Automated Identification of Vaccine Products (AIVP) Advisory Task Group

Canada Vaccine Project:
Cost-Benefit Analysis & Conclusions on Barcode Requirements

Outline

- Historical Context & Scope
- Study Objectives
- Cost-Benefit Framework
- Revisions to Draft Report
- Results (Quantifiable, Non-Quantifiable)
- Caveats and Limitations
- Conclusion

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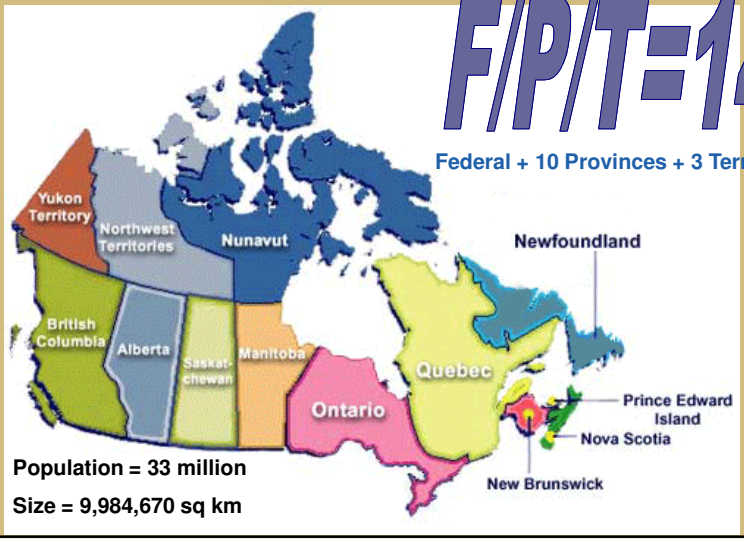
Canada – Federal Provincial Territorial Governments



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Immunization Governance

- 85% public market – 15% private market
- Most vaccines are paid for by the provincial/territorial governments
- One central purchasing group (VSWG)
- Public Health distribution system in each province or Territory
- Vaccines distributed from central provincial/territorial depot to regional public health offices to individual health care professionals
- About half of the immunization is performed by physicians and about half by public health professionals

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Vaccine Distribution: Unique Considerations & Issues

- Cold chain
- Manufacturing lead time – 1 to 2 years
- Expiry dating – 1 to 3 years
- Vaccine wastage
- Inventory management
- Demand forecasting
- Outbreaks, Pandemics
- Product Recalls
- Immunization Records

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Electronic Health Records

- Canada Health Infoway
  - *Federal initiative to develop electronic health records for Canadians*
  - *Estimated $10 billion cost for infrastructure*
- Panorama
  - *Electronic records system for Public Health applications*
    - Immunization registries
    - Inventory management
    - Outbreak management

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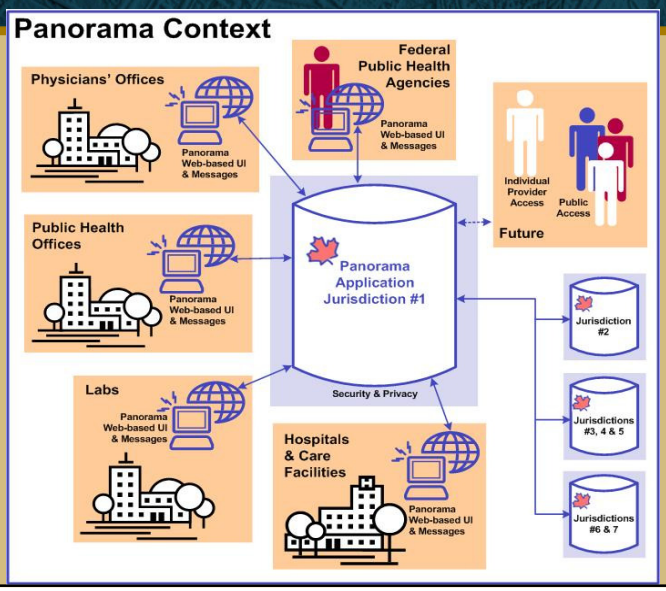

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Historical Context

1999

NACI recommendation to "Incorporate bar codes into vaccine product labelling to improve immunization record keeping and inventory management."

Public Health discussions with individual companies and some other stakeholders begins

Development of Public Health Software begins – Immunization Registries

National Immunization Strategy – Formation of CIRN

Public Health vaccine bar code pilot project Final Report Sept 2005

Public Health proposed standards to Vaccine Industry Committee of BIOTECanada – Nov 2005 *included variable data and 2 peel off labels.*

Industry evaluates proposed standards, current state of labeling technology, regulatory implications, impact on global manufacturing operations.

VIC proposes that:

- ***Canadian standards for vaccines must be consistent with global standards***
- ***Standards for vaccines should be consistent with standards for other pharmaceutical products***
- ***All stakeholders should be consulted and implementation into immunization programs, from vaccine manufacturer to end user, should be evaluated***

2007

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Automated Identification of Vaccine Products

- Formed in March 2007
- Co-Chaired by the Public Health Agency of Canada and the vaccine industry
- Established to provide leadership, overall guidance, direction, advice and support for the development and the implementation of bar codes in Canada and to contribute to the development of global standards for bar coding of vaccines.
- Collaborative effort between all stakeholders and includes representation from: vaccine manufacturers, jurisdictions, health authorities, health professional associations, regulators, international standard setting agencies, EHR, and clinical management software developers.

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AIVP Key Issues:
Identification, Recommendations and Actions

- Costs
  - *Cost Benefit Analysis*
  - *Shared Investment Strategy*
- Research/Data
  - *Identification of existing and supporting research*
  - *Pilot projects in different regions and immunization settings*
- Manufacturing Issues
  - *Technological & Regulatory issues*
- Global Standards Harmonization
  - *Ensure Cdn standards are harmonized with global standards*
- Strategic Plan
  - *Form steering/advisory committee*
  - *Develop strategic plan*
- State of Readiness
  - *Assess State of readiness for all stakeholders in Canada*
- Vaccine Identification Database System
  - *Develop SOP's*
  - *Pilot with existing VIDS functionality*
  - *Continuous improvement plan*

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Study Objectives

- Literature review of costs and benefits
  - *direct and indirect*
- Develop 'structure and logic' of benefit and cost categories
  - *pre-determined implementation options*
- Conduct cost-benefit analysis
  - *risk analysis to account for uncertainty*
- Recommend preferred implementation option

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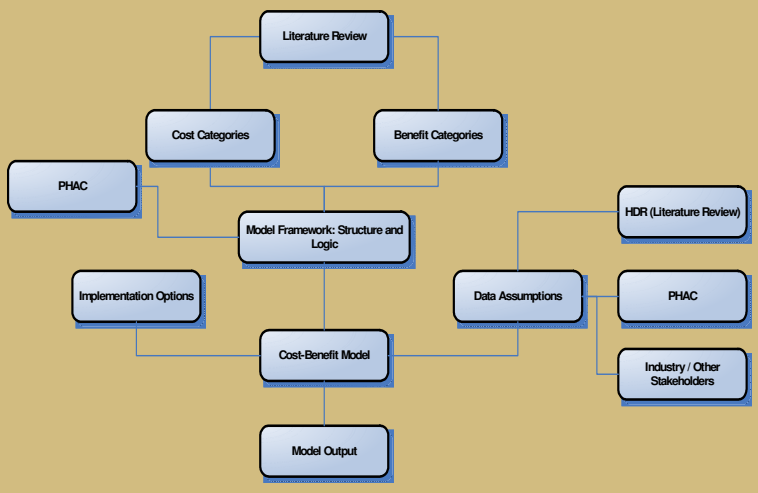
Cost-Benefit Framework

Development Process



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Cost-Benefit Framework

Quantitative Costs

#	Category	Description
C1	Pre-development work	Initial costs of planning and researching the initiative.
C2	Development and implementation of agreed-upon standards	Start-up costs associated with developing and implementing standards and procedures.
C3	Bar code design development	Designing and developing the bar codes.
C4	Database development:: vaccine inventory management database	Developing the Vaccine Identification Database Systems (VIDS).
C5	Database configuration: immunization registry	Reconfiguring the centralized immunization record database.
C6	Scanner purchase	Initial scanner purchase cost.

Note: Sunk costs excluded

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Cost-Benefit Framework

Quantitative Costs (Cont'd)

#	Category	Description
C7A	Re-design of procedures & layout at clinics	Re-designing clinic layouts and procedures.
C7B	Re-design of procedures & layout at manufacturing plants	Re-designing plant layout to produce/process bar codes.
C8	Bar code printing	Additional cost of printing the new bar codes and attaching them to the vaccine.
C9	Training practitioners	Training practitioners to use the scanning equipment and the new information systems.
C10	Ongoing collection and maintenance of vaccine data for VIDS	Populating VIDS with vaccine data and maintaining the database.
C11	Scanner and printer maintenance & replacement	Maintaining and periodically replacing scanning and printing equipment.

Note: Sunk costs excluded

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Cost-Benefit Framework

Quantitative Benefits

#	Category	Description
B1	Time savings	Time savings of record-keeping and processing of bar code scanning relative to manual entry of information
B2	Improved immunization record completeness and accuracy	Quicker follow-up to adverse events following immunization (time savings) and improved health outcomes (via decrease in number of vaccine preventable disease incidents)
B3	Reduction in supply shortages	Reduction in supply shortages (by ensuring that the right vaccine is in the right place at the right time)
B4	Fewer re-immunizations	Reduced expenditures due to fewer re-immunizations
B5	Improved supply chain management	Reduction in inventory holding costs and reduced wastage.

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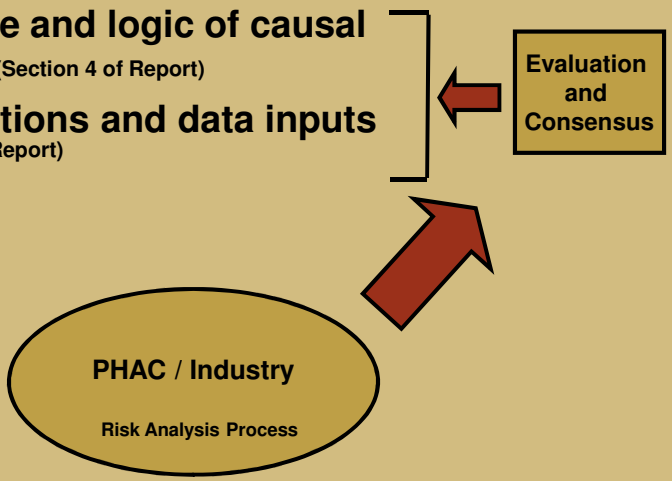
Cost-Benefit Framework

Enumeration of Quantitative Costs and Benefits

a) **Structure and logic of causal models** (Section 4 of Report)

b) **Assumptions and data inputs** (Section 5 of Report)



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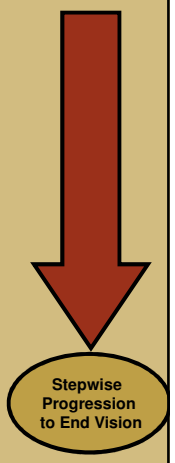
Cost-Benefit Framework

Enumeration Subject to Implementation Options

Option	Description
Option A: Base Scenario *Minimum Requirements*	•1D bar code on secondary package which includes GTIN
Option B: Non-variable data bar code on 1° and 2° package	•RSS bar code on primary package which includes GTIN •1D bar code on secondary package which includes GTIN
Option C: *Variable data bar code on 2° package*	•2D or 1D bar code on secondary package which includes GTIN, lot # and expiry date •Expiry date is optional; if included, must be human readable
Option D: *Variable data bar code on 1° and 2° package*	•2D bar code on primary package which includes GTIN and lot # •2D or 1D bar code on secondary package which includes GTIN and lot # (expiry date optional)
Option E: Variable data on 1° and 2° package, 2 peel-off labels on primary package (one peel-off label with bar code)	•2D bar code on primary package which includes GTIN and lot # (no expiry date) •2D or 1D bar code on secondary package which includes GTIN and lot # (expiry date optional) •2 peel-off labels on primary package, both with human readable information, and one with a bar code which contains GTIN and lot #
Option F: *CIRN Recommendations* Variable data on 1° and 2° package,2 peel-off labels on primary package (both peel-off labels with bar codes)	•2D bar code on primary package which includes GTIN, lot # and expiry date •2D or 1D bar code on secondary package which includes GTIN, lot # and expiry date •2 peel-off labels with human readable information and a 2D bar code that includes GTIN and lot # (expiry date optional)



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Cost-Benefit Framework

General Assumptions

- Implementation year: 2012
- Evaluation period: 20 years (2012-2031)
- Costs before 2008 considered sunk; 2008+ costs included as part of implementation
- Social discount rate used to account for timing of future costs and benefits (7%)
- Dollar values are in real terms (CDN $2008)
- Output metrics for 5 implementation options
  - *Relative to the base case (Option A: minimum requirements)*

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Revisions to Draft Report

Key Section Changes

- Executive Summary
  - *Summary that walks reader through to process to results and recommendations*
- Section 3: Implementation Options
  - *More details on implementation options (i.e. terminology / descriptions)*
- Section 6: Results of Cost-Benefit Analysis
  - *Caveats and limitations*
  - *Quantifiable outcomes vs. non-quantifiable outcomes*
  - *Ranking of non-quantifiable benefits*
  - *Allocation of costs and benefits across stakeholder groups*
- Section 7: Conclusion and Recommendations
  - *Quantifiable outcomes vs. non-quantifiable outcomes*

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Revisions to Draft Report

Key Technical and Other Changes

- Evaluation period changed from 2010-2030 to 2012-2031
- Changed training frequency
- Updated time savings to reflect pilot study
- Modified AEFI calculations: capture time savings from quicker follow-up to AEFI
- Significant number of editorial changes

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Quantifiable Results (Mean Estimates)

Option	Net Present Value ($ million)	Benefit/Cost Ratio	Average Rank
Option B	919	8.2	1
Option C	893	6.3	2
Option D	836	4.7	3
Option E	800	4.1	4
Option F	797	4.0	5

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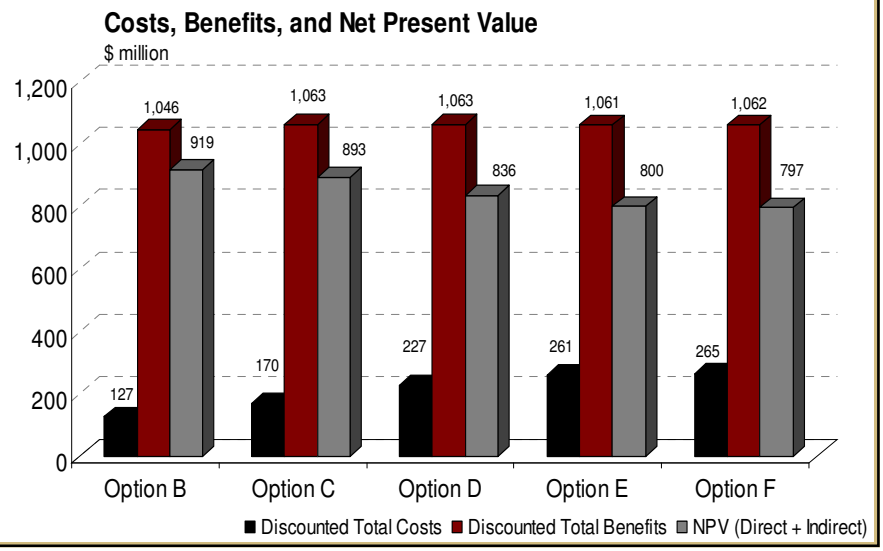
Quantifiable Results (Mean Estimates)



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Quantifiable Results (Mean Estimates)

Cost Differentiators	Range between Implementation Options ($ million, ..2031)
Label printing costs (peel-off labels)	108.3
Printer replacement	48.4
Process and procedure re-design (manufacturers)	41.9
Printer maintenance	32.3
Printer purchase	24.2
Label and printing cost (packaging)	20.8
Training (physicians)	13.2

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Quantifiable Results (Mean Estimates)

Benefit Differentiators	Range between Implementation Options ($ million, ..2031)
Reduction in supply shortages	38.6
Time savings during immunization	6.1

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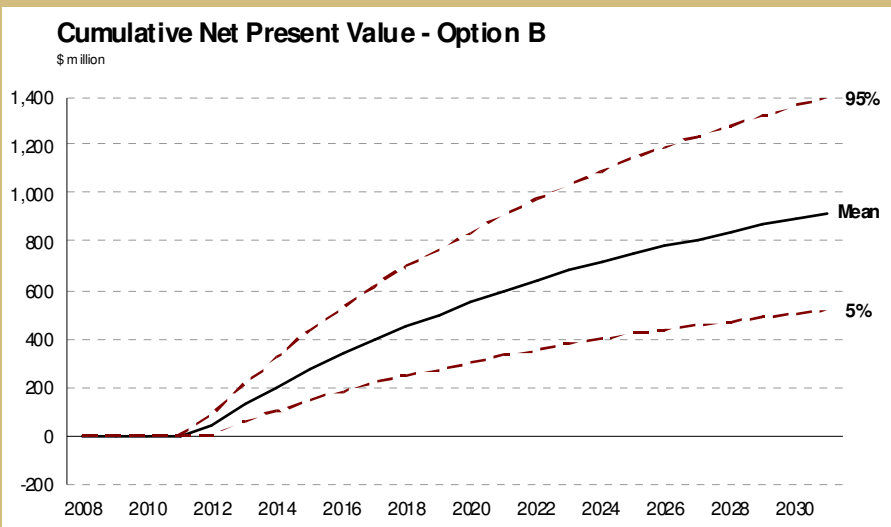
Quantifiable Results



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Non-Quantifiable Benefits

- Improved patient care
- Improved data sharing between stakeholders & enhanced data availability for research and analysis
- Increased confidence in health care system
- Easing transition from paper-based to computer-based system
- Improved usability of bar code system and reduction in likelihood of recording errors

➢ **Benefits ranked by Option: Highest for peel-off**

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Caveats and Limitations

- Lack of empirical estimates for some inputs
- Large variability in results driven by uncertainty in inputs
- Excluded future technological advances
- Distinguishing between options difficult for many input values
- Not exhaustive quantifiable costs and benefits

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Conclusion

- Implementation of AIVP yields significant value to Canadian society; all options preferred relative to the “minimum requirements”
- Option B is most cost-effective; but all options are of similar scale (i.e. NPV of Option B exceeds Option F by only 15%)
- Issue: Are non-quantifiable benefits > incremental costs for peel-off options?

➢ **Strong support for implementation of bar codes on vaccines in Canada**

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Recommendations

- **2 dimensional (2D) bar codes on the primary package which include**
  - ***the Global Trade Identification Number (GTIN) and***
  - ***the lot number.***
  - ***Including the expiry date in the bar code is optional as it can be determined through the lot number.***
  - ***Lot number and expiry date will continue to appear in human readable form on the primary packaging as per Canadian labelling requirements.***
- **2D or 1D bar codes on the secondary package that include:**
  - ***GTIN and***
  - ***lot number***
  - ***Including the expiry date in the bar code is optional as it can be determined through the lot number.***
  - ***Lot number and expiry date will continue to appear in human readable form on the secondary packaging as per Canadian labelling requirements.***

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Rational

- **A 2D bar code (data matrix symbology) consists of printed squares or dots, spiralling outwards from the centre of the symbol.**
  - ***The main advantage of the 2D bar codes is the ability to provide a significant amount of information on a very small surface (for example on a vial or pre-filled syringe)***
  - ***In addition, they are easier to read on curved surfaces and are more resilient, especially when handheld multiple times and still maintain high scanning efficiency.***
- **The GTIN is recommended for use instead of the Drug Identification Number (DIN) because it is a global e-commerce number and not a number that is unique to Canada.**
- **Including the lot number ensures that there is a fully unique product ID.**
  - ***Including the lot number supports increased efficiency in electronic record keeping as it prevents users from having to select the lot from a drop down list or using other work around solutions to uniquely identify the product.***
  - ***Including the lot numbers is especially important from a patient safety perspective as it is used for recalls and the follow up of adverse events following an immunization.***

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Benefits

Fully unique product identification on both the primary and secondary packages:

1. ***encourages efficient and complete electronic health record keeping by the immunizer or clerical staff,***
2. ***reduces the number of immunization errors through improved completeness and accuracy of records and expedites the follow up of adverse events following immunization.***
3. ***improved inventory management and forecasting throughout the vaccine supply chain and***
4. ***improved record keeping resulting in accurate coverage rates.***

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Nest Steps

2009 – 2010 AIVP has established three working groups

- ***Communications working group***
  - **Establish communications plans and training plans for all stakeholders**
- ***State of Readiness Working Group***
  - **Comprehensive assessment of the state of readiness of industry, public health, private health, hospitals, wholesalers, distributors, pharmacies and all other stakeholder groups**
- ***Implementation Roadmap***
  - **A detailed roadmap of the implementation process and timelines for all stakeholders will be developed to establish reasonable time lines and phase in of the AIVP project**

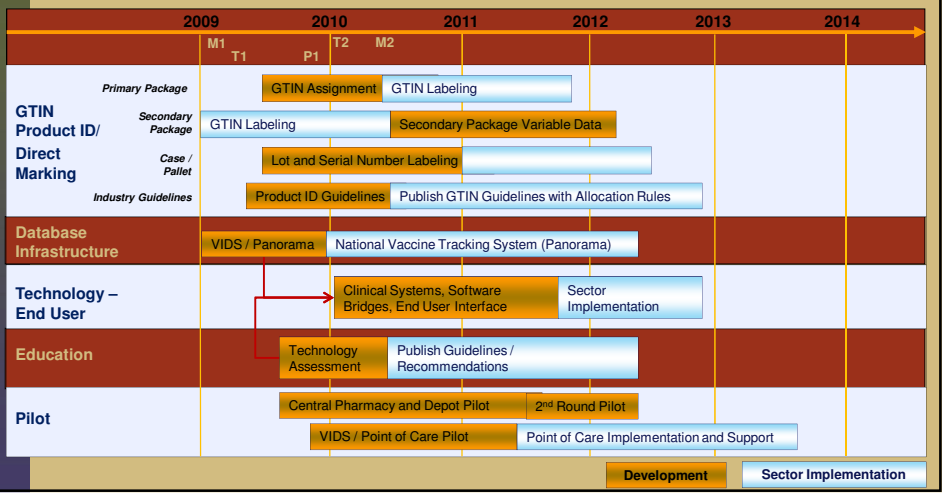
Manufacturers will continue to work towards implementing the standards for bar coding on vaccine products

AIVP Implementation Roadmap – DRAFT V3

Milestones

M1	Mar. '09	GTIN on secondary package
M2	Jun. '10	GTIN on primary package
M3	TBD	Variable data on secondary package
M4	TBD	Reconstituted /diluent or vaccines
M5	TBD	Lot and serial number marked on shipping container
M6	TBD	Serialization on secondary package
M7	TBD	Variable data on primary package

T1	May '09	Attributes and data sources identified for VIDS
T2	Jan. '10	VIDS launch
T3	TBD	VIDS integrated into Panorama
E1	TBD	Technology scan completed and published.
E2	TBD	Preliminary communications plan available
E3	TBD	Detailed sector communications plan available
P1	Nov. '09	VIDS pilot launch (clinic and public health)
P2	TBD	Central pharmacy and depot pilot launched

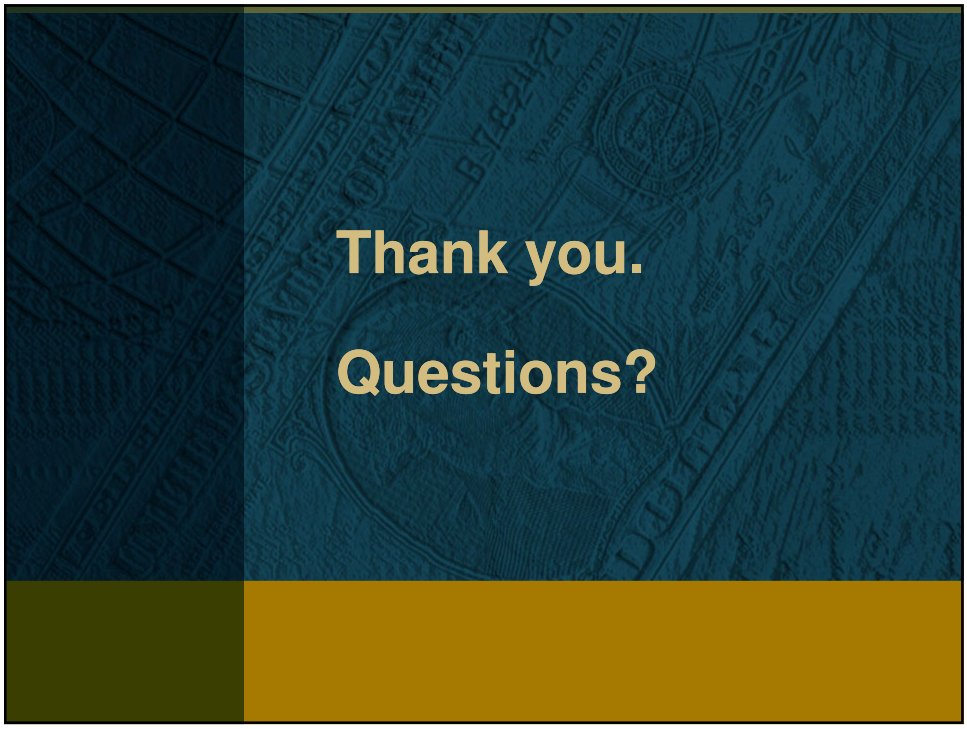


Contributing Organizations

- BIOTECH Canada
- Canadian Coalition for Immunization and Awareness and Promotion (CCIAP)
- Canadian Immunization Registry Network (CIRN)
- Canadian Nurses Coalition on Immunization (CNCI)
- Canadian Paediatric Society (CPS)
- Canadian Health Information Technology Trade Association (CHITTA)
- Canadian Medical Association (CMA)
- GlaxoSmithKline (GSK)
- GS1 Canada
- Health Canada
- Institute for Safe Medical Practices (ISMP)
- Merck Frosst Canada
- Novartis Vaccines
- Public Health Agency of Canada
- Sanofi pasteur limited
- Solvay Pharma Inc.
- Wyeth Pharmaceuticals
- **Special Acknowledgements**
- American Academy of Paediatrics
- GS1 International
- NHS England

AIVP

A significant undertaking made possible by collaboration and partnership between Industry, Governments & the Health Care Professions in Canada


Thank you.
Questions?