expiration date information encoded.
- FDA suggested that bar coded patient identifiers contain a minimum of:
  - Lot number relating to the drug
  - Product code, and
  - ASID and 13 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 not be abused).

Final Rule Position on Exemptions

- Individual exemptions granted for allergic extracts, intradermal composites, devices, medical gases, medical instruments, and specialty products such as blood and platelets.
- General exemption provision creates, but it would only apply if:
  - Compliance would adversely affect the drug’s safety, efficacy, quality, or potency or would not be technologically feasible,
  - An alternative regulatory program or method of product use makes the bar code unnecessary.

Final Rule Position on: OTC Drugs

- The final rule: the concept of “OTC drugs” commonly used in hospitals and dispensed pursuant to an order. The alternatives were either costly, cumbersome, or offered no advantage over the rule.
- Rejected case-by-case review of OTC drugs.
- Allows firms to make bar-coded and non-bar-coded OTC package labels.

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 these drugs were sold to hospitals.

Summary of Principal Changes in the Final Rule

- Exemptions granted for allergic extracts, intradermal composites, devices, medical gases, medical instruments, low-density polymers, and specialty products such as blood and platelets.
- HIBC 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 mostly, but some were slow to comply or claimed exceptions
- Bar code quality issues - poor quality bar codes, multiple bar codes, inadequate reporting
- Technology implementation identification issues - RFID, 2D, "no standard" - continued tension between predictability for purchasers vs. innovation