



Immunizations

Implementation Guide

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Table of Contents

- Acronyms and Abbreviations Guide..... 3
- Definitions 4
- 1 Introduction 7
 - 1.1 Purpose of Use Case 7
 - 1.2 Message Content..... 8
 - 1.3 Data Flow and Actors 8
- 2 Standard Overview 9
 - 2.1 Message Format..... 9
 - 2.2 Message Example..... 9
- 3 Onboarding Process..... 10
 - 3.1 Initial Onboarding..... 10
 - 3.1.1 Initial Legal Process..... 10
 - 3.1.2 Initial Technical Connectivity Process 10
 - 3.2 Onboarding Additional Sending Facilities..... 11
- 4 Specifications..... 12
 - 4.1 Message Trigger Events 12
 - 4.2 General Message Requirements 12
 - 4.3 Specific Segment and Field Definitions 12
 - 4.3.1 Segment 1 – Message Header 12
 - 4.3.2 All Remaining Segments..... 13
- 5 Troubleshooting..... 14
 - Production Support 14
- 6 Legal Advisory Language 15
- Appendix A..... 17
 - Sample Immunizations Message..... 17

Acronyms and Abbreviations Guide

ACK	HL7 Acknowledgement message
DQA	Data Quality Assurance
DSA	Data Sharing Agreement
DSM	Direct Secure Messaging
EHNAC-DTAAP	Electronic Healthcare Network Accreditation Commission – Direct Trusted Agent Accreditation Program
FHIR	Fast Healthcare Interoperability Resources
HIPAA	Health Insurance Portability and Accountability Act
HL7	Health Level 7
IPsec	Internet Protocol Security
LLP	Lower Layer Protocol
MCIR	Michigan Care Improvement Registry
MDHHS	Michigan Department of Health and Human Services

MiHIN	Michigan Health Information Network Shared Services
MSH	Message Header segment within HL7
MUCA	Master Use Case Agreement
NACK	Negative Acknowledgement
NwHIN	Nationwide Health Information Network
PI	Promoting Interoperability
QO	Qualified Organization
REST	Representational State Transfer
TDSO	Trusted Data Sharing Organization
UCE	Use Case Exhibit
UCS	Use Case Summary
VPN	Virtual Private Network
VXU	Unsolicited Vaccination Update
V04	Message Trigger Event
XCA	Cross-Community Access

Definitions

Acknowledgement (ACK). In data networking, telecommunications, and computer buses, an acknowledgement is a signal that is passed between communicating processes, computers, or devices to signify acknowledgement, or receipt of message, as part of a communications protocol.

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 HIN and organization.

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

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.

HIN Infrastructure Service. Certain services that are shared by numerous use cases. HIN Infrastructure Services include, but are not limited to, ACRS, HPD, Statewide Consumer Directory (SCD), and the Medical Information Direct GATEway (MIDIGATE®).

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

Immunization Information System (IIS). A confidential, population-based, computerized database that records all immunization doses administered by participating providers to persons residing within a given geopolitical area.

Information Source. Any organization that provides information that is added to a HIN Infrastructure Service.

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

Message Content. Information which is sent, received, found or used by an organization to or from HIN Services, including, but not limited to, PHI, common



keys, de-identified data, metadata, Digital Credentials, and data schema. Message Content includes the Message Content Header.

Message Header (MSH). 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. The IIS for the State of Michigan.

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

Negative Acknowledgment (NACK). “Not acknowledged” and is used to negatively acknowledge or to reject previously received message content or to indicate an error.

Notice. A message transmission that is not message content and which may include but not be limited to an acknowledgement of receipt or error response.

Promoting Interoperability. Using certified EHR technology to improve quality, safety and efficiency of healthcare, and to reduce health disparities.

Send / Receive / Find / Use (SRFU). Means sending, receiving, finding, or using message content. Sending involves transport of message content. Receiving involves accepting and possibly consuming/storing message content. Finding means querying to locate message content. Using means any use of the message content other than sending, receiving and finding.

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

Unsolicited Vaccination Record Update (VXU). Represents a regular report to a registry that a shot has been given; no information requested.

Use Case. A specific scenario or group of scenarios for sharing patient health information.

Use Case Exhibit (UCE). 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 organizations, HIN, and other TDSOs. Use Case Implementation Guides are made available via URLs in exhibits.

Use Case Summary (UCS). The document providing the executive summary, business justification and value proposition of a use case. Use case summaries are provided by HIN upon request and are available via www.mihin.org.



XCA. The IHE (Integrating the Healthcare Enterprise®) standard for Cross-Community Access to support the means to query and retrieve patient relevant healthcare data held by other communities.

XDS.b. The IHE (Integrating the Healthcare Enterprise®) standard for Cross-Enterprise Document Sharing revision b, to support the means to query and retrieve patient relevant healthcare data held within a community.



1 Introduction

1.1 Purpose of Use Case

The Immunizations use case describes the requirements for healthcare providers to use the health information network (HIN) to automatically, electronically send immunization records through a state's Department of Health (DoH - in Michigan the Department of Health and Human Services) to the state's IIS.

“Vaccines have been hailed as one of the greatest public health achievements of the 20th Century. Nearly 20 million cases of infectious diseases and 42,000 deaths are averted every year in the United States through vaccination.”¹

Immunizations must be closely monitored to ensure they are administered correctly and in a timely fashion. Healthcare providers (including pharmacies) in Michigan are required to report immunizations to the state immunization information system (IIS) within 72 hours of administration.²

“Vaccines are the most economical health interventions known to man. For every \$1 spent on each of the eleven vaccines given routinely to children, our country saves \$10.10 in medical costs by averting costs to treat diseases.”³

Immunizations are vital to the maintenance of public health due to their power to help prevent and sometimes eradicate deadly diseases and potential epidemics. A state immunization information system (IIS) is a confidential, population-based, computerized database that records all immunization doses administered by participating providers to persons residing within a given geopolitical area.

An IIS also benefits health care organizations, schools, licensed childcare programs, pharmacies and citizens by consolidating immunization information from multiple providers into a comprehensive immunization record. This consolidation reduces vaccine-preventable diseases and over-vaccination, allowing providers to view up-to-date patient immunization history in one system.

- At the *point of clinical care*, an IIS provides consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations.

¹ “Facts,” Every Child By Two, accessed on June 27, 2016, http://www.ecbt.org/index.php/facts_and_issues/

² In Michigan, these healthcare providers are required to report immunizations for every child born after December 31, 1993 and less than 20 years of age.

³ “Facts.”

- At the *population level*, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease.⁴

In Michigan, the statewide IIS is part of the Michigan Care Improvement Registry (MCIR), which was created in 1998 to collect reliable immunization information for children and make it accessible to authorized users. A 2006 change to the Michigan Public Health Code enabled the MCIR to transition from a childhood immunization registry to a lifespan registry including citizens of all ages.

This use case aids in providing current and correct administration of vaccinations and can help healthcare providers ensure that all necessary vaccinations are provided to patients on a correct schedule by helping maintain a record of all immunizations administered. The adoption of this use case also ensures compliance with Meaningful Use legislation, which requires the ability for healthcare providers to communicate immunizations electronically with a public health agency.

1.2 Message Content

For this use case, Message Content means an Unsolicited Vaccination Update (VXU) HL7 2.x conforming message.

1.3 Data Flow and Actors

In this use case, MiHIN brokers the transport of messages to and from trusted data sharing organizations (TDSOs), called participating organizations in the diagram below.

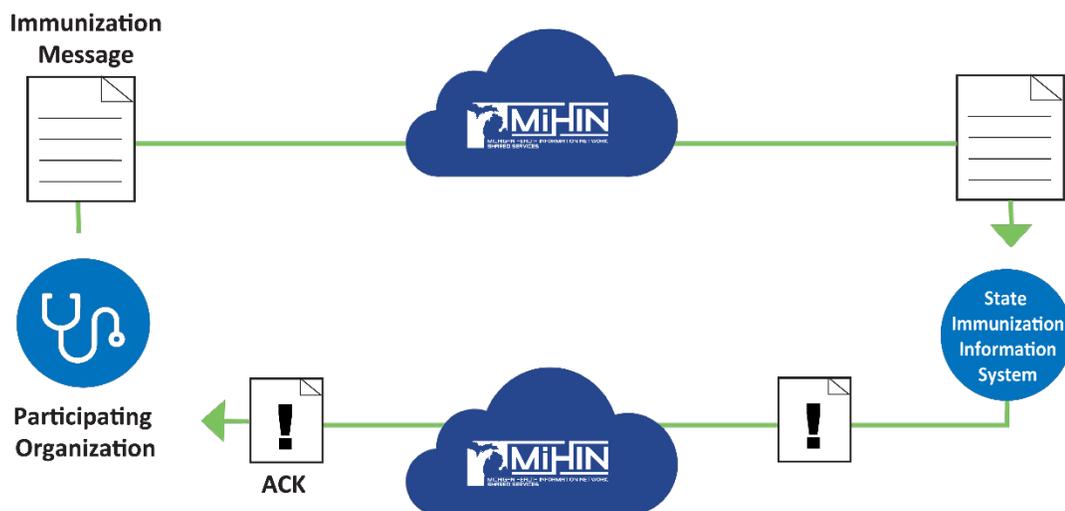


Figure 1. Workflow between Participating Organizations, MiHIN, and MDHHS

⁴ “Immunization Information Systems (IIS),” Centers for Disease Control and Prevention, accessed on June 27, 2016, <http://www.cdc.gov/vaccines/programs/iis/about.html>

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 on FHIR, 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 Appendix A at the end of this document.



3 Onboarding Process

3.1 Initial Onboarding

For organizations to share data with HIN under this use case, the organization undergoes two onboarding processes. The two onboarding processes are legal onboarding and technical connectivity onboarding. To initiate these two onboarding processes, notify HIN at www.mihin.org/requesthelp.

3.1.1 Initial Legal Process

The first time an organization undergoes the legal onboarding process with HIN, the organization negotiates and enters into a master Participating Organization agreement and Master Use Case Agreement which then allows the Participating Organization to enter into one or more use cases via Use Case Exhibits.

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

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

3.1.2 Initial Technical Connectivity Process

HIN considers itself “transport agnostic” and offers multiple options for organizations to establish technical connectivity to transport data to HIN. Organizations should select one or more connectivity methods for message transport based on their technical capabilities, and should communicate the selection(s) to www.mihin.org/requesthelp early in the onboarding process. Currently HIN 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, HIN 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 supported transport method and establishes connectivity with HIN. This step varies based on the method selected:
 - a. **LLP over IPsec VPN** – HIN's site-to-site VPN request form must be completed, submitted and approved by HIN. Visit www.mihin.org/requesthelp to obtain the



- VPN request form. A pre-shared key exchanges between the organization and HIN to initialize the connection. The LLP over IPsec VPN is the most efficient transport for very high volumes of messages.
- b. **Direct Secure Messaging** – HIN 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 HIN.
 - a. All test messages must have a “T” in the Message Header – field 11
 - b. Test traffic is routed via HIN to the appropriate destination. For Immunizations, the destination is MCIR via MDHHS.
 - c. The end destination monitors for inbound test traffic and confirm receipt with HIN, which confirms with the organization.
 3. For the Immunizations 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 HIN.
 - a. Until completion of the DQA process, sending facilities should continue to dually send their immunizations through HIN 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 HIN. 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 submitted to www.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 HL7 Implementation Guide:

<https://www.mcir.org/hl7-landing-page/hl7-3/>

4 Specifications

4.1 Message Trigger Events

The HL7 message type for Immunizations is VXU and the trigger event is V04.

4.2 General Message Requirements

For general rules that apply to the entire message, refer to the MCIR HL7 Implementation Guide, located at:

<https://www.mcir.org/hl7-landing-page/hl7-3/>

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	
2	4	ST	R	1..1		00002	Encoding Characters	
3	180	HD	R	1..1	0361	00003	Sending Application	
4	180	HD	R	1..1	0362	00004	Sending Facility	MCIR Facility PIN
5	180	HD	R	1..1	0361	00005	Receiving Application	MCIR
6	180	HD	R	1..1	0362	00006	Receiving Facility	MDHHS
7	26	TS	R	1..1		00007	Date/Time of Message	Should include the time zone.
8	40	ST	X	0..0		00008	Security	
9	7	CM	R	1..1	0076 0003	00009	Message Type	VXU^V04^VXU_V04
10	20	ST	R	1..1		00010	Message Control ID	Should be a unique number with a unique ID per day.
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	
13	15	NM	X	0..0		00013	Sequence Number	Optional



Sequence	Length	DT	Usage	Cardinality	TBL#	Item #	Element Name	Comments
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 HIN requires to be formatted in a certain way. HIN 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 from the MCIR HL7 Implementation Guide:

<https://www.mcir.org/hl7-landing-page/hl7-3/>

5 Troubleshooting

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 transmitted.	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

If you are experiencing difficulties or 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 organizations can exchange messages through the HIN 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 “Promoting Interoperability” 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. HIN applies its best efforts to keep all information in this guide up to date. It is ultimately the responsibility of the organization and sending facilities to be knowledgeable of changes outside of HIN's control.



Appendix A

Sample Immunizations Message

MSH|^~\&|MIHIN PATIENT
GEN|1.2.3.4.5.9.99.999.9999.1273||2.16.840.1.113883.3.1481|20190110130000-0500||VXU^V04^VXU_V04|1072|P|2.6|1071|||||||Global Southside Urgent Care Center
PID|1|3271|b4a82051c1bd4b54804c90e6e7a46e15^^^^CKS~000003271^^^^||McIntyre
^Wanda||20171113|F||2106-3^White^HL70005|202 SE Danube
Place^^Detroit^MI^48228||||||000003271||N^Not Hispanic or
Latino^HL70189||||||20190110132000-0500|N
PD1|||Global Southside Urgent Care
Center^^^^^^^^1.2.3.4.5.9.99.999.9999.1273|9999992888^Avila^Tracy^^^^^^^^NPI
^^^^^^^^MD
PV1|1|I|^4^1.2.3.4.5.9.99.999.9999.1273|||9999992888^Avila^Tracy^^^^^^^^NPI|||
||||||8e54840fb65d48e3ae6413a6582870f8|||||||&HOME^20190110132000-
0500
IN1|1|1772^STATE HEALTH
PLAN|1027|MEDICAID|||||||McIntyre^Wanda^Andrade|||202 SE Danube
Place^^Detroit^MI^48228
ORC|RE||ad81cf92-b116-4bb6-8609-b4e7b07b9362
RXA|1|1|20190110130000-0500|20190110130000-0500|08^Hep B, adolescent or
pediatric^^^^CVX|1|ml
RXR|IM^IM (Intramuscular)

