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 research 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) and XXXXXX 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](http://nationalacademies.org/hmd/Reports/2016/Eliminating-the-Public-Health-Problem-of-Hepatitis-B-and-C-in-the-US.aspx).

Problem Statement

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

Effective public health action and research depends on access to timely, relevant, and complete data. Unfortunately, the availability and quality of data to public health, particularly data captured in EHRs, remains limited: current data systems and exchange standards are siloed, and existing interoperability standards are administratively cumbersome, underutilized, or otherwise limited in application and scope. 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 cure cascade (as shown in Figure 1 below). 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. The public health consequences of this current state are well illustrated by—but certainly not unique to—hepatitis C surveillance.

**Figure 1. HCV Cure Cascade**

# 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, researchers, and other potential users, such as clinical registries and quality reporting entities.
* Principles to help guide this goal include:
  + Optimize access to hepatitis C data that are already captured within the EHR
  + Reduce the implementation and reporting burden on providers and health systems by automating electronic reporting and minimizing duplicative data demands whenever possible
  + Align with existing legal requirements

# User Stories

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

User Story 1: Uncomplicated Adult Male - HCV Cure Cascade

### HCV Testing and Diagnosis (Cure 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 an order for [FDA approved hepatitis C antibody test](https://www.hcvguidelines.org/evaluate/testing-and-linkage), with automatic reflex to an FDA-approved Nucleic Acid Testing (NAT) assay intended for detection of hepatitis C virus (HCV) RNA to confirm the diagnosis. An onsite lab tech draws a blood specimen from Patient X via venipuncture and sends the specimen to an offsite lab.

The lab performs the recommended testing sequence. In this case, the anti-HCV test is reactive, so an FDA-approved NAT assay for HCV RNA is performed on the same specimen (reflex testing). This, too, is reactive, indicating that Patient X is currently infected with HCV. The lab sends results electronically to Dr. Y. Receipt of any HCV antibody and/or HCV RNA test result in the EHR automatically triggers an initial electronic case report to public health, as well as any clinical registry with which Dr. Y’s practice is affiliated.

### Hepatitis C Pretreatment Assessment (Cure Cascade)

A member of Dr. Y’s office calls Patient X to schedule a follow up appointment with the doctor to review/discuss test results. During that follow up appointment, Dr. Y orders a transient elastrography test (to evaluate the degree of hepatic fibrosis present); HCV genotype; and a series of lab tests, including complete HBV serology testing, complete blood count (CBC), HIV tests, and a 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)). The results of these will be used by Dr. Y to inform his recommended HCV treatment strategy. Dr. Y’s office receives the results from these follow up tests.

Depending on registry protocols and state/local reporting requirements (e.g., around acute case reporting), receipt of these pretreatment test results triggers additional reporting to public health and/or the clinical registry.

Patient X meets with Dr. Y to discuss treatment options. The results, which are shared 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)
    - Aaron: Only lab results for HIV/HBV if HIV+ or HBsAg+ (though this is out of scope for this project, but HIV and HBV should also be reported to public health), no other results needed for public health

### Treatment (Cure Cascade)

Dr. Y performs a complete medication reconciliation to ascertain any potential drug-drug interactions and learns there is no risk. Dr. Y 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. Y 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.

When the electronic order for the prescription is entered by Dr. Y, it also triggers a new report to public health and the clinical registry with which Dr. Y’s practice is affiliated.

* 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)

### Cured (Cure 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 follows 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 orders an 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).

Receipt of the HCV RNA test result in the EHR automatically triggers a report to public health, as well as any clinical registry with which Dr. Y’s practice is affiliated.

User Story 2: Pregnant Woman and Exposed Infant – HCV Care Cascade

### Diagnostic Flow

Patient A, a pregnant woman (hereafter, “Mom”), visits her OBGYN, Dr. A, for her initial prenatal care visit. During this visit, Dr. A orders routine prenatal labs, including an [FDA-approved hepatitis C antibody test](https://www.hcvguidelines.org/evaluate/testing-and-linkage). An onsite lab tech draws a blood specimen from Mom via venipuncture and sends the specimen to an offsite lab.

The lab performs the recommended testing. In this case, the anti-HCV test is reactive, so an FDA-approved NAT assay for HCV RNA is performed on the same specimen (reflex testing). This, too, is reactive, indicating that Mom is currently infected with HCV. The lab sends results electronically to Dr. A. Receipt of any HCV antibody and/or HCV RNA test result in the EHR automatically triggers an initial electronic case report to public health, as well as any clinical registry with which Dr. A’s practice is affiliated.

* Importantly, the report triggered should include information indicative of current pregnancy. Ideally, this information would be communicated using emerging standards (if that’s not too great a stretch) for representing pregnancy status (see <https://www.healthit.gov/isa/representing-patient-pregnancy-status>). Alternatively, and/or additionally, other information in the EHR could be defined as being a reasonably reliable proxy indicator of potential pregnancy and so included in the report if present (e.g., calculated time since last menstrual period; recent prenatal panel test ordered)

Because current HCV treatment regimens are not approved for use during pregnancy, Dr. A does not immediately initiate a referral for treatment.

### Delivery Flow

Several months later, Mom goes into labor and arrives at the hospital. Mom’s HCV infection status is communicated to the hospital staff and captured in its EHR (e.g., in the problem list or medical history) so healthcare staff can take necessary additional precautions.

Mom delivers a healthy baby girl (hereafter “Baby”). Data on the delivery and its outcome are captured in the hospital’s EHR. The combination of information indicating a live birth, as well as Mom’s documented HCV infection status, triggers the hospital EHR to send a report to public health. That report includes information on Mom; her HCV infection status (diagnosis and/or test results and date); and her delivery (delivery date and outcome).

The delivery records are also forwarded to Baby’s pediatrician, Dr. P, where it also triggers a report to public health that includes information on Baby and Baby’s exposure to HCV (recognized based on Mom’s HCV infection status).

NOTE: the hospital “delivery” and pediatrician “exposure” reports triggered under this flow allow for public health follow up to ensure the exposed infant receives appropriate care. In an ideal world, the “infant” flow outlined further below would itself ensure such follow up care. But reality is often far messier, especially when it comes to communication of data across different institutions and providers for different individuals (mom, baby). Adding these reporting steps better positions public health to help ensure those connections are made—and that providers like the pediatrician know what steps to take when caring for an exposed infant.

### Delivery Flow

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Mom delivers a healthy baby girl (hereafter “Baby”). Data on the delivery and its outcome are captured in the hospital’s EHR. The combination of information indicating a live birth, as well as Mom’s documented HCV infection status, triggers the hospital EHR to send a report to public health. That report includes information on Mom; her HCV infection status (diagnosis and/or test results and date); and her delivery (delivery date and outcome).

The delivery records are also forwarded to Baby’s pediatrician, Dr. P, where it also triggers a report to public health that includes information on Baby and Baby’s exposure to HCV (recognized based on Mom’s HCV infection status).

NOTE: the hospital “delivery” and pediatrician “exposure” reports triggered under this flow allow for public health follow up to ensure the exposed infant receives appropriate care. In an ideal world, the “infant” flow outlined further below would itself ensure such follow up care. But reality is often far messier, especially when it comes to communication of data across different institutions and providers for different individuals (mom, baby). Adding these reporting steps better positions public health to help ensure those connections are made—and that providers like the pediatrician know what steps to take when caring for an exposed infant.

### Post-Partum Treatment Flow for Mother

Mom has a post-delivery visit with Dr. A at 2 weeks, at which time Dr. A makes a referral for Mom to see Dr. Z, an HCV treatment provider.

At her first appointment with Dr. Z, he orders a transient elastrography test (to evaluate the degree of hepatic fibrosis present); HCV genotype; and a series of lab tests, including complete HBV serology, complete blood count (CBC), HIV tests, and a 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)). The results of these will be used by Dr. Z to inform his recommended HCV treatment strategy. Dr. Z’s office receives the results from these follow up tests.

Mom has a second appointment with Dr. Z to discuss options. The results, which are shared with Mom, indicate that there is no liver cirrhosis present and Patient X is infected with genotype 1b. Mom indicates that she is breast feeding and would like to continue to do so until Baby is at least 6 months old. Dr. Z and Mom thus decide to defer treatment for several months, until Baby has transitioned to bottle feeding.

Approximately 5 months later, Mom has a follow up visit with Dr. Z. Mom is no longer breast feeding, and she and Dr. Z agree to initiative treatment for her hepatitis C.

From here, the flow for Mom is identical to User Story #1 (treatment and post-treatment assessment of cure).

### Testing, Diagnosis and Treatment Flow for Infant

Based on the records he received from the hospital, Dr.P knows that Baby was exposed to HCV.

According, during Baby’s 2 month well child check, Dr. P orders an FDA-approved Nucleic Acid Test (NAT) intended for detection of hepatitis C virus (HCV) RNA. An onsite lab tech draws a blood specimen from Baby and sends the specimen to an offsite lab.

The lab performs the recommended test, and the results are reactive. The lab sends results electronically to Dr. P. Receipt of the HCV RNA test result in the EHR automatically triggers an initial electronic case report to public health.

Dr. P makes a referral for Baby to see Dr. X, a pediatric gastroenterologist. During Baby B’s first visit with Dr. X., Dr. X explains to Mom that it is too early to initiate treatment for Baby—and that there is a possibility that Baby’s viremia will prove transient. They will retest her at 18 months to determine if she remains infected, and, in the interim, monitor her.

At 18 months, an [FDA-approved hepatitis C antibody test](https://www.hcvguidelines.org/evaluate/testing-and-linkage), with automatic reflex to FDA-approved NAT assay for HCV RNA, is performed and, again, Baby’s results are positive. The positive results are sent by the lab to Dr. X, who also shares them electronically with Dr. P. Receipt of the HCV RNA test result in Dr. X’s EHR automatically triggers an initial electronic case report to public health, as well as any clinical registry with which Dr. X’s practice is affiliated.

Because HCV DAAs are not approved for use in children as young as Baby, Dr. X does not initiate treatment at this time. Instead, he will continue to monitor Baby’s health until she reaches age 3.

Once Baby is 3 years old, Dr. X will evaluate Baby and make a treatment recommendation.

At that point, the flow for Baby is similar to that outlined for User Story #1 (treatment and post-treatment assessment of cure).

# Scope of the Use Case

In-Scope

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

* Identify and report current HCV infection to public health and through bi-directional communication send information back to health care systems.
* Improving data flow and reporting/sharing at the following jurisdictional “level(s)” should be prioritized under this use case:
* Among local stakeholders
* Local -> State
* State -> National

Out-of-Scope

<What the use case will not cover or will not attempt to solve.>

* Data captured outside the EHR and communicated directly to registries or public health
  + This includes electronic reporting from laboratories directly to public health, as well as data sent from pharmacy systems directly to clinical registries.
* Policies of the clinical care setting to collect consent for data sharing

# Use Case Actors

<List of actors and the definitions of those actors related to the use case.>

* **EHR System:** Conforms to the electronic health record (EHR) definition in Appendix C of this document. The EHR System in this use case has the requisite FHIR APIs available**.**
* **Backend App:** Interacts with the EHR to determine the trigger rules and subscribes to the EHR for topics. The App will interact with the EHR, gather the appropriate data, and then transmit the data to the appropriate system(s).
* **Trust Service:** Provides anonymization services of various types that can be invoked by the Backend App.
* **RCKMS/AIMS Platform:** A system that applies business logic and informs the Reportability Response.
* **Public Health Authority Data Store:** A FHIR server or service that receives and stores the hepatitis C data.

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*

Coming soon…

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.>

* Data use agreements are in place when needed
* Public Health uses allowed by HIPAA and other statutory authority have been defined and implemented
* All patient encounters required to initiate and move through the cure cascade take place (i.e., patient attends) with authorized providers, and requisite steps (e.g., tests ordered; performed; and results received; drug prescribed) are performed and captured in the EHR using approved standards

Main Flow

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

### Hepatitis C Test Result Flow (eICR)

| **Step** | **Actor** | **Role** | **Activity** | **Input(s)** | **Output(s)** |
| --- | --- | --- | --- | --- | --- |
| 1 | EHR System | Data Inputter/ Receiver | Patient encounter occurs and lab results are posted | Encounter data and test results from lab | Encounter data and lab results written to EHR’s FHIR Server |
| 2 | EHR System | Notifier | Notify the Backend App that there has been activity in topics the app subscribes to | Trigger codes (limited to lab results?) | Notification message |
| 2.5 | Backend App | Evaluator | Evaluates criteria (and timing if need to wait on lab results?) | Notification message, criteria, rules | Yes/No query decision |
| 3 | Backend App | Data Extractor | Query the EHR for case data | *Query decision* | FHIR query |
| 4 | EHR System | Query Responder | Return case data | FHIR query | FHIR bundle |
| 5 | Backend App | Data Receiver | Receive and validate FHIR bundle | FHIR bundle | FHIR validated bundle |
| 6 | Backend App | Data Sender | Send validated FHIR bundle as eICR to RCKMS | FHIR validated bundle | FHIR bundle |
| 7 | RCKMS | Data Receiver | Receive and validate FHIR bundle | FHIR bundle | validated FHIR bundle |
| 8 | *RCKMS* | *Evaluator* | *Performs necessary transforms and applies rules to content of eICR* | *FHIR bundle* | *Reportability Response (RR)* |
| 9 | *RCKMS* | *RR Sender* | *Transforms and transmits RR to EHR system* | *RR* | *RR as FHIR Bundle* |
| 10 | EHR System | Data Receiver | Receive and validate RR | RR as FHIR Bundle | Validated RR |

### Hepatitis C Chronic Reporting Flow

| **Step** | **Actor** | **Role** | **Activity** | **Input(s)** | **Output(s)** |
| --- | --- | --- | --- | --- | --- |
| 1 | EHR System | Data Inputter/ Receiver | Patient encounter associated with steps in care cascade (e.g., initial screen, pretreatment assessment, treatment, post treatment test for cure) | Encounter data (and optional test results from lab, prescription order) | encounter data written to EHR |
| 2 | EHR System | Notifier | Notify the Backend App that there has been activity in topics the app subscribes to | Trigger codes | Notification message |
| 2.5 | Backend App | Evaluator | Evaluates criteria | Notification message, criteria, rules | Yes/no decision (and timing) for querying EHR |
| 3 | Backend App | Data Extractor | Query the EHR for case data | Timing criteria | FHIR query |
| 4 | EHR System | Query Responder | Return case data | FHIR query | FHIR bundle |
| 5 | Backend App | Data Receiver | Receive and validate FHIR bundle | FHIR bundle | FHIR validated bundle |
| 6 | Backend App | Data Sender | Send validated FHIR bundle to trust service | FHIR validated bundle | FHIR bundle |
| 7 | Trust Service | Data Receiver | Receive and validate FHIR bundle | FHIR bundle | validated FHIR bundle |
| 8 | Trust Service | Data Anonymizer | Anonymize FHIR bundle | FHIR bundle | anonymized FHIR bundle |
| 9 | Trust Service | Data Sender | Send anonymized FHIR bundle | Anonymized FHIR bundle | Anonymized FHIR bundle |
| 10 | Backend App | Data Receiver | Receive and validate anonymized FHIR bundle | validate FHIR bundle | FHIR bundle |
| 11 | Backend App | Data Sender | Send FHIR bundle to PHA | Validated FHIR bundle | FHIR bundle |
| 12 | PHA | Data Receiver | Receive and validate FHIR bundle | FHIR bundle | Validated FHIR bundle |

Postconditions

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

* A hepatitis C case report and longitudinal case information resides in a registry.

Alternate Flow

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

* Convey cure cascade elements to clinical registries and HIEs to support population health management activities by healthcare providers and payer
* 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 level 6 months after starting treatment |  |  |  |
| Other labs (e.g., ALT) |  |  |  |  |
| Pregnancy Status |  | HCG result positive |  |  |
| Last Menstrual Period |  |  |  |  |
| Pregnancy Outcome |  |  |  |  |
| Gestational Age at Outcome |  |  |  |  |
| Infant Born with Neonatal Abstinence Syndrome (NAS) |  |  |  |  |
| Injected Drug Use (ever) |  |  |  | Need natural language processing to read clinical notes. There is no code for this. |
| 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

1. Related Use Cases and Links
2. References to appropriate documentation
3. Terms and definitions
   1. **Electronic Health Record (EHR):** a real-time, patient-centered record that makes information available instantly and securely to authorized users. While an EHR contains the medical and treatment histories of patients, an EHR system is built to go beyond standard clinical data collected in a provider’s provision of care location and can be inclusive of a broader view of a patient’s care. EHRs are a vital part of health IT and can:
      * Contain a patient’s medical history, diagnoses, medications, treatment plans, immunization dates, allergies, radiology images, and laboratory and test results
      * Allow access to evidence-based tools that providers can use to make decisions about a patient’s care
      * Automate and streamline provider workflow

*(Adapted from - Source:* [*https://www.healthit.gov/faq/what-electronic-health-record-ehr*](https://www.healthit.gov/faq/what-electronic-health-record-ehr)*)*

1. Topics for Technical Work Groups

* Reference Architecture:
  + Come up with a standardized definition for “EHR System”
* Clinical Workflows/Business Processes/Data Flows:
  + Closed/Completed Encounter - what term should be used as the trigger event?
* Unassigned:
  + What assumptions are we making an EHR registration of an APP and what does it entail on what is being pushed back to the App
    - We are looking at FHIR subscription models and provisioning of Trigger codes
    - Work through this with the App orchard
  + A comment regarding lossiness, provenance, etc. was raised but it was determined that the topic could be secondary goal of the MedMorph project and doesn’t belong in a use case document - but more of a technical artifact. A concise bullet point was provided “Ensure integrity of shared data, including formatting and metadata (e.g., about provenance) as possible while enabling comparability and adherence to standards.”
    - Original topics: 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 / be aware of/accommodate for missingness/incompleteness of data? A person's records are scattered all over different health systems.