

Disease Surveillance

Implementation Guide

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Table of Contents

| 1. Introduction | 1 |
|--|----|
| 1.1 Purpose of Use Case | 1 |
| 1.2 Message Content | 2 |
| 1.3 Data Flow and Actors | 2 |
| 2 Standard Overview | 2 |
| 2.1 Message Format | 2 |
| 2.2 Message Example | 2 |
| 2.3 Required Message Fields | 3 |
| 3 Onboarding Process | 3 |
| 3.1 Initial Onboarding | 3 |
| 3.1.1 Initial Legal Process | 3 |
| 3.1.2 Initial Technical Connectivity Process | 4 |
| 3.2 Onboarding Additional Sending Facilities | 5 |
| 4 Specifications | 5 |
| 4.1 Message Trigger Events | 5 |
| 4.2 General Message Requirements | 5 |
| 4.3 Specific Segment and Field Definitions | 5 |
| 4.3.1 Segment 1 – Message Header | 5 |
| 4.3.2 All Remaining Segments | 6 |
| 5 Troubleshooting | 7 |
| 5.1 Production Support | 7 |
| 6 Legal Advisory Language | 8 |
| Appendix A | 10 |
| A.1 Sample Disease Surveillance Message | 10 |
| Acronyms and Abbreviations Guide | 11 |
| Definitions | 13 |



1. Introduction

Offers a standard, consistent method to automatically and electronically send lab results regarding reportable diseases to the state.

1.1 Purpose of Use Case

Accurate and complete disease reporting is essential to a community's health. One of the most important functions of any public health agency is to monitor laboratory test results in the form of lab reports for trends that can help identify and address outbreaks of illnesses. These trends may indicate the spread of infectious disease, bioterrorism, or other public health threats such as elevated blood lead levels in a region.

Monitoring trends on certain diseases found in lab results is called disease surveillance. Automating this process improves accuracy, completeness, and timeliness, and allows staff members at participating organizations to focus more time on their other duties.

The State of Michigan requires physicians, clinical laboratories, primary and secondary schools, childcare centers and camps to report the occurrence, or suspected occurrence, of any disease, condition, or infection described in the Michigan Communicable Disease Rules. Any laboratory test result that indicates one of these occurrences is known as a reportable lab result and must be sent to the state. Examples of required submissions can include rabies, chicken pox, HIV, hepatitis, Lyme disease, measles, and influenza. The public health system depends on these reportable lab results for many reasons:

- ☐ To identify outbreaks and epidemics. If an unusual number of cases are reported for any condition, local health authorities can investigate and take appropriate action.
- ☐ To encourage preventive treatment and/or education when needed
- ☐ To help target prevention programs and identify care needs, so resources can be used efficiently
- ☐ To evaluate the success of long-term control efforts
- ☐ To facilitate research for finding a preventable cause
- To assist with national and international disease monitoring efforts. If an unusual disease or condition is detected in a region, the federal government is contacted to determine whether national or international investigation is needed.

Historically, reportable lab results were sent by mail or fax to a local health authority. In this communication, a staff member for the reporting organization provided details on the

¹ "Michigan's Communicable Disease Rules," Michigan Department of Health & Human Services, accessed on April 21, 2016, http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5103_26138-15166--,00.html



reportable lab result including a small amount of information about the patient. These nonelectronic communications were inefficient because:

- ☐ They took the staff member's time away from other duties
- ☐ Errors can easily occur when reporting a case from written notes
- Answering the required questions took additional time reviewing patient records
- ☐ School and childcare workers were not always properly prepared to send these reports because they only encounter these types of situations a few times a year

1.2 Message Content

For this use case, Message Content means a conforming HL7 2.5.1 message with a message type of ORU^R01.

1.3 Data Flow and Actors

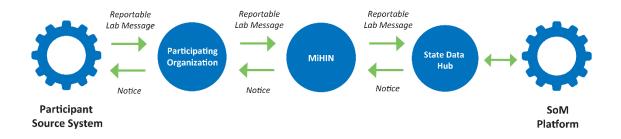


Figure 1. Workflow Between Participating Organizations, MiHIN, state Data Hub, and state Disease Surveillance System

2 Standard Overview

2.1 Message Format

The current message format supported by MDSS is HL7 v2.5.1. Future versions of HL7 Message Content 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 properly formatted message should look like for this use case, refer to Appendix A. For more information, refer to the MDHHS DSS Reportable Lab Submission Implementation Guide, located at:

http://mihin.org/disease-surveillance/



2.3 Required Message Fields

- MSH-10: Message Control ID
- ☐ MSH-3.1: Sending Application Namespace ID
- MSH-4.1: Sending Facility Namespace ID
- ☐ MSH-4.2: Sending Facility Universal ID
- ☐ MSH-9.2: Trigger Event
- ☐ PID-10: Race
- ☐ PID-11.1: Street Address
- □ PID-11.5: ZIP
- ☐ PID-2: Patient ID or PID-3: Patient Identifier List will be accepted
- ☐ PID-5.1: Patient Family Name
- ☐ PID-5.2: Patient Given Name
- □ PID-7: DOB
- □ PID-8: Sex
- PV1-2: Patient Class
- □ OBR-16: Ordering Provider
- □ OBX-11: Observation Results Status
- □ OBX-2: Value Type
- □ OBX-3: Observation Identifier
- □ OBX-5: Observation Value

3 Onboarding Process

3.1 Initial Onboarding

For organizations to share data with MiHIN 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 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 MiHIN 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 Initial sending facility must register with the Michigan Disease Surveillance System (MDSS).
- 2. The Initial sending facility must send their Clinical Laboratory Improvement Amendment (CLIA) number to MiHIN at http://mihin.org/requesthelp.
- 3. The participating organization selects one supported transport method 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 an email via http://mihin.org/requesthelp to obtain the VPN request form. A pre-shared key is then exchanged between the participating 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 verifies for appropriate routing configuration.
- 4. Test messages are sent by the participating organization to MiHIN.
 - a. All test messages must have a "T" in the Message Header field 11
 - b. Test traffic routes via MiHIN to the appropriate destination. For Disease Surveillance: i. MSH-5 = MDSS ii. MSH-6 = MDCH
 - c. The end-destination monitors for inbound test traffic and confirm receipt with MiHIN, which confirms with the participating organization.
- 5. For the Disease Surveillance use case, the state DSS deems the sending facility to have entered into Data Quality Assurance (DQA) status once they have successfully received a



properly formatted message from the sending facility via the participating organization through MiHIN.

- a. Until completion of the DQA process, sending facilities that are already sending data to the state DSS should dually send their disease surveillance messages through MiHIN as well as their current method.
- 6. The state DSS 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 then sends production messages through the participating 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 a participating organization wishes to onboard additional sending facilities, those facilities must first register with the state DSS. Once successful, the registration information from the state DSS, including the Facility CLIA number, must be requested through http://mihin.org/requesthelp/. The new sending facility should then begin sending test messages to the state DSS 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 state DSS deems the sending facility to be in DQA and eventually production status.

4 Specifications

4.1 Message Trigger Events

The HL7 message type for Disease Surveillance is an ORU and the trigger event is ORU^R01^ORU_R01.

4.2 General Message Requirements

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

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.

| Sequ ence | Len gth | DT | Usage | Cardin ality | TBL# | Item # | Element Name | Comments |
|--------------|------------|----|-------|-----------------|------|--------|---------------------|-------------|
| 1 | 1 | ST | R | 11 | | 00001 | Field Separator | |
| 2 | 4 | ST | R | 11 | | 00002 | Encoding Characters | |
| 3 | 180 | HD | R | 11 | 0361 | 00003 | Sending Application | |
| 4 | 180 | HD | R | 11 | 0362 | 00004 | Sending Facility | CLIA number |



| 5 | 180 | HD | R | 11 | 0361 | 00005 | Receiving Application | MDSS |
|--------------|------------|-----|-------|-----------------|--------------|--------|--|-------------------------------------|
| 6 | 180 | HD | R | 11 | 0362 | 00006 | Receiving Facility | MDCH |
| 7 | 26 | TS | R | 11 | | 00007 | Date/Time of Message | |
| 8 | 40 | ST | X | 00 | | 00008 | Security | |
| 9 | 7 | СМ | R | 11 | 0076 0003 | 00009 | Message Type | ORU^R01^0 RU_R01 |
| 10 | 20 | ST | R | 11 | | 00010 | Message Control ID | |
| 11 | 3 | РТ | R | 11 | | 00011 | Processing ID | P when in production, T for testing |
| 12 | 60 | VID | R | 11 | 0104 | 00012 | Version ID | |
| 13 | 15 | NM | X | 00 | | 00013 | Sequence Number | |
| 14 | 180 | ST | X | 00 | | 00014 | Continuation Pointer | |
| 15 | 2 | ID | X | 00 | 0155 | 00015 | Accept Acknowledgment Type | |
| Sequ ence | Len gth | DT | Usage | Cardin ality | TBL# | Item # | Element Name | Comments |
| 16 | 2 | ID | X | 00 | 0155 | 00016 | Application Acknowledgment Type | Comments |
| 17 | 2 | ID | X | 00 | | 00017 | Country Code | |
| 18 | 16 | ID | X | 00 | | 00692 | Character Set | |
| 19 | 60 | CE | X | 00 | | | Principal Language of Message | |
| 20 | 20 | ID | X | 00 | | 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 state DSS standards, which can be retrieved here:



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 Disease Surveillance Use Case can be found at:

https://mihin.org/disease-surveillance/

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

- □ <u>www.mihin.org/requesthelp</u>
- 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 "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 MCLA § 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.



Appendix A

A.1 Sample Disease Surveillance Message

 $\label{eq:msh-patient} $$ MSH|^{\sim}\&|MIHIN\ PATIENT$ $$ GEN|1.2.3.4.5.9.99.999.9999.1246||2.16.840.1.113883.3.1481|202002141300000500|| $$ ORU^R30^ORU_R30|1612|P|2.6|1611||||||||||Soldier\ Westside\ Urgent\ Care\ Center $$ PID|1|4707|2b5c7d0ad60c4dedb8452dfb7c9cbff1^^^CKS~000004707^^^SS||Miles ^Dave||19580606|M||2106-3^White^HL70005|179\ E\ Orange $$ Court^^Dryden^MI^48428||||||000004707|||N^Not\ Hispanic\ or\ Latino^HL70189||||||20200214132000-0500|N $$ PD1|||Soldier\ Westside\ Urgent\ Care\ Center^^^^^^^^^1.2.3.4.5.9.99.999.9999.1246|9999992855^Moore^Richard^^^^^^^^^NPI^^^^^^MD $$ OBR||||||20200214130000-0500$



Acronyms and Abbreviations Guide

| 1 | |
|-------|---|
| API | Application Programming Interface |
| CLIA | Clinical Laboratory Improvement Amendments |
| DQA | Data Quality Assurance |
| DSA | Data Sharing Agreement |
| DSM | Direct Secure Messaging |
| EHR | Electronic Health Record |
| ELR | Electronic Laboratory Result |
| FHIR | Fast Healthcare Interoperability Resources |
| HIE | Health Information Exchange |
| HIN | Health Information Network |
| HISP | Health Internet Service Provider |
| HL7 | Health Level Seven |
| MDCH | Michigan Department of Community Health |
| MDHHS | Michigan Department of Health and Human Services |
| MDSS | Michigan Disease Surveillance System |
| MiHIN | Michigan Health Information Network Shared Services |



| NwHIN | Nationwide Health Information Network |
|-------|--|
| РНІ | Protected Health Information |
| SMTP | Simple Mail Transfer Protocol |
| TDSO | Trusted Data Sharing Organization |
| VPN | Virtual Private Network |
| XCA | Cross Community Access |
| XDR | Cross-Enterprise Document Reliable Interchange |
| REST | Representational State Transfer |



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.
- **Conforming Message.** A message that is in a standard format that strictly adheres to the implementation guide for its applicable use case.
- 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.
- **Electronic Medical Record or Electronic Health Record (EMR/EHR)**. A digital version of a patient's paper medical chart.
- Electronic Service Information (ESI). All information reasonably necessary to define an electronic destination's ability to receive and use a specific type of information (e.g., discharge summary, patient summary, laboratory report, query for patient/provider/healthcare data). ESI may include the type of information (e.g. patient summary or query), the destination's electronic address, the messaging framework supported (e.g., SMTP, HTTP/SOAP, XDR, REST, FHIR), security information supported or required (e.g., digital certificate) and specific payload definitions (e.g., CCD C32 V2.5). In addition, ESI may include labels that help identify the type of recipient (e.g., medical records department).
- **Exhibit.** Collectively, a use case exhibit or a pilot activity exhibit.
- **Health Directory**. The statewide shared service established by MiHIN that contains contact information on health providers, electronic addresses, end points, and ESI, as a resource for authorized users to obtain contact information and to securely exchange health information.
- 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.
- **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.
- **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 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.
- Nationwide Health Information Network (NwHIN). See the definition for Sequoia Project.
- **Pilot Activity**. The activities set forth in the applicable exhibit and typically includes sharing message content through early trials of a new use case that is still being defined and is still under development and which may include participating organization feedback to MiHIN to assist in finalizing a use case and use case and use case exhibit upon conclusion of the pilot activity.
- **Principal.** A person or a system utilizing a federated identity through a federated organization.



- **Promoting Interoperability**. 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 American Recovery and Reinvestment Act of 2009.
- **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.
- **Simple Mail Transfer Protocol (SMTP).** The Simple Mail Transfer Protocol is a communication protocol for electronic mail transmission.
- **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 (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 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.
- **View Download Transmit (VDT).** A requirement for Meaningful Use with the objective to provide patients with the ability to view online, download and transmit their health information within a certain period of the information being available to an eligible professional.
- **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

