GS1 Healthcare Conference
Enabling Immunization Traceability
Vaccine Industry Committee
June 17, 2008
Toronto
Established Dec 2003
• As a subcommittee of BIOTECanada
• Formed to provide a common voice for the vaccine industry in Canada and to create a vaccine environment conducive to the goals of Public Health and the manufacturers.

Mission Statement
• Foster full access to and ensuring availability of all vaccines including, existing, new and innovative vaccines for all Canadians.
• Promoting the value of immunization to all Canadians.
• Promoting high quality nature of Canadian research, development, manufacturing and distribution of vaccines.
Vaccine Industry Committee
Canadian Bar Code Initiative

Consultative meeting with key stakeholders (Jan 2007)

- Costs
- Research/Data
- Manufacturing Issues
- Strategic Planning
- Standards Harmonization
- State of Readiness
- Vaccine Identification Database System (VIDS).
  Single source of comprehensive information on vaccines approved for use in Canada.
Canadian Bar Code Initiative

Costs
• No current cost-benefit analysis of Canadian Bar Code Initiative and no strategic investment plan or funding formula.

Recommendations
• Develop a comprehensive cost-benefit analysis with input from all stakeholders.
• Develop a shared investment strategy to define funding for full implementation (including research, pilots, technology acquisition, etc.).
Cost-Benefit Analysis

- Conducted by the PHAC in collaboration with consultants, HDR Economics.
- Input and support from Vaccine Industry, Provinces/Territories, Professional Associations (CMA, CPS, etc.), Healthcare professionals and others.
- Cost-benefit analysis requires project’s benefits to be valued in monetary units, thus enabling a direct comparison of the project’s incremental costs with its incremental benefits.
Scope of Cost-Benefit Analysis

- Conduct a literature review on the costs and benefits (direct and indirect) associated with bar-coding of vaccine products
- Describe all costs and benefits (direct and indirect) related to:
  (a) the voluntary adoption of bar code standards by vaccine manufacturers and;
  (b) the implementation, by vaccine providers (end-users) of bar codes into immunization programs
- Conduct a cost-benefit analysis using pre-determined implementation options / scenarios
- Recommend the preferred option(s) with rationale for achieving adoption and implementation of bar codes on vaccine products in Canada
## Cost Categories

<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Pre-development work</td>
<td>Initial costs of planning and researching the initiative.</td>
</tr>
<tr>
<td>C2</td>
<td>Development and implementation of agreed-upon standards</td>
<td>Start-up costs associated with developing and implementing standards and procedures.</td>
</tr>
<tr>
<td>C3</td>
<td>Bar code design development</td>
<td>Designing and developing the bar codes.</td>
</tr>
<tr>
<td>C4</td>
<td>Database development: Vaccine inventory management database</td>
<td>Developing the Vaccine Identification Database Systems (VIDS).</td>
</tr>
<tr>
<td>C5</td>
<td>Database configuration: immunization registry</td>
<td>Reconfiguring the centralized immunization record database.</td>
</tr>
<tr>
<td>C6</td>
<td>Software configuration</td>
<td>Configuring the Clinical Management Software (CMS).</td>
</tr>
<tr>
<td>C7</td>
<td>Scanner purchase</td>
<td>Initial scanner purchase cost.</td>
</tr>
</tbody>
</table>

Source: PHAC and HDR consultants
## Cost Categories (cont’d)

<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C8A</td>
<td>Re-design of procedures &amp; layout at clinics</td>
<td>Re-designing clinic layouts and procedures.</td>
</tr>
<tr>
<td>C8B</td>
<td>Re-design of procedures &amp; layout at manufacturing plants</td>
<td>Re-designing plant layout to produce/process bar codes.</td>
</tr>
<tr>
<td>C9</td>
<td>Bar code printing</td>
<td>Additional cost of printing the new bar codes and attaching them to the vaccine.</td>
</tr>
<tr>
<td>C10</td>
<td>Training practitioners</td>
<td>Training practitioners to use the scanning equipment and the new information systems.</td>
</tr>
<tr>
<td>C11</td>
<td>Ongoing collection and maintenance of vaccine data for VIDS</td>
<td>Populating VIDS with vaccine data and maintaining the database.</td>
</tr>
<tr>
<td>C12</td>
<td>Scanner and printer maintenance &amp; replacement</td>
<td>Maintaining and periodically replacing scanning and printing equipment.</td>
</tr>
<tr>
<td>C13</td>
<td>Technical support</td>
<td>Ongoing technical support provided to system users.</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
<td>Description</td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>B1</td>
<td>Processing time savings</td>
<td>Time savings of record-keeping and processing of barcode scanning relative to manual entry of information</td>
</tr>
<tr>
<td>B2</td>
<td>Improved immunization record completeness and accuracy</td>
<td>Reduction in adverse health events attributable to vaccination and a reduction in disease incidence.</td>
</tr>
<tr>
<td>B3</td>
<td>Improved patient care</td>
<td>Quicker response to vaccine recalls and reduction in supply shortages.</td>
</tr>
<tr>
<td>B4</td>
<td>Fewer re-immunizations</td>
<td>Reduced expenditures and increased time savings due to fewer re-immunizations and unnecessary immunizations.</td>
</tr>
<tr>
<td>B5</td>
<td>Improved supply chain management</td>
<td>Reduction in inventory holding costs and reduced wastage.</td>
</tr>
<tr>
<td>B6</td>
<td>Enhanced data availability for research and analysis</td>
<td>Enhanced research opportunities leading to future improvements in safety and efficiency.</td>
</tr>
<tr>
<td>B7</td>
<td>Increased confidence in the health care system</td>
<td>Increased confidence of patients and improved reputation of health care system.</td>
</tr>
</tbody>
</table>
Cost-benefit Analysis

- Cost-benefit horizon: 2030
- Costs and benefits monetized to the extent possible
- Discount rate used to account for timing of future costs and benefits
- Output metrics provided for the pre-determined implementation options
Implementation Options Task Group

Mandate
• Develop implementation options (including early adoption scenarios) to be considered in the cost-benefit analysis and overall project implementation planning.

Objectives
• Research available options, using options previously developed by CIRN and VIC as a starting points
• Describe each option including potential benefits / challenges
• Present the recommended options to the Advisory Committee
Selected Implementation Options

Option #1 - Minimum requirement
• 1D bar code on secondary packaging which contains the GTIN.
• Survey by GS1 Canada indicates that approx. 95% of vaccine products meets the minimum requirement.

Option #2 – Bar code with non variable data on primary and secondary packaging
• 1D bar code on secondary packaging which includes GTIN.
• GS1 Databar (RSS) on primary packaging which contains the GTIN.
Selected Implementation Options

Option # 3 - Bar code with variable data on secondary packaging

- GS1 Databar (RSS) on primary packaging which contains the GTIN.
- 1D or 2D bar code on secondary packaging which includes GTIN, lot # (variable data), and expiry date (variable data).
- The ability to link expiry date to lot # may allow to exclude the expiry date as a required bar code element.
- Lot # and expiry date must continue to appear in human readable form both on primary and secondary packaging.
Selected Implementation Options

Option # 4 - Bar code with variable data on primary and secondary packaging

• 1D or 2D bar code on secondary packaging which includes GTIN, lot # and expiry date (optional).
• 2D bar code on primary packaging which includes GTIN, lot # and expiry date (optional).
• Lot # and expiry date must continue to appear in human readable form both on primary and secondary packaging.
Selected Implementation Options

Option # 5 - Bar code with variable data on primary and secondary packaging, peel-off labels (multi-parts labels) on primary packaging

- 1D or 2D bar code on secondary packaging which includes GTIN, lot # and expiry date (optional).
- 2D bar code on primary packaging which includes GTIN, lot #, and expiry date (optional).
- 2 peel-off labels both containing the GTIN, lot # and expiry date in human readable format; one peel-off label would have a 2D bar code which includes GTIN, lot # and expiry date (optional).
Option # 6 - CIRN Recommendations

- 1D or 2D bar code on secondary packaging which includes GTIN, lot # and expiry date (optional).
- 2D bar code on primary packaging which includes GTIN, lot #, and expiry date (optional).
- 2 peel-off labels with human readable information and 2D bar codes that includes GTIN, lot #, and expiry date (optional).
Flowchart

- Literature Review
  - Cost Categories
  - Benefit Categories
- Model Framework: Structure and Logic
- Implementation Options
- Cost-Benefit Model
- Model Output
- Data Assumptions
- HDR (Literature Review)
- PHAC
- Industry / Other Stakeholders

Source: PHAC and HDR consultants
Next Steps

• Work with stakeholders to address data gaps
• Validate data assumptions
• Conduct cost-benefit analysis
• Review Implementation Options
• Acceptability by end users
  • Must meet the needs of all stakeholders
Conclusion

• VIC supports initiatives that will help improve the safety of patients and help increase disease prevention through improved compliance by patient/healthcare professionals.

• Completion of a cost-benefit analysis has been identified by the AIVP Advisory Committee as a priority item within the Strategic Plan.

• The selected implementation options proposed for the Cost-Benefit Analysis can be used as a roadmap to implement bar codes on vaccine products in Canada (i.e., step-wise approach).
Conclusion (cont’d)

• This roadmap needs to be flexible and to allow a staged implementation that accommodates varying degrees of readiness in labeling standards and technology.
• This roadmap can be used until "Global Standards" are developed and adopted by major vaccine markets.
Thank you !!!
Back Up Slides
Comparison of online print requirements

<table>
<thead>
<tr>
<th>Elements of the proposed Cdn standard</th>
<th>Current Single label No detachable</th>
<th>Proposed Cdn Standard Double detachable</th>
<th>Possible Amendment to Cdn Standard Double Detachable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Trade Name - Preprinted</td>
<td>Yes</td>
<td>Print 3 times</td>
<td>Yes</td>
</tr>
<tr>
<td>Lot # (Human Readable)</td>
<td>Print once</td>
<td>Read 3 times</td>
<td>On each label piece</td>
</tr>
<tr>
<td>Expiry Date (Human Readable)</td>
<td>Print once</td>
<td>Read once</td>
<td>Print once</td>
</tr>
<tr>
<td>GTIN # (Human Readable)</td>
<td>2 times</td>
<td>2 times</td>
<td>Print 1 times</td>
</tr>
<tr>
<td>2D bar code (GTIN, Lot #, Exp Date)</td>
<td>Print 1 times</td>
<td>Read 1 times</td>
<td>Print 1 times</td>
</tr>
<tr>
<td>Total information printed</td>
<td>10 Print/reads</td>
<td>5 Print/reads</td>
<td></td>
</tr>
</tbody>
</table>

**Exp Date**
Not needed on detachable labels

**GTIN (human readable)**
Not needed on detachable label

**Bar code on one detachable label for Doctor records**

**Issues:**
Line speed
Label space
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.
Example: Cost C7 - Scanner Purchase

- Number of Public Health Sites (# of sites)
- Number of Scanners per Site – Public Health (# scanners/site)
- Number of Physicians per Site (# physicians/site)
- Number of Physician Sites (# of sites)
- Number of Scanners per Site – Physician Office (# scanners/site)

- Scanners Required for Public Health Sites (# of scanners)
- Number of Scanners at Other Locations (e.g., vaccine depots, provincial health authorities, etc)
- Scanners Required for Physician Sites (# of scanners)

- Total Number of Scanners Required (# of scanners)
- Cost per scanner ($/scanner)

Direct Cost (One-Time)

(C7) Scanner Purchase ($)

Source: PHAC and HDR consultants
Structure and Logic Model

Example: Benefit B5 - Improved Supply Chain Management

Source: PHAC and HDR consultants