MedMorph Hepatitis C Use Case

# Description <Describe the goal or objective of the use case.>

The purpose of the use case is to demonstrate how public health programs and stakeholders can leverage current investments in [electronic case reporting (eCR)](https://www.cdc.gov/surveillance/projects/bridging-public-health-and-health-care-better-exchange-better-data.html) to improve the availability of data that advance national public health priorities – in this case, eliminating hepatitis C as a public health threat in the United States.

Hepatitis C cases should be reported to state and local Public Health Agencies in all US states and territories.

In electronic case reporting, the HL7 electronic Initial Case Report (eICR) is transmitted to the appropriate Public Health Agencies whenever certain hepatitis C diagnoses, problems, lab results, lab orders, and treatments are recorded or modified in Electronic Health Records.

This use case will supplement eICR and ensure hepatitis C surveillance needs are met and enhance management needs by including hepatitis C treatment rates.

Problem Statement <What is the challenge/problem the use case is attempting to address?>

Effective public health action depends on access to timely, relevant, and complete data. Unfortunately, the availability of data to public health, particularly, data captured in EHRs, remains limited, in part because current data systems and exchange standards are siloed, and administratively cumbersome. The public health consequences of this current state are well illustrated by—but certainly not unique to—hepatitis C surveillance.

Data isn’t consistently available to public health due to limitations in interoperability standards or utilization of standards.

Many state and local programs do not have the data necessary to assess hepatitis C disease burden and its distribution in their communities, let alone monitor trends in key epidemiological parameters and health outcomes, like those captured in the [HCV care cascade](https://images.app.goo.gl/sCQQ3hTNLs7Cyg3z8).

In the absence of such situational awareness, public health programs lack the information necessary to efficiently and effectively direct public health action and population health research activities.

# Goals of the Use Case<List of objectives to ensure use case meets the need.>

* Develop a complete use case to ensure the MedMorph architecture supports the electronic reporting of comprehensive hepatitis C data by health care providers and health systems to public health, clinical registries, and researchers.
* Principles to help guide this goal include:
  + hepatitis C are captured within the EHR
  + Reduce the implementation and reporting burden on providers and health systems by automated reporting and minimizing duplicative demands whenever possible
  + Align with existing legal requirements
  + Preserve source data (persist the source data in original format) / Minimize the transformation of data / be aware and accommodate for lossiness / preserve provenance and semantics of the source data

# User Stories <One or more user stories that can be observed in the real-world including actors, events, systems, trigger events and actions.>

HCV Testing and Diagnosis (Care Cascade)

Patient X visits his primary care doctor, Dr. Y, for a non-emergent matter, and during the visit, Dr. Y notices that the EHR has flagged Patient X as being eligible/due for a hepatitis C test. Dr. Y places/approves order for [FDA approved hepatitis C antibody test](https://www.hcvguidelines.org/evaluate/testing-and-linkage), with automatic reflex to an FDA-approved NAT assay intended for detection of hepatitis C virus (HCV) RNA to confirm the diagnosis. Lab tech (onsite) draws blood specimen form patient X via venipuncture and sends to lab (off site).

Lab performs recommended testing sequence. In this case, the anti-HCV test is reactive, so an HCV RNA test is performed on the same specimen (reflex testing). This, too, is reactive, indicating that Patient X is currently infected with HCV. Lab sends results electronically to Dr. Y.

* Questions for Workgroup:
  + Would/should receipt of results trigger generation of the initial electronic case report to public health?
    - Aaron: The positive HCV RNA result should automatically trigger a case report. A problem may arise if the patient had been previously tested in another health system which may lead to duplication
  + Does physician or one of his/her team members have to take any action to “send” initial report, or is it automatic? (primary use case)
    - Aaron: The physician should not be involved. We can automate the electronic case report based on the HCV RNA result from the laboratory.
  + Would answers to the above two questions be the same if the information was being “sent” to (or pulled by) a clinical registry operated by Dr. Y’s health system? (supplement 1)

Hepatitis C Pretreatment Assessment (Care Cascade)

Member of Dr. Y’s office calls Patient X to schedule follow up appointment with doctor to review/discuss test results. Patient X comes in for follow up appointment to discuss HCV test results with Dr. Y. Dr. Y generates a referral for Patient X to initiate care with a specialist, Dr. Z, within the same health system who has experience/expertise managing HCV treatment. Dr. Y orders an imaging test of the liver (ultrasound or MRI) and HCV genotype, HIV test, complete HBV serology testing, and a series of follow up laboratory tests (complete blood count (CBC), complete metabolic profile including a hepatic function panel (i.e., albumin, total and direct bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), calculated glomerular filtration rate (eGFR), and the results of which will be used by the treating physician to inform his/her HCV treatment strategy. Dr. Y’s office receives the results from these follow up tests and shares them with Dr. Z’s office.

Patient X calls the office of Dr. Z and schedules an appointment. Patient X meets with Dr. Z to discuss treatment options. At this time, Dr. Z performs a transient elastrography test (to evaluate the degree of hepatic fibrosis present). The results, which are shared with Dr. Z and Patient X, indicate that there is no liver cirrhosis present and Patient X is infected with genotype 1b.

* Questions for Workgroup:
  + If certain additional test results (e.g., ALT results indicative of acute infection) should be sent to public health, when should that report trigger? Is it a new report, or an “amendment” to the initial report? (primary use case)
  + If a new report, what other information would public health need to link to the previous report (tracking cascade of outcomes)?
  + Does physician or one of his/her team members have to take any action to “send” that new/amended report, or is it automatic? (primary use case)
  + Would answers to the above two questions be the same if the information was being “sent” to (or pulled by) a clinical registry operated by Dr. z’s health system? (supplement 1)
  + Are there additional results and associated triggers that need to be considered when the receiving system is a clinical registry (vs. public health)? (supplement 1)

Treatment (Care Cascade)

Dr. Z performs a complete medication reconciliation to ascertain any potential drug-drug interactions and learns there is no risk. Dr. Z prescribes a daily fixed-dose combination of ledipasvir (90mg)/sofosbuvir (400mg) for 12 weeks as [recommended by AASLD](https://www.hcvguidelines.org/treatment-naive/simplified-treatment). Patient X’s insurer has a PA process in place for the medication Dr. Z is recommending, so the clinical pharmacist assembles and submits the necessary paperwork. Patient X is called by the case manager in 2 weeks that the medication has been approved and follows up with the next available appointment with the clinical pharmacist. Patient X follows up with the clinical pharmacist and receives counseling about adherence to the medication and picks up the medication and starts to take it.

* Questions for Workgroup:
  + Would the e-prescription trigger a new or “amended” report to public health? Immediately—or at some lag? Are there other triggers or trigger conditions to consider? (primary use case)
    - If a new report, what other information would public health need to link to the previous report (tracking cascade of outcomes)?
  + Does physician or one of his/her team members have to take any action to “send” that new/amended report, or is it automatic? (primary use case)
  + Would answers to the above two questions be the same if the information was being “sent” to (or pulled by) a clinical registry operated by Dr. z’s health system? (supplement 1)
  + Are there data or associated triggers that need to be considered when the receiving system is a clinical registry (vs. public health)? (supplement 1)

Cured (Care Cascade)

Patient X follows up with the clinical pharmacist 4 weeks after starting treatment. During each visit, the clinical pharmacist reviews any adverse events and or newly started prescriptions that may pose risk of drug-drug interactions and discusses/reinforces the importance of adherence to the regimen. Patient X will follow up every 4 weeks with the clinical pharmacist while being treated. During the 3rd visit which is the end of treatment visit (12 weeks after starting treatment), the clinical pharmacist will order a HCV RNA test for 3 months later for the post treatment assessment of cure. Patient X goes to the lab 3 months later to be tested and returns to Dr. Y’s office to confirm HCV RNA is undetectable (virologic cure).

* Questions for Workgroup:
  + Would test confirming SVR trigger a new or “amended” report to public health? Immediately—or at some lag? Are there other triggers or trigger conditions to consider? (primary use case)
    - If a new report, what other information would public health need to link to the previous report (tracking cascade of outcomes)?
  + Does physician or one of his/her team members have to take any action to “send” that new/amended report, or is it automatic? (primary use case)
  + Would answers to the above two questions be the same if the information was being “sent” to (or pulled by) a clinical registry operated by Dr. Z’s health system? (supplement 1)
  + Are there data or associated triggers that need to be considered when the receiving system is a clinical registry (vs. public health)? (supplement 1)

# Scope of the Use Case <Identifies the scope for the use case.>

In-Scope <What we will accomplish and do with this use case.>

* Identify and report hepatitis c data to public health and through bi-directional communication send information back to health care systems.
* The following jurisdictional “level(s)” should be pursued for use case function development:
* Among local stakeholders
* Local -> State
* State -> National

Out-of-Scope <What the use case will not cover or will not attempt to solve.>

Example:

* How a lab test result is transmitted between lab and clinical care.
* Policies of the clinical care setting to collect consent for data sharing.

# Use Case Actors <List of actors and the definition of those actors related to the use case.>

**Example Actors and Definitions:**

* **CRN Instrument**: The CRN Instrument is a form or a questionnaire that is used to collect data from patients. The instrument is designed based on data that needs to be collected using the data element definitions previously described. The CRN Instrument is also referred to as the CRN Form and CRN Questionnaire.
* **CRN Instrument and Metadata Repository**: The CRN Instrument and Metadata Repository is a system capable of storing the CRN Instruments along with its metadata. In addition to storing the CRN Instruments, the repository provides APIs to health IT systems to retrieve the instruments for administration. The repository may be hosted by an organization (e.g. Specific Registry) individually or can be hosted centrally by a federal agency (e.g. NIH/NLM) or a network such as Common Well or an independent organization providing CRN services.
* **EHR or Other Health IT System**: The EHR or Other Health IT Systems are used by providers to deliver care and can capture and store the health information about the patient. These EHR or Other Health IT systems can also be used to administer CRN Instruments to patient as part of routine care.

Use Case Abstract Model <Visual diagram with actors, activity, and systems involved in the workflows.>

*Paragraph to define what the model is showing and what it means*

Example Abstract Model:

A screenshot of a cell phone

Description automatically generated

Use Case Flow and Diagrams <Chronological steps of interactions among actors to include the activity undertaken by the actor the inputs and outputs. This includes the Main, Precondition, Postcondition, Alternate flows.>

Preconditions <Conditions that must exist for the use case to start. These conditions describe the state of the system, from a technical perspective, that must be true before an operation, process, activity or task can be executed. It lists what needs to be in place before executing the use case flow.>

* Public Health uses allowed by HIPPA have been defined and implemented

Main Flow < Main Flow is the most common way in which the use case is executed.>

Example: Use Case Flow for Collecting Registry Data

| **Step** | **Actor** | **Role** | **Activity** | **Input(s)** | **Output(s)** |
| --- | --- | --- | --- | --- | --- |
| 1 | Researcher | CRN Instrument Creator | Create CRN Instrument along with its metadata and publish the instrument in the CRN Instrument and Metadata Repository | Questionnaire and associated metadata | Published CRN Instrument in the Metadata Repository |
| 2 | Provider | Care Manager | Launch the External CRN Data Collection System (App) from within the context of an EHR or Other care delivery Health IT system. | N/A | Launched CRN instrument ready for completion by the provider |
| 3 | CONTINUED | | | | |

Postconditions <Describes the state of the system, from a technical perspective, that will result after the execution of the operation, process activity or task.>

Example:

* A completed FHIR QuestionnaireResponse is submitted to a registry.

Alternate Flow < Alternate Flows present a new pathway for the information exchange (e.g., capture error messages returned if the data are unavailable or not permitted to be shared).>

* Care Cascade Elements are conveyed to clinical registries
* Transfer HCV data elements for research, augmented surveillance, and population health management

Use Case Diagram <Illustrates the actors and systems interactions.>

Activity Diagram <Illustrates the flow of events and information between the Actors.>

Sequence Diagram <Represents the interactions between objects in the sequential order that they occur in the User Story.>

# Data Requirements <Identify the data requirements for the use case based on the abstract model and the use case flows.>

**A link to the detailed data requirements spreadsheet will be provided.**

Hepatitis C Data Elements:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Data Element Name** | **Definition** | **Sample Values** | **Availability (Always, Maybe, Never)** | **Source (Manual Entry, API, Transform, PH Investigation)** |
| HCV Test |  | Anti-HCV, HCV RNA, HCV genotype |  |  |
| Hepatitis C Diagnosis |  | Acute, Chronic |  |  |
| HCV Treatment |  | Prescribed direct acting antiviral (DAA) |  |  |
| HCV Cure (SVR) | Negative HCV RNA > 3 months after completing treatment |  |  |  |
| Pregnancy Status |  |  |  |  |
| Last Menstrual Period |  |  |  |  |
| Pregnancy Outcome |  |  |  |  |
| Gestational Age at Outcome |  |  |  |  |
| Infant Born with Neonatal Abstinence Syndrome (NAS) |  |  |  |  |
| Injected Drug Use (ever) |  |  |  |  |
| Current Drug Use |  |  |  |  |
| SUD/OUD Diagnosis |  |  |  |  |
| MAT Prescribed |  |  |  |  |
| MAT Administered |  |  |  |  |
| Patient Name |  |  |  |  |
| Patient Address |  |  |  |  |
| Patient Age |  |  |  |  |
| Patient Sex |  |  |  |  |
| Patient Race |  |  |  |  |
| Patient Ethnicity |  |  |  |  |
|  |  |  |  |  |

# Policy Considerations <Capture policy considerations for the use case to be implemented in the real-world such as authorities, data use agreements, etc.>

# Non-Technical Considerations <Capture non-technical considerations for the use case to be implemented in the real-world such as performance, SLAs etc.>

# Appendices

Examples:

1. Related Use Cases and Links
2. References to appropriate documentation
3. Terms and definitions
4. Acronyms