Helios Align and Optimize Hepatitis C Use Case

Key
- Black = evaluation framework questions
- Red = legal questions
- Blue = summary of public health experts’ responses

Public Health Questions
1. Describe the project – receipt of negative hepatitis C (hep C) RNA results – why, why now, how does this benefit PH?
   - Positive lab results for hep C are all reportable but public health agencies (PHAs) typically only receive hepatitis C antibody result and no confirmatory result. Making negative hepatitis C results reportable to confirm the standard of care is being met (if someone has an antibody test, they should automatically have a hepatitis C RNA order) would support a public health goal of eliminating hepatitis in the US.
2. What are the challenges/obstacles to receiving the information you need for this project?
   - There are a lot of states that are not getting the negative test results in a usable, meaningful, or quick results. Most have not, will not, or it’ll be a multiyear process.
3. What are you doing now to get the information you need?
   - NYC receives information through ELR based on the health code of the city.
   - Oregon receives information through voluntary reporting from certain labs.
4. In a perfect world, could/should/would you get this information differently (and what might that look like)?

Use Case Questions
- What is the public health purpose?
  - Purpose: To eliminate hep C by tracking the people tested, confirmed, and not confirmed, as well as if confirmed cases are receiving treatment.
  - The purpose varies by jurisdiction. In NYC, there was an active program to link patients to care. But they would also like to use the data to find out how many people are getting treatment, how many people are spontaneously resolving, and which populations are not being treated then target those populations to get linked to care.
  - What questions are you trying to answer?
  - Is this surveillance or research?
    - Oregon: This is solely surveillance data—tracking whether people are getting tested, confirmatory testing, and if they’re receiving treatment on an annual basis.
- What are your data needs?
  1. The observation of both positive and negative results of the hep C RNA test.
  2. Receipt of treatment for hep C.
  3. Patient demographics to identify patients of need.
- Where do you get this data? Via what means?
Is this question being answered through manual intervention today?
- Oregon: Negative hep C result and confirmatory testing via voluntary reports from certain labs.
- NYC: Through electronic laboratory reporting (specifically made negative hep C RNA tests reportable through health code for all tests).

Who are the actors (HIE, QHIN, EHR, STLT, CDC, etc.) who are part of this query?
- Which types of data holder(s) are the source of data today?
- Labs have the data, and potentially EHRs and HIEs. STLTs are seeking this data.

Do you need to answer this question for a group of people or an individual? Is this query for an individual or is this for a set of patients? (Line level)
- If it’s a set of patients, are the set of patients specifically defined? If so, how are they defined? (attribute or enumerated list)
- How do you know when to query for a specific patient? (Line level)
- It may be useful to differentiate individual case investigations where there may be bidirectional data from information that is more population-wide (negative cases) in the use case or data flow.
- In the individual case, the information required would be the positive to negative result for that specific patient as well as treatment data.
- In the population case, the information required would be the number of occurrences and ties to demographics such as zip code or county.

Are you getting timely information?
- How often do you send the report? Does it need to be sent in real-time or could the information be sent as a batch? Does the response need to be sent back immediately or when it is ready?
- How do we determine the urgency/frequency of this request?
- Oregon is not equipped to reach out to ensure someone positive is linked to care. This information is currently updated on an annual basis but increased frequency would be ideal. Negative hep C test results trigger eICRs currently. They are not passed on to jurisdictions that do not include them in their reporting rules in Reportable Conditions Knowledge Management System (RCKMS).

Are you getting accurate information?
- Are you getting an appropriately scoped grouping of information? (Too much? Too little?)
- How do we know we are receiving the correct information for the correct patient? Which system (requestor or responder) should determine that?
- This use case is less about the accuracy of data and is more about the completeness of data.

Are you getting complete information?
- This varies by jurisdiction. In Oregon, positive cases are received but RNA results are not received.
- What is the minimum necessary data?
- After the data is consumed, what additional data is needed to complete the query?
- Potentially need a record locator + new authorization requests.

What are the policies/law that allow manual requests for data?
- Is the data required to be reported by law under the jurisdiction?
- What information is allowed to be disclosed under state, federal, and local law?
Which data or reportable infectious disease is required to be sent under state or local law?

Data access varies by state. Some jurisdictions can request access based on local laws. Requestor authorization is based on state law and there is nothing federally mandating its reportability. In some states, there are methodologies to access this data by special policies. And in some others, there is voluntary submission.

Can you request access under a specific scope?

- Is the requestor authorized to receive data under state or local law about a specific disease/condition? Is there any federal policy that would require the requestor to receive patient authorization?
- Are there per access authorization to access the data decisions that need to be made? What are the exceptions to the authorities?
- In Oregon, there is a special studies statute. In NYC, hep C negative reportable by ELR, then health code allows for case investigation of any hep C.

Is this a costly question/issue to answer?

- Oregon gets 5,000-6,000 positive reports a year then about half have an RNA confirmation, which leaves a couple thousand uncertain results, which should not be overwhelming. Follow-up would accumulate additional costs and is not yet implemented.

How is the record of what information was accessed, by whom, for how long, for what purpose, etc. retained for oversight/breach notification purposes?

- What are the privacy protections in place for any identifiable data?
- Are the individual(s) aware that their data might be accessed by a public health authority beyond the information that is reportable by law? What is the minimum necessary information required by the query?
- In NYC, hep C negative reportable by ELR, then health code allows for case investigation of any hep C—additional information well supported for any authority for any known case of hep C but authorization for person with negative result only, not sure about authorization to get any additional identified information since they’re not a case.

Which of the FHIR resources help support the business need?

- FHIR Messaging and FHIR Subscription
  - Better fit for also triggering negative results.
  - Subscription to find the negative results through alerts.
  - Messaging to promote this other FHIR workflow.
- Proposed FHIR resources
  - Patient FHIR resource (assumed to be there for all use cases)
  - Encounter FHIR resource (assumed to be there for all use cases)
  - Conditions FHIR resource
  - Observations FHIR resource
  - MedicationStatement FHIR resource
  - MedicationRequest FHIR resource
- Query retrieve/response
  - Mature paradigm.
  - NYC serves as an example. There is a decent trigger that starts the workflow through a positive antibody or RNA test.
- Scenario: PHA knows where patient received care → case-investigation styled query to see if the patient has medication associated to them via medicine admin or statement
- Question about whether there is more data than necessary but can set up parameters that can specify the code based on medication/prescription.
  - Concern: Some individual healthcare organizations may not have fully adopted RxNorm, which would have technical development and implementation implications.

**Workflow**

1. **ELR Triggered**
2. **HEP C?**
   - Yes → **RNA lab result**
   - No → **Ignore**
3. **RNA lab result**
   - No → **Schedule follow-up check on Procedure?**
   - Yes → **Medication Statement FHIR call**
4. **Medication ICD / CPT Code?**
   - Yes → **Mark for future follow-up on outcomes**
   - No → **Contact Provider or Patient**
5. **Is this one or many codes?**
   - Under threshold → **Repeat for acceptable time frame**
   - Over threshold → **Is this one or many codes?**