Implementing Biomedical Query Mediation for the Shriners Health Outcomes Network

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Capstone Project

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CERTIFICATE OF APPROVAL

This is to certify that the Master's Capstone Project of

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Implementing Biomedical Query Mediation for the Shriners Health Outcomes Network

Has been approved

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Executive Statement

Shriners Hospitals for Children is a healthcare organization with 22 hospitals and a global network of outreach clinics, dedicated to helping children with burn, orthopedic, neuromuscular and other conditions free of charge. One of the three pillars of the Shriner mission is research, with an emphasis on developing new care and proving efficacy of established practices. In an effort to accelerate the research programs at Shriners, the Shriners Health Outcomes Networks was developed in 2016. It is designed as a health learning system, inclusive of a data repository for secondary use of clinical electronic medical record data, educational and healthcare quality resources.

Access and appropriate use of research repositories improves the quality and timeliness of research projects; however, an effective approach to reuse of clinical data requires a structured system of information retrieval. Biomedical Query Mediation is a process that can bridge the gap between clinical science and information science, helping to refine questions from research teams, and make data retrieval and disclosure more effective. The process helps to refine research questions, define data and its characteristics and act as a development map for enhancing the repository. Implementation of the Biomedical Query Mediation process will act as the framework to enable effective inter-departmental communication and enhance clinical research being done by Shriners Hospitals for Children.

SHOnet End-user

Purpose

Documentation of defined end user use of the Shriners Health Outcomes Network within the scope of use for retrospective clinical research. This purpose is limited to research that meets institutional and regulatory requirements and is conducted on SHC patients who have data in the SHC medical record. The intent is to assist communication between research teams and data analysts to enhance the clinical research process in the stages between protocol development and data collection (Figure 1) (1).

Review

This guide is built to enhance to current retrospective research process at Shriners Hospitals for Children, listed below:

Shriners Hospitals for Children current retrospective study data process (Appendix 2):

1. Site submits a protocol on the SHC template (Appendix 2); section 5.1.2 describes data to be collected
    a. The two column chart includes data element and source of data (defined to system it comes from)
2. Data elements are examined from a compliance/privacy perspective based on the IRB status
3. Sites collect, store and analyze based on their protocol.

Background

In 2014, SHC developed a research health learning system named Shriners Health Outcomes Network (SHOnet) for use in research, quality improvement and operational improvement (2) . A main element of SHOnet is a clinical data repository, which is available for secondary use of patient data. At SHC, approximately 50% of the research is classified as unfunded retrospective chart review, and therefore SHOnet provides a great opportunity to streamline research processes and reduce effort. This document will severe as an end user requirements document for the use of SHOnet in the SHC research process.

Successful application of clinical data reuse research is dependent on comprehensive understanding how study objectives will be met with using the data collected. While study teams generally understand the conceptual framework of the research question being asked they are highly reliant on data analysts to produce valid information pertaining to the research objectives. Communication between the parties is critical in the validity of information for projects, and should be augmented with a structured dialogue to ensure critical understandings are met (3).

The Biomedical Query Mediation (BQM) framework was developed in 2013-14 as a structured methodology for directing the communication between study teams and data analysts in projects utilizing secondary use of clinical data (4, 5). The framework directs the communication in a bottom up approach with the goal of producing a concise and valid study query. Working from the base level of the data elements and their characteristics and building clinical context around them helps investigators to describe the scope of their question in relation to the data and it helps analysts to define the data infrastructure locations of the data and context in which they exist.

Use of the BQM framework for developing SHOnet research queries will enhance the validity of data use to address research questions in the SHC system. Additionally, but refining the scope and breadth of data reuse, the security of patient data will be enhanced by applying a true 'Minimum Necessary' policy as defined by the Health Insurance Portability and Accountability Act Privacy Rule (6).

Definitions

Data – discrete descriptor elements associated with an object or person

Data set- a compilation of data containing one or more data elements pertaining to one or more objects or people

End User – a clinical research investigator or designee of a clinical research investigator

Information – compiled data that describes an object or person

Acronyms

BQM - Biomedical Query Mediation

EHR – Electronic Health Record

HIPAA – Health Insurance Portability and Accountability Act

IRB – Institutional Review Board

OMOP – Observational Medical Outcomes Partnership

PHI – Protected Health Information

SHOnet – Shriners Health Outcomes Network

SHC – Shriners Hospitals for Children

SHC-HQ – Shriners Hospitals for Children International Headquarters

Acceptable Use

1. Use of SHOnet for retrospective clinical research studies must follow SHC policies and regulations regarding clinical research and the use of retrospective data.
    1.1. Study timelines must be defined and only contain dates historic relative to the initial protocol version date.
    1.2. Protocol amendments may not extend the date range to dates that have occurred after the initial protocol version date.
    1.3. Collection, storage and disclosure of PHI may only occur with a granted of a HIPAA Waiver of Authorization.
    1.4. Studies must be submitted to SHC-HQ for review and IRB submission or exemption.
    1.5. Any amendments or modifications must be resubmitted for SHC-HQ for review and IRB submission or exemption.

2. SHOnet is limited to the availability of data within the repository
   2.1. SHOnet's use of an ETL process in moving data from the SHC Cerner Millennium Tables to the SHOnet OMOP restricts data to EHR availability.
   2.2. SHOnet's data refresh occurs quarterly and may restrict or delay protocol dates.
   2.3. Official requests can be made to SHC-HQ and the SHOnet team to request added elements.
3. SHOnet queries will not return identified data sets, they are restricted to limited or de-identified datasets.
4. SHOnet queries will not return datasets with fewer than 10 patients.
5. Results from SHOnet queries must comply with all SHC Compliance and Research data policies for retrieval, storage and disclosure of data.

SHOnet Retrospective Procedures

1. Upon SHC-HQ approval, studies must be submitted for evaluation by the SHOnet team using SHOnet@shrinenet.org, and will initiate the BQM process (Figure 1).
   1.1. Core data elements listed in section 5.1.2 of the SHC retrospective clinical research protocol template (Appendix 1) will be assessed to initiate the conversation between the SHOnet data concierge and the investigator or investigator delegate.
   1.2. The study objectives from section 2.0 of the SHC retrospective clinical research protocol template (Appendix 1) will be used to determine the scope of the requested data.
   1.3. Study inclusion and exclusion criteria from sections 3.1 and 3.2 of the SHC retrospective clinical research protocol template (Appendix 1) will be used to define which patient records will be included.
2. After the SHOnet team's Data Concierge has extracted the data elements from the study protocol and associated them with the scope of the research, end-users will be engaged in dialogue about the related clinical process.
   2.1. Investigators and applicable staff will be contacted by a SHOnet analyst for discussion of core data elements and their relationship to the research objectives.
   2.2. Additional conversation of the required data will be framed in the clinical context of how the observations and measurements are made and during what parts of the clinical process they are recorded.
   2.3. Quality dimensions of the requested data will be scoped and confirmed with the study team within the following(7):
      2.3.1. Conformance
      2.3.2. Completeness
      2.3.3. Plausibility
   2.4. Upon agreement of data elements and the associated characteristics, the analyst will work with investigators to refine the cohort based on study inclusion and exclusion criteria.
   2.5. When the final query is defined, the SHOnet analyst will communicate with the study team about data availability and alternative strategies if needed.
      2.5.1. Some data may not be available through SHOnet, and the SHOnet staff will offer a directory of resource contacts that may be used to locate the source of those data.
      2.5.2. Some data may not be complete or representative of the defined scope in SHOnet, and the analyst will inform the study team of the limits of the data that is available.

3. Study teams will work with the SHOnet Data Concierge to provide a final codebook to the SHOnet analyst prior to the query being run. Codebooks must include:
    3.1. Variable/column names
    3.2. Specific data element coding if non-standard coding is needed
    3.3. Scoring instruction for scored items
4. Once the BMQ dialogue process is complete, study teams will be advised of the current wait times for the return of results from the SHOnet repository.
5. Completed data pulls and SQL scripts will be returned to study teams using Box, in designated study folders.
    5.1. Folders creation and oversight will be performed by the Department of Research Programs to ensure compliance with privacy and security policies.
    5.2. Data sets can be returned to study teams in various formats including but not limited to .csv, .r, .sav, .sas and .xlsx.
    5.3. Data stets will be un-altered from the agreed upon BMQ query and study teams will be responsible for performing their own cleaning and analysis.
    5.4. Study team may contact the SHOnet team at SHOnet@shrinenet.org for follow up questions about the data set.
6. Publications using data from the SHOnet query must include a citation of SHOnet in a format similar to the following:
    6.1. Shriners Hospitals for Children (*date of query*) Shriners Health Outcomes Network [database].

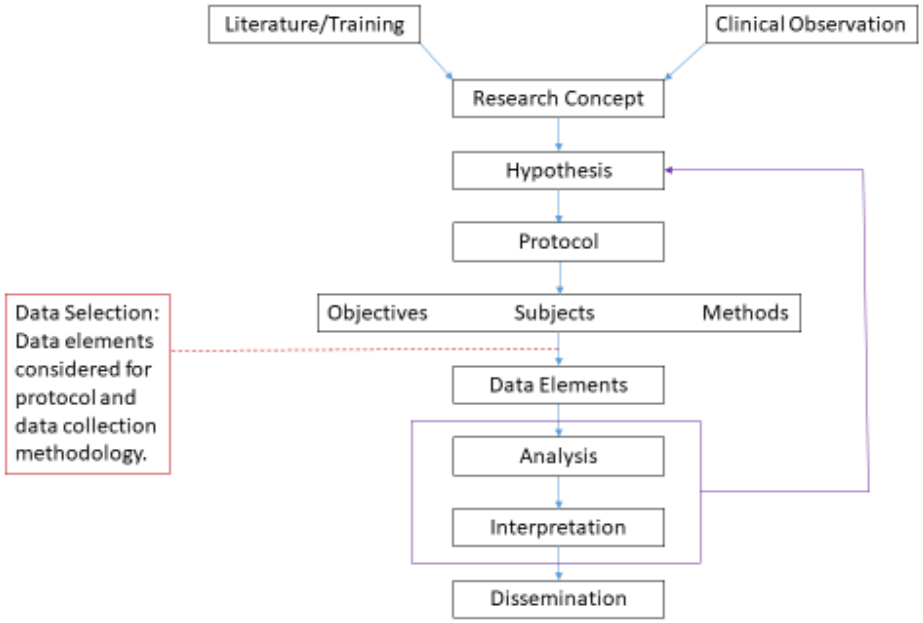

Figure 1 – STROBE Statement Research Process (1)

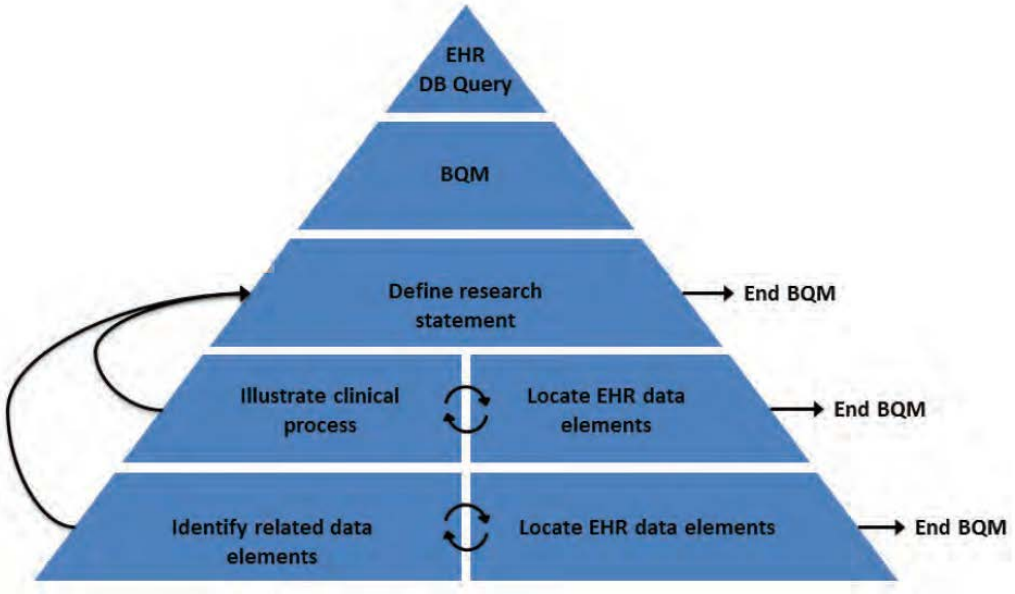

Figure 2 - BQM Taskflow (5)

References

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3. Weng C, Mir AK, Hanauer D, Cimino J. Dialogue Analysis for Clinical Data Query Mediation. Stud Health Technol Inform. 2019;264:1398-402.
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5. Hruby G, Cimino J, Patel V, Weng C. Toward a Cognitive Task Analysis for Biomedical Query Mediation. AMIA Jt Summits Transl Sci Proc. 2014;2014:218-22.
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7. Kahn MG, Callahan TJ, Barnard J, Bauck AE, Brown J, Davidson BN, et al. A Harmonized Data Quality Assessment Terminology and Framework for the Secondary Use of Electronic Health Record Data. EGEMS (Wash DC). 2016;4(1):1244.

Attachments:

Appendix 1: Shriners Hospitals for Children Retrospective Research Protocol Template

Appendix 2: Retrospective Studies – Standard

Appendix 3: Data Concierge SOP

Shriners Hospitals for Children®

TITLE:

Protocols submitted as an IRB application or in abstract format will not be reviewed.
*The Instructions for this **Retrospective protocol template** are available as "comments" in the document and should be removed, similarly to how you can "accept all changes" when tracking changes in your document.*

Principal Investigator:
Name
Address
Address
Telephone
E-mail address

For Multi-site studies: *Site Name*
Research Site(s): *Address*
Address
Telephone

Sponsor: **Shriners Hospitals for Children**
International Headquarters
2900 Rocky Point Drive
Tampa, Florida 33607

Initial Version: 5/15/2013
Amendment 1: 6/2/2013
Amendment 2: 7/24/2014

Amendment History of Changes

Version	Description & Rationale of Changes
May 15, 2013	Original Document
Version 1.0 – June 2, 2013	Minor administrative changes Changed Eligibility Criteria to include….
Version 2.0 – July 24, 2014	Study plan changed to include blood work at visit 2 New risks added to consent form

PROTOCOL SIGNATURE PAGE

Protocol Title: _____

This page is often copied, scanned and posted separately from the original protocol document.
When this is the case, the protocol title needs to be added to this page.

The signature below provides the necessary assurances that this trial will be conducted according to the stipulations of the protocol, including all statements regarding confidentiality. This is in compliance with the principles outlined in applicable US Code of Federal Regulations and Good Clinical Practice Guidelines (ICH E6 Section 4.5.1, 6.2.5, and 8.2.2)

_____

Site Principal Investigator's Name*: (please print)

_____ _____

Site Principal Investigator Signature Date Signed

** The protocol should be signed by the local investigator who is responsible for the study implementation at his/her specific site.*

Table of Contents

List of Abbreviations

Health Insurance Portability and Accountability Act	HIPAA
Institutional Review Board	IRB
Private Health Information	PHI
Shriners Hospitals for Children	SHC

STUDY SUMMARY

Title	*Full title of protocol*
Short Title	*Short title of the protocol*
Population:	*Include sample size, gender, age*
Number of Subjects	*Number of subjects projected for the entire study*
Study Duration	*State duration of study*
Study site	*Single-center*
Objectives	*Brief statement of primary study objectives*
Statistical Methodology	*A very brief description of the main elements of the statistical methodology to be used in the study.*

1.0 Introduction:

1.1 Background and Rationale

1.2 Risk/Benefits

1.2.1 Risk Category: Minimal Risk

1.2.2 The primary risks for this study relate to privacy and confidentiality. The probability of a security breach is lessened with the use of password protected computer systems requiring a login. Risk will be minimized with the close adherence to both IRB and HIPAA guidelines to help prevent a breach in security.

1.2.3 As this is a retrospective study design, there is no potential direct benefit to the subjects and no alternative to participation.

2.0 Objectives:

2.1 The primary objective of this study is to determine ……

2.2 The secondary objectives of this study are to:

2.3 Rationale for selection of outcome measures

3.0 Subject Selection:

3.1 Inclusion Criteria

3.2 Exclusion Criteria

3.3 Inclusion of Gender, Minorities and vulnerable populations

3.3.1 The study population will be a consecutive case review, including all eligible pediatric patients of both genders, all ethnic backgrounds, and females of childbearing potential.

3.3.1.1 As this is a retrospective study design, pregnant females would not be automatically excluded as a review of their medical records does not pose a safety risk to the subject or the fetus.

4.0 Study Design/ Procedures:

4.1 General Design

4.1.1 The type/design of the study is a retrospective study of children with….

4.1.2 The study population will be a consecutive case review, including all patients meeting inclusion criteria to minimize bias.

.

4.2 Study Procedures

4.3 Subject Selection

4.3.1 Describe how subjects will be identified

4.3.2 Describe the method of selection, e.g. database search for subject who have given prior permission to be contacted, personal contact, referrals, etc.

4.4 Waiver of informed consent and a Waiver of HIPAA authorization will be requested from the IRB.

4.4.1 This research cannot be practicably carried out without these waivers. The research involves no more than minimal risk to the subjects.

4.4.2 The research is not FDA regulated.

4.4.3 For limited data sets (contains some identifiable data, e.g. dates, etc.): The waivers will not adversely affect the rights and welfare of the subjects as the data will not be reused or disclosed to (1) any other person or entity, except as required by law, for authorized oversight of the research, or (2) for other research for which the use or disclosure of the protected health information would be permitted.

5.0 Data Collection, Storage & Security, Handling and Record Keeping

5.1 Data Collection

5.1.1 The “Minimum Necessary” standard has been applied to this study meaning that only the least amount of data, reasonably necessary to answer the study question, is being abstracted.

5.1.2 Critical data values to be collected/abstracted:

List exact data elements to be collected from existing records	Source of information, e.g. EMR, clinical database, radiographic images, etc.

5.1.3 The time period of the medical information under review is from *DATE* to *DATE (day, month, and year).* Chart information will not be used from data sources created outside of this study period.

5.1.4 Data set

The study will collect and/or abstract data creating an "identifiable data set," meaning that the dataset will contains at least one of the 18 identifiers restricted by the HIPAA Privacy Rule. However, it will be a "limited data set," meaning that it will not include any direct identifiers such as name, MRN.

A key code will be used to store any direct identifier that uniquely identifies the patient (other than dates).

5.2 Storing of Electronic Research Dataset

5.2.1 Option #1: The data collected for this study will be stored (during and after the study) in OnCore, SHC's clinical research data management system housed on SHC servers.

5.2.1.1 Data extracted manually from the medical record or other sources will be entered into OnCore via OnCore designed eCFRs.

OR

Data electronically obtained from another database will be compiled in a spreadsheet, with the spreadsheet uploaded and stored in OnCore.

5.2.1.2 As the research dataset will be uploaded and stored in OnCore, the key code will be stored in a restricted research study folder, created by SHC IS, per study, on SHC Provisioned Enterprise Storage (SPES).

OR

5.2.1 Option #2: The data collected for this study will be stored in a restricted research study folder, created by SHC IS, per study, on SHC Provisioned Enterprise Storage (SPES).

5.2.1.1 Only those individuals who are part of the study will have access to the folder containing study data.

5.2.1.2 Study data stored in a restricted folder does not negate the requirement to use OnCore as a clinical research management system for SHC.

5.2.1.3 As the research dataset will not be uploaded and stored in OnCore, the key code will be entered and kept in OnCore (separate from the data).

5.3 Confidentiality and Security of Data

5.3.1 There will be limited access to the data collected.

For information collected electronically, members of the SHC research team will enter data into OnCore using unique user IDs and passwords.

OR

Any paper data collected will be stored in a secure area in a locked cabinet.

5.3.1 Investigators, approved study staff, and appropriate organizations such as the sponsor, government agencies, and the IRB may review records for research, quality assurance, and data analysis.

5.3.2 Data with subject identifiers

5.3.2.1 If any PHI is used, it is only for use as regulated under 45 CFR §§160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR §164.501.

5.3.2.2 Subject identifiers will not be released to any other persons or agencies for any reason or purpose.

OR

Data with subject identifiers will be released to *specify the person(s) or agency to whom the information will be released*, for the purpose of *specify the purpose of releasing the data, e.g. statistical review, etc.*

5.3.2.3 If data share is required, *specify how the data will be securely released and/or transmitted, e.g. all secure web-based information transmissions will be encrypted.*

5.4 Quality Control and Quality Assurance

5.4.1 The PI and all members of the research team are responsible for the evaluation of data quality with regard to accuracy and completeness.

5.4.2 Each member of the study staff who collects data will be responsible for spot-checking their data and comparing it with source data to ensure accuracy of data.

5.4.3 Assigned study staff will quarterly monitor minimally 10% of the data collected during that quarter to ensure accuracy, completeness and consistency.

5.4.4 The Principal Investigator will have final responsibility for the data, ensuring that the data is attributable, legible, contemporaneous, and accurate as compared to the source.

5.5 Record Retention

5.5.1 Clinical research records will be retained per SHC Policy MR-002 on *Clinical Research Records Retention and Storage*

6.0 Statistical Considerations

6.1 Study Endpoints

6.1.1 Primary Study Endpoints

6.1.2 Secondary Study Endpoints, if any

6.2 Statistical Methods

6.3 Sample Size Determination and Power/Accrual Rate-

OR

No power analysis or sample size determination was made because all patient records that meet the eligibility criteria from the time period specified will be included in the study.

7.0 References

Retrospective Chart Review Studies

Requirements pertaining to SHC, human subjects, and HIPAA

Summary

Retrospective clinical studies play a significant role in medical research. These studies can be an effective way to gather clinical characteristics, treatment patterns, and outcome data, providing preliminary measures of association to develop future prospective studies.

While patients are not directly involved in the research, their private health information is involved. Per the Common Rule, this means that retrospective research is considered human subject research and falls under all applicable regulations.

This overview is designed to answer frequently asked questions related to the requirements for retrospective studies pertaining to both human subjects and HIPAA privacy requirements.

Human Subject Requirements

All human subject research requires informed consent from the subject. However, for retrospective studies, investigators can request from the Institutional Review Board (IRB) that the informed consent requirements be waived.

A "waiver of consent" is possible if the project:

- involves no more than minimal risk to the subject
- will not adversely affect the subjects' rights/welfare
- could not practicably be done without the waiver

HIPAA Privacy Requirements

A retrospective chart review involves the use of medical information for research without seeking written permission from the subject. Therefore, the investigator must also request, from the IRB, a waiver from the requirements for HIPAA Research Authorization.

A "HIPAA waiver of authorization" is possible if the project:

- has an adequate plan to protect identifiers from improper use and disclosure
- has an adequate plan to destroy identifiers at the earliest opportunity, per SHC policies.
- will not be re-used or disclosed protected health information (PHI) for another purpose
- could not practicably be conducted without the waiver of privacy authorization.
- could not practicably be conducted without the use of PHI.

Category 4 exemption:

If retrospective data is needed to answer your research question and could be collected without **any** of the 18 PHI defined identifiers, the retrospective project **may** qualify for a Category 4 exemption status under human subject regulations.

These exempted studies are still considered research, but do not require IRB oversight. An "exemption" may be possible if the project:

- involves the use of existing data, documents, records, or specimens.
- does not identify the subject, in **any** manner.

Federal guidance indicates that researchers themselves should not determine whether their project or activity is exempt. To assist you in this determination, please submit to HQ a *Request for IRB Exemption* and a description of the proposed research (a simple template is available on the Medical Research page of the ShrineNet).

SHC Requirements for Retro Studies

Protocol

- The protocol must request a waiver of consent **and** waiver of HIPAA authorization with justification supporting the specific regulatory requirements.
- Retrospective research (chart reviews) collect & analyze existing data within a specific time period. The date range of the data must be found in the protocol, e.g. Jan 1, 2000 – Dec 31, 2015.
- Protocol amendments that move the dates of data collection forward to capture current or recent subjects are not acceptable, as this circumvents the subjects' basic right to consent.

Completion Timeline

As the data for retrospective studies should already be available for immediate research data extraction, the expectation is that retrospective projects be completed in 2 years.

Data Collection and Storage

For retrospective studies, data collection and storage in OnCore (during and after the study) has been a requirement for SHC sponsored retrospective studies for several years.

- Data extracted manually from the EMR or other sources will be entered into OnCore via study specific designed electronic case report forms (eCFRs).
- Data electronically obtained will be uploaded and stored in OnCore as an attachment.

Shriners Hospitals for Children®

Appendix 3

Data Concierge Interview Tool – Standard Operating Procedure

Purpose

This tool is designed to assist the SHOnet data concierge in collection of a refined data query request. Successful use of this tool will yield a data request defined within the scope of the study objectives with defined data attributes for each element specific to the SHOnet OMOP Common Data Model. This standard operating procedure is to be used in conjunction with the Query Mediation Case Report Form, for recording and submission of information. Upon completion, all case report forms should be submitted to the SHOnet team for database logging.

1. Identify Related Data Elements

1.1. Using the objectives provided in the study protocol, define the scope of each objective and the data required to satisfy that objective.
Table 1 Example:

Objective	Scope	Data Elements
***Example**: The objective of this study is to determine if weight has an effect on bone density in adolescents.*	*Data collection limited to the ages of adolescence, including characteristics of body weight and bone density*	*Collection Dates* *Weight* *Bone density*

1.2. Verify that the data elements identified in the above table are listed in the protocol.

1.3. Using the concept-mapping tool, Usagi (figure 3), find all concepts that have similar descriptions to fill Table 2 with the related concepts.
Table 2 Example:

Data Element	OMOP Code	Concept name	Vocabulary	Concept Code

1.3.1. Using keywords, find the parent concepts most similar, and note any children concepts that may be included in this query (figure 1)

2. Engage the Study Team in Conversation About Data Elements (repeat at needed)

2.1. Discuss elements as identified in Table 2, and their applicability to the study objectives

2.1.1. Identify elements that meet study team approval

2.1.1.1. Define the characteristics of the approved elements; Examples include:

2.1.1.1.1. What are the expected ranges and values for data?

2.1.1.1.2. How will missing data be handled?

2.1.1.1.3. When and where is data collected and recorded?

2.1.1.1.4. How should conflicting values be handled?

2.1.1.1.5. Will data be verified against another source?

2.1.2. Annotate elements that need concept revision to fit, or that are missing

2.1.2.1. Include a summary of the clinical process where the study team perceives the desired element comes from, who records the data, where it is recorded and any specific characteristics of that data.

2.1.3. Use Table 3 from the CRF to record the approved data elements and their characterizations.

Table 3 example:

OMOP Code	Data Element (variable name)	Characterizations	Comments
Example: 4003218	Weight (weight)	a) Positive number b) Units are kg c) Date corresponds with a study visit d) Range from 0 to 500 e) One data point is tied to only one patient	*Include comments about any scoring instructions, recoding or special considerations.*

2.2. Have the Study Team Provide Specifics About Inclusion and Exclusion Criteria

2.2.1. What patient characteristics will be included/excluded?

2.2.2. What condition characteristics will be included/excluded?

2.2.3. What timeframe will the study take place? (relative to calendar dates and/or patient dates)

2.2.4. What locations will be included/excluded?

2.2.5. What care or clinician information affects inclusion/exclusion?

3. Evaluate Mapped and Unmapped Data

3.1. Provide the data characterizations to the SHOnet team for both accepted elements and elements that need revision. This documentation will aggregated into the SHOnet Data Characterization documentation.

3.2. Engage with the SHOnet team and ETL analysts to explore data availability and quality aspects for concepts identified in Section 2.1.2, recorded in Table 3.

3.2.1. If a positive mapping to the site described source of the data can be made, repeat Section 2 for verification that the data is in concordance with the listed data characteristics and quality standards.

3.2.2. If a positive mapping to the site described source cannot be made, engage the study team in a discussion of alternate data collection strategies.

3.2.2.1. Use Table 4 to record all data elements without mapping.

4. Final Query and Return of Results

4.1. Provide Table 3, the study protocol and a written description of the inclusion/exclusion criteria to the SHOnet query analysts.

4.1.1. Verify the query projected timeline for return of results.

4.1.2. Upon notification of the return of results, verify that they were placed in the appropriate folder and documentation of the query used is included.

4.1.3. Communicate with the study team to ensure there is no follow up needed.

Supporting Documents

Figure 3: Usagi Tool

Figure 4: BMQ ER Diagram

Figure 3: Usagi Tool

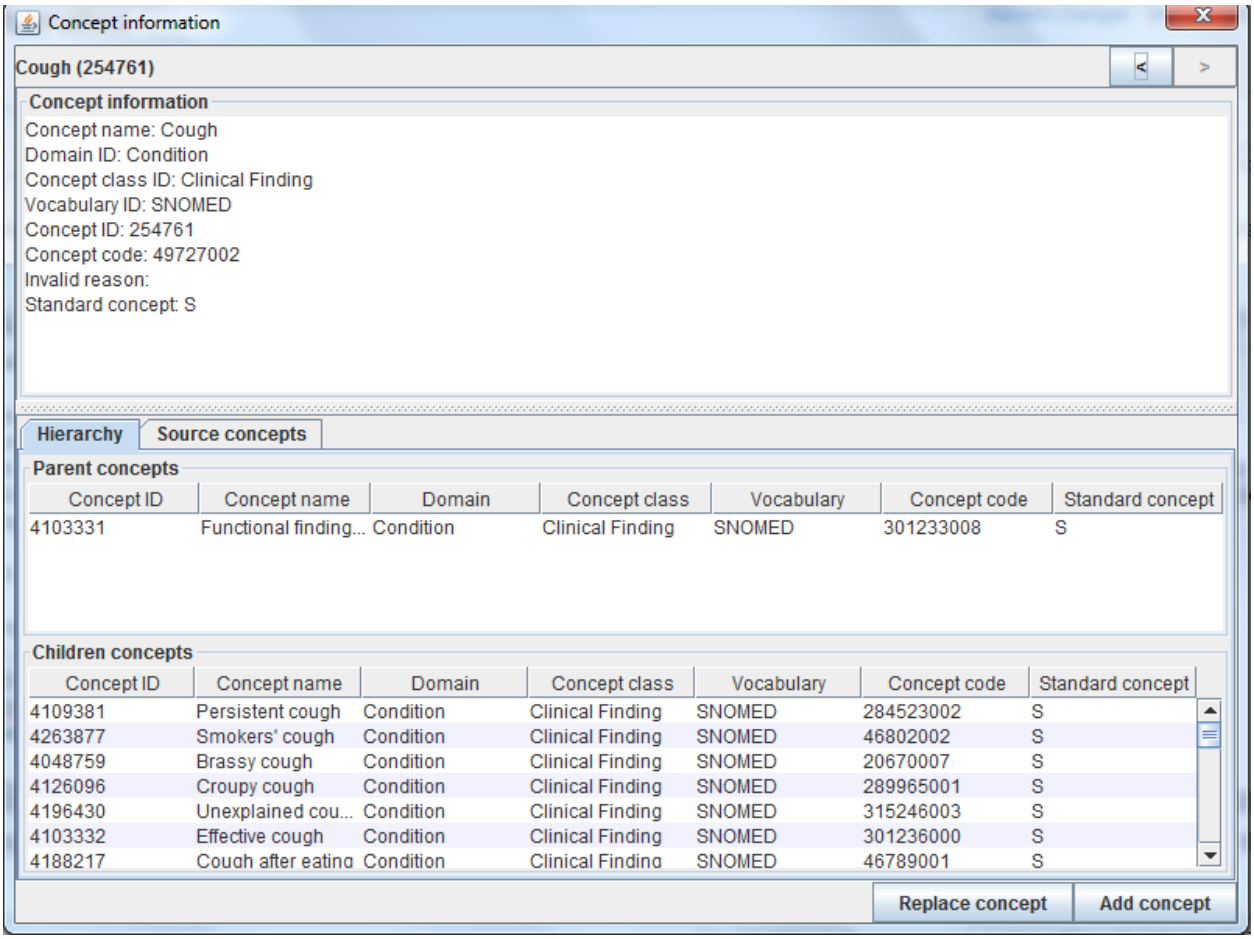

Figure 1: Usagi Concept Information

Query Mediation Case Report Form

1. **Identification of related data elements:** Record the study objectives and their corresponding characteristics based on the study protocol and the initial meeting with the study team.

Objective	Scope	Data Elements
***Example**:* *1. The objective of this study is to determine if weight has an effect on bone density in adolescents.*	*Data collection limited to the ages of adolescence, including characteristics of body weight and bone density*	*1.Collection Dates* *2.Weight* *3.Bone density*
1.		1. 2. 3. 4. 5. 6.
2.		1. 2. 3. 4. 5. 6.
3.		1. 2. 3. 4. 5. 6.
4.		1. 2. 3. 4. 5. 6.
5.		1. 2. 3. 4. 5. 6.
6.		1. 2. 3. 4. 5. 6.

2. **Mapped Concepts:** List the data elements identified on page one in the Data Element column. Using the Usagi tool, search the concept mapping and record the remaining columns. Repeat this page as many times as needed to record all mappings. If the mapping is not available, record the data element in the table in section 4.

Data Element	OMOP Code	Concept name	Vocabulary	Concept Code
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				
17.				
18.				
19.				
20.				
21.				
22.				
23.				
24.				
25.				

3. **Approved Data Elements:** Use the following table to document the characterizations of the data elements from the final study team meeting. Repeat use of this page as needed.

OMOP Code	**Data Element (variable name)**	**Characterizations**	**Comments**
Example: 4003218	Weight (weight)	1. Positive number 2. Units are kg 3. Date corresponds with a study visit 4. Range from 0 to 500 5. One data point is tied to only one patient	*Include comments about any scoring instructions, recoding or special considerations.*
		1. 2. 3. 4. 5.	
		1. 2. 3. 4. 5.	
		1. 2. 3. 4. 5.	
		1. 2. 3. 4. 5.	

Unavailable Data Elements: Use the table below to record any data elements that could not be mapped in SHOnet. Repeat use of this page as needed.

Data Element (variable name)	Characterizations	Comments
	1. 2. 3. 4. 5.	
	1. 2. 3. 4. 5.	
	1. 2. 3. 4. 5.	
	1. 2. 3. 4. 5.	
	1. 2. 3. 4. 5.	

Figure 4: BMQ Entity Relationship Diagram