British Columbia Data Standards

Minimum Immunization Data Set Interoperability Guide

Version: 1.0
October 23, 2017

Sponsors
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Canada Health Infoway

DOCUMENT CONTROL

DOCUMENT HISTORY

Version	Author	Date	Notes
0.1	V Brown	2017-03-23	Draft Based on IIWG materials
0.2	J Reedijk	May 10 2017	Refined and updated for BC
0.3	M Kashyap	Sept. 27, 2017	Refined and Format consistency
0.4	V Brown	October 16, 2017	Final review
1.0	J Reedijk	October 23, 2017	Final Version

Version recording:

Large or small edits to the context or structure of the document that must be signed off on are to be regarded as significant edits and marked with whole numbers, e.g. 1.0,2.0,3.0 etc.

Edits not altering the context, structure, or not requiring sign off are regarded as minor edits and minor version updates and will be marked with 1.5, 2.5, 3.5, etc. following the last significant edit

APPROVAL & SIGN-OFF

This Minimum Data Set has been reviewed, approved and endorsed by the following sponsors as listed below and made FINAL in British Columbia on December 7, 2016. All executive stakeholders and sponsors have a common understanding of and agree with the purpose and scope as described within this document.

National Executive Sponsor	Canada Health Infoway and the National Immunization Interoperability Working Group	Date: May 2016
BC Executive Sponsor	Jill Reedijk, Director, Clinical Information Solutions, PHSA	Date: May 2016
Health Information Standards Standing Committee (HISSC)	Consensus approval for Complete Data Set and Minimum Data Set for Interoperability	Date: Dec 2016
BC Ministry of Health	Conformance and Integration Services	Date: Oct 2017

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BACKGROUND AND RATIONALE

Background

Canada Health Infoway in collaboration with numerous national immunization stakeholders has developed a standard for the exchange of immunization data between systems in Canada. The stakeholders included pan-Canadian community and public health vaccine providers: nurses, physicians and pharmacists, surveillance and epidemiology, vendors and clinical informatics specialists. This data standard prescribes the Minimum Immunization Data Set (MIDS) to be used in the various business scenarios defined by the clinical stakeholders of the Immunization Interoperability Working Group.

Additionally, the standard describes a more fulsome list of variables approved in British Columbia (B.C.) to support best practice in documentation of immunizations services by B.C. vaccine providers.

Following national development and approval of the standard, provincial and territorial jurisdictions in Canada may seek further endorsement from their provincial standards bodies.

Purpose

This standard is intended to be applied to all forms of electronic transfer of Immunization information.

The purpose of this MIDS is to enable data exchange between immunization systems. In B.C. it is expected to be used between Panorama (the immunization repository for B.C.) and PARIS (the immunization system used by Vancouver Coastal Health), and Electronic Medical Record (EMR) solutions used by community vaccine providers.

Ideally, all immunizers in the province will be able to conform to this approved data set to establish an exchange of data from their system (sending immunizations provided to clients) to the repository and in return, either receive or be able to view the complete client history and recommended immunizations the client has yet to receive.

This MIDS supports interoperability of immunization data, (i.e., the ability to exchange data with meaning) which is essential as immunization records are consolidated and transferred across the health care system (e.g., messaging between EMRs and the provincial immunization repository). This standard will further enable the province to reach its vision of having an immunization repository for all immunizations for all British Columbians.

Strategic Alignment

Panorama is the strategic platform for province wide public health information and the Provincial Immunization Repository. Once implemented, this MIDS will allow Panorama to integrate and receive immunization data from other systems within and outside of the provincial health network (i.e. community vaccine providers including physicians, pharmacies and travel clinics) rather than limited to those provided by public health units.

SCENARIO DEFINITIONS AND CONFORMANCE

Submit to repository: administered immunization record

- Clinician has the "vial in hand" and therefore can provide specific details on the event including the product, client, and clinician details.

Submit to repository: reported immunization record

- Clinician or client / parent is reporting on an immunization that was previously administered ("historic event"). The information may be provided as a verbal or written report.
- Complete and accurate details on the product and /or event may or may not be available. Fewer data elements are required, but all information is accepted if available.

Response from repository: view client immunization history and forecast (recommended vaccines)

- Clinician, community vaccine provider or client / parent is viewing a client's immunization history.
- Clinician, community vaccine provider or client / parent is viewing the recommended “forecasted” immunizations for the client.

Conformance Levels	Description of Data Element Usage Level
Mandatory:	Data elements that are highly desirable to be supported for the use case(s) for accurate and complete recording and immunization coverage surveillance data (even if not required by the message specification). **Message will be rejected if not provided.**
Required:	Data elements that are required for some aspect of the immunization record AND without which accurate forecasting (which drives under or over immunizing) would not be possible. **Message will not be rejected if not provided.**
Not Required:	These data elements can be derived from other sources when pan-Canadian subsets are used or are not applicable.

IMMUNIZATION MINIMUM DATA SET

Mandatory Variables – subset (*Message fails if absent*)

HIGH LEVEL DATA SET		
Information Sent To Repository		
Data Element	**2.1 "Vial in Hand"**	**2.2 "Historic Event"**
Immunizing Agent (Generic)		Mandatory
Immunizing Agent (specific Trade Name provided)	Mandatory	
Date/Time of Immunization	Mandatory	Mandatory
Reporting Source		Mandatory
Lot Number and Expiry Date	Mandatory	
Information Received From Repository		
Data Element	**2.3 "Client History"**	**2.4 "Recommended**
Immunizing Agent (Generic)	Mandatory	
Immunizing Agent (specific Trade Name provided)		Mandatory
Date/Time of Immunization	Mandatory	
Reporting Source	Mandatory	
Recommended Immunizations "current as of" date		Mandatory
Recommended Date for Immunization		Mandatory
Status of Recommended Immunization (Due/Overdue, Etc)		Mandatory

Complete Immunization Data Set

- Recommended for fulsome Immunization Records
- Message only fails when Mandatory variable is absent

DETAILED DATA SET		
Information Sent To Repository		
Data Element	**2.1 "Vial in Hand"**	**2.2 "Historic Event"**
Immunizing Agent (Generic)		Mandatory
Immunizing Agent (specific Trade Name provided)	Mandatory	
Date/Time of Immunization	Mandatory	Mandatory
Estimated Date flag		
Reporting Source		Mandatory
Lot Number and Expiry Date	Mandatory	
Manufacturer		
Dose volume and Unit of measure		
Route of Administration		
Anatomical Site		
Additional Notes/Comments		

DETAILED DATA SET		
Information Received From Repository		
Data Element	**2.3"Client History"**	**2.4 "Recommended Immunizations"**
Immunizing Agent (Generic)	Mandatory	
Immunizing Agent (specific Trade Name provided)		Mandatory
Date/Time of Immunization	Mandatory	
Estimated Date flag		
Reporting Source	Mandatory	
Lot Number and Expiry Date		
Manufacturer		
Dose volume and Unit of measure		
Route of Administration		
Anatomical Site		
Additional Notes/Comments		
Recommended Immunizations "current as of" date		Mandatory
Recommended Date for Immunization		Mandatory
Status of Recommended Immunization (Due, Overdue, EtcEtc.)		Mandatory

Data Element Details

DATA ELEMENTS		
Description	**Conformance**	**Requirements**
Immunizing Agent (Generic)		
Generic representation of the formulation administered to a client that includes one or more specific antigen(s) aimed at developing an immune response in an individual to provide protection from vaccine preventable infectious disease(s).	2.1 Vial in Hand Not Required	The values to support this data element include both active immunizing agents (vaccines), used for the prevention of infection, and passive immunizing agents, used in certain circumstances when vaccines have not been used before exposure to the infective agent (e.g., rabies immunoglobulin). This data element should be sent to the JIS when the trade name is not known or required. See the Clinical Requirements for recommendations for use at the point of care. The Immunizing Agent can be derived from Administrable Immunizing Agent. Data type – Coded
	2.2 Historic Event Mandatory	
	2.3 Client History Mandatory	
	2.4 Recommended Immunizations Not Required	

Immunizing Agent (specific Trade Name provided)		
Product formulations administered to a client that include one or more specific antigen(s). Aimed at developing an immune response in an individual to provide protection from infectious disease(s) and include: the trade name, immunizing agent and manufacturer.	2.1 Vial in Hand Mandatory 2.2 Historic Event Required 2.3 Client History Required 2.4 Recommended Immunizations Mandatory	The values to support this data element include both active immunizing agents (vaccines), used for the prevention of infection, and passive immunizing agents, used in certain circumstances when vaccines have not been used before exposure to the infective agent (e.g., rabies immunoglobulin). See the Clinical Requirements for recommendations for use at the point of care. The Administrable Immunizing Agent, along with the Lot Number and Expiry Date, uniquely identifies an immunizing product. Data type –Coded
Date/Time of Immunization		
The date and time (if available) that the immunization was administered to the client.	2.1 Vial in Hand Mandatory 2.2 Historic Event Mandatory 2.3 Client History Mandatory 2.4 Recommended Immunizations Not Required	Used to facilitate immunization coverage surveillance and to assess whether the client is protected against a particular disease, i.e., up to date, eligible, due or overdue for vaccine(s). Partial dates should not be sent to the JIS when complete dates are not known (i.e., must populate DD/MM/YY). To be used in conjunction with "Estimated Date Flag". Data type – date / time

Estimated Date flag		
A flag to indicate the recorded date that the immunization was administered to the client was estimated.	2.1 Vial in Hand Not Required	Used to indicate that an estimate date was recorded for a particular immunization event as part of the client history. Jurisdictions may have different business rules for dealing with partial or estimated dates. Data type – Boolean
	2.2 Historic Event Required	
	2.3 Client History Required	
	2.4 Recommended Immunizations Not Required	
Reporting Source		
Source of information regarding the reported immunization event.	2.1 Vial in Hand Not Required	Confidence in the accuracy of the immunization record is dependent on the source: e.g., client / parent documented; client / parent undocumented; provider documented; provider undocumented. This is important in reviewing the client history and the risk / benefit decision whether it is necessary to re-vaccinate a client. Data type – Coded Recommended that the System be included in the value.
	2.2 Historic Event Mandatory	
	2.3 Client History Mandatory	
	2.4 Recommended Immunizations Not Required	

<table>
<tr><th colspan="3">Lot Number and Expiry Date</th></tr>
<tr><td rowspan="4">The lot number of the Administrable Immunizing Agent, as assigned by the manufacturer.

The Expiry date, assigned to the administrable immunizing agent by the manufacturer, after which the agent should not be administered as product integrity cannot be guaranteed.</td><td>2.1 Vial in Hand
Mandatory</td><td rowspan="4">The Administrable Immunizing Agent, along with the Lot Number and Expiry Date, uniquely identifies an immunizing product.

Lot number is not always unique.
Data type – string, e.g., C3721AS

Expiry date is a key variable in vaccine recalls because each lot number may have more than one expiry date. Expiry date may be changed (reduced) due to a cold chain break.
Data type – date / time</td></tr>
<tr><td>2.2 Historic Event
Required</td></tr>
<tr><td>2.3 Client History
Required</td></tr>
<tr><td>2.4 Recommended Immunizations
Not Required</td></tr>
<tr><th colspan="3">Manufacturer</th></tr>
<tr><td rowspan="4">Manufacturer of the Administrable Immunizing Agent</td><td>2.1 Vial in Hand
Required</td><td rowspan="4">Currently used for analytics (jurisdictional and federal), particularly for vaccine inventory. It can be derived from trade name (Administrable Immunizing Agent).

Data Type – coded or string</td></tr>
<tr><td>2.2 Historic Event
Required</td></tr>
<tr><td>2.3 Client History
Not Required</td></tr>
<tr><td>2.4 Recommended Immunizations
Not Required</td></tr>
</table>

Dose volume and Unit of measure (UOM)		
The liquid volume of the dose injected; e.g., influenza dose is 0.25 or 0.5, depending on client age. UOM is used to specify the units for dose volume quantities	2.1 Vial in Hand Required 2.2 Historic Event Required 2.3 Client History Required 2.4 Recommended Immunizations Required	For products such as influenza, Hepatitis B vaccines, and passive agents, the recommended volume of product to be injected may vary (based on client age or weight) and may impact the client's immunization forecast. Business rules could be created for the specific agents where this is applicable. The dose (e.g. 15 micrograms per 0.5 mL) and dose volume (e.g. 0.5 mL) of the product could potentially be derived or available from some of the Administrable Immunizing Agents, and allow the user to modify the value at the point of service. Data type – string UOM is used together with the Dose Volume data element. For products such as influenza Hepatitis B vaccines and passive agents, the volume of product injected may vary and can impact the client's immunization forecast. At this moment the only unit of measure in use is "mL". Note: Can be derived from some Administrable Immunizing Agents. The default value for dose volume unit of measure could be "mL" but should be configurable at the point of service. Data type – Coded

Route of Administration		
Route by which the immunizing agent is administered to the body (intramuscular injection, subcutaneous injection, oral, etc.).	2.1 Vial in Hand Required	Part of record of immunization event - assists with adverse event management (e.g., was the correct route of administration used, or is this an administration error?). May be considered for client forecast (i.e., valid or invalid dose) if the incorrect route is used. The coded values for this data element should align with those used for the broader drug management domain. Data type – Coded
	2.2 Historic Event Required	
	2.3 Client History Required	
	2.4 Recommended Immunizations Not Required	
Anatomical Site		
Site by which the immunizing agent is administered to the body	2.1 Vial in Hand Required	It is important to record where the immunizing agent was delivered to the body in the event of a reported local reaction to a vaccine. When multiple agents are administered to multiple sites on the body, anatomical site helps determine which vaccine may have been responsible. The coded values for this data element should align with those used for the broader drug management domain. Data type –coded
	2.2 Historic Event Required	
	2.3 Client History Required	
	2.4 Recommended Immunizations Not Required	

Additional Notes/Comments		
Additional information relevant to the immunization record.	2.1 Vial in Hand Required	The note is specific to the immunization event, agent or antigen Data type – String
	2.2 Historic Event Required	
	2.3 Client History Required	
	2.4 Recommended Immunizations Required	
Recommended Immunizations "current as of" date		
The date the client's immunization forecast was generated.	2.1 Vial in Hand Not Required	The date the forecast is generated is needed because a client's immunization forecast changes over time, depending on the interval of time between vaccines, the client's age and other risk factors (e.g. pregnancy). Data type – date / time
	2.2 Historic Event Not Required	
	2.3 Client History Not Required	
	2.4 Recommended Immunizations Mandatory	

<table>
<tr><th colspan="3">Recommended Date for Immunization</th></tr>
<tr><td rowspan="4">The date provided in the client’s immunization forecast.

Date Type provides an indication of the type of date in the forecast.</td><td>2.1 Vial in Hand
Not Required</td><td rowspan="4">This data element must align and be used with the Immunization Forecast Type data element: the date provided in the forecast.
Data type – date / time

This data element must align and be used with Immunization Forecast Date data element: e.g., the date provided in the forecast may be the eligible date (the earliest acceptable) or the due date (the recommended date) for administration of the vaccine.
Data type – Coded</td></tr>
<tr><td>2.2 Historic Event
Not Required</td></tr>
<tr><td>2.3 Client History
Not Required</td></tr>
<tr><td>2.4 Recommended Immunizations
Mandatory</td></tr>
<tr><td colspan="3">Status of Recommended Immunization (Due, Overdue, Etc.)</td></tr>
<tr><td rowspan="4">Represents the client's requirement for a particular Administrable Immunizing Agent.</td><td>2.1 Vial in Hand
Not Required</td><td rowspan="4">Provides detail for the client on the Administrable Immunizing Agent in the forecast, e.g., whether a client is due for a vaccine (the recommended time) or overdue.
Data type – Coded</td></tr>
<tr><td>2.2 Historic Event
Not Required</td></tr>
<tr><td>2.3 Client History
Not Required</td></tr>
<tr><td>2.4 Recommended Immunizations
Mandatory</td></tr>
</table>

SCOPE AND ASSUMPTIONS

Scope

The following are out of scope for the Minimum Data Set:

1. Messaging Standards/ Requirements
    a. A technical working group should determine the messaging approach for exchanging the data
2. Various specific data elements related to Immunizations are out of scope, but may be developed at a later time. These include:
    a. Adverse Events
    b. Allergies
    c. Conditions impacting Immunization
        i. I.e. Panorama: Special Considerations, Deferrals, Risk Factors
        ii. I.e. PARIS: Imms Alerts

Assumptions

1. Client Matching and demographic information handling are assumed to be determined by jurisdictions prior to exchange of the immunization information
2. Systems will negotiate the standards of exchange between them – i.e. if a system sending to the repository meets the standards for “Vial in Hand” or if all records will be sent as “Historical Events”

PROVINCIAL READINESS

The following represents the current immunization systems in use in BC and the existence of data elements required for the MIDS.

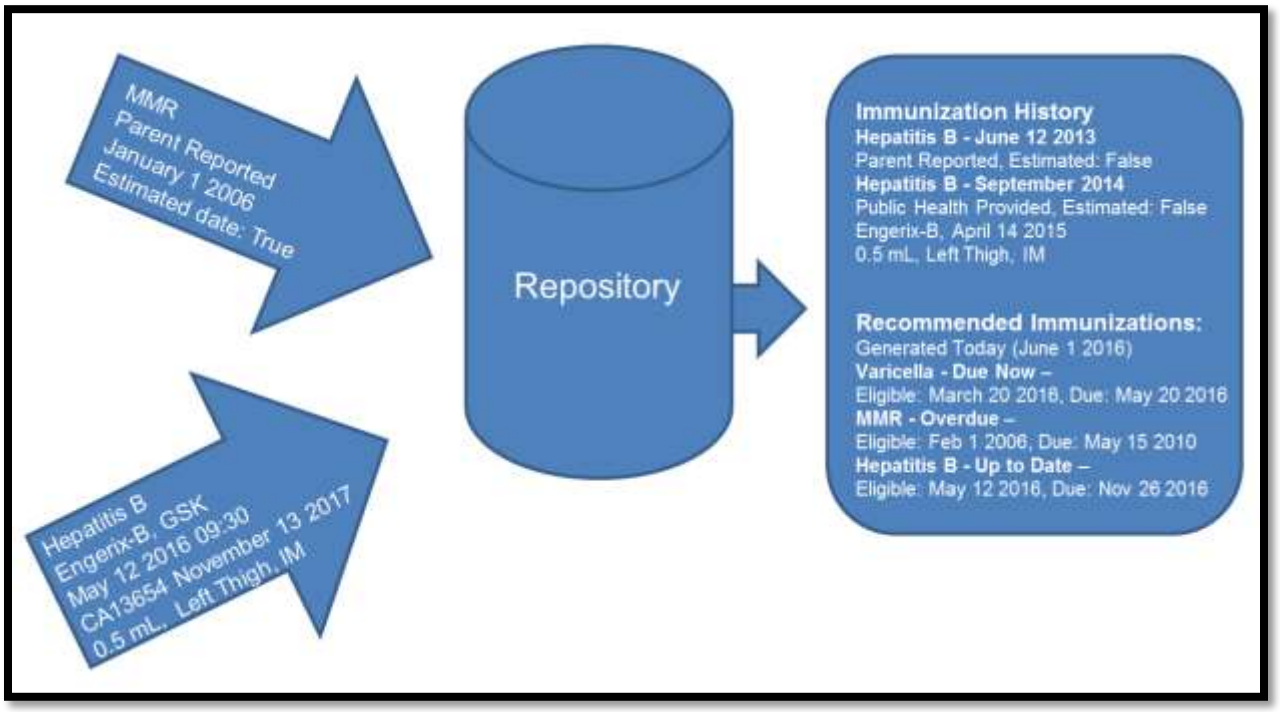
Data Elements Required for Minimum Data Set			
Data Element	**Panorama**	**PARIS**	**IntraHealth [1]**
Immunizing Agent (Generic)	√	√	√
Immunizing Agent (specific Trade Name provided)	√	√	Via Lot #[2]
Date/Time of Immunization	√	√	√
Estimated Date flag	√	√	TBD
Reporting Source	√	External vs Internal[3]	External vs Internal
Lot Number and Expiry Date	√	√	√
Manufacturer	√	Via Lot #	Via Lot #
Dose volume and Unit of measure	√	√	√
Route of Administration	√	√	√
Anatomical Site	√	√	√
Additional Notes/Comments	√	√	√
Future Immunization Recommendation for Client (Forecasted/Planned, Immunization Decision Support)	√	√	TBD

1. Intrahealth used as an example of EMR used in BC
2. With Lot # - any details around tradename and manufacturer can be derived
3. External vs Internal → Either a user of the system, i.e. a PHN or MD using PARIS/Intrahealth or a “done elsewhere – i.e. Out of country, or province”

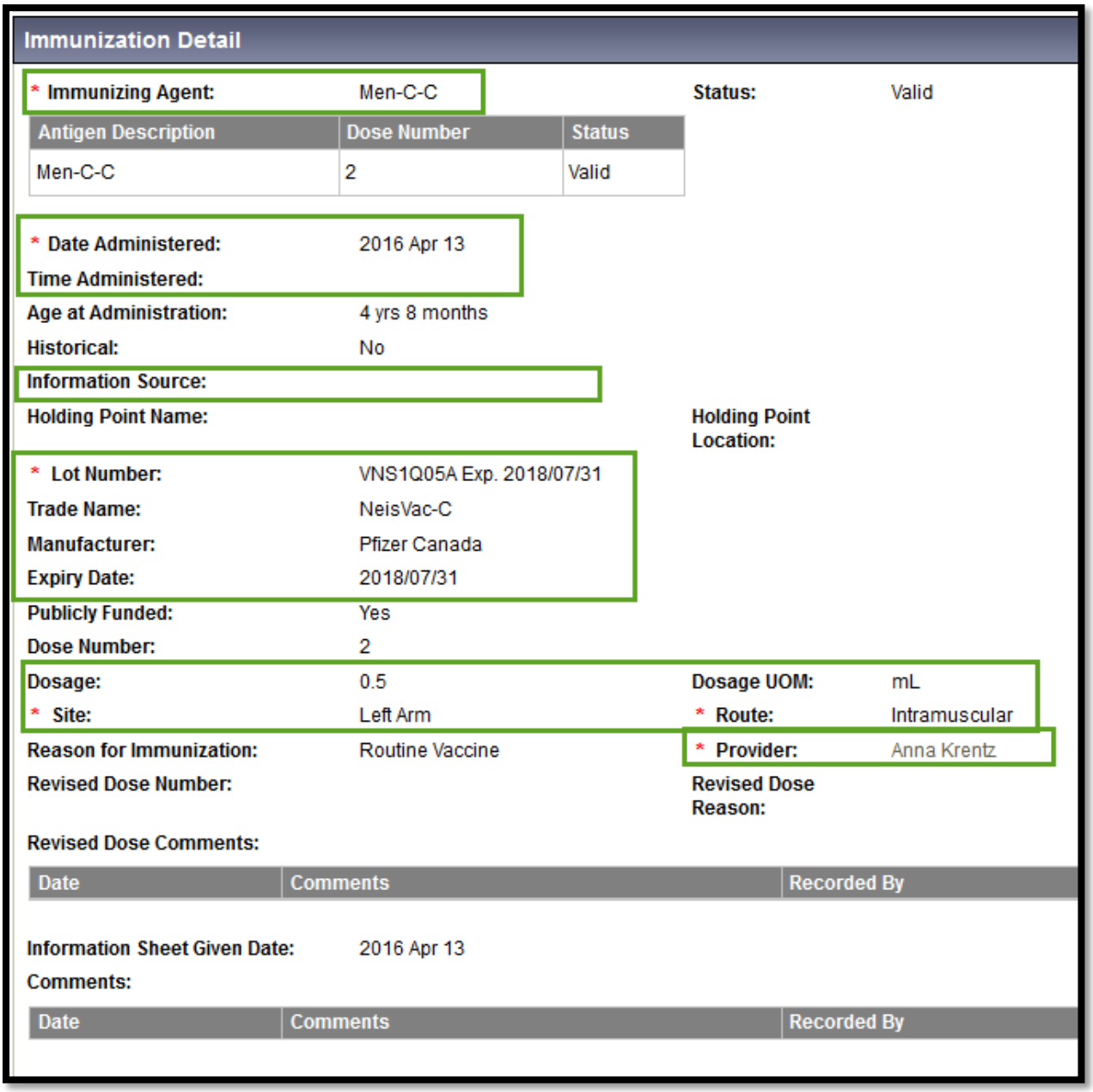
APPENDIX

Use Case Example

The following illustrates information sent to the Repository, after client matching, and information returned from the Repository



Panorama Data Set



Immunization Detail

* **Immunizing Agent:**	Men-C-C	**Status:**	Valid

Antigen Description	Dose Number	Status
Men-C-C	2	Valid

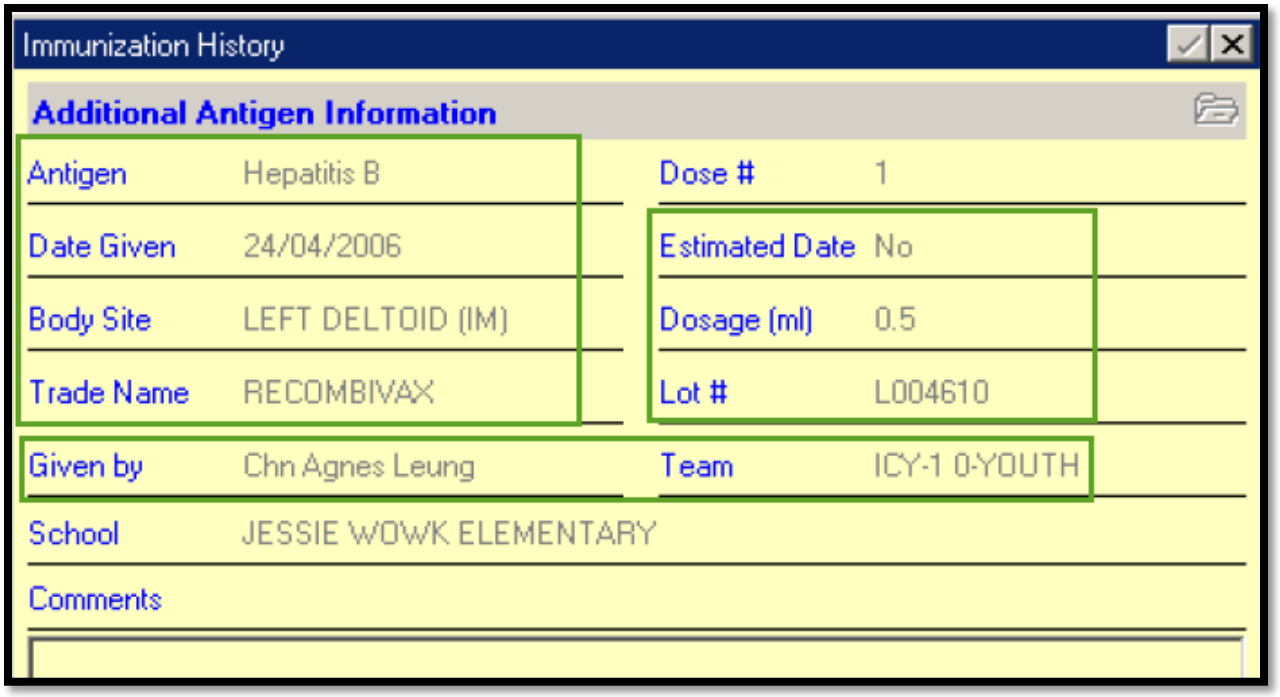
* **Date Administered:**	2016 Apr 13		
Time Administered:			
Age at Administration:	4 yrs 8 months		
Historical:	No		
Information Source:			
Holding Point Name:		**Holding Point Location:**	
* **Lot Number:**	VNS1Q05A Exp. 2018/07/31		
Trade Name:	NeisVac-C		
Manufacturer:	Pfizer Canada		
Expiry Date:	2018/07/31		
Publicly Funded:	Yes		
Dose Number:	2		
Dosage:	0.5	**Dosage UOM:**	mL
* **Site:**	Left Arm	* **Route:**	Intramuscular
Reason for Immunization:	Routine Vaccine	* **Provider:**	Anna Krentz
Revised Dose Number:		**Revised Dose Reason:**	
Revised Dose Comments:			

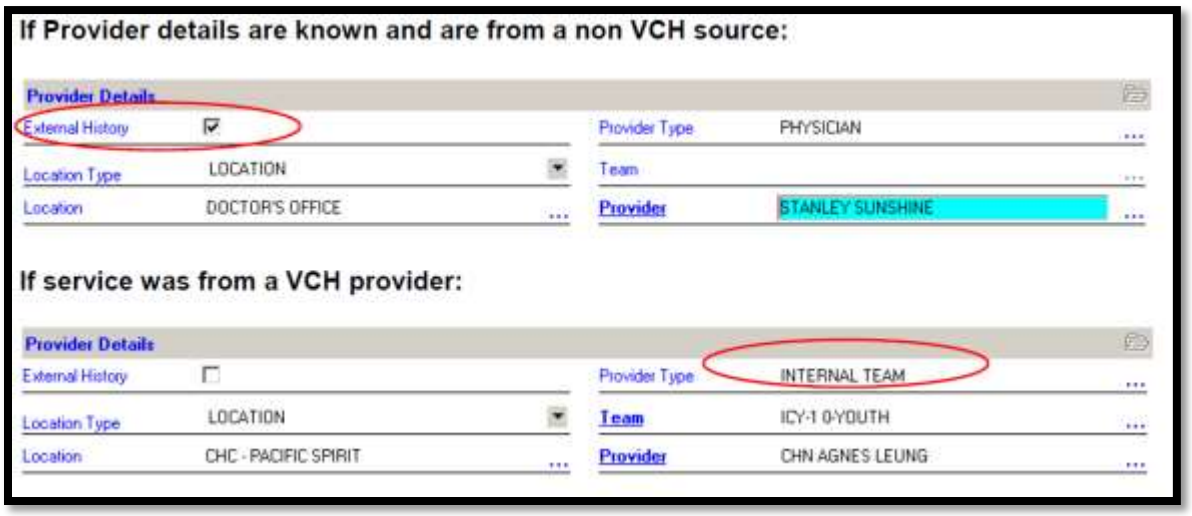
Date	Comments	Recorded By

Information Sheet Given Date:	2016 Apr 13
Comments:	

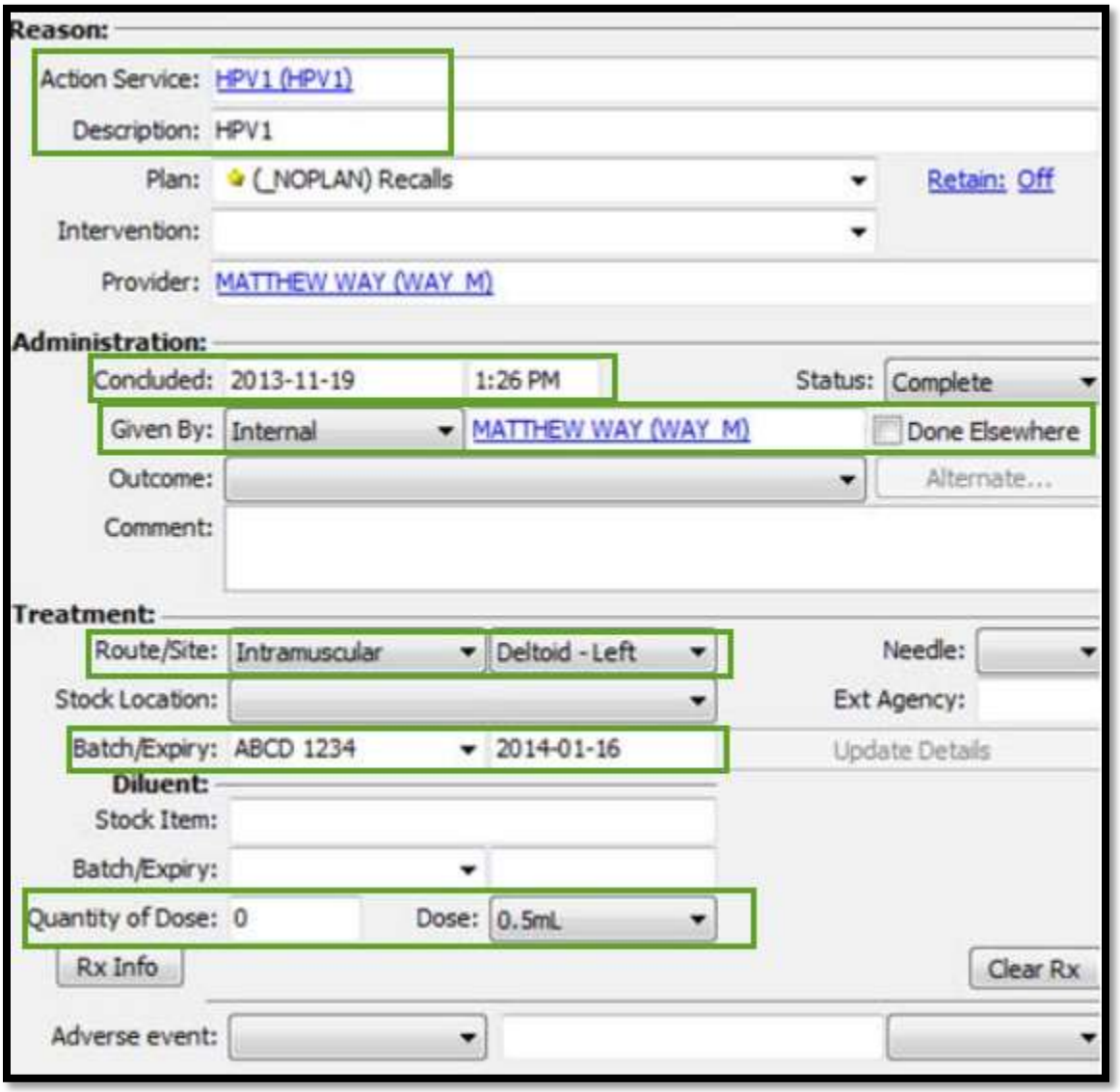
Date	Comments	Recorded By

PARIS Data Set





IntraHealth Data Set



B.C. Ministry of Health
Conformance and Integration Services

Send your questions to the Ministry of Health at:
HLTH.CISSupport@gov.bc.ca