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

GS1 Healthcare Conference
Enabling Immunization Traceability

Vaccine Industry Committee

June 17, 2008
Toronto

Vaccine Industry Committee

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.

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Vaccine Industry Committee

MERCK FROSST

sanofi pasteur
The vaccines business of sanofi-aventis Group

Wyeth

VIDO

medicago

Solvay Pharma

SOLVAY

ivt ImmunoVaccine Technologies

VARIATION BIOTECHNOLOGIES

ICID
International Centre for Infectious Diseases

OSLER
Osler, Hoskin & Harcourt LLP

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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.

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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.).

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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.

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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

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Cost Categories

#	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	Software configuration	Configuring the Clinical Management Software (CMS).
C7	Scanner purchase	Initial scanner purchase cost.

Source: PHAC and HDR consultants

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Cost Categories (cont'd)

#	Category	Description
C8A	Re-design of procedures & layout at clinics	Re-designing clinic layouts and procedures.
C8B	Re-design of procedures & layout at manufacturing plants	Re-designing plant layout to produce/process bar codes.
C9	Bar code printing	Additional cost of printing the new bar codes and attaching them to the vaccine.
C10	Training practitioners	Training practitioners to use the scanning equipment and the new information systems.
C11	Ongoing collection and maintenance of vaccine data for VIDS	Populating VIDS with vaccine data and maintaining the database.
C12	Scanner and printer maintenance & replacement	Maintaining and periodically replacing scanning and printing equipment.
C13	Technical support	Ongoing technical support provided to system users.

Source: PHAC and HDR consultants

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Benefits Categories

#	Category	Description
B1	Processing 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	Reduction in adverse health events attributable to vaccination and a reduction in disease incidence.
B3	Improved patient care	Quicker response to vaccine recalls and reduction in supply shortages.
B4	Fewer re-immunizations	Reduced expenditures and increased time savings due to fewer re-immunizations and unnecessary immunizations.
B5	Improved supply chain management	Reduction in inventory holding costs and reduced wastage.
B6	Enhanced data availability for research and analysis	Enhanced research opportunities leading to future improvements in safety and efficiency.
B7	Increased confidence in the health care system	Increased confidence of patients and improved reputation of health care system.

Source: PHAC and HDR consultants

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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

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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

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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.

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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.

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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).

Selected Implementation Options

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).

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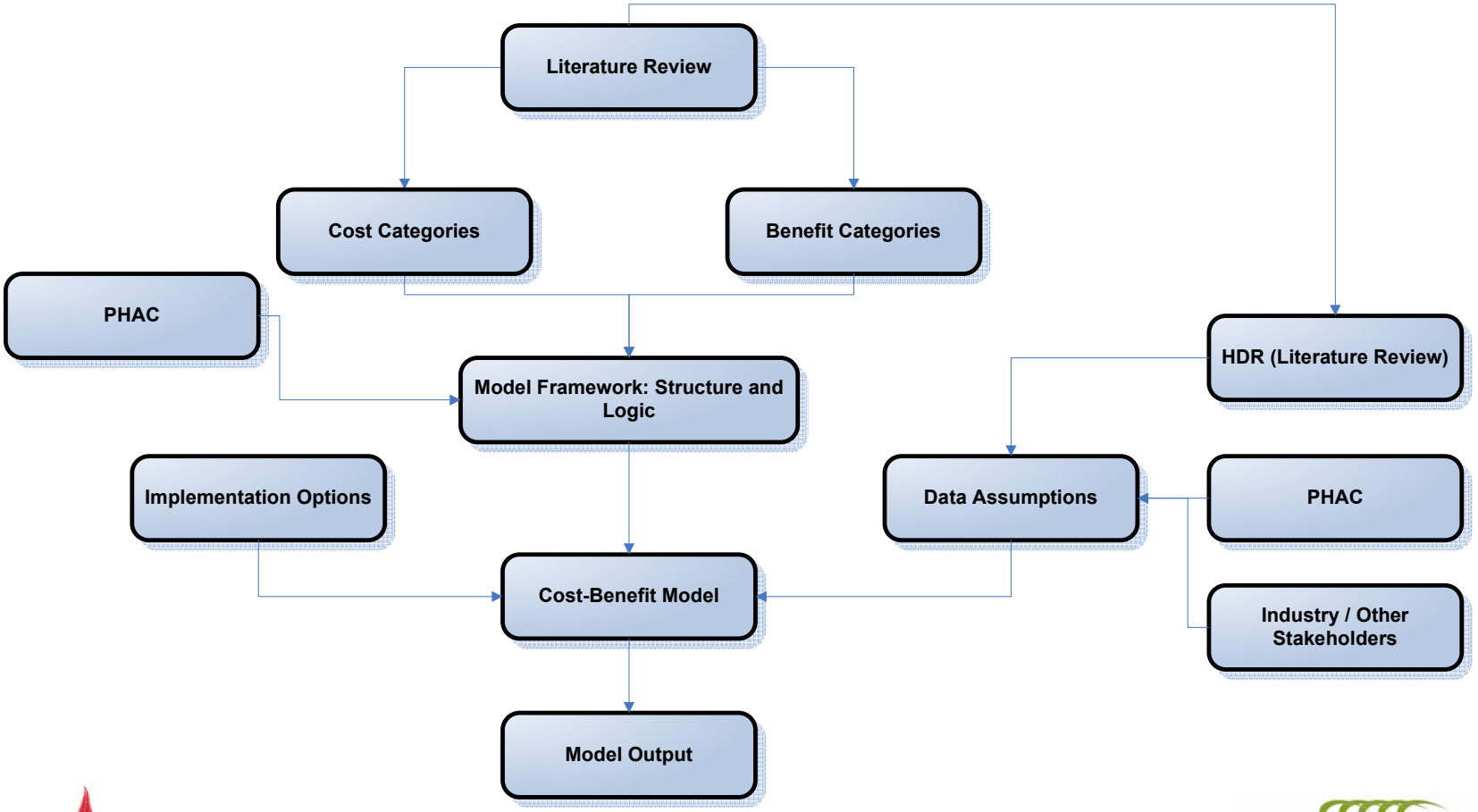
Flowchart



Source: PHAC and HDR consultants

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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

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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).

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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.

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Thank you !!!

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Back Up Slides

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Comparison of on line print requirements

Elements of the proposed Cdn standard	Current Single label No detachable	Proposed Cdn Standard Double detachable	Possible Amendment to Cdn Standard Double Detachable
Vaccine Trade Name - Preprinted	Yes		Yes On each label piece
Lot # (Human Readable)	Print once Read once	Read 3 times	Print 3 times Read 3 times
Expiry Date (Human Readable)	Print once Read once	Print 3 times Read 3 times	Print once Read once
GTIN # (Human Readable)		2 times d 2 times	
2D bar code (Exp Date)		t 2 times Read 2 times	Print 1 times Read 1 times
Total informa		10 Print/reads	5 Print/reads

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

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Other Technical Issues

Multidose Vials:

There is no technology to permit adding 20 detachable labels with variable data to a 10 dose vial.

If this causes a shift in demand from 10 dose vials to single dose presentations, then industry production capacity will be negatively affected at least in the short run.

Small volume specialized products:

Yellow Fever – low volume, freeze dried, shipped on dry ice etc.

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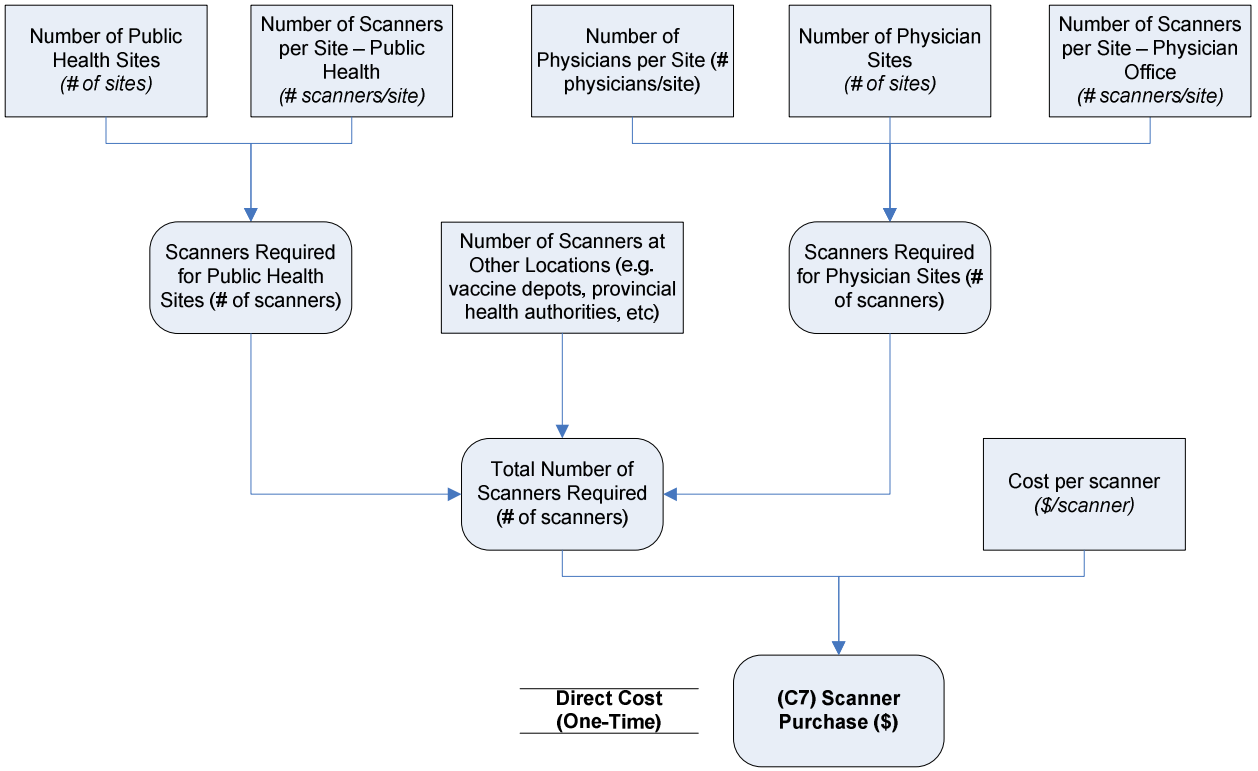
Structure and Logic Model

Example: Cost C7 - Scanner Purchase



Source: PHAC and HDR consultants

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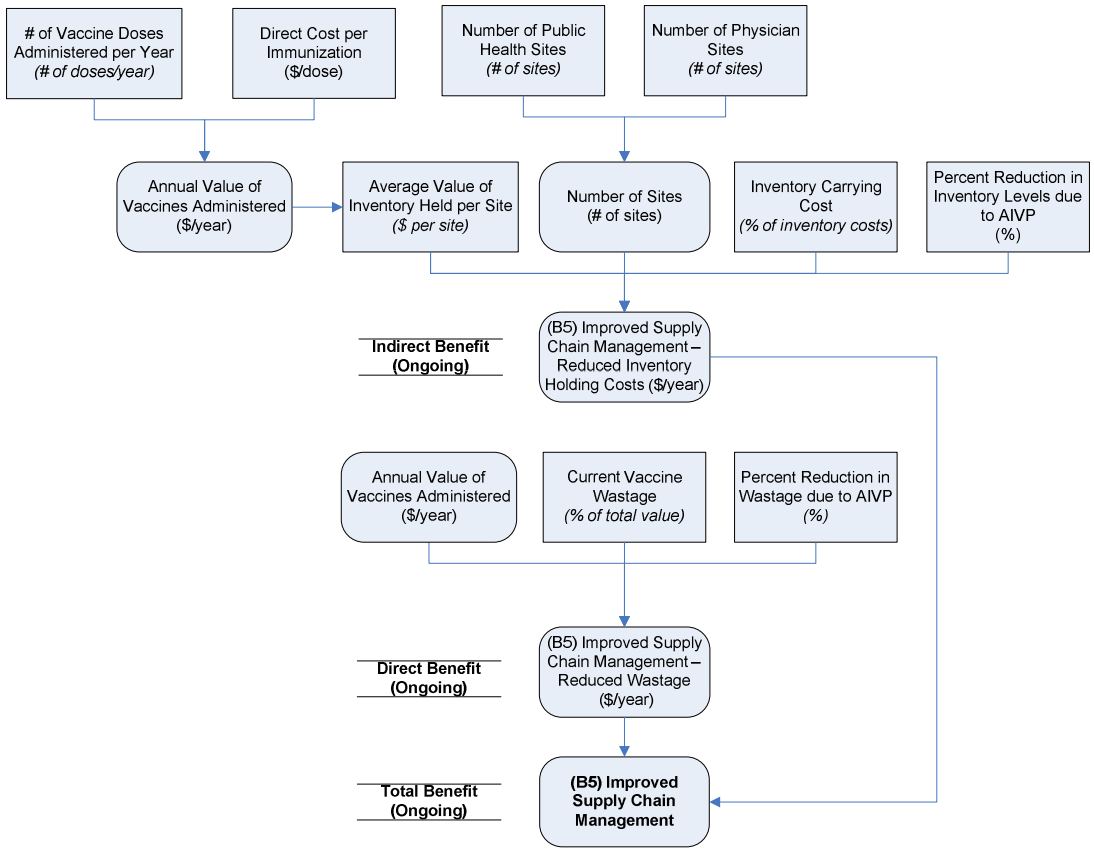
Structure and Logic Model

Example: Benefit B5 - Improved Supply Chain Management



Source: PHAC and HDR consultants

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