Enabling vaccine traceability in Canada using GS1 Standards

The Public Health Agency of Canada's Automated Identification of Vaccine Project

ABSTRACT

The Public Health Agency of Canada's (PHAC) Automated Identification of Vaccine Projects (AIVP) initiative was established in 2002 to improve the safe use of vaccines, as well as immunisation record keeping, by incorporating standardised bar codes onto vaccine product labeling. To examine this issue, PHAC established the AIVP Advisory Task Group, a collaborative effort between all stakeholder groups in the area of immunisation, co-chaired by PHAC and the vaccine industry, including key representation from GS1 Canada. In 2010, the AIVP Advisory Task Group reached consensus on the use of GS1 Standards for the identification of vaccine products approved for use in Canada.

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Introduction

Over 20 million doses of vaccines are administered in Canada every year, with each patient's health record manually updated by Healthcare providers to track the details of the vaccination. However, such transcription of the details of the vaccine given may not be accurate or complete. Studies examining immunisation records in the provinces of British Columbia and Manitoba estimated that between 5 and 15 percent of patient immunisation records are missing core data elements. Up to 24 percent of records lack data or contain errors that can cause barriers to detailed follow-up of adverse events following an immunisation.

In order to reduce costs associated with correcting errors, support the use of electronic information systems, minimise manual data entry, and enhance patient safety through improved vaccine traceability – from the point delivery of a vaccine to its administration – the Public Health Agency of Canada (PHAC), GS1 Canada, and the Vaccine Industry Committee of BIOTECanada (VIC), are working to determine the Canadian requirements for product identification in the global standards-setting process.

At the Point-of-Care

The idea of bar coding vaccines in Canada is not a recent development. The potential benefits of vaccine bar coding for both inventory management and efficient population of immunisation registries have been evident for over a decade, stimulated by the increasing number of vaccines in use in Canada.[1] The collaboration with GS1 Canada supports PHAC's immunisation traceability initiative, the Automated Identification of Vaccine Projects (AIVP). Established in 2002, the initiative's goal is to improve the safe use of vaccines as well as immunisation record-keeping by incorporating bar codes onto vaccine product labeling.

The AIVP initiative was developed in response to a resolution passed in 1999 by the National Advisory Committee on Immunization (NACI), a longstanding group of experts that develop evidence-based recommendations for vaccine use in Canada. NACI recommended that bar codes be placed on all vaccine products to facilitate much needed cost savings in Healthcare, improve patient health record-keeping, and ultimately the safe use of vaccines. In support of this

1 Naus, Monika. Bar Coding Vaccines – More than a "check-out" issue. Invited editorial. Canadian Journal of Infectious Diseases, July/August 2000; 11(3): 173-4.

recommendation, NACI recommends the following variables related to the identity of the vaccine be recorded on the patient record: trade name of the product, disease(s) against which it protects, dose, manufacturer and lot number.[2]

Bar code enabled identification of a vaccine, when used in conjunction with an electronic system that has built-in product recognition functionality, has the potential to optimise the safe administration of vaccines. For instance, an optimally configured system could identify that a patient has already received the vaccine, or that the vaccine has expired, prior to its administration. As well, bar code enabled product identification facilitates complete recording of the product, format and lot number should an adverse event requiring lot-specific follow-up occur in the future.

While vaccines have an admirable safety record, lot specific investigations in recent years have occurred with the measles, mumps and rubella vaccine[3] and the adjuvanted 2009 H1N1 pandemic vaccine,[4] complete electronic data would obviate the need for paper-based record searches and limitations in investigations hampered by missing data.

Ensuring public confidence in the Healthcare system to handle vaccine products and their administration in as safe a manner as possible is yet another benefit that can be realised through the AIVP initiative.

First steps

In the initial phase of the project, PHAC, in collaboration with VIC, established the AIVP Advisory Task Group to support the use of product identification based on global standards. A collaborative effort between all stakeholder groups in the area of immunisation and co-chaired by PHAC and VIC, the Task Group included representation from vaccine manufacturers, provincial/territorial jurisdictions, health authorities, health professional associations, regulators, international standard setting agencies, electronic health record (EHR) and clinical management software developers, as well as key representation from GS1 Canada.

The AIVP Advisory Task Group developed a five year strategic plan, spanning from 2008 to 2013. One of the first missions was the undertaking of an independent cost-benefit analysis for the adoption and implementation of bar coding of vaccine products. This cost-benefit analysis is the first of its kind, determining the return on investment (ROI) of implementing GS1 Standards in the Canadian vaccine industry. Previously, studies on Healthcare information technology were chiefly concerned with electronic health records and patient administrative processing, with research on bar coding in Healthcare primarily focused on medicines and patient bedside tracking.[5] For example, previous studies included reviews of the errors resulting from early or late administration of medications to determine their potential to harm patients[6], or how bar coding patient identification tags, caregiver badges, and immediate-container medications can increase patient safety during medication administration.[7]

2 Canadian Immunization Guide, 7th Edition, 2006. Part I, General Guidelines, Immunization Records. Public Health Agency of Canada. Text Prepared by the National Advisory Committee on Immunization. www.phac-aspc.gc.ca/naci-ccni/index-eng.php

3 MMR Vaccine Recall Issued by Merck in Canada After 5 Injuries. www.newsinferno.com/legal-news/mmr-vaccine-recall-issued-by-merck-in-canada-after-5-injuries/, December 14, 2007.

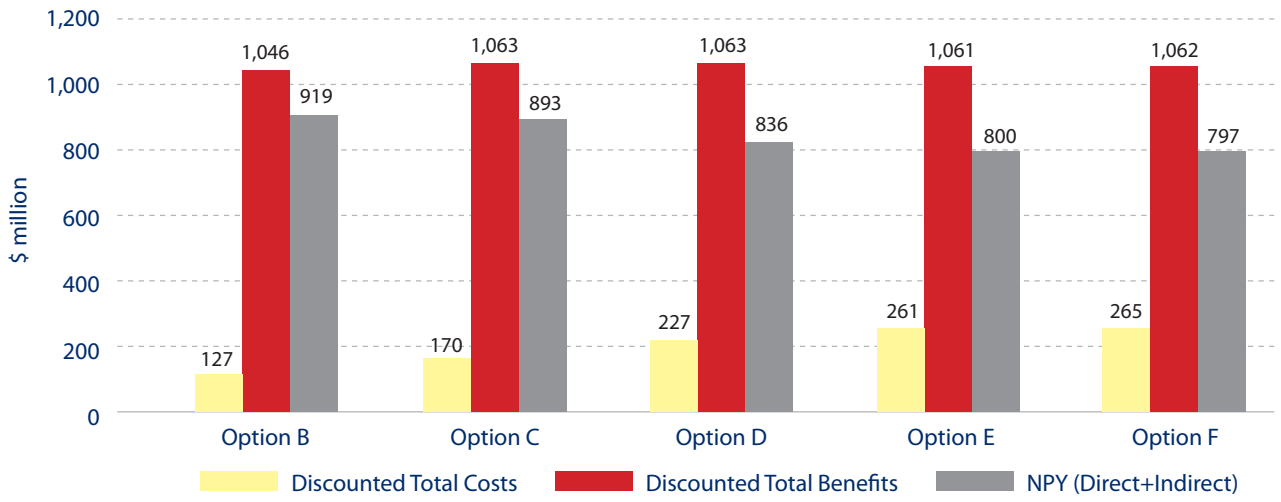
4 Health Canada, Drugs and Health Products. www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/qual-vaccin-eng.php. March 19, 2010.

5 Cost-Benefit Analysis for Adoption and Implementation of the Automated Identification (Bar Coding) of Vaccine Products, Final Report. February 6, 2009. HDR|Decision Economics

6 Poon, Eric G et al. Effect of Bar-Code Technology on the Safety of Medication Administration, The New England Journal of Medicine. May 6, 2010.

7 Neuenschwander, M et al. Practical guide to bar coding for patient medication safety, American Journal of Health-System Pharmacy. Vol 60, April 15, 2011.

Figure 1: **Quantifiable results of CBA**
Costs, Benefits, and Net Present Value



Cost-benefit analysis

The cost-benefit analysis was completed in February 2009 by HDR | Decision Economics (HDR) and focused on achieving three main objectives: reviewing previous documentation concerning potential costs and benefits associated with implementing the GS1 bar code on vaccine products; providing a description and enumeration, where possible, of the relevant costs and benefits based on implementation options; and ultimately recommending the preferred bar coding options with supporting rationale.

Six different bar code implementation options were selected by the AIVP Advisory Task Group and the Implementation Options Task Group, a temporary sub-group set up to carry out this specific task. These six options varied in technical detail and the relative cost and benefits anticipated. The options, labeled A through F, considered bar coding primary (vial or ampoule containing the vaccine) and secondary packaging (the carton which is the unit of issue and contains one or multiple doses of the vaccine product), one dimensional (1D) versus two dimensional (2D) bar codes, as well as bar codes carrying variable data (lot number and expiration date) versus non-variable data.[5]

This cost-benefit analysis examined the savings the Healthcare system could realise compared to what was labeled Option A, which was considered the status quo at the time. The costs and benefits of each option were assessed based on an assumption that 2012 would be the year of implementation for all the options. In order to better understand the long-term versus short-term costs, the cost-benefit analysis evaluated costs over a 20-year evaluation period for each option. The analysis concluded that Options B through F were expected to have a "significantly positive net present value, ranging from CA$797 million to CA$919 million (mean estimates, 2008 dollars)."[5]

The cost-benefit analysis was the first such analysis conducted on this issue, and concluded that significant ROI could be achieved by implementing the GS1 bar code on vaccines. It indicated that, as technology in the Healthcare sector improves and as new vaccines are launched, the cost savings and efficiencies achieved would continue to increase.

Consensus: The GS1 Bar Code System

One of the primary objectives of the AIVP Advisory Task Group was to develop a proposed standard for bar codes on vaccine products in Canada by working with GS1 Canada and taking into consideration the results of the cost-benefit analysis. In February 2009, at their annual meeting, the Task Group reached a consensus on the Canadian bar code proposed standards for vaccine products.

The AIVP Advisory Task Group agreed on the following recommendations to bar code vaccines in Canada, documented in the Canadian Consensus Statement on Proposed Standards for Bar Codes on Vaccine Products released in late 2009:

- 2D bar codes on the primary package, which include the Global Trade Item Number (GTIN) and the lot number
- 2D or linear (also known as 1D) bar codes on the secondary package, which include the GTIN and the lot number [8]

By identifying primary and secondary packaging, electronic health records can be maintained efficiently and completely, the number of immunisation errors are reduced due to complete and accurate record-keeping and any follow-up resulting from immunisation is sped up. In addition, inventory management and vaccine supply chain forecasting are improved, which results in fewer interruptions in supply and less wastage due to expiry.[8]

8 Lamarche, Louis et al. Canadian Consensus Statement on Proposed Standards for Bar Codes on Vaccine Products. 2009.

Figure 2: **Quantifiable Benefits and Analysis**[5]

QUANTIFIABLE COSTS	QUANTIFIABLE BENEFITS
• Pre-development work • Development and implementation of agreed upon standards • Bar code design development • Database development: The Vaccine Identification Database System (VIDS) and ongoing data collection and maintenance • Database configuration – immunisation registry • Scanner purchase and replacement • Redesign of procedures and layout at clinics • Redesign of procedures at manufacturing plants • Bar code printing • Training practitioners	• Time savings (bar code scanning vs. manual entry) – Patient and practitioner • Improved immunisation record completeness and accuracy – Decrease in number of vaccine-preventable disease incidents – Quicker follow-up (time savings) to adverse events following immunisation • Reduction in supply shortages – Decrease in social costs from insufficient supply • Fewer re-immunisations – Cost of immunisation – Time savings (patient and practitioner) • Improved supply chain management – Reduced waste – Reduced inventory holding costs

The GS1 bar codes of choice[8]

GS1 DataMatrix

Increasingly the bar code of choice in Healthcare is the 2D bar code, or GS1 DataMatrix. This format is resilient, holding up well on products that are handled frequently. Its benefits include the ability to provide a significant amount of information on a very small surface such as a vaccine vial.

Figure 3: **GS1 DataMatrix**

(01)07612345678900(17)100503
(10)AC3453G3

GS1 DataBar™

Both linear and 2D, the GS1 DataBar™ is also appropriate for vaccines due to its small size.

Figure 4: **GS1 DataBar™**

GS1 - 128

GS1 -128 is linear in structure and already used on products throughout the world.

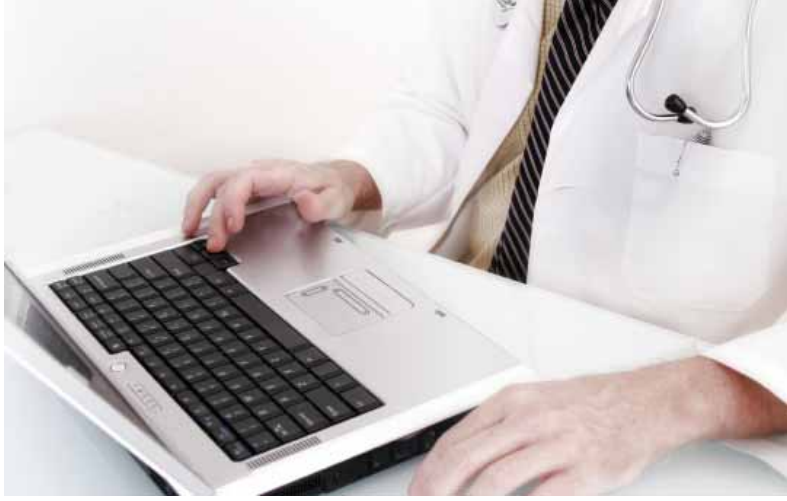
Figure 5: **GS1-128**

The Vaccine Identification Database System (VIDS)

In addition to the AIVP Advisory Task Group's work to determine the Canadian requirements for product identification in the global standards setting process, the AIVP project is also pursuing the development of the VIDS, set to become the single, web-based repository of comprehensive information on all vaccines licensed for use in Canada.

The VIDS is being established to act as the link between bar coded vaccines, including travel vaccines, which are not publicly funded in Canada, and the electronic health record or immunisation registry. More specifically, when a Healthcare worker scans the bar code on a vaccine, the VIDS will enable vaccine information to be electronically populated into a patient's health record. Available for access by all Healthcare professionals in Canada, the VIDS will help support the tracking and administration of vaccines at point-of-care by leveraging GTINs as an identifier. The GTIN is recommended in place of the Canadian Drug Identification Number (DIN), which is neither unique to the format of the product nor is it used outside Canada, limiting the interoperability of the supply chain across borders. In order to support population of the VIDS, GS1 Canada will be working with Canadian vaccine manufacturers to publish vaccine product information to the VIDS currently loaded to ECC net Registry, a comprehensive and continually-validated product registry in Canada. Managed by GS1 Canada, ECCnet Registry enables Canadian suppliers across various sectors to share their product data with providers and/or retail trading partners.

Product attribute fields in ECCnet Registry that will be fed to the VIDS were determined by Canadian industry to meet the demands of Canadian businesses for trading partner transactions such as product listing.



Any information that is not available in ECCnet Registry will be manually entered into the VIDS by PHAC or received electronically from the regulatory agency within Health Canada. This information could include transaction information such as lot number or serial number. In support of the use of vaccine product identification based on global standards, the AIVP Advisory Task Group has set milestones for every vaccine sold and/or marketed in Canada to have an assigned GTIN at both the primary and secondary packaging levels, using bar codes that include variable date information.

Next steps

Over the next year, the AIVP Advisory Task Group will continue conducting its comprehensive assessment of the state of readiness of public health, private health and hospitals to use bar code technology, which began in 2009. The results of this assessment will guide the Canadian Healthcare sector's next steps as it continues to work towards implementing the standards for bar coding on vaccine products.

GS1 Canada is now leading the Implementation Roadmap Work Group, which is working to identify product identification, technology, and education timelines required to support immunisation traceability in Canada using the GS1 System of standards. As of 2011, this Work Group is currently assessing the capabilities of Canadian manufacturers to bar code their vaccine products with variable data on primary packages and create a work plan to operationalise the VIDS and populate supplier data.

ABOUT THE AUTHORS

Dr. Monika Naus, MD MHSc FRCPC FACPM, Associate Director, Epidemiology Services, British Columbia Centre for Disease Control

Dr. Naus obtained her medical training in Canada at the University of Alberta and her training in community medicine at the University of Toronto. Prior to joining the British Columbia Centre for Disease Control in 2001, she was the Provincial Epidemiologist in Ontario and Senior Medical Consultant in Vaccine Preventable Diseases and TB Control for the Ontario Ministry of Health. In addition, Dr. Naus was member of the National Advisory Committee on Immunization for 12 years, including acting as chair person between 2003-2007.

Her interests include various aspects of planning and evaluation of old and new immunization programs, surveillance of communicable diseases, and outbreak investigation, including participating on the Automated Identification of Vaccine Products (AIVP) Advisory Task Group.

Dr. Robert Van Exan, PhD, Director, Immunization Policy, Sanofi Pasteur Limited

Dr. Van Exan joined Sanofi Pasteur in 1981 as a cell biologist and manager of the Cell Culture Production Department – Viral Vaccine Production Division. Since 2002, he has been the Director of Immunization Policy and is responsible for industry collaboration and input for the development of a national immunization strategy in Canada.

A member of various advisory boards, he is a founding chair of the Vaccine Industry Committee of BIOTECanada. In addition, Dr. Van Exan is a current member of the Automated Identification of Vaccine Products (AIVP) Advisory Task Group and a co-chair of the GS1 Canada Healthcare Pharmacy Sector Board.