Helios FHIR Query & Response Guidance (DRAFT)

## Introduction

The [Helios FHIR Accelerator for Public Health](https://confluence.hl7.org/pages/viewpage.action?pageId=216238674) is exploring the application of the FHIR Query & Response paradigm to public health use cases. The goal is for public health agencies to leverage FHIR endpoints exposed by clinical data systems such as EHRs as a replacement for more manual data exchange processes such as EHR abstraction, faxes and phone calls.

<revise once content is finalized>

### Purpose of this Document

The purpose of this document is to describe the use of the HL7 FHIR RESTful API model for sharing data with public health. This approach seeks to leverage existing FHIR API support to enhance public health access to the data necessary to perform critical functions such as case investigation and the provision of services and support to impacted individuals by allowing public health programs to proactively access authorized data held by healthcare providers and other data sources. By implementing this strategy, authorized public health users can efficiently retrieve data through the use of a standardized and reusable approach and allows data sources such as healthcare providers minimize the amount of time and effort expended on responding to data requests using manual and bespoke approaches. This approach also supports the concept of “minimum necessary” data by allowing public health to implement granular requests for only the data necessary to carry out authorized public health activities.

The purpose of this document is not to describe the RESTful application of the FHIR standard but rather to describe the application of this approach to public health data sharing use cases. We refer readers to the base [FHIR RESTful API documentation](http://hl7.org/fhir/http.html) for a thorough description of FHIR as a RESTful specification.

### Roles

<describe the role involved (FHIR server (EHRs and other data sources), FHIR client (Public Health), intermediaries/networks, etc)> This will help implementers understand their role and partners.

<include definitions and examples for each actor, written in such a way that if one knows nothing about Q&R, one can navigate this document first pass>

Several major partner roles are anticipated to be involved in the development and implementation of FHIR-based RESTful queries to exchange data for public health use cases. In later sections of this document, we will discuss specific expectations and activities required of each of these roles during the development and implementation process. The major roles are:

* Public health program
* Data source organization
* FHIR Client HIT vendor (i.e., the system requesting data)
* FHIR Server HIT vendor (i.e., the system responding to requests for data)
* Health Information Network (HIN)/Health Information Exchange (HIE)

Note that both the FHIR Client and FHIR Server functionality may be directly integrated into the primary systems utilized by the public health program and data source organization or they may be less integrated (e.g., a stand-alone application, a replica data source, a FHIR facade). The technical implementation of these functionalities is independent of most of the considerations described in this document.

For different public health use cases, different types of organizations might be considered data source organizations. These include:

* Healthcare providers (e.g., hospitals and clinics)
* Payers
* Other public health programs
  + Within the jurisdiction
  + Within other jurisdictions such as a neighboring state or local agency
* Community-based organizations
* Others as determined by the public health program sharing the data

An HIN/HIE

### Value Proposition

<overall for leadership support>

## Query & Response Use Cases

Should be relatively high-level. Point to outside documentation if necessary. Goal is to interest readers in exploring/testing use cases.

List of Use cases with hyperlinks to Appendix A for a long description of the use case.

[Newborn Screening Use Case](#kpacu0acohs4)

<below is a template for all use cases to align with>

### <Use Case Template>

#### Description

<description of use case - should include current pain points>

#### Actors

<provide use case specific actors related to the Roles provided above. E.g. A newborn screening system (client) queries an EHR (server) for screening data>

#### Benefits

#### <summary of the benefits of using FHIR query for all Actors>

#### Triggering Event

<What causes the queries to be generated? This could be automated (ELR message received) and/or manual (case investigator opens a case record)>

#### Query Content

<what sort of data is relevant to retrieve? Doesn’t need to be specific or comprehensive, just gives the readers an idea of what is in scope>

#### Data Usage

<How is the data returned expected to be used by PH? Can touch on benefits again>

### Newborn Screening

#### Description

The goal of the Newborn Screening (NBS) query use case is to ensure that public health programs have access to the data they need to effectively care for newborns with potential hearing and cardiac conditions. The application of the FHIR query & response paradigm can help to ensure that newborns identified for follow-up through bedside screening at birthing facilities receive the follow up and care they require. These results typically come in the form of an interpretation of screening data resulting in a value of either “pass” or “refer”, where “refer” often triggers further diagnostic testing and/or services provided to the newborn and their family. While HL7 version 2 (v2) standards for transmitting early hearing detection and intervention (EHDI) and critical congenital heart disease (CCHD) results from EHRs to public health systems have existed for many years, there is very little practical implementation of these standards and data is still largely exchanged through manual and paper-based workflows. FHIR offers new opportunities for NBS programs to proactively access screening results captured by birthing facilities.

#### Actors

The newborn screening system in use by the jurisdictional program will play the role of the FHIR client querying for data. Alternatively, an intermediary system (such as an integration engine) or third-party tool may play the role of the FHIR client on behalf of the NBS system.The EHR system in use at a birth facility will play the role of the FHIR server. Intermediaries such as a Health Information Network (HIN) may facilitate the FHIR query.

#### Benefits

Benefits for NBS programs include improving the accuracy, completeness and

timeliness of EHDI and CCHD reporting as well as saving staff time by replacing manual processes with automated ones. Benefits for birthing facilities include the automation of existing manual reporting processes, a reduction in redundant documentation of screening results in multiple systems, and ensuring the best care for newborns with potential hearing or cardiac conditions.

#### Triggering Event

The query for newborn screening results may be initiated by any number of triggering events that notify the NBS program of the birth of the child. This may include v2 ADT messages, the receipt of a dried blood spot order or specimen or notification from the local Vital Records Office. Any triggering event must contain enough demographic information on the newborn to be able to uniquely identify the patient in the birthing facility EHR system.

#### Query Content

The first FHIR interaction is for positive identification of the newborn in the birthing facility EHR system. Demographics from the triggering event are used by the FHIR client to formulate a FHIR query to retrieve the Patient resource. Depending on the capabilities of the FHIR server, this may use either a standard Patient search or the $match operation. Once a matching Patient resource has been returned to the FHIR client, one or more subsequent queries for clinical data are constructed. Common Observations queried for, typically via LOINC code, include:

* CCHD
  + CCHD Newborn Screening Interpretation (73700-7)
  + Infant factors that affect newborn screening interpretation (57713-0)
  + Birth weight (8339-4)
* EHDI
  + Newborn hearing screen of Ear - right (54109-4)
  + Newborn hearing screen of Ear - left (54108-6)
  + Hearing loss risk indicators [Identifier] (58232-0)

#### Data Usage

The triggering events received by the NBS program contribute to the denominator of infants in the jurisdiction. NBS staff use the data returned by the FHIR queries to ensure that all infants have received screening (or have been identified as abstaining from screening) and ensure that additional diagnostic testing is provided to those newborns who have outcomes of “refer”.

## Policy Consideration

### Legally Appropriate Access

A given healthcare provider needs options to help them understand what should be considered when determining whether to respond to a public health query. Providers in some jurisdictions may have legal obligations to respond to some public health authorities and legal obligations to not respond to other public health authorities.

### Authority to Query

Certain jurisdictions interpret governing statutes as prohibiting case investigation queries, which could create significant challenges for healthcare organizations. This interpretation hinders efforts to conduct case investigations within systems, ultimately failing to reduce the need for manual case follow-up processes performed by jurisdictions today.

### Relationship to TEFCA

Guidance on how TEFCA can be used to facilitate queries and the relationship to the TEFCA Exchange Purposes outlined in the Public Health standard operating procedure (SOP) may be helpful to implementers.

### Federal Regulatory Requirements, HIT Certification

A description of the existing HTI-1/HTI-2 (g)(10) and (g)(20) certification requirements for HIT (both Public Health and EHR), United States Core Data for Interoperability (USCDI), and CMS Interoperability and Prior Authorization final rules, should be discussed as a means of outlining the types of data likely to be available via FHIR API query. Details may be found in the documentation linked below.

Assistant Secretary for Technology Policy (ASTP) Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1): <https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program>

HTI-1 Federal Register: <https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and>

Assistant Secretary for Technology Policy (ASTP) Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA) (HTI-2) Final Rule Homepage: <https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-trusted-exchange>

HTI-2 Federal Register: <https://www.federalregister.gov/documents/2024/12/16/2024-29163/health-data-technology-and-interoperability-trusted-exchange-framework-and-common-agreement-tefca>

ASTP United States Core Data for Interoperability (USCDI): <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi>

Centers for Medicare & Medicaid Services (CMS) Interoperability and Prior Authorization Final Rule (CMS-0057-F): <https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/policies-and-regulations/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f>

CMS-0057-F Federal Register: <https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability>

### Data Governance

<Among other things, this could describe any considerations about data use agreements, etc regarding subsequent use and sharing of data retrieved by a FHIR query>

## Technical Concepts

### FHIR Query Basics

<things like the difference between a search and a read, all the bits and pieces of connecting>

### Data Payloads

Different public health authorities have provided EHRs with different requirements of query-able data (USCDI, USCDI+, USPHL). Without guidance on data elements, different jurisdictions will require different development from EHRs to support their underlying data needs, impeding speed/ease of adoption. Provider organizations will not be able to meet their diverse public health needs, depriving them of the eventual goal of removing phone and fax based public health exchange.

### Exchange Pattern

Regulation suggests several different exchange patterns that conflict and may be utilized differently by different jurisdictions (Individual Query, Bulk Query, Subscription, etc.). Without this guidance, some public health authorities will focus on queries for affected individuals while some will focus on queries for populations of interest. Provider organizations will not be able to easily meet the diversity of public health needs, depriving them of the eventual goal of removing phone and fax based public health exchange.

### Minimization of Queries

Guidance on [search result modifiers](https://www.hl7.org/fhir/search.html#modifyingresults) such as \_include and \_revinclude, \_summary, paging, etc. can help implementers to minimize the number of individual queries performed by maximizing the data payload of each query.

### Point-to-Point vs Brokered/Facilitated/Networked Queries

Discussion of the role of intermediaries such as HIEs and QHINs will help implementers establish an efficient architecture.

### Resource & Scalability

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### Security Authentication Authorization, ex.

<content>

## Workflow Considerations

### Query Frequency

For a given patient/case, there is no guidance for how frequently queries should be initiated. Without this guidance, we may see automated or recurring queries for individuals both too rapidly and for too long a duration, causing inefficient use of system resources.

### Query Quantity

For a given population/condition, there is no guidance for how many individuals within the population should be queried for. Without this guidance, we may see automated queries for the entire affected population on a recurring basis, causing inefficient use of system resources.

### Query Specificity

For the superset of conditions of interest to a public health program, consideration should be given to which conditions provide the most benefit given condition specific workflows. For example, if a particular condition is rarely followed up on, the automated triggering of FHIR queries for additional information may not be an efficient use of system resources.

### Patient Identification

A discussion on the mechanisms of patient matching and validation will help guide implementer workflows in terms of defining acceptable patient matching outcomes and the role (if any) of human validation in the process.

### Consolidation of Data from Multiple Sources

When a query is fanned out to multiple potential responders, implements must understand the ramifications of receiving data from more than one source and the reconciliation of potentially duplicate (or conflicting) data.

### Partner Engagement Strategy Considerations

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### Testing and Piloting

<content>

## Trading Partner Expectations

The Actors section of this document describes the basic roles related to the exchange of data using FHIR RESTful queries. These are the <update with the list of actors developed>. Each of these roles are expected to implement basic technical and/or operational functionality in support of FHR queries regardless of the specific technology selected by trading partners. These basic functionalities are described below. Additional requirements may also be documented on a use case specific basis.

### Foundational Technical Requirements

<a description of the basic technical support that the various roles must have to most/all PH use cases. One example might be that the client system must have a mechanism for handling cases where a single matching Patient resource is not returned (either none are or multiple are). This is common to all types of use cases regardless of the clinical data payload being sought.>

### Foundational Technical Requirements

The FHIR Client HIT Vendor should expect to develop functionality to:

* Identify one or more query trigger events to initiate the query & response workflow
  + The nature of the triggering event will vary by use case but may include but are not limited to the receipt and parsing of data from a submitter (e.g., v2 message, CDA), ingestion of a flat file from a data submitter or end user action in a public health system
* Use demographics provided as part of the triggering event to execute patient look up in the FHIR Server
  + Support for Patient.search and/or the Patient $match operation
* Validate returned Patient resource(s) before searching for clinical data
  + Includes support for non-happy path outcomes which may include but are not limited to no matching patients, one or more low confidence matches, and multiple high confidence matches.
  + Human input may be required to identify the appropriate Patient resource to use for clinical queries
* Based on the nature of the triggering event, execute one or more queries for relevant clinical and/or administrative data from the FHIR server
* Parse, store and/or display retrieved data as appropriate for the use case

The FHIR Server HIT Vendor should expect to develop functionality to:

* Response to Patient.search and/or the Patient $match operation request from the FHIR Client
* Respond to queries from the FHIR Client for relevant clinical and/or administrative data

### Foundational Operational Requirements

<a description of the basic operational support that the various roles must have to most/all PH use cases>

### Foundational Operational Requirements

The public health program should expect to develop processes and functionality to work with the data source organization to:

* Implement any data use agreements required to exchange data via FHIR query
  + May include data governance and data use agreements
* Map required data elements to one or more queries for FHIR resources
  + This includes any parameters used by the queries to limit data requests to minimum necessary data
* Implement functionality and workflows to address ambiguous patient look up outcomes prior to subsequent queries
* Implement functionality and workflows to utilize returned data by end users or public health systems

The Authorized User organization should expect to develop processes and functionality to work with the immunization program to:

* Implement any data use agreements required to exchange data via FHIR query
  + May include data governance and data use agreements
* Clearly document scope of data available through FHIR query

## Additional Resources and Support

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Examples:

* Contact HL7 Helios FHIR Accelerator for Public Health: [helios@hl7.org](mailto:helios@hl7.org)
* HL7 Helios FHIR Accelerator for Public Health listserv: [helios@lists.hl7.org](mailto:helios@lists.hl7.org)
  + Join Helios listserv:
* HL7 Helios FHIR Accelerator for Public Health confluence homepage: <https://confluence.hl7.org/display/PH/Helios+FHIR+Accelerator+for+Public+Health+Home>
* HL7 Helios FHIR Accelerator for Public Health: Query & Response Priority Area confluence pages: <https://confluence.hl7.org/pages/viewpage.action?pageId=216238674>
* HL7 Helios FHIR Accelerator for Public Health: Query & Response Priority Area Calls (upcoming and archive of past meetings, recordings, and materials): <https://confluence.hl7.org/pages/viewpage.action?pageId=216238678>
* HL7 Zulip Channels (chat.fhir.org) :
  + Public Health Stream: <https://chat.fhir.org/#narrow/channel/379724-Public-Health>
  + Helios Accelerator Stream: <https://chat.fhir.org/#narrow/channel/307807-Helios-Accelerator>
  + Helios Query & Response Stream: <https://chat.fhir.org/#narrow/channel/416755-Helios-Query-.26-Response>
* HL7 Public Health Work Group Confluence Homepage: <https://confluence.hl7.org/display/PHWG/Public+Health+Work+Group>
* HL7 Public Health Work Group Meetings:
  + <https://confluence.hl7.org/display/PHWG/Upcoming+Meeting+Agendas>
* CDC FHIR Community of Practice (CoP) Calls
* Public Health FHIR Implementation Collaborative (PHFIC) Playbook: <https://www.cdc.gov/data-interoperability/media/pdfs/PHFIC_Public-Health-FHIR-Playbook.pdf>

## Appendix A: Use Case Descriptions

Newborn Screening