

Automated Identification of Vaccine Products Project (AIVP)

A Strategy for Action

GS1 Health Care User Group

Orlando, FL, USA
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Public Health Agency of Canada



Presentation Overview

- A bit about Canada and what we do at the Public Health Agency
- Some interesting facts on vaccine use and delivery in Canada
- An historical overview of process to establish standards for barcodes on vaccine products
- Key partnerships
 - Linkages with other countries
 - GS1 global standards
 - GS1 HUG Canada
- Meeting in Montreal and the outcomes
 - Advisory Committee
 - Issues
 - Action plan
- Lessons learned



"Some Canadiana—eh!"

- Canada is just north of the 49th parallel
- Population of approximately 32 million
- 90% of Canadians live in urban centers within an hour's drive of the US
- 10 provinces and 3 territories each have the responsibility for delivering health care services
- Each Canadian has personal health insurance and number provided by their respective government
- Canada consumes the most salt per capita than any other country (but not on our poutine)



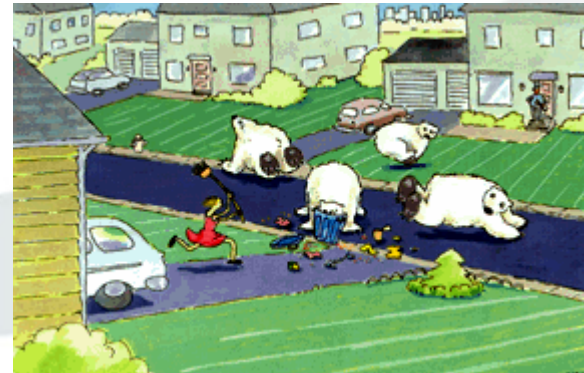
Public Health Agency of Canada

- Established in 2004
- Mandate: Work with the provinces and territories and other national governments and agencies to promote and protect the health and safety of Canadians.
 - Infectious disease prevention and control and emergency preparedness and response
 - Chronic disease prevention and control and healthy human development
 - Public health practice



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Vaccine Use and Delivery in Canada

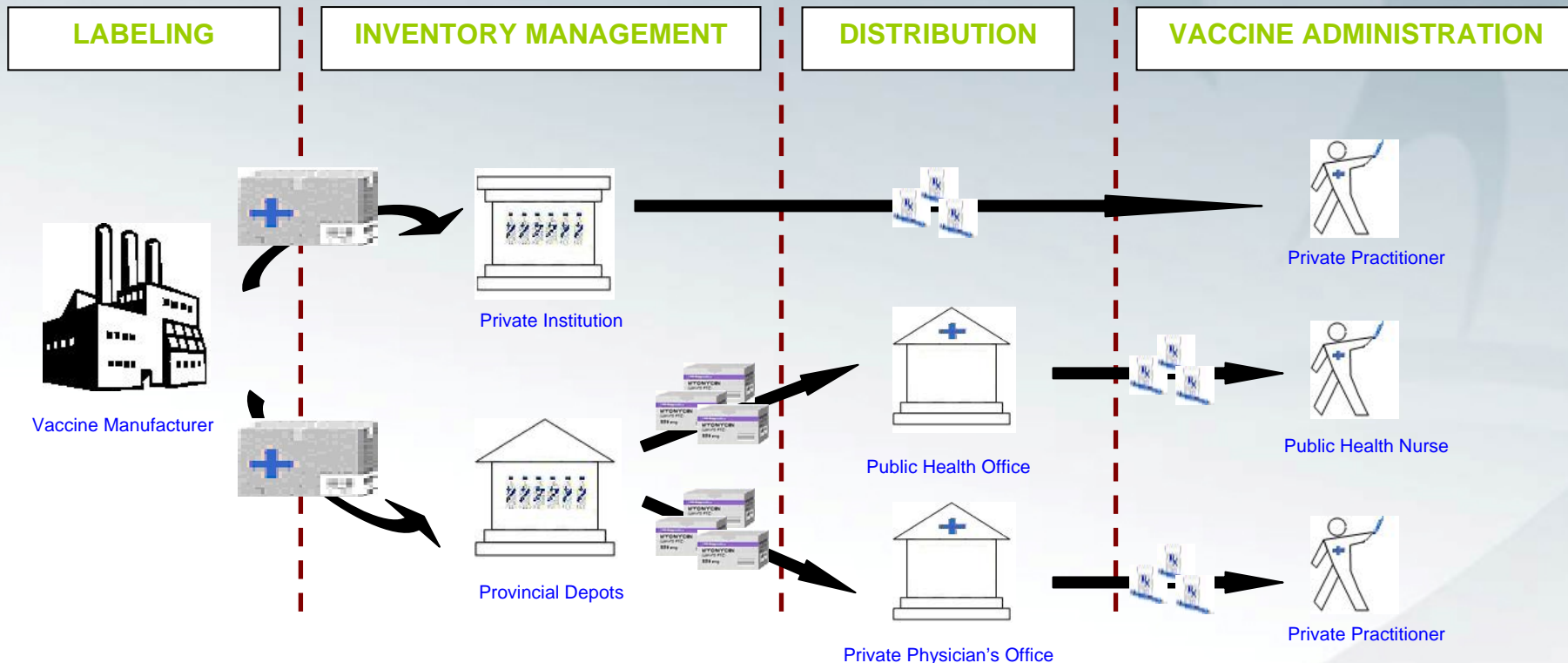
- Over 15 million doses of vaccines are provided to Canadians annually
- 50% of all vaccines are provided by public health nurses and the other 50% by medical doctors in private practice.



* Only publicly funded programs



Canadian Vaccine Supply Chain



PRIMARY VACCINE PACKAGES (1°)
e.g. vials, ampoules, pre-loaded syringes

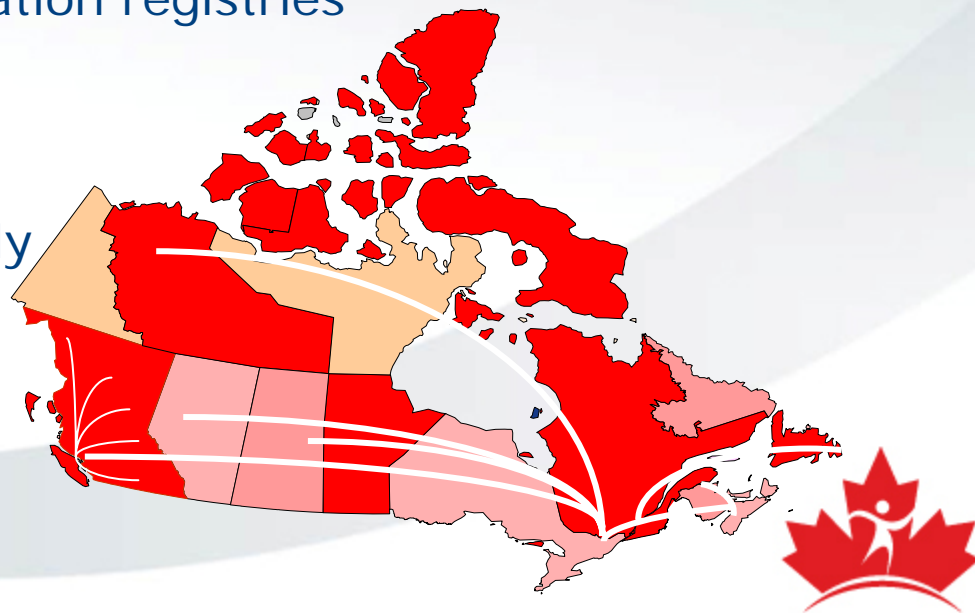
SECONDARY VACCINE PACKAGES (2°)
e.g. boxes with multiple single-dose vials

TERTIARY VACCINE PACKAGES (3°)
e.g. shipping cartons



Immunization Registries Network and the Electronic Health Record

- An immunization registry is a confidential, population-based electronic information system used to support immunization program delivery in a jurisdiction.
- 5 of 13 provinces and territories currently use immunization registries to manage immunization records
- By 2009 there will be a national surveillance system that will include a network of immunization registries
- This system will have the ability to read bar codes off vaccine packages and eventually link to the EHR.
- Developers are awaiting standards for bar codes



How immunization registries work

1. Provider enters the client's information and scans bar code on vaccine package



2. Bar code number is loaded into the text field of a client's immunization e-record

The screenshot displays the PHIS Application interface in Microsoft Internet Explorer. The browser title is "PHIS Application - Microsoft Internet Explorer". The navigation menu includes: Home, Client Search, Wait Queue, Scheduling, Outstanding Referrals, Lab, Site Map, Help, About, and Logoff. The main heading is "Immunizations".

Client Information:
Client: / FRASER, COLIN / 1959-03-02 / MALE (250) 546-4444
HA/Branch: SAMPLE HA /

Navigation Tabs: Summary, NWBA, ECHA, Imms, PSTA, EDCO, Hearing, Dental, Vision, NOB, Other, Adverse, Contraind, Notes

Immunizations Section:

Appt Date	2004-11-05
HA	SAMPLE HA
Branch	SAMPLE BRANCH - A
Provider	DCALDWELL
Created By	Tan Do

Barcode: [(01)40697177000322(10)C2064AA(17)051031]

Other Fields:
Agent: [Dropdown]
Lot Number (Expiry Date): [Dropdown]
Site: [Dropdown]
Route: [Dropdown]
Dosage: [Text Field]
Dosage Units: [Dropdown]
Dose #: [Text Field]
Consent:
Reason For Immunization: [Dropdown]
Comments: [Text Area]

Local intranet



3. Vaccine related data is loaded from a data repository or manually entered into other fields

The screenshot displays the PHIS Application interface in Microsoft Internet Explorer. The browser title is "PHIS Application - Microsoft Internet Explorer" and the language is set to "EN English (Canada)". The top navigation bar includes links for Home, Client Search, Wait Queue, Scheduling, Outstanding Referrals, Lab, Site Map, Help, About, and Logoff. The main content area is titled "Immunizations" and shows client information for Fraser, Colin (1959-03-02, MALE, 250) 546-4444, with a Health Passport button. Below this, there are tabs for Adverse, Contraindication, Notes, and File. A secondary set of tabs includes Summary, NWBA, ECHA, Imms, PSTA, EDCO, Hearing, Dental, and Vision, with sub-tabs for NOB, Other, Adverse, Contraind, and Notes. The "Immunizations" section contains the following details:

- Appt Date: 2004-11-05
- HA: SAMPLE HA
- Branch: SAMPLE BRANCH - A
- Provider: DCALDWELL
- Created By: Tan Do
- Barcode: (01)40697177000322(10)C2064AA(17)051031
- Agent: Diphtheria, Tetanus, aPertussis, iPolio, Hib (circled in red)
- Lot Number (Expiry Date): C2064AA (2005-10-31) (circled in red)
- Site: (circled in red)
- Route: INTRAMUSCULAR (circled in red)
- Dosage: 0.5 (circled in red)
- Dosage Units: ML (circled in red)
- Dose #: (empty)
- Consent: (checkbox)
- Reason For Immunization: (dropdown)
- Comments: (text area)

A "Product Details" button is located to the right of the Agent field. The bottom of the browser window shows "Done" and "Local intranet".



4. After the immunization event the provider fills in the remaining fields

PHIS Application - Microsoft Internet Explorer

EN English (Canada)

Home • Client Search • Wait Queue • Scheduling • Outstanding Referrals • Lab • Site Map • Help • About • Logoff

Immunizations

Client / FRASER, COLIN / 1959-03-02 / MALE (250) 546-4444 Health Passport

HA/Branch SAMPLE HA /

Adverse Contraindication Notes File

Summary NWBA ECHA Imms PSTA EDCO Hearing Dental Vision
NOB Other Adverse Contraind Notes

Immunizations

Appt Date 2004-11-05
HA SAMPLE HA
Branch SAMPLE BRANCH - A
Provider DCALDWELL
Created By Tan Do

Barcode (01)40697177000322(10)C2064AA(17)051031

Agent Diphtheria, Tetanus, aPertussis, iPolio, Hib Product Details

Lot Number (Expiry Date) C2064AA (2005-10-31)

Site

Route INTRAMUSCULAR

Dosage 0.5

Dosage Units ML

Dose #

Consent

Reason For Immunization

Comments

Done Local intranet



5. Additional data can be retrieved from the Vaccine Identification Database System

VIDS** a web-based repository of information on all vaccines approved for use in Canada.

Public Health Agency of Canada | Agence de santé publique du Canada

Canada

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Home Products Immunizing Agents Manufacturers Alerts Recalls

A-Z Index

VIDS ONLINE

VACCINE IDENTIFICATION DATABASE SYSTEM

IMMUNIZATION AND RESPIRATORY INFECTIONS DIVISION

SEARCH PRODUCTS IMMUNIZING AGENTS MANUFACTURERS IMMUNIZATION SCHEDULES

Product Detail

Information

Trade Name ACT-HIB

ATC Description HEMOPHILUS INFLUENZA B, COMBINATIONS WITH TOXIODS

DIN 01959034

Manufacturer AVENTIS PASTEUR SA

Active Ingredient(s) HAEMOPHILUS INFLUENZAE TYPE B-PRP

TETANUS PROTEIN

Route INTRAMUSCULAR

Form POWDER FOR SOLUTION
KIT

Immunizing Agent*

Haemophilus influenzae type b conjugate vaccine (tetanus toxoid conjugate)

Lots

Lot Number	Expiry Date (YYYY-MM-DD)
C0675AA	2010-06-20
C1947AA	2005-07-31
C2196AA22	2000-12-12
C2163AA	2005-06-01

VIDS proposed content

- GTIN (*Global Trade Item Number*)
- Lot Number
- Expiry Date
- DIN (*Drug Identification Number*)
- Immunizing Agent
- Dosage
- Dosage Unit
- Route of Administration
- Active ingredients
- Non-medical Ingredients
- Product Form
- Strength
- Contraindications
- Storage information
- Manufacturer
- Trade Name
- CCI Codes (*Canadian Classification of Health Intervention Codes*)
- ATC Code (*WHO Anatomical Therapeutic Chemical Classification Codes*)

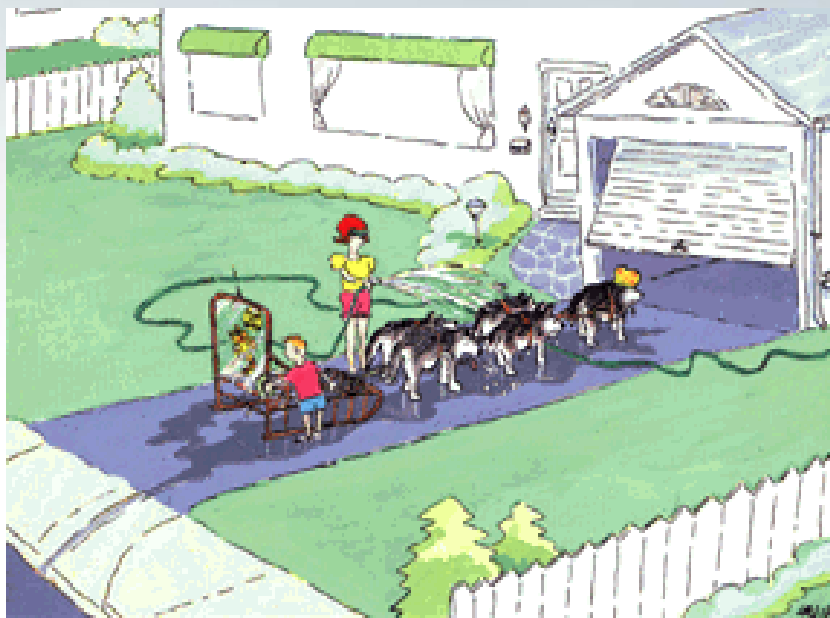
** VIDS Phase 1 was developed for AIVP pilot in cooperation with HPFB

VIDS Phase 2 is under development

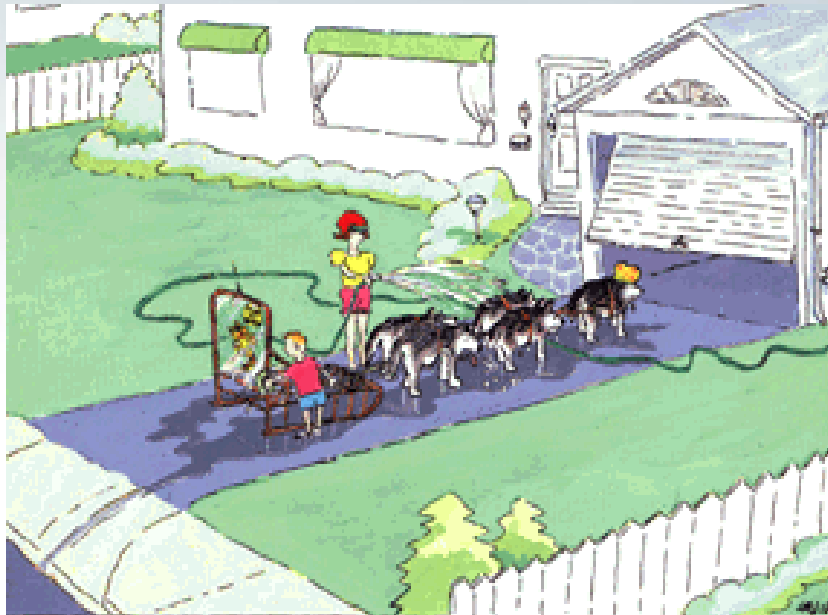
VIDS content to be negotiated with contributors



That is pretty good for Canadian technology



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.....So how did we get there and what is left to do?



AI VP Process

*“Incorporate bar codes into vaccine product labelling to improve immunization record keeping and inventory management and improve the safe use of vaccines”
(NACI², 1999)*



² **NACI** – National Advisory Committee on Immunizations

³ **CIRN** – Canadian Immunization Registry Network



Recommendations (Nov.2005)

1. Bar Code Content:

- Encoded the following data into bar codes on both the primary & the secondary vaccine packages:

GTIN (GS1-14⁴) + Expiry Date + Lot #

2. Bar Code Specification:

- Use the GS1-128 Code Structure to encode the data into the bar. Example:

(01)40697177000322(17)060904(10)J001740

GTIN + Expiry Date + Lot #

3. Bar Coding Symbology:

- Use Data Matrix (2-D) bar code on primary vaccine packages;
- Use Linear (1-D) bar code, at the minimum, on secondary vaccine packages; optionally with a Data Matrix.



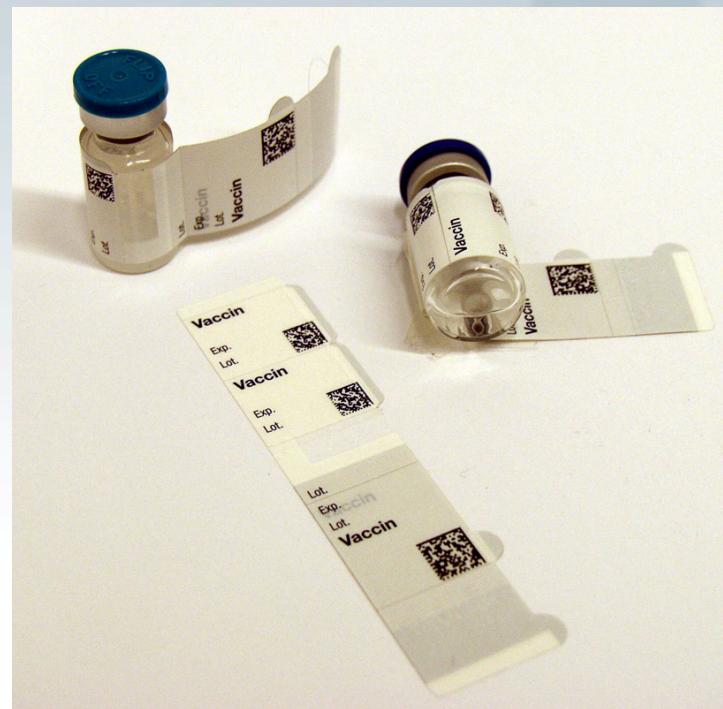
⁴ **GS1-14** – previously EAN/UCC-14, 14-digit GTIN number consisting of a packaging indicator, a company reference (company id + product id) and a check digit value.



Recommendations continued

4. Peel-off/Detachable Labels:

- Two peel-off labels, with bar code⁵ & human readable information⁶, to be provided for each unit dose of vaccine enclosed in a secondary vaccine package.
- Peel-off labels should be affixed to primary package and should not obscure the information on the package.



⁵ **Bar code content** – GTIN, Expiry Date and Lot #

⁶ **Human readable information** – Vaccine Trade Name, GTIN, Expiry Date and Lot #



Montreal Meeting Jan. 2007

PURPOSE

- To identify issues, to determine next steps and timelines and to describe roles and responsibilities of all key stakeholders to voluntarily implement bar codes on vaccines in Canada.

PARTICIPANTS

- GS1, public health authorities from the U.S., U.K. and Canada, regulators, NGOs, professional associations (representing end users) and the vaccine industry – including labelling and printing experts.



Outcomes of the meeting

Seven main initiatives were identified as priorities:

1. the development of a strategic plan;
2. an analysis of costs;
3. the identification of further research priorities;
4. the need to address manufacturing issues;
5. the harmonization of standards;
6. an assessment on the state of readiness, and
7. Populate the Vaccine Identification Database System (VIDS).



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Advisory Committee

Mandate

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

Membership

- GS1, the Agency, end users from public health, private practice, professional associations, NGOs, regulators, and the vaccine industry – including labelling and printing experts.



Work Plan: Analysis of costs

- Develop an independent, 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.) and
- Outline financial, in-kind and other cost-sharing arrangements between governments, manufacturers, providers and others.



Work Plan: Research

- Consolidate existing national and international data/evidence
- Identify areas requiring further data collection, research and analysis
- Work with GS1 and other countries to optimize research priorities
- Work with Canadian provinces/territories to develop pilot projects to promote early adoption of standards



Work Plan: Manufacturing Issues

- Promote the need for variable data (lot number and expiry date) on bar codes for vaccine products to all stakeholders
- Provide the forum for Canadian vaccine manufacturers to work with equipment makers and label manufacturers to develop solutions for implementing the global standards



Work Plan: Standards Harmonization

- Establish a Canadian HUG-Canada and interface with other national HUGs (UK, US, Australia) to ensure global commonality
- Develop Canadian guidelines for implementation of global standards in Canada (business requirements, data structure, carriers)



Work Plan: Canadian state of readiness

- 75% of physician offices are computerized
- Pilot test showed that clinic/office system can easily be modified to incorporate bar codes
- More than 30% of Canadian provinces and territories currently have immunization registries and the rest will have the capacity by 2009
- A database system to support bar codes has been developed
- Need to agree upon the standards with all stakeholders
- Need to work with industry to develop an implementation strategy to voluntarily print bar codes with variable data on all vaccine products.



Work Plan: Database (VIDS)

- Establish standard operating practices (SOPs) for the collection, validation and control of data in the database
- Initiate database using existing functionality (GTIN, bar codes on current secondary packaging), with additional functionality to be phased-in over time
- Develop a continuous improvement plan for VIDS, including evolving bar code functionality and reflecting end user feedback, to support a staged approach to full functionality

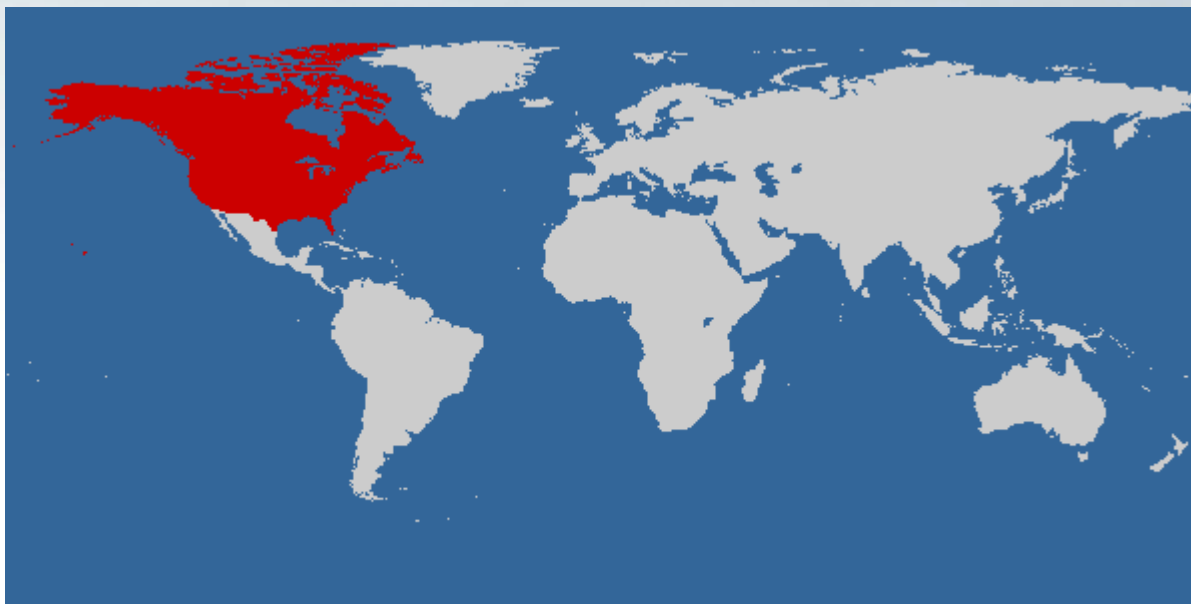


GSI -HUG International and GS1-HUG Canada

- Through GSI –HUG Canada has been able to become a vocal advocate for bar coding of vaccines in the global community
- The GSI- HUG committee structure has provided invaluable support and context to Canada's bar coding initiative in connecting with global partners
- Canada will continue to contribute to the Vaccines and Biologics working committee that has helped to highlight special considerations for vaccines.
- And to continue to work to build a global community



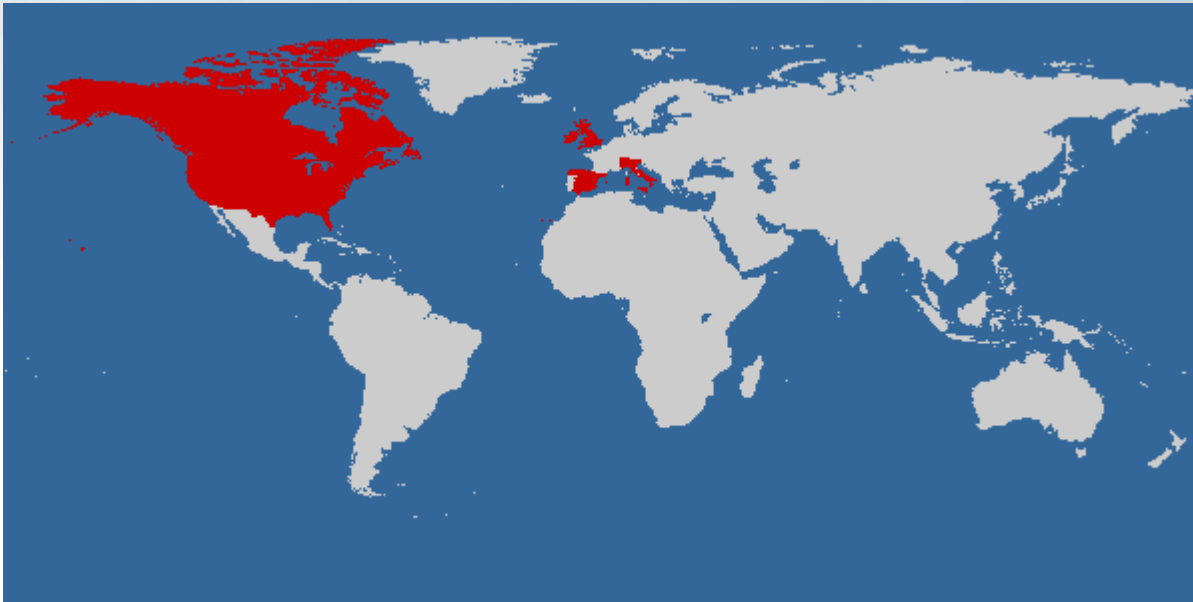
Creating a bigger community of international partners



Countries contemplating or currently bar coding vaccines:
US, Canada



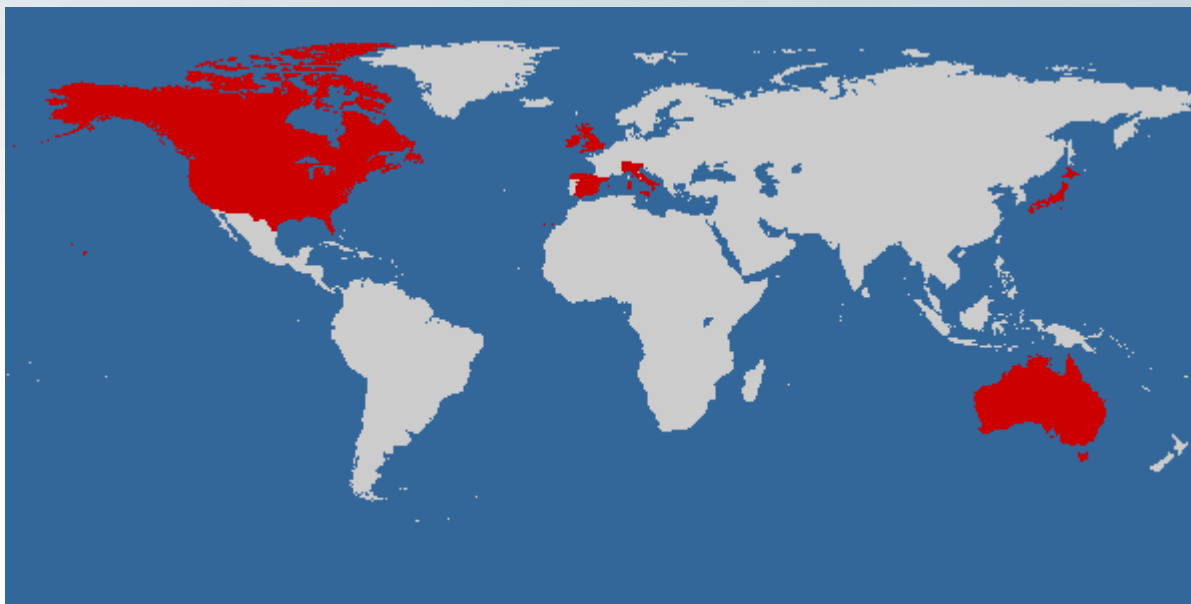
Creating a bigger community of international partners



Countries contemplating or currently bar coding vaccines:
US, Canada, Ireland, UK, Spain, Italy



Creating a bigger community of international partners



Countries contemplating or currently bar coding vaccines:
US, Canada, Ireland, UK, Spain, Italy, Japan, Australia...



Lessons Learned

- Use global **standards in national** implementation plans;
- **International** partners are key (need to create a bigger slice of the pie);
- **Use** all stakeholders across the supply chain, especially private and public end users, to advocate for bar code standards;
- Regulator **participation and support** is key with voluntary implementation;
- **Everyone** must participate or we won't achieve the desired benefits.



Key Contacts

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Thank you ...any questions?

