Immunization History-Forecast

Implementation Guide

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Document History

Date	Version	Sections Revised	Description	Modifier
04/05/19	11	All	Revised into new template	S. Southard

Table of Contents

Acronyms and Abbreviations Guide

API	Application Programming Interface
DQA	Data Quality Assurance
DSM	Direct Secure Messaging
FHIR	Fast Healthcare Interoperability Resources
HIN	Health Information Network
HL7	Health Level Seven
HD	Health Directory
MDHHS	Michigan Department of Health and Human Services
MIDIGATE	Medical Information Direct Gateway
MiHIN	Michigan Health Information Network Shared Services
MU	Meaningful Use
NwHIN	Nationwide Health Information Network
REST	Representational State Transfer
VPN	Virtual Private Network
XCA	Cross Community Access

Definitions

Applicable Laws and Standards. In addition to the definition set forth in the Data Sharing Agreement, the federal Confidentiality of Alcohol and Drug Abuse Patient Records statute, section 543 of the Public Health Service Act, 42 U.S.C. 290dd-2, and its implementing regulation, 42 CFR Part 2; the Michigan Mental Health Code, at MCLA §§ 333.1748 and 333.1748a; and the Michigan Public Health Code, at MCL § 333.5131, 5114a.

Data Sharing Agreement. Any data sharing organization agreement signed by both MiHIN and a participating organization. Data sharing organization agreements include but are not limited to: Qualified Data Sharing Organization Agreement, Virtual Qualified Data Sharing Organization Agreement, Consumer Qualified Data Sharing Agreement, Sponsored Shared Organization Agreement, State Sponsored Sharing Organization Agreement, Direct Data Sharing Organization Agreement, Simple Data Sharing Organization Agreement, or other data sharing organization agreements developed by MiHIN.

eHealth Exchange. See the definition for Sequoia Project.

Exhibit. Collectively, a use case exhibit or a pilot activity exhibit.

Health Level 7 (HL7). An interface standard and specifications for clinical and administrative healthcare data developed by the Health Level Seven organization and approved by the American National Standards Institute (ANSI). HL7 provides a method for disparate systems to communicate clinical and administrative information in a normalized format with acknowledgement of receipt

Health Information. Any information, including genetic information, whether oral or recorded in any form or medium, that (a) is created or received by a health provider, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and (b) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health Information Network (HIN). An organization or group of organizations responsible for coordinating the exchange of protected health information (PHI) in a region, state, or nationally.

Health Plan. An individual or group plan that provides, or pays the cost of medical care (as "group health plan" and "medical care" are defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg-91(a)(2)). Health plan further includes those entities defined as a health plan under HIPAA, 45 C.F.R 160.103.

Health Professional means (a) any individual licensed, registered, or certified under applicable Federal or State laws or regulations to provide healthcare services; (b) any person holding a nonclinical position within or associated with an organization that provides or coordinates healthcare or healthcare related services; and (c) people who contribute to the gathering, recording, processing, analysis or communication of health

information. Examples include, but are not limited to, physicians, physician assistants, nurse practitioners, nurses, medical assistants, home health professionals, administrative assistants, care managers, care coordinators, receptionists and clerks.

Health Provider means facilities/hospitals, health professionals, health plans, caregivers, pharmacists/other qualified professionals, or any other person or organization involved in providing healthcare.

Immunization Information System (IIS). A registry that stores immunization records.

Master Use Case Agreement (MUCA). Legal document covering expected rules of engagement across all use cases. Trusted data sharing organizations sign master use case agreement one time, then sign use case exhibits for participation in specific use cases.

Meaningful Use. Using certified EHR technology to improve quality, safety and efficiency of healthcare, and to reduce health disparities as further contemplated by title XIII of the the American Recovery and Reinvestment Act of 2009.

Message. A mechanism for exchanging message content between the participating organization to MiHIN services, including query and retrieve.

Message Content. Information, as further defined in an Exhibit, which is sent, received, found or used by a participating organization to or from MiHIN services. Message content includes the message content header.

Message Header ("MSH") or Message Content Header. The MSH segment present in every HL7 message type that defines the Message's source, purpose, destination, and certain syntax specifics such as delimiters (separator characters) and character sets. It is always the first segment in the HL7 message, with the only exception being HL7 batch messages.

Michigan Care Improvement Registry (MCIR). The IIS for the State of Michigan operated by the Michigan Department of Health and Human Services (MDHHS).

Michigan Health Information Network Shared Services. The MiHIN for the State of Michigan.

MiHIN Infrastructure Service. Certain services that are shared by numerous use cases. MiHIN infrastructure services include, but are not limited to, Active Care Relationship Service (ACRS), Health Directory, Statewide Consumer Directory (SCD), and the Medical Information DIrect GATEway (MIDIGATE®).

MiHIN Services. The MiHIN infrastructure services and additional services and functionality provided by MiHIN allowing the participating organizations to send, receive, find, or use information to or from MiHIN as further set forth in an exhibit.

REST. REST stands for Representational State Transfer, which is an architectural style, and an approach to communications that is often used in the development of web services.

Send / Receive / Find / Use (SRFU). Means sending, receiving, finding, or using message content. Sending involves the transport of message content. Receiving involves accepting and possibly consuming or storing message content. Finding means querying to locate message content. Using means any use of the message content other than sending, receiving and finding. Examples of use include consuming into workflow, reporting, storing, or analysis. Send/Receive/Find/Use (SRFU) activities must comply with Applicable Laws & Standards or State Administrative Code as that term is defined in this agreement and the data sharing agreement.

Service Interruption. A party is unable to send, receive or find message content for any reason, including the failure of network equipment or software, scheduled or unscheduled maintenance, general Internet outages, and events of force majeure.

Specifications. Specifications provide a standard set of service interfaces that enable the exchange of interoperable health information among the health information exchanges.

Trusted Data Sharing Organization (TDSO). An organization that has signed any form of agreement with MiHIN for data sharing.

Use Case. (a) A use case agreement previously executed by a participating organization; or (b) the use case summary, use case exhibit and a use case implementation guide that participating organization or TDSO must follow to share specific message content with the MiHIN.

Use Case Exhibit. The legal agreement attached as an exhibit to the master use case agreement that governs participation in any specific use case.

Use Case Implementation Guide (UCIG). The document providing technical specifications related to message content and transport of message content between participating organization, MiHIN, and other TDSOs. use case implementation guides are made available via URLs in exhibits.

Use Case Summary. The document providing the executive summary, business justification and value proposition of a use case. Use case summaries are provided by MiHIN upon request and via the MiHIN website at www.mihin.org.

XCA. The IHE (Integrating the Healthcare Enterprise®) standard for Cross-Community Access which provides specifications to query and retrieve patient relevant health information held by other communities.

1. Introduction

1.1 Purpose of Use Case

> *Allows participating organizations to send electronic queries through the statewide health information network to an Immunization Information System (IIS) to retrieve electronic data containing a patient's immunization records.*

Immunizations are vital to the maintenance of public health due to their power to prevent and sometimes eradicate deadly diseases and potential epidemics. Immunizations must be closely monitored to ensure they are administered correctly and in a timely fashion because vaccination errors can hurt and possibly kill patients.

From 2010-2013, the Vaccination Adverse Events Reporting System—jointly administered by the Centers for Disease Control and the Food and Drug Administration— received 311,185 reports, of which 20,585 were eventually classified as vaccination errors.[1] The most common errors included incorrect dosage, incorrect scheduling (vaccine administered at wrong age, or at wrong duration between vaccinations), and incorrect vaccine.

On a national basis, immunization records are not collectively maintained by any one organization. Most states have an Immunization Information System (IIS) that maintains immunization records for their residents.[2] An IIS collects immunization records and makes that information accessible to authorized healthcare providers.

Using a message standard known as Query by Parameter (QBP), the Immunization History-Forecast use case allows participating organizations to find electronic vaccination histories and forecasts in real-time through MIHIN from an IIS.

With this use case, an organization is able to query the IIS (via MiHIN) to retrieve electronic information containing a patient's immunization records, including an up-to-date list of immunizations received by the patient (history) as well as a list and schedule of vaccinations that the patient should receive in the future (forecast).

This is useful because the information can help:

- Prevent incorrect administration of vaccinations
- Ensure that all necessary vaccinations are provided to patients on a correct schedule

An immunization query with this use case follows the path below:

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[1] Beth Hibbs, "Vaccination Errors, Reported to the Vaccine Adverse Event Reporting (VAERS), 2000-2013," *Centers for Disease Control and Prevention*, accessed July 24, 2016, http://www.cdc.gov/vaccines/adults/ vaccination-records.html
[2] In Michigan the IIS is the Michigan Care Improvement Registry (MCIR)

1. Participating organization sends an immunization query to MiHIN
2. MiHIN passes the query to state data hub
3. Data hub sends the query to IIS
4. Registry processes query and generates response to state data hub
5. State data hub returns response from IIS to MiHIN
6. MiHIN then routes response to participating organization that originally requested vaccination information

If the request originated from a consumer, the consumer now has an electronic copy of the history/forecast that they can then share electronically as they wish, such as with a school or camp counselor, eliminating the time-consuming need to physically go to the pediatrician's clinic to obtain a paper copy.[3]

Pharmacies are expected to frequently participate in this use case, as they might wish to check immunization history before administering vaccinations, or may want to determine if additional vaccinations are due such as for upsell opportunities.

1.2 Message Content

For this use case, Message Content means a conforming HL7 2.5.1 message with a message type of QBP Z34^CDC, RSP Z32^CDC, or ACK.
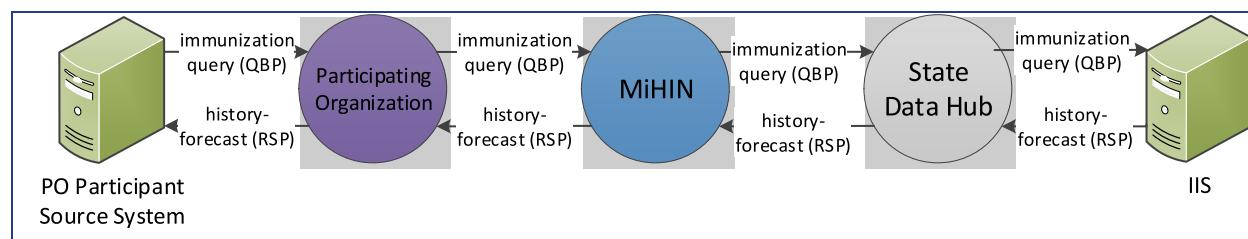
1.3 Data Flow and Actors

Figure 1. The Path of the Immunization Query (VXQ)

For more information about this use case, refer to the documents that can be found online here:

https://mihin.org/immunization-history-forecast/

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[3] MCIR mails paper copies of a child's immunization history and forecast to parents annually.

2 Standard Overview

2.1 Message Format

The current message formats supported by the IIS are HL7 v2.5.1 (preferred) and HL7 v2.3.1. Future versions of HL7 messages may be implemented and supported in the future, such as the Fast Healthcare Interoperability Resources (FHIR). For more information, refer to this website:

http://www.hl7.org/implement/standards/fhir

2.2 Message Example

For an example of what a properly formatted message should look like for this use case, refer to the IIS Testing and Submission Guide, located at:

https://www.michiganhealthit.org/public-health/mcir/

3 Onboarding Process

3.1 Initial Onboarding

For organizations to share data with MiHIN under this use case, the organization undergoes two onboarding processes simultaneously. The two onboarding processes are legal onboarding and technical connectivity onboarding. These may occur in parallel – i.e., the organization can review and complete legal agreements with MiHIN while simultaneously establishing and testing technical connectivity. To initiate these two parallel onboarding processes, notify MiHIN via http://mihin.org/requesthelp/.

3.1.1 Initial Legal Process

The first time an organization undergoes the legal onboarding process with MiHIN, the organization negotiates and enters into a master organization agreement and master use case agreement which then allows the organization to enter into one or more use cases via use case exhibits.

Once an organization has entered into a master organization agreement, the organization can enter into an unlimited number of use cases with MiHIN. All of MiHIN's use cases are available at:

http://mihin.org/about-mihin/resources/

3.1.2 Initial Technical Connectivity Process

MiHIN considers itself "transport agnostic" and offers multiple options for organizations to establish technical connectivity to transport data to MiHIN. Organizations should select one or more connectivity methods for message transport based on their technical capabilities, and put in a service request at www.mihin.org/requesthelp. Currently MiHIN accepts the following transport methods:

- LLP over IPsec VPN – Lower-Layer Protocol over Internet Protocol Security Virtual Private Network
- DSM – Direct Secure Messaging

For VPN connectivity two VPNs are required. A primary VPN will facilitate regular traffic. A secondary will be established for fail-over purposes.

Additional transport methods may be added in the future. These can include NwHIN, XCA, REST/RESTFUL APIs, FHIR, and others.

The following steps describe the technical onboarding process. However, MiHIN typically conducts "onboarding kickoff" meetings with new organizations to go through each of these steps in detail and answer any questions.

1. The organization selects one or more supported transport methods and establishes connectivity with MiHIN. This step varies based on the method selected:
    a. LLP over IPsec VPN – MiHIN's site-to-site VPN request form must be completed, sent and approved by MiHIN. Send a request via www.mihin.org/requesthelp to obtain

the VPN request form. A pre-shared key is then exchanged between the organization and MiHIN to initialize the connection. The LLP over IPsec VPN is the most efficient transport for very high volumes of messages.

    b. Direct Secure Messaging – MiHIN accepts Direct Secure Messages from Health Internet Service Provider (HISPs) that have EHNAC-DTAAP (DirectTrust) accreditation. Test messages are sent to verify HISP connectivity ("ping pong"). The Message Header section in the test messages is verified for appropriate routing configuration.

2. Test messages are sent by the organization to MiHIN.
    a. All test messages must have a "T" in the Message Header – field 11
    b. Test traffic is routed via MiHIN to the appropriate destination. For Immunization Records, the destination is the IIS via the state data hub.
    c. The end destination monitors for inbound test traffic and confirm receipt with MiHIN, which confirms with the organization.

3. For the Immunization Records use case, the IIS deems the sending facility to have entered into Data Quality Assurance Status (DQA) once they have successfully received a properly formatted message from the sending facility via the organization through MiHIN.
    a. Until completion of the DQA process, sending facilities should continue to dually send their Immunization Records through MiHIN as well as continuing to send using any current method.

4. The IIS declares the sending facility to be at production status after another period of successful testing and exiting DQA status.
    a. At this time, the sending facility may then send production messages through the organization to MiHIN. The sending facility now places a "P" (for production) value in the MSH-11 instead of the "T" used during testing.

3.2 Onboarding Additional Sending Facilities

When an organization wishes to onboard additional sending facilities, those facilities must first register with the IIS. Once successful, the registration information from the IIS, including the Facility ID Number, must be sent to http://mihin.org/requesthelp/. The new sending facility should then begin sending test messages to the IIS in the same fashion as the initial facility as detailed in section 3.1.2, making sure that to place a "T" value in MSH-11. The IIS deems the sending facility to be in DQA and eventually Production Status.

For specific information regarding testing with the IIS, refer to the MCIR Testing and Submission Guide:

https://www.michiganhealthit.org/public-health/mcir/

4 Specifications

4.1 Message Trigger Events

The HL7 message type for Immunizations is QBP and the trigger event is Q11.

4.2 General Message Requirements

For general rules that apply to the entire message, refer to the MCIR Testing and Submission Guide, located at:

https://www.michiganhealthit.org/public-health/mcir/

4.3 Specific Segment and Field Definitions

4.3.1 Segment 1 – Message Header

The definitions in the table below shall be conformed to by all HL7 messages communicating the message header (MSH) segment.

Sequence	Length	DT	Usage	Cardinality	TBL#	Item #	Element Name	Comments
1	1	ST	R	1..1		00001	Field Separator	The MSH.1 field shall be |
2	4	ST	R	1..1		00002	Encoding Characters	The MSH.2 field shall be ^~\&
3	180	HD	R	1..1	0361	00003	Sending Application	This is the system that created this message.
4	180	HD	R	1..1	0362	00004	Sending Facility	This is the Immunization History Consumer.
5	180	HD	R	1..1	0361	00005	Receiving Application	This is the system that is receiving this message.
6	180	HD	R	1..1	0362	00006	Receiving Facility	This is the Immunization History Consumer or the Immunization History supplier, depending on the message.
7	26	TS	R	1..1		00007	Date/Time of Message	The degree of precision must be at least to the second, and the time zone must be included (format YYYYMMDDHHMMSS[.S[S [S[S]]]]+/-ZZZZ).
8	40	ST	X	0..0		00008	Security	

Sequence	Length	DT	Usage	Cardinality	TBL#	Item #	Element Name	Comments
9	7	CM	R	1..1	0076 0003	00009	Message Type	QBP^Q11^QBP_Q11
10	20	ST	R	1..1		00010	Message Control ID	Should be repopulated (rather than pass-through) for outbound message header
11	3	PT	R	1..1		00011	Processing ID	**P** when in production, **T** for testing
12	60	VID	R	1..1	0104	00012	Version ID	2.5.1
13	15	NM	X	0..0		00013	Sequence Number	
14	180	ST	X	0..0		00014	Continuation Pointer	
15	2	ID	X	0..0	0155	00015	Accept Acknowledgment Type	
16	2	ID	X	0..0	0155	00016	Application Acknowledgment Type	
17	2	ID	X	0..0		00017	Country Code	
18	16	ID	X	0..0		00692	Character Set	
19	60	CE	X	0..0			Principal Language of Message	
20	20	ID	X	0..0		00356	Alternate Character Set Handling Scheme	

4.3.2 All Remaining Segments

The message header is the only segment which MiHIN requires to be formatted in a certain way. MiHIN does not evaluate or verify any other part of the message. For all remaining segment and field, follow the IIS standards, which can be retrieved here:

https://www.michiganhealthit.org/public-health/mcir/

5 Troubleshooting

5.1 Production Support

	Severity Levels			
	1	*2*	*3*	*4*
Description	***Critical Impact/ System Down:*** Business critical software is down or critical interface has failed. The issue is impacting all production systems, causing all participating organizations' or other organizations' ability to function to be unusable.	***Significant Business Impact:*** Software component severely restricted. Entire organization is unable to continue business functions, causing all communications and transfer of messages to be halted.	**Partial Failure or Downtime:** Program is useable and less significant features unavailable. The service is online, though may not working as intended or may not currently working as intended or may not currently be accessible, though other systems are currently available.	**Minimal Business:** A non-critical software component is malfunctioning, causing minimal impact, or a test system is down.
Example	All messages to and from MiHIN are unable to be sent and received, let alone tracked	MiHIN cannot communication (send or receive) messages between single or multiple participating organizations, but can still successfully communicate with other organizations.	Messages are lost in transit; messages can be received but not sent.	Additional feature requested.
Primary Initiation Method	***Phone:*** (517) 336-1430	***Phone:*** (517) 336-1430	Web form at http://mihin.org/ requesthelp	Web form at http://mihin.org/ requesthelp
Secondary Initiation Method	Web form at http://mihin.org/ requesthelp	Web form at http://mihin.org/ requesthelp	Email to help@mihin.org	Email to help@mihin.org
Tertiary Initiation Method	Email to help@mihin.org	Email to help@mihin.org	N/A	N/A
Initial Response	Within 2 hours	Within 2 hours	1 business day	1 business day
Resolution Goal	24 hours	24 hours	3 business days	7 business days

A list of common questions regarding the Immunization History-Forecast Use Case can be found at:

https://mihin.org/immunization-history-forecast-use-case/

If you have questions, please contact the MiHIN Help Desk:

- www.mihin.org/requesthelp
- Phone: (517) 336-1430
- Monday – Friday 8:00 AM – 5:00 PM (Eastern)

6 Legal Advisory Language

This reminder applies to all use cases covering the exchange of electronic health information:

The Data Sharing Agreement (DSA) establishes the legal framework under which participating organizations can exchange messages through the MiHIN Platform, and sets forth the following approved reasons for which messages may be exchanged:

a. By health care providers for Treatment, Payment and/or Health Care Operations consistent with the requirements set forth in HIPAA
b. Public health activities and reporting as permitted by HIPAA and other Applicable Laws and Standards
c. To facilitate the implementation of "Meaningful Use" criteria as specified in the American Recovery and Reinvestment Act of 2009 and as permitted by HIPAA
d. Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual's personal representative in accordance with HIPAA
e. By Data Sharing Organizations for any and all purposes, including but not limited to pilot programs and testing, provided that such purposes are consistent with Applicable Laws and Standards
f. For any additional purposes as specified in any use case, provided that such purposes are consistent with Applicable Laws and Standards

Under the DSA, "*Applicable Laws and Standards*" means all applicable federal, state, and local laws, statutes, acts, ordinances, rules, codes, standards, regulations and judicial or administrative decisions promulgated by any governmental or self-regulatory agency, including the State of Michigan, the Michigan Health Information Technology Commission, or the Michigan Health and Hospital Association, as any of the foregoing may be amended, modified, codified, reenacted, promulgated or published, in whole or in part, and in effect from time to time. "Applicable Laws and Standards" includes but is not limited to HIPAA; the federal Confidentiality of Alcohol and Drug Abuse Patient Records statute, section 543 of the Public Health Service Act, 42 U.S.C. 290dd-2, and its implementing regulation, 42 CFR Part 2; the Michigan Mental Health Code, at MCLA §§ 333.1748 and 333.1748a; and the Michigan Public Health Code, at MCL § 333.5131, 5114a.

It is each participating organization's obligation and responsibility to ensure that it is aware of Applicable Laws and Standards as they pertain to the content of each message sent, and that its delivery of each message complies with the Applicable Laws and Standards. This means, for example, that if a use case is directed to the exchange of physical health information that may be exchanged without patient authorization under HIPAA, the participating organization must not deliver any message containing health information for which an express patient authorization or consent is required (e.g., mental or behavioral health information).

Disclaimer: The information contained in this implementation guide was current as of the date of the latest revision in the Document History in this guide. However, Medicare and

Medicaid policies are subject to change and do so frequently. HL7 versions and formatting are also subject to updates. Therefore, links to any source documents have been provided within this guide for reference. MiHIN applies its best efforts to keep all information in this guide up-to-date. It is ultimately the responsibility of the participating organization and sending facilities to be knowledgeable of changes outside of MiHIN's control.