Automated Identification of Vaccines Project (AIVP)

PUBLIC HEALTH AGENCY *of* CANADA
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Canada

Automated Identification of Vaccines Project (AIVP)

Project Overview with Proposed Standards

GS1 Healthcare Users Group Conference
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Presenter: Lisa Belzak

FACTS...

*Medical errors in U.S. hospitals, resulting in **preventable** adverse events, kill between (est.) 44,000 – 98,000[1] people per year!*

- Highway accidents (43,458)
- Breast Cancer (42,297)
- AIDS (16,516)

[1] *"To Err Is Human: Building a Safer Health System", U.S., 1997*

FACTS...

Data quality audits of client immunization records in Canada indicate:

- 15% of records with incomplete dose number and agent codes (BC);
- 24% data discrepancy rate and 5% data missing rate in records (Manitoba);
- 10% of population were re-vaccinated with a vaccine due to inaccurate records (unpublished source);
- Over 20% of P/T adverse events immunization reports received by PHAC from 1987 to 2003 were missing the lot number.

What we are doing about this…

"Incorporate bar codes into vaccine product labelling to improve immunization record keeping and inventory management"
(NACI[2], 1999)

Collaboration

⬇

2000 – Industry & International Consultation

2001 – Recommendations to Immunization Working Group

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

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Collaboration → Feasibility Study

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2002 – Survey of Stakeholders: vaccine manufacturers, nurses, standards organizations (GS1) (pub. Dec. 2002)

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Collaboration → **Feasibility Study** → **Pilot Study**

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2003 – Planning meeting w/ vaccine manufacturers and F/P/T representatives

2004/05- Pilot

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AIVP = Automated Identification of Vaccines Project

Bar coding of vaccine (1^0 & 2^0) packages

w/GTIN[3], Lot # & Expiry Date

and/or

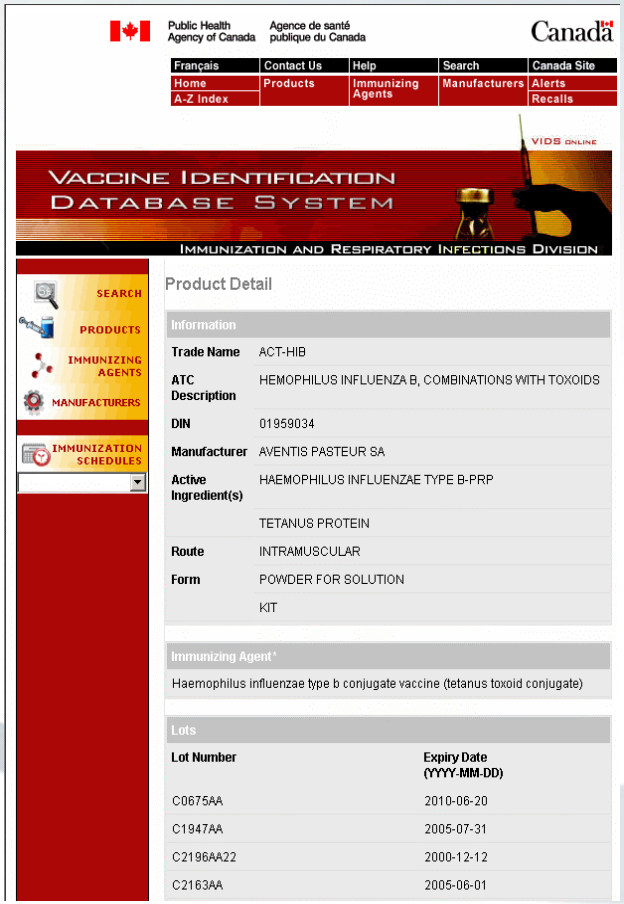
VIDS

(Vaccine Identification Database System)

[3] ***GTIN*** *– Global Trade Item Number*

Vaccine Identification Database System (VIDS)[4]

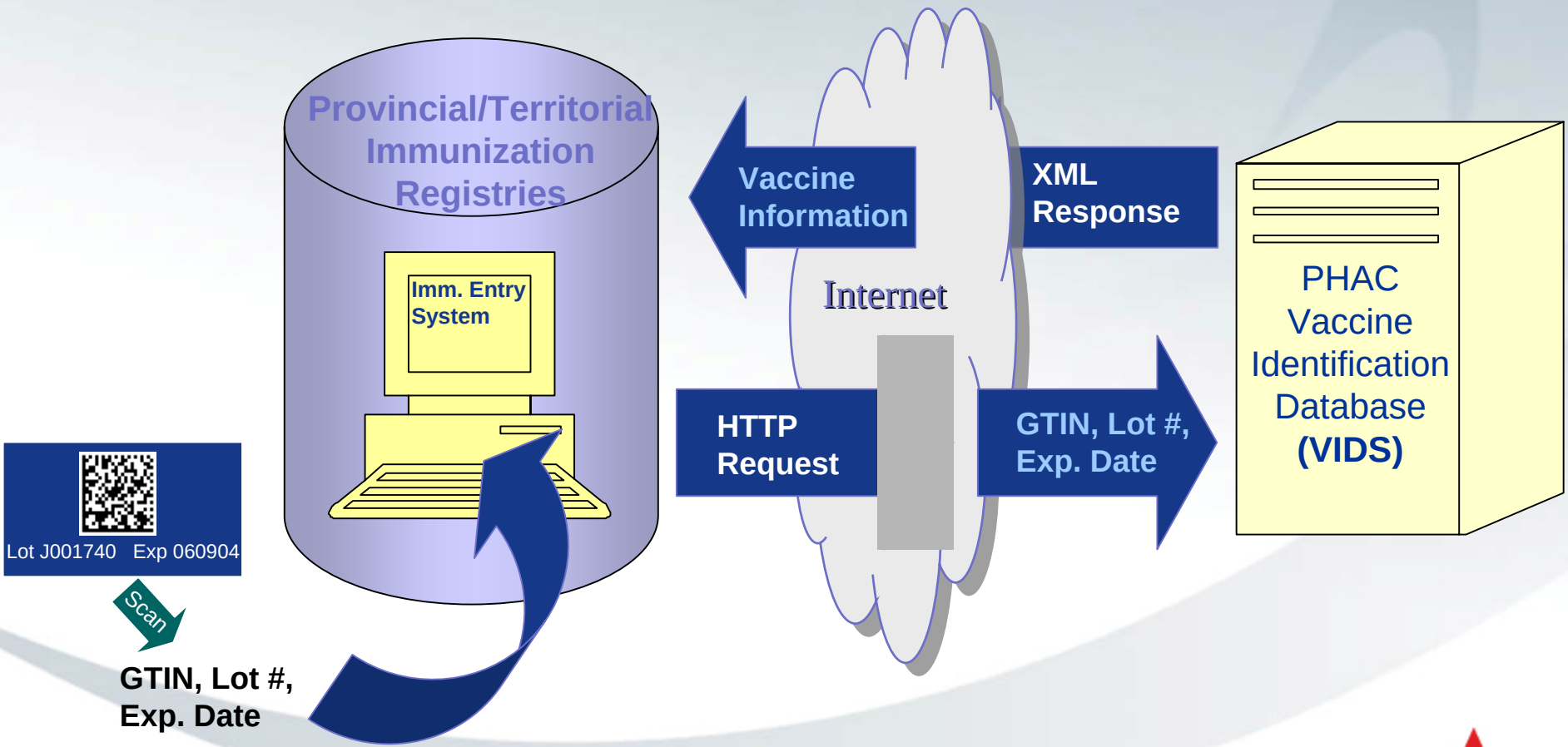
Single source of comprehensive information on all vaccines approved for use in Canada.



- 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)*

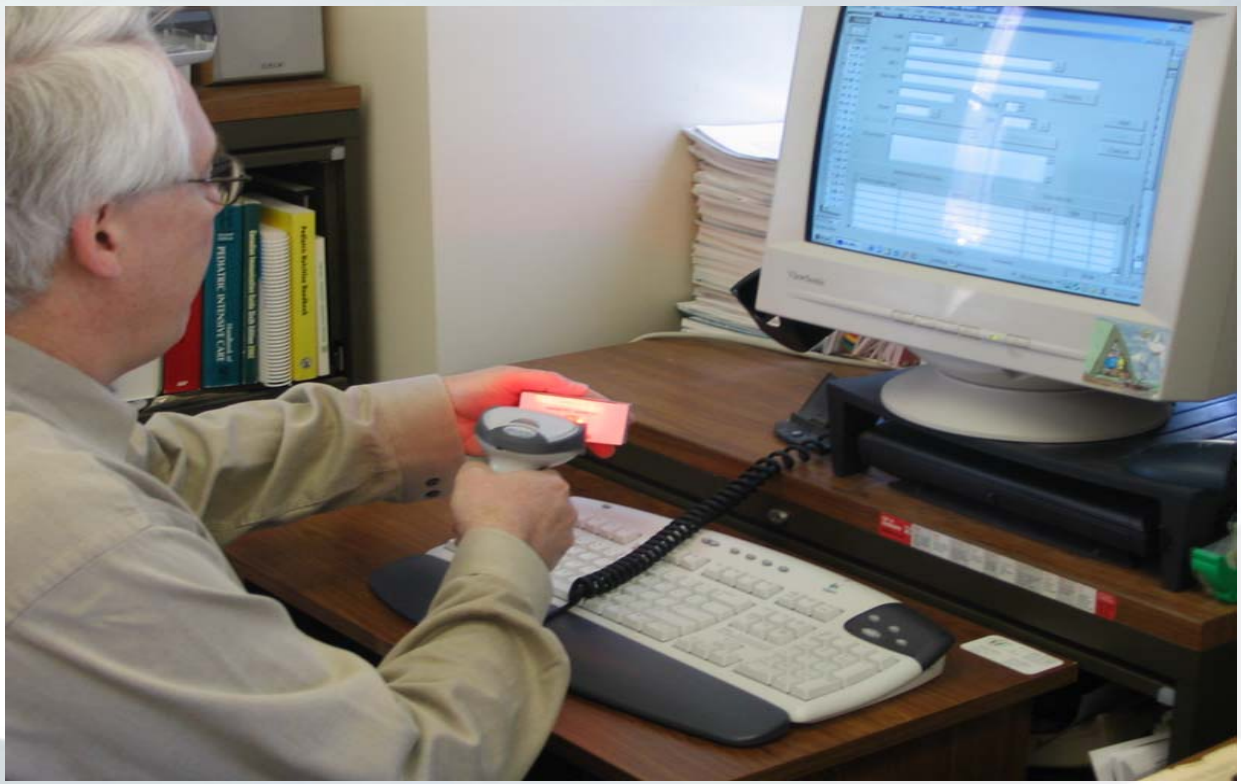
[4] VIDS Phase 1 was developed for AIVP pilot; VIDS Phase 2 is under development

AIVP Data Flow

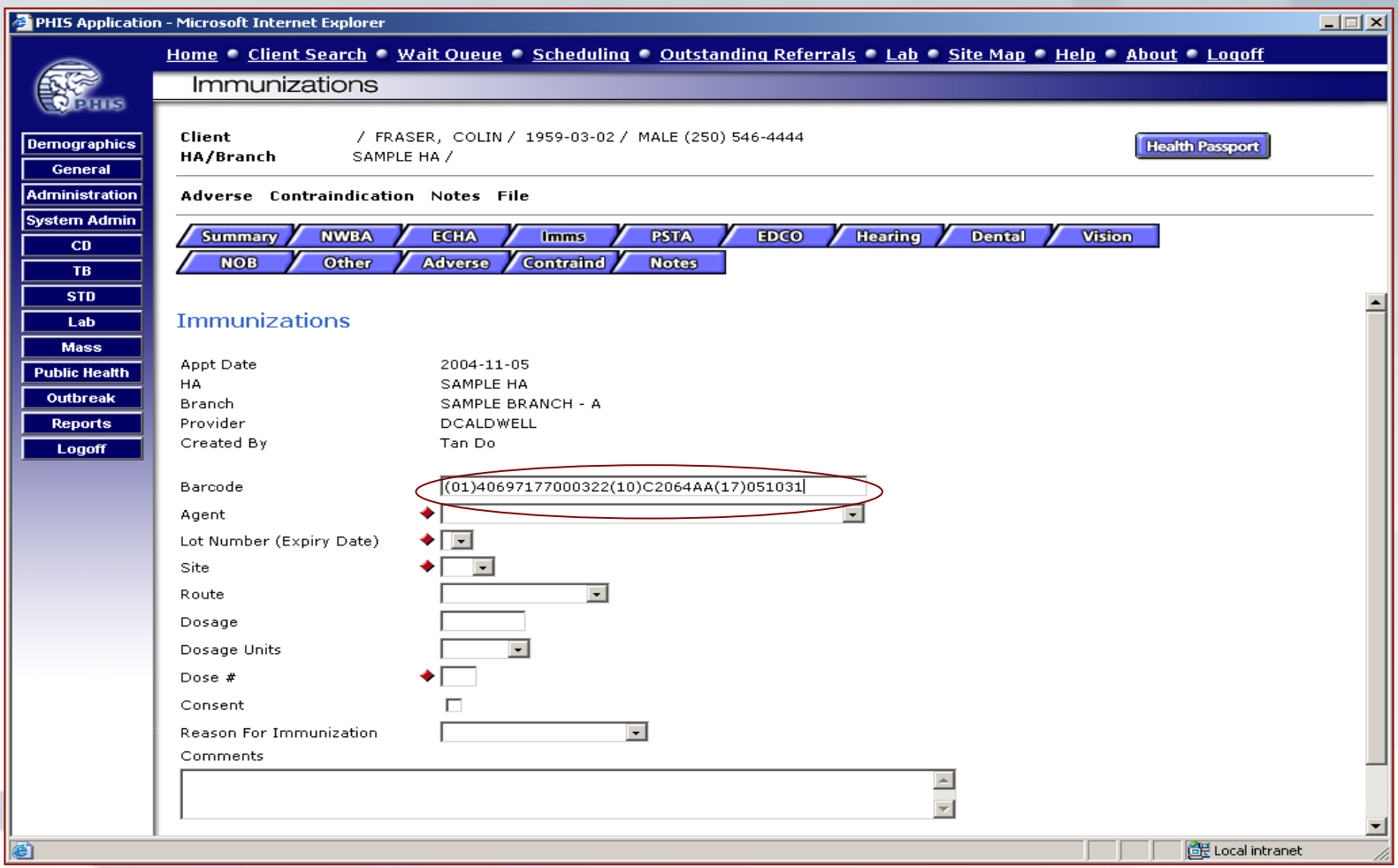


How does the Automated Identification of Vaccines Work?

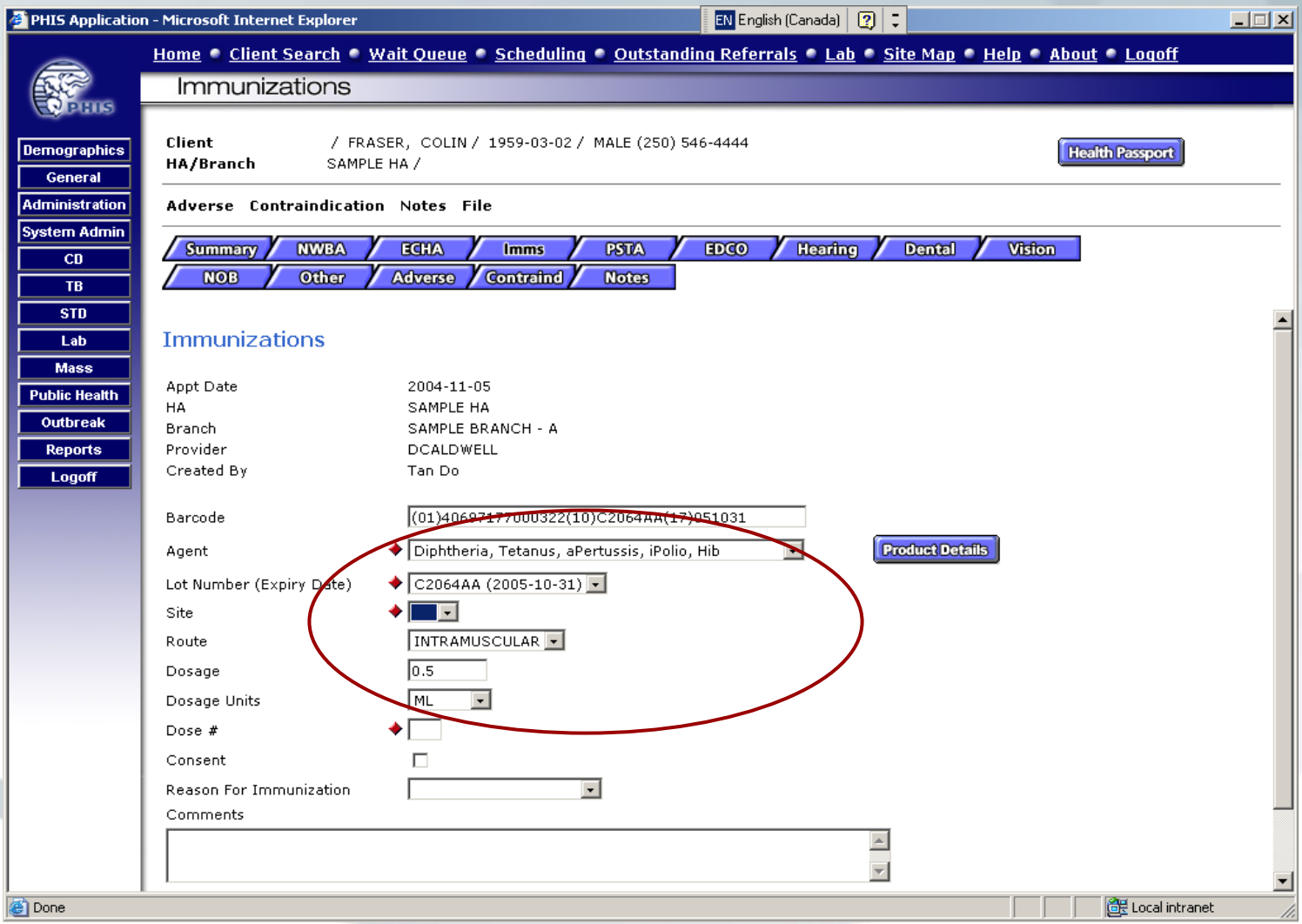
1. User scans bar code on vaccine package



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



3. Vaccine related data is retrieved from VIDS and loaded into other fields



4. Additional Data can be retrieved from VIDS

Product Detail

Trade Name	Manufacturers
PENTACEL	AVENTIS PASTEUR LIMITED CONNAUGHT LABORATORIES LTD.

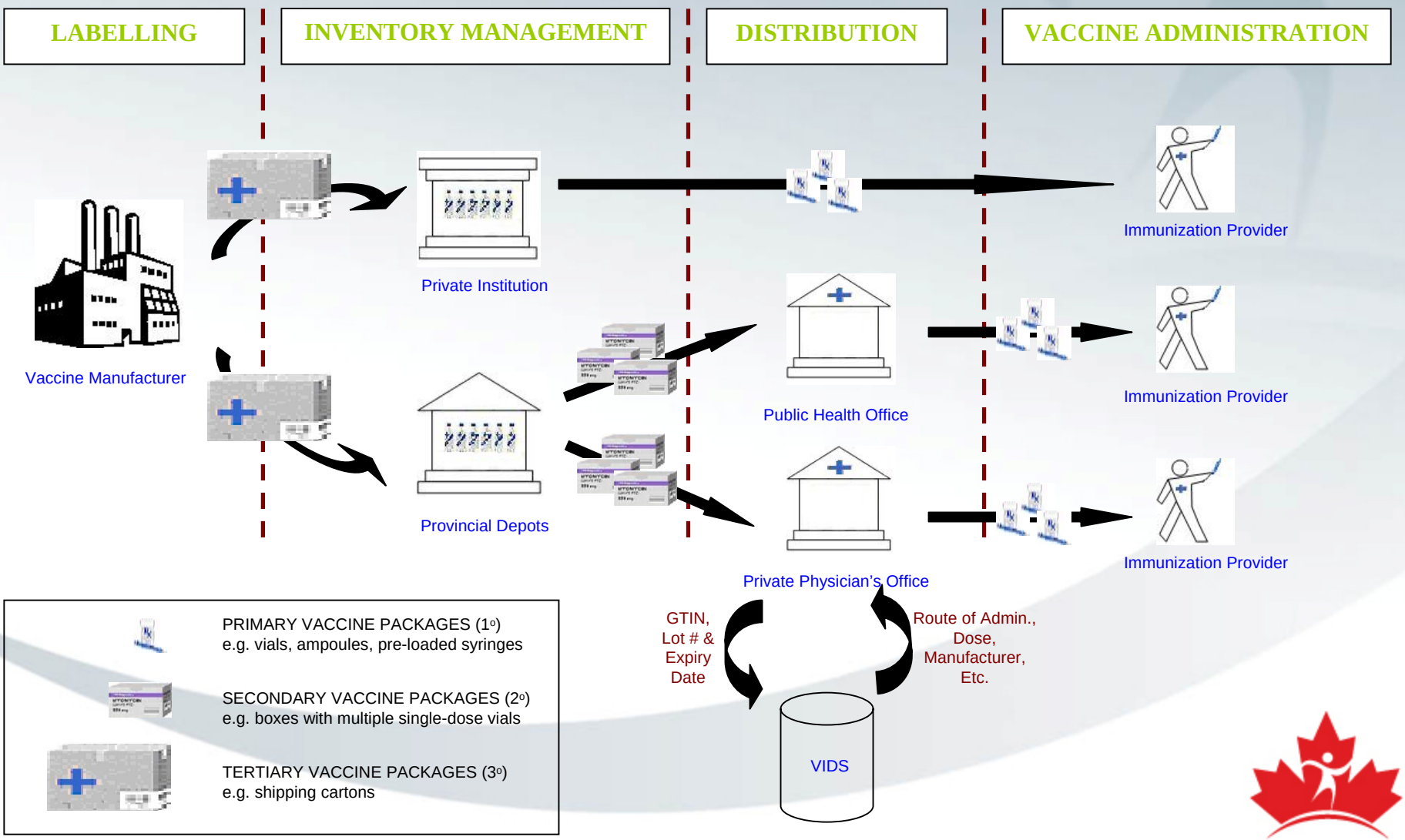
Active Ingredient(s)	Strength / Concentration
PERTUSSIS TOXOID	20MCG / 0.5ML
FILAMENTOUS HAEMAGGLUTININ	20MCG / 0.5ML
FIMBRIAE	5MCG / 0.5ML
PERTACTIN	3MCG / 0.5ML
DIPHTHERIA TOXOID	15LF / 0.5ML
TETANUS TOXOID	5LF / 0.5ML
INACTIVATED POLIOMYELITIS VACCINE (D.C.O.) TYPE 1 MAHONEY	40UNIT / 0.5ML
INACTIVATED POLIOMYELITIS VACCINE (D.C.O.) TYPE 2 M.E.F.1	8UNIT / 0.5ML
INACTIVATED POLIOMYELITIS VACCINE (D.C.O.) TYPE 3 SAUKETT	32UNIT / 0.5ML
HAEMOPHILUS INFLUENZAE TYPE B-PRP	10MCG / 0.5ML
TETANUS PROTEIN	20MCG / 0.5ML

Non-Medical Ingredient(s)	Strength
Aluminium Phosphate	N/A
Bovine serum	N/A
Formaldehyde	N/A
Polymyxin B + Neomycin	N/A
2-phenoxyethanol	N/A
Sucrose	N/A

Route	Form
INTRAMUSCULAR	LIQUID POWDER FOR SOLUTION

Dosage	Contraindications
0.5 ML	Any acute illness including febrile illness. Allergy to any component of Act-HIB including tetanus protein. Contraindications of Quadracel or Tripacel. outbreak of poliomyelitis for individuals over 6 months of age.

Bar Coding, VIDS, and the Vaccine Distribution Chain



AIVP Pilot Overview

- Conducted at 2 pilot sites (January – May 2005):
  - Public Health Community Centre, Red Deer, Alberta
  - Private Physician's Office, Winnipeg, Manitoba
- Objectives of the pilot:
  - Determine the success of data upload from VIDS to client records;
  - Assess the completeness, accuracy and efficiency of data capture using the bar coding technology;
  - Measure user acceptance of the technology on work process.

Summary of AIVP Pilot Evaluation Results

- Time is saved entering vaccine data using a bar code scanner vs. manually. *(Efficiency)*
- Providers were able to adapt workflow to accommodate the bar coding technology with minimal disruption, but bar coding *must facilitate entry of data post-client encounter*. *(User Acceptance)*
- Users felt more confident in the data entered using bar code scanner vs. manually, *however* labels must be on primary packages (vials/syringes/ampoules), but this must be easier to scan. *(Accuracy/VIDS upload)*
- Measuring completeness of data for pilot sites was difficult to quantify, but there was a perceived improvement in completeness. *(Completeness)*
- Data matrix bar code read better on flat surfaces e.g. vaccine boxes vs. vials. *(Usability)*

AIVP Proposed Standards

1. Bar Code Content:
   - Encoded the following data into bar codes on both the primary & the secondary vaccine packages:

     GTIN (GS1-14[5]) + 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

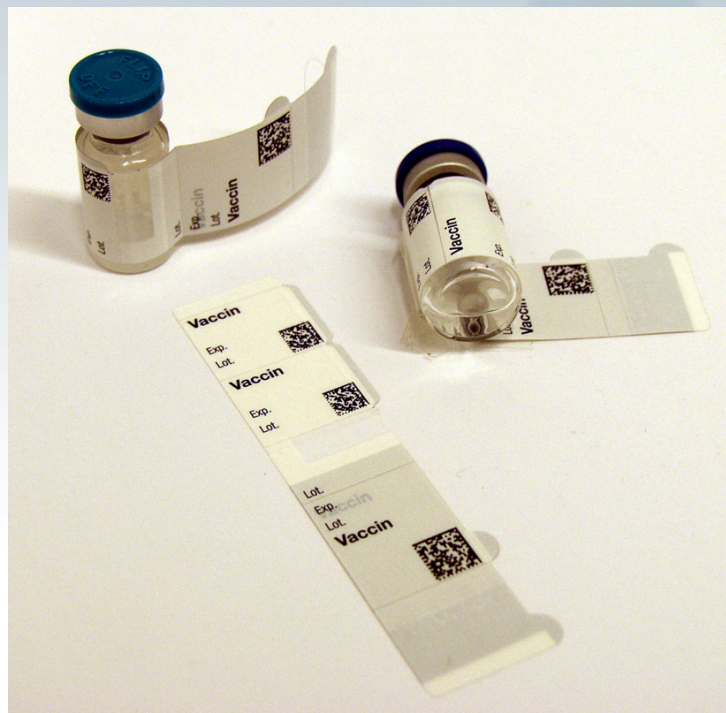
     GTIN + Expiry Date +Lot #

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.

[5] ***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.*

AIVP Proposed Standards

4. Peel-off/Detachable Labels:
   - Two peel-off labels, with bar code[6] & human readable information[7], 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.



[6] ***Bar code content*** *– GTIN, Expiry Date and Lot #*
[7] ***Human readable information*** *– Vaccine Trade Name, GTIN, Expiry Date and Lot #*

Next Steps (bar coding)

- Work with industry and regulators to:
  - finalize standards for bar coding of vaccine packages;
  - implement bar code standards on vaccine products.
- Publish and post:
  - standards for bar coding of vaccine packages;
  - technical standards for incorporating bar coding service with immunization applications/registries.
- Develop an implementation strategy for roll-out of bar coding capabilities in jurisdictions.

Next Steps (VIDS)

- Ongoing development of VIDS Phase II:
  - Host a VIDS design review to finalize user requirements for VIDS Phase II.
  - Evaluate the feasibility of VIDS to determine the potential usage of an online public portal.
  - Load vaccine-specific data into VIDS.
    - Finalize data sources (DPD, CIHI, NACI, vaccine manufacturers etc.)
    - Create automated processes for managing data updates
    - Validation of data entered into VIDS: review committee
    - Ongoing maintenance of VIDS data

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Questions…

In Closing…

- Vaccines have an exceptional safety record but complete and accurate recording of their administration is "best practise" and at present does not consistently occur.
- Bar coding of vaccines will facilitate:
  - efficient and accurate recording of vaccine administration at the level of the provider, and will tie into the electronic health record, immunization registries, and surveillance of adverse events following immunization;
  - more efficient and accurate inventory management;
  - linkages to systems (e.g. VIDS) that store reliable, comprehensive information on vaccine products.

Our thanks to…

- …CIRN for their valuable input and ongoing collaboration on this initiative;
- …the AIVP Pilot Participants for their time and expertise in testing the bar coding technology;
- …Health Canada for providing guidance on regulations and sharing vaccine-specific data with us;
- …our national and international counterparts for being a source/helping direct us to important sources of information;
- …the vaccine manufacturers for your interest in the project and for working with us to help us achieve our goal;
- …GS1 for helping us promote this initiative internationally, for guidance on the use of e-commerce standards and for leading us to valuable contacts.

"To Err Is Human…"

"People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer. "

Extracted from "To err is Human: Building a Safer Health System"

Project Contacts…

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