CRISP

Connecting Providers with Technology to Improve Patient Care

ONC LEAP Grant - Development and Testing of Data Sharing Functionality for Health System Participating in the National Cardiovascular Disease Registries of the American College of Cardiology

Final Report, March 2023

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Structured Abstract

Our nation's health depends on the acceleration of our collective understanding of disease, therapeutics and procedures, and the administration of healthcare services to address them. To that end, the ability to collect and measure increasingly precise healthcare data is critical. Efforts such as those undertaken by clinical registries serve a vital function in meeting these goals. The purpose of this project was to explore ways to support a new vision of clinical-registry data management that could help to accelerate the pace of discovery and innovation borne from clinical registries.

A new FHIR IG was developed for clinical registry submission. The Clinical Registry Extraction and Data Submission (CREDS) IG was designed to be registry-agnostic, allowing the sponsors of any registry to leverage it for their specific needs. With this IG in hand, the project explored on how registry operators, HIEs, EHR vendors, FHIR, and interoperability can support the value and effectiveness of registries, thus addressing the last two outcomes.

The project demonstrated "net new" capabilities in a technology proof of concept, formally presented at an HL7 FHIR Connect-a-thon—including how to use FHIR to collect as much of the required data for a single cardiac-focused clinical registry electronically, the American College of Cardiology's (ACC) CathPCI registry, and then how to submit registry reporting to FHIR endpoints that were established by ACC for the project.
Through this work, the project explored four hypothesis related to the use of FHIR for clinical registry submission:

- Hypothesis 1: HIEs can provide useful historical data for the CathPCI registry use case on consistent basis.
- Hypothesis 2: Registries can utilize the new FHIR IG as an improvement over the status quo, where no universal standards exist.
- Hypothesis 3: Registry vendors, representing an established market, are willing to invest in FHIR-based reporting because they see the benefits. They need demonstrated learnings and examples to adopt and innovate.
- Hypothesis 4: Hospitals can benefit from accessing specific CathPCI patient data when it's available at the point of care.

The result was to demonstrate technical feasibility of the use of FHIR for registry submission. The project also demonstrated that real efficiencies may be gained by the use of FHIR for submitting data to the CathPCI registry specifically. Insights were gained about the benefits and limitations of relying on FHIR and clinical data native to EHRs and HIEs.

Keywords: *FHIR, Interoperability, Clinical Registries, Research Registries, Standards Development, Terminology, Cardiology, Cardiac Catheterization, Quality Measurement, Clinical Outcomes*

Purpose (Project Objectives)

Our nation's health depends on the acceleration of our collective understanding of disease, therapeutics and procedures, and the administration of healthcare services to address them. To that end, the ability to collect and measure increasingly precise healthcare data is critical. Efforts such as those undertaken by clinical registries serve a vital function in meeting these goals. Broadly speaking, clinical registries encompass a wide range of patient, condition or disease specific aggregations of secondary data for the purposes of surveillance or quality improvement.

Despite these imperatives, healthcare provider organizations such as hospitals, clinics and labs continue to be burdened by the process of collecting data for these purposes. Clinical registries, in turn, face key data challenges of their own: latency, completeness, accuracy, and lack of integration into provider workflows. In combination, these issues introduce friction into the administration of registries in the form of cost, complexity, and—perhaps most importantly—throttling the pace of discovery and innovation that can improve the quality and cost of care.

The purpose of this project was to explore ways to overcome this friction, resulting in a new vision of clinical-registry data management that could help to accelerate the pace of discovery and innovation borne from clinical registries. In developing this vision, the project sought to accomplish the following goals:

- Reduce provider burden and operational expenses by capturing key data elements from new and old electronic health records (EHRs)
- Develop a framework for integrating registries into provider workflows by using and further constraining the FHIR standard and Bulk FHIR Implementation Guide through a new clinical research network framework FHIR implementation guide
- Build on the lessons learned from the Women's Health Technologies CRN FHIR Implementation Guide, allowing registries to focus on the insights and knowledge gained from the data rather than cleaning and validating data
- Leverage SMART on FHIR by allowing CRISP to securely access APIs
- Scale the clinical registries' abilities to acquire existing and novel data from across the country and demonstrate how EHR systems can sustainably support integration with clinical registries

Scope

Background

Clinical registries, or collections of person-level information on patients suffering from a common condition or having undergone a common condition, have existed in various forms for centuries.[i] These registries arose to conduct population-level disease surveillance and protect the public health, for instance in the case of infectious diseases that could spread rapidly, were not be well-treated at the time, and inflicted high mortality. An early example of such a registry is Norway's National Leprosy Registry, established in 1856, which is thought to be the first nationwide registry of its kind.[ii]

In the second half of the twentieth century, clinical registries became more numerous and complex—and have come to play an important role in the practice of healthcare, medical device manufacturing, and clinical research. In our otherwise fragmented care delivery system, this importance stems from registries' unique, normalized perspective on specific aspects of care across many (sometimes hundreds or even thousands of) care settings and organizational boundaries and over long periods of time. Registries provide vital, longitudinal real-world evidence that is available nowhere else.

At the same time, against the backdrop of accelerating nationwide health data interoperability since the enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009, it's become clear that clinical registries risk becoming too far out of step with the way health data is otherwise collected, managed and exchanged across the delivery system. A 2018 report by the Pew Foundation and Duke University highlighted this dilemma:

> [S]ubmission of data to clinical registries has typically been labor intensive, costly, and focused on retrospective analysis. … Registries often are designed for or support a single business purpose, with those supporting patient-centered outcomes research usually also support operational needs. Central to the success and value of registry data is the uniformity of the clinical and administrative data definitions adhered to by the registry as defined by a group of clinical subject matter experts. A deep understanding of the body of literature in the clinical domain, the workflow in which those data are generated during patient care activities, and how the data might be used by providers and other team members are critical elements. Registries have traditionally been highly effective at creating these definitions within their own specialty and scope of practice.
>
> Data submitted to registries has typically not been encoded in EHR systems and captured as structured data integrated into care delivery workflow. Instead, the typical model is manual chart abstraction and data re-entry into electronic systems. A 2017 survey on the status of US registries notes that while the predominant purposes of registries are for quality improvement and clinical research informing value-based payment models, 88% percent utilized manual data entry to accomplish same. Lack of data interoperability was cited as the top barrier to registry development and improvement.
>
> Not all registries make their data dictionaries available to the public, a factor that contributes to the proliferation of similar but non-identical clinical content concepts in registry data models and further degrades data liquidity. Without transparency and harmonization of related but non-aligned content, the path to EHR-enabled data extraction across registries remains difficult.[iii]

Context

Formed in 2008, CRISP is formally designated as Maryland's statewide Health Information Exchange (HIE). The mission of the organization is to enable and support the healthcare community of Maryland and surrounding regions to appropriately and securely share data in order to facilitate care, reduce costs, and improve health outcomes.

In 2015, the Maryland Health Services Cost Review Commission (HSCRC) selected CRISP as the primary provider to develop the Statewide Integrated Care Network Infrastructure. This network allows users including providers, patients, public health officials, care coordinators, and clinicians to share clinical data electronically. Starting in 2016, CRISP has established contractual relationships with several other HIEs, including in the District of Columbia, West Virginia, Connecticut, Alaska and Virginia. Starting in 2018, CRISP began providing finance-related services to some of the regions under the shared-services model, and in November 2020 formed CRISP Shared Services (CSS). The purpose of CSS is to operate centralized services for each region, such as core IT infrastructure, privacy and security governance, financial management, and human resources.

By virtue of its mission and its growing multi-state footprint, multi-stakeholder collaboration is at the core of what CRISP does. CRISP has collaborated and supported hundreds of participating healthcare organizations, ranging from hospital and labs to health insurance carriers and public health authorities. Many of these organizations serve on CRISP's board of directors or other parts of its broad governance structure. While CRISP's initial use cases supported delivering actionable data to the point of care, over its history its services have steadily expanded to include a wide range of use cases where its participants agree that collaboration is more beneficial than competition.

In this context, and amidst an organizational culture where new use cases are often discussed, two of CRISP's physician-advisors, Samit Desai, MD, an emergency medicine physician, and Mark Kelemen, MD, a cardiologist and former CRISP , began to have informal conversations about how cardiology-specific registry data could be useful to emergency department clinicians—for instance by supplying unique insights into a patient's history of coronary artery disease or catheterization procedures. The discussions broadened to other ways HIEs and clinical registries could benefit from collaboration, including solutions to some of the well-known challenges with registry data collection described above. Their shared interest, supported by CRISP as a collaboration platform, led to the formalization of the project and CRISP's request to ONC for funding support. The topic aligned with ONC's stated interest area of tackling "the creation of new standards, methods, and tools to improve care delivery and advance research capabilities."[iv]

Participants

In addition to CRISP, the project team included the following participants:

AMERICAN COLLEGE of CARDIOLOGY®	The American College of Cardiology (ACC), based in Washington, D.C., is a nonprofit medical association established in 1949. It bestows credentials upon cardiovascular specialists who meet its qualifications. The National Cardiovascular Data Registry (NCDR) is ACC's suite of data registries helping hospitals, health systems and practices measure and improve the quality of cardiovascular care they provide. More than just data collection, NCDR is a comprehensive network of cardiovascular care providers committed to ensuring evidence-based care, improving patient outcomes and lowering health care costs. Currently, the NCDR suite

	of cardiovascular data registries covers the following clinical areas: • Acute myocardial infarction treatment • Diagnostic cardiac catheterization and percutaneous coronary intervention • Implantable cardioverter defibrillator and leads procedures • Lower extremity peripheral vascular interventions, carotid artery revascularization, and endarterectomy procedures • Pediatric and adult congenital treatment procedures • Catheter-based atrial fibrillation ablation procedures • Left atrial appendage occlusion procedures • Transcatheter valve therapy procedures • Outpatient cardiovascular care for coronary artery disease, heart failure, hypertension, atrial fibrillation, and diabetes • Outpatient diabetes and cardiometabolic care across multiple healthcare specialties
DukeHealth	James Tcheng, MD is Professor of Medicine, Assistant Dean for Academic Appointments, and Professor of Family Medicine and Community Health at the Duke University School of Medicine. In addition to his clinical responsibilities as an interventional cardiologist, Dr. Tcheng's research interests include the study of antithrombotic therapies in cardiovascular disease, clinical informatics, artificial intelligence, and information technology systems. Dr. Tcheng's current focus is in clinical informatics, including initiatives spanning professional societies, regulatory and other government agencies, industry, and non-governmental organizations to develop clinical data standards, interoperability solutions, and to integrate structured reporting into clinical workflows. This includes harmonizing the clinical definitions of cardiovascular concepts across academia, regulatory agencies, the life sciences industry, professional societies, and standards organizations, to improve the capture, communication, interoperability, and analysis of healthcare information.

PointClickCare® Care confidently.™	Audacious Inquiry was a national industry-shaping health IT company that provides a connected care platform facilitating the secure transmission of actionable, accurate, and event-driven data across the U.S. healthcare system. Its team includes senior subject matter experts in the HL7 FHIR standard for interoperability. Audacious Inquiry's pioneering software solutions help providers and care managers be proactive during the most important moments, including during transitions of care. Audacious Inquiry's trusted solutions serve more than 75 million people nationwide. The firm was acquired by PointClickCare in 2022.
Leap Orbit	Founded in 2015, Leap Orbit is the trusted innovation partner to market-leading health data networks. Leap Orbit's philosophy is to run toward healthcare's biggest challenges, providing technology and solutions to assist with the opioid crisis and patient data privacy. Leap Orbit's solutions touch the lives of more than 45 million patients from Alaska to Maryland. Leap Orbit's principals have provided strategic consulting, program management and software development services to CRISP since its inception in 2008.

Settings

The data reported to clinical registries is collected in a wide range of settings. As is described in more detail in the following section, the data submitted to NCDR is typically collected by staff within a catheterization laboratory at a hospital. This data may reside in the hospital's EHR system, a system specific to the lab, or in a system elsewhere. Data in CRISP's custody resides a secure, cloud-based environment. The NCDR registry technical infrastructure is located in a dedicated physical data center.

Approach

Initial Project Design

The initial project design set out to document as-is data collection processes for two of the component NCDR registries, the Chest Pain – MI Registry and the CathPCI Registry. A new to-be process would be synthesized from the project findings. The intention was to develop a process that would be generic—that is, registry agnostic and could be used for any registry at all.

The As-Is Process

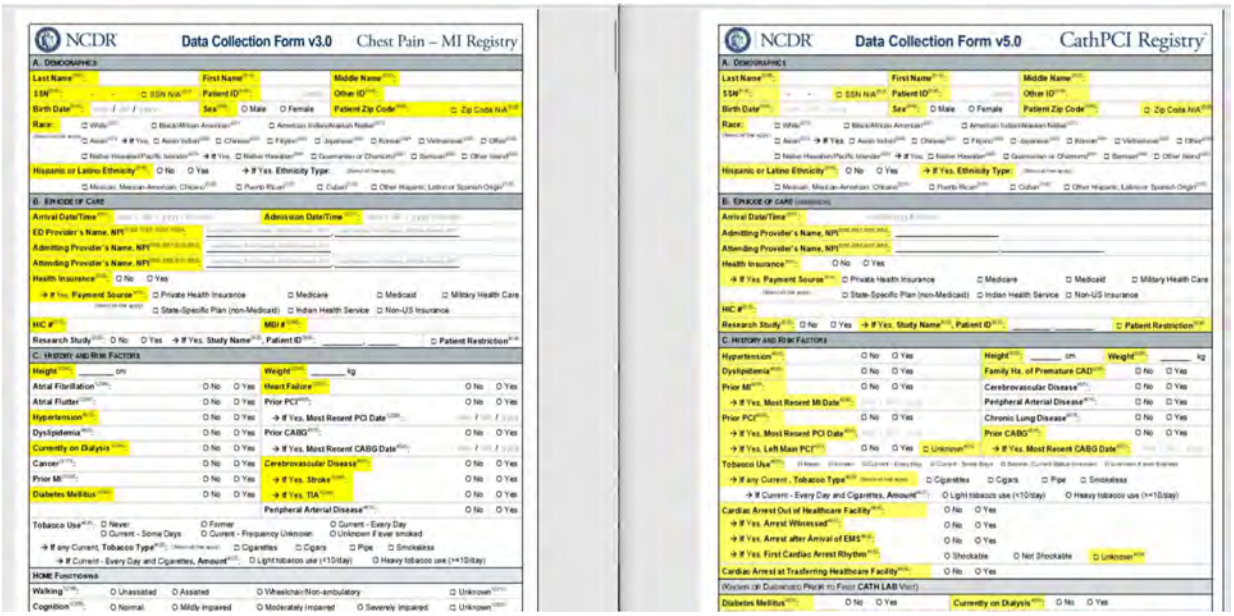
Historically, participants in NCDR registries have submitted data using one of the following three options:

Submission Method	Description	Challenges and Constraints
NCDR-certified software vendor	Hospital systems can choose from a list of certified vendors who can facilitate the submission of data to the NCDR.	• Data is submitted on quarterly basis • Data • Provider and staff burden
NCDR-compatible data abstraction provider	Clinical specialists experienced in data abstraction for NCDR registries manage the data-collection process.	• Provider and staff burden
Web-based data collection	A PDF form tool provided by the NCDR allows participants to submit data online.	• Data quality due to lack of validation • Provider and staff burden • Registry burden

Data in the two identified registries contain common data elements, demonstrated by the table below which displays the targeted registry and the data currently collected. The common data elements could create immediate opportunities to be extracted from EHRs to support registry submissions.

Chest Pain - MI Registry	CathPCI Registry
• STEMI and NSTEMI patient demographics • Provider and facility characteristics • Adverse event rates • AMI performance measures and selected quality measures and outcomes • All other test measures, including medication dosing errors and risk-adjusted metrics • Transfer facility therapies and reperfusion strategies • Compliance with ACC/AHA clinical guideline recommendations • Data needed to qualify registry performance achievement award recognition	• Patient demographics for diagnostic coronary angiography and percutaneous coronary intervention (PCI) procedures • Patient history/risk factors, cath lab visit indications and coronary lesion information • Provider and facility characteristics • PCI Indications, lesion information, intracoronary device utilization and intra/post- procedure events • 30-day and 1-year follow-up information on patients who had PCI

Similar data elements exist for patient demographics, episodes of care and history and risk factors:



Opportunities could also exist to model and explore data capture from applicable questionnaires, such as the Seattle Angina Questionnaire in the CathPCI registry:

D. PRE-PROCEDURE INFORMATION (CONT.)

OPTIONAL SECTION: SEATTLE ANGINA QUESTIONNAIRE (SAQ)[7] – FOR PARTICIPANTS CAPTURING LONG TERM CARE

OVER THE PAST 4 WEEKS, AS A RESULT OF YOUR ANGINA, HOW MUCH DIFFICULTY HAVE YOU HAD IN:

	EXTREMELY LIMITED	QUITE A BIT LIMITED	MODERATELY LIMITED	SLIGHTLY LIMITED	NOT AT ALL LIMITED	LIMITED FOR OTHER REASONS OR DID NOT DO THESE ACTIVITIES
(1a) Walking indoors on level ground	o	o	o	o	o	o
(1b) Gardening, vacuuming, or carrying groceries	o	o	o	o	o	o
(1c) Lifting or moving heavy objects (e.g. furniture, children)	o	o	o	o	o	o

OVER THE PAST 4 WEEKS, ON AVERAGE, HOW MANY TIMES HAVE YOU...

	4 OR MORE TIMES PER DAY	1 – 3 TIMES PER DAY	3 OR MORE TIMES PER WEEK BUT NOT EVERY DAY	1 – 2 TIMES PER WEEK	LESS THAN ONCE A WEEK	NONE OVER THE PAST 4 WEEKS
(2) ...HAD CHEST PAIN, CHEST TIGHTNESS, OR ANGINA?	o	o	o	o	o	o
(3) ...HAD TO TAKE NITROGLYCERIN (TABLETS OR SPRAY) FOR YOUR CHEST PAIN, CHEST TIGHTNESS OR ANGINA?	o	o	o	o	o	o

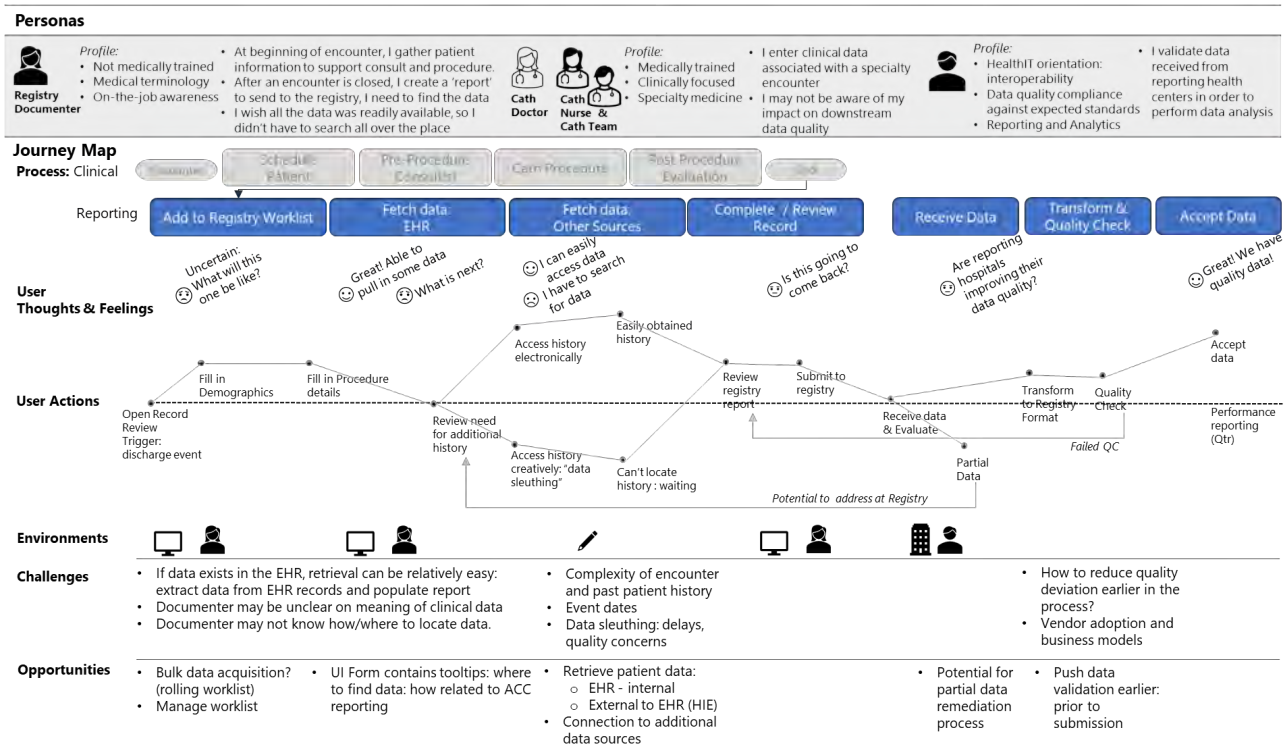
OVER THE PAST 4 WEEKS, HOW MUCH HAS YOUR...:

	IT HAS EXTREMELY LIMITED MY ENJOYMENT OF LIFE	IT HAS LIMITED MY ENJOYMENT OF LIFE QUITE A BIT	IT HAS MODERATELY LIMITED MY ENJOYMENT OF LIFE	IT HAS SLIGHTLY LIMITED MY ENJOYMENT OF LIFE	IT HAS NOT LIMITED MY ENJOYMENT OF LIFE AT ALL
(4) ...CHEST PAIN, CHEST TIGHTNESS OR ANGINA LIMITED YOUR ENJOYMENT OF LIFE?	o	o	o	o	o

IF YOU HAD TO SPEND THE REST OF YOUR LIFE WITH YOUR CHEST PAIN, CHEST TIGHTNESS OR ANGINA THE WAY IT IS RIGHT NOW...

	NOT SATISFIED AT ALL	MOSTLY DISSATISFIED	SOMEWHAT SATISFIED	MOSTLY SATISFIED	COMPLETELY SATISFIED
(5) ...HOW WOULD YOU FEEL ABOUT THIS?	o	o	o	o	o

The project team conducted a detailed mapping process to understand exactly who carries out the activities in the data submission process and what each step is on the journey from a reportable event to the validation and acceptance of a report by the registry. The result of that process is below:



To-Be Process

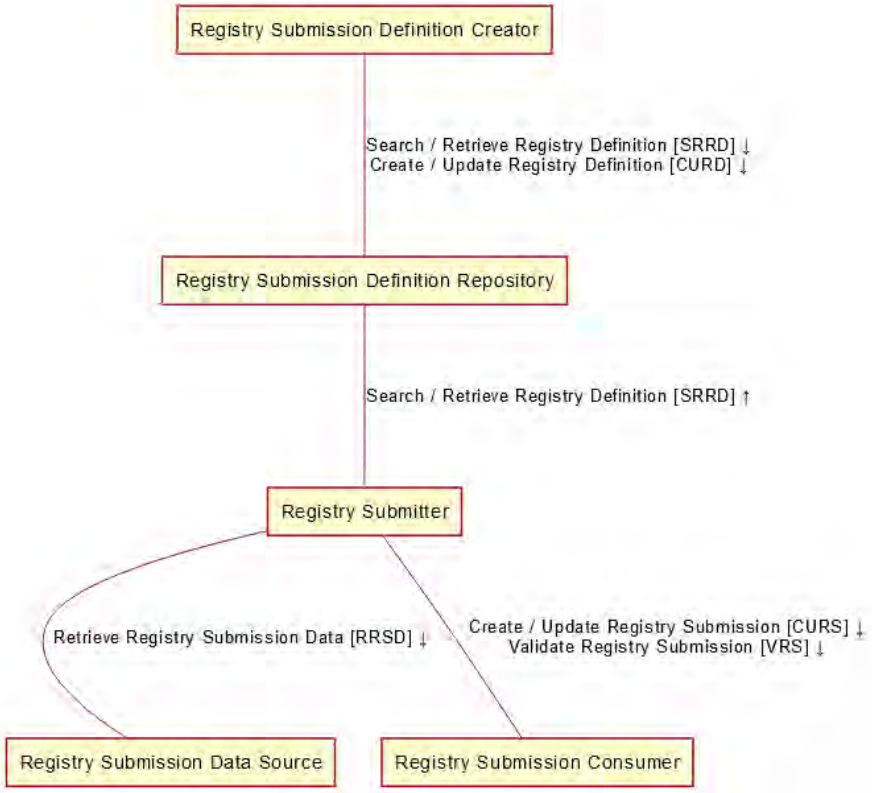
The original project design set out to then develop a to-be vision for data collection and submission to these NCDR registries that could ultimately be extensible to all registries. Doing so would involve the following key activities:

- Identify common data elements and methods for extraction from EHR to support registry submission. Review additional registries to identify opportunities to capture data in the provider workflow to be reported later.
- Engage in a data mapping activity: Encode data requirements, map each registry's data dictionary to USCDI and FHIR resources.
- Explore how to "write" data back to EHRs or other systems so it could benefit clinicians at the point of care.
- Create a framework for registry submissions based on other emerging FHIR Implementation Guides (IGs).

Modified Project Design

In the initial phase of work, a new FHIR IG was developed for clinical registry submission (https://build.fhir.org/ig/HL7/fhir-registry-protocols-ig/), largely addressing the first two key

activities above. The Clinical Registry Extraction and Data Submission (CREDS) IG was designed to be registry-agnostic, allowing the sponsors of any registry to leverage it for their specific needs.



In the CREDS model, a registry sponsor would create a registry submission definition (or StructureDefinition in the FHIR lexicon) that would provide the details of its data model.

Based on discussions in the FHIR community concerning the new FHIR IG as well as team insights into designing its implementations, in early 2022 ONC approved a modification of the project design for the remainder of the grant to promote learning opportunities that can benefit adopters using just a single NCDR component registry, CathPCI, as the focus. The new design explored on how registry operators, HIEs, EHR vendors, FHIR, and interoperability can support the value and effectiveness of registries, thus addressing the last two outcomes. The project plan involved demonstrating "net new" capabilities in a technology proof of concept, to be formally presented at an HL7 FHIR Connect-a-thon—including how to use FHIR to collect as much of the required data for the CathPCI electronically, and then how to submit registry reporting to FHIR endpoints that have been established by ACC.

Refined, Focused Learning Objectives

The remainder of the scope of work centered around the testing of four hypothesis that have emerged as critical to the use of FHIR both with respect to the CathPCI registry and clinical registries in general.

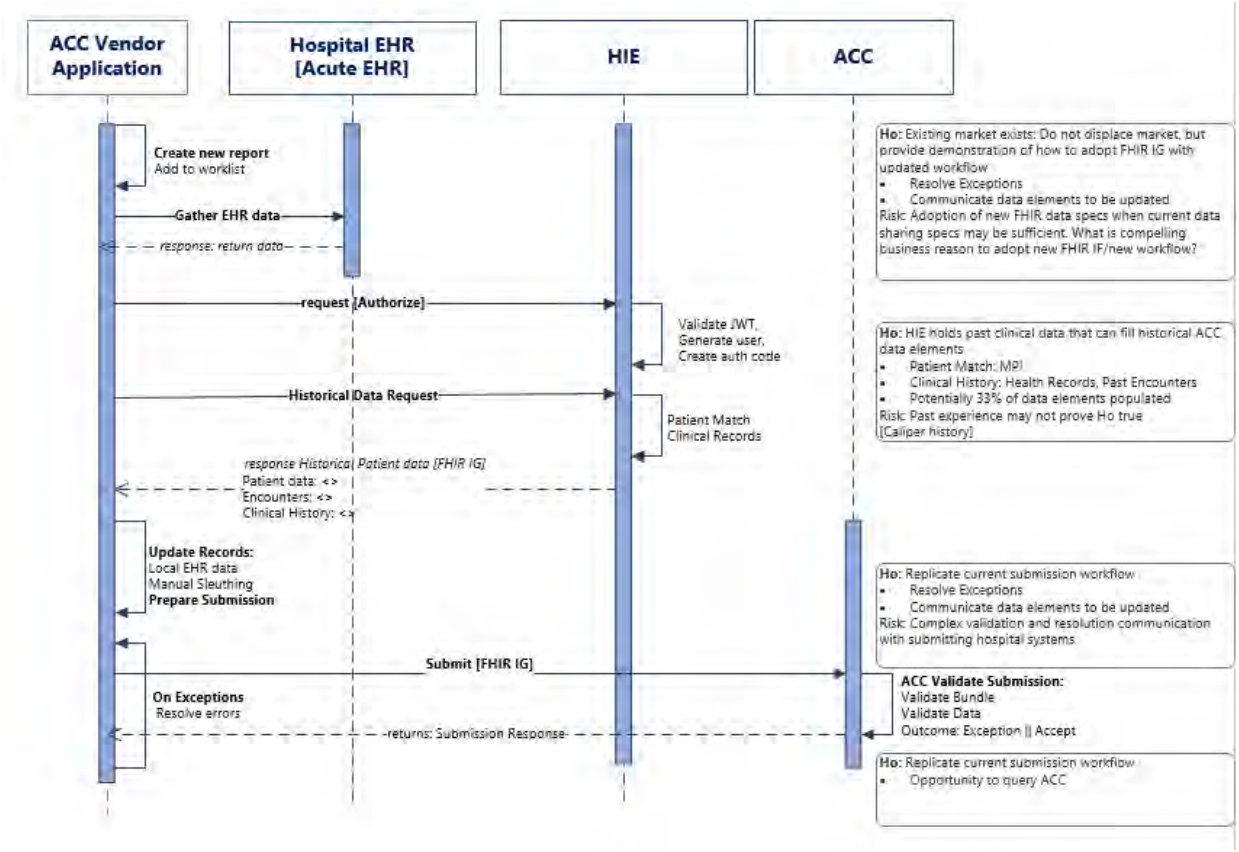
- Hypothesis 1: HIEs can provide useful historical data for the CathPCI registry use case on consistent basis.
- Hypothesis 2: Registries can utilize the new FHIR IG as an improvement over the status quo, where no universal standards exist.
- Hypothesis 3: Registry vendors, representing an established market, are willing to invest in FHIR-based reporting because they see the benefits. They need demonstrated learnings and examples to adopt and innovate.
- Hypothesis 4: Hospitals can benefit from accessing specific CathPCI patient data when it's available at the point of care.

Workstreams

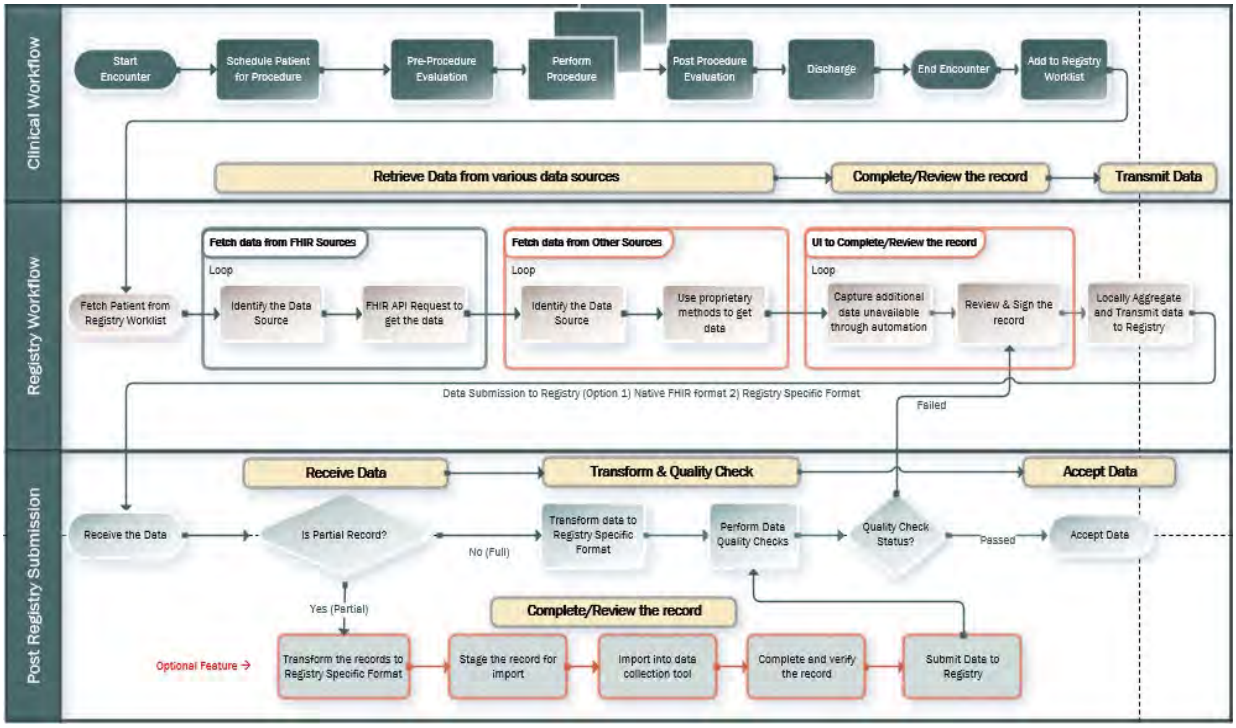
In order to explore these hypotheses, the project team pursued multiple workstreams as described below.

Develop notional future state workflow

Based on the process mapping exercise of the existing approach to registry data collection and submission—and with input from the clinicians on the team about documentation and workflow—a notional FHIR-enabled registry-submission workflow was developed. The workflow was designed to utilize established FHIR-based integration patterns wherever possible. It also assumed that a local EHR and an HIE would offer suitable FHIR endpoints that could be queried for relevant data while allowing for extensibility: any number of such endpoints could be queried based upon configuration.



The workflow imagined a future, fully-automated process whereby the manual chart abstraction, "data sleuthing" and "swivel chair interoperability," as it is variously referred to, could be squeezed out of the process. In other words, this process could be done fully on the back-end, requiring no user interface or manual intervention. At the same time, the team recognized that such a workflow, should it be pursued in the real-world, would initially be aspirational; manual intervention and the supplementing of offline information into the submission bundle would be required in initial phases of implementation. A hybrid version of the workflow that included both FHIR-based and non-FHIR-based collection approaches can be seen here:



Analyze CathPCI data dictionary (discrete clinical concepts and metadata)

Drs. Tcheng and Kelemen were tasked with assessing the availability of data in clinical systems that aligns with the CathPCI registry data model. This work required not only a structured analysis of the 497 elements in the model, but also a deep understanding of the practice of cardiology and associated clinical documentation. The full results of this analysis can be found here:

Harmonized NCDR Dictionary CathPCI_C

The first step in the analysis was to organize the data elements into unique concepts (344 in total). Each concept had more than a dozen attributes, such as:

- NCDR data element name, reference number
- NCDR definition, target value, data type, etc.
- Code system name and code (e.g., SNOMED, LOINC)

Of vital importance among the attributes was the code system and code associated with each element, as that would help determine whether a corresponding concept may be captured in an EHR or HIE. Across the entire CathPCI data model, it was determined that 233 had no mapping to a code system other than the ACC's own NCDR codes, 54 primarily clinical elements mapped to SNOMED CT, 36 primarily lab-related elements mapped to LOINC, and 21 mapped to other HL7 or Social Security standards.

In evaluating the bindings to external terminologies like SNOMED and LOINC, the details and context are vitally important. As illustration, in a number of cases, the analysis raised questions about ACC's

own mappings between the concepts articulated in the NCDR definition and NCDR's own mappings to external terminologies. Of the SNOMED mappings indicated by NCDR, 43% appeared to require further qualification or were questionable based on the project team's analysis. Likewise, 6% of the LOINC mappings were questionable. Here are two examples:

NCDR Concept / Definition	NCDR Mapping	Comment
"Heart failure" (4001): "Indicate if the patient has been diagnosed with heart failure"	SNOMED 84114007, Name: Heart failure (disorder)	SNOMED hierarchy for "disorder" is to represent presence of a disease – what is being asked is history of, or "situation" – which is 161505003
"Family History of Premature CAD" (4287)	SNOMED 134439009, Family history: premature coronary heart disease (situation)	SNOMED code does not include definition sufficient for NCDR purposes (SNOMED is an ontology, not a dictionary) - LOINC 80985-5 includes actual definition (and is the NCDR registry definition)

Nuanced questions about terminology binding are just one factor informing what CathPCI data elements could or could not reasonably be extracted from an EHR / HIE. Other factors include:

- Concepts are entirely NCDR-specific – e.g., participant ID, time frame of data submission
- Standard lexicon available, but information not routinely collected per the controlled vocabulary – e.g., race-Asian Indian (OMB PHIN VADS classification)
- Summative clinical concepts – e.g., newly diagnosed heart failure, significant coronary dissection: while some have SNOMED codes, information not typically captured in clinical workflows as data
- Compound clinical concepts – e.g., witnessed cardiac arrest, new antiarrhythmic started before PCI

Given all of these factors, the analysis suggested that around 44% of the elements in the CathPCI data model should be routinely available in an EHR / HIE, while 56% at present will still require chart abstraction or data sleuthing.

Author computer code to query FHIR endpoints for registry-specific data

Based on the analysis of the CathPCI data dictionary, the project team then created a logical model that could be used to extract all available data elements via FHIR from an EHR / HIE. This model constituted over 11,000 lines of code, largely FHIRPath expressions. For the purposes of using CathPCI as a test case for the overall CREDS IG, the FHIRPath expressions were embedded into a StructureDefinition artifact that was stood up in a registry submission definition repository hosted by ACC. Interested registry submitters could use a FHIR API to access this StructureDefinition and understand what CathPCI's submission expectations were.

Other members of the project team developed a proof-of-concept registry submission application that could access and read the CathPCI StructureDefinition then carry out the series of transactions described in the diagram on page 11. Test FHIR endpoints were established to represent the EHR and HIE, and representative test data was synthesized. The application was designed to be extensible and configurable with regards to the APIs it accessed as well as the registry or use case for which it was being employed. The full source code for the application is open source and available for use here.

Enable registry acceptance by NCDR of FHIR-based data payload (.json)

Meanwhile, members of the ACC team were preparing additional proof-of-concept technical infrastructure beyond a repository and endpoint for the StructureDefinition. As the registry submission consumer, ACC established FHIR endpoints to interact with a registry submitter (in this case, the project team's registry submission app. ACC established the means to validate that the submission bundle was a valid FHIR object and return result messages as appropriate to the submitter.

The workstreams culminated with the project team's participation in a formal track at the January 2023 HL7 Connectathon in Las Vegas. Details on the connectathon track can be found here. At the connectathon, successful end-to-end tests were conducted. No major feedback was received as a result of this testing, and the intention is for the implementation guide to be balloted at HL7 in May 2023.

Limitations

- A lack of representative test data for CathPCI was found to exist. Therefore, synthetic test data was developed by hand.
- FHIR endpoints representing an EHR and an HIE were mocked for the purposes of this project. CRISP, in fact, does not currently support the kind of FHIR endpoints contemplated in the CREDS Implementation Guide.
- The analysis of the CathPCI data dictionary was conducted by two practicing cardiologists with deep backgrounds in informatics. However, it relied on their experience and professional judgement. Their conclusions about the availability of certain types of data were not tested in a production environment.
- During testing, the American College of Cardiology validated FHIR submission bundles but did not complete the process of parsing them into their existing canonical data model, a much more complex undertaking.

Results

Findings

Through the project, we were able to test all four of the hypotheses articulated in the modified project scope. Principal findings related to each hypothesis are as follows:

Hypothesis 1: HIEs can provide useful historical data for the CathPCI registry use case on consistent basis.

Based on the evaluation of the CathPCI data dictionary, it was determined that an EHR or HIE should be able to reliably yield around half of the data required for a registry submission. While this is insufficient to fully automate the data-collection process right now, tapping into these existing repositories of relevant clinical data could meaningfully reduce the amount of manual work for staff in the catheterization lab while also improving the consistency and quality of data.

At the same time, while EHR vendors are being driven to support increasingly complex FHIR-based interoperability via ONC's certification program, most HIEs—including CRISP—do not currently offer the FHIR APIs contemplated by the CREDS IG. This is gradually changing, due to TEFCA and other nationwide initiatives, however it will take time, potentially limiting some of the historical/longitudinal data that exists outside of local systems at the reporting facility.

Hypothesis 2: Registries can utilize the new FHIR IG as an improvement over the status quo, where no universal standards exist.

The project demonstrated that it is feasible to map a complex registry's data model from its proprietary format to FHIR. It took a considerable amount of work—over 11,000 lines of code were written—but it can be done. The process raised questions about the fidelity of the coding concepts used in the existing data models, perhaps serving as a reminder that a review of a registry's data model should be undertaken more frequently to stay abreast of the evolving terminologies used elsewhere in clinical informatics.

The project also demonstrated that ACC's NCDR could stand up FHIR APIs and accept a FHIR-based JSON payload. The amount of work was meaningful but not outside the capabilities of ACC's technical staff. While not in scope for the project, the exercise also gave the same ACC staff confidence that the payload could be transformed to NCDR's native data format and loaded into the registry system itself.

Hypothesis 3: Registry vendors, representing an established market, are willing to invest in FHIR-based reporting because they see the benefits. They need demonstrated learnings and examples to adopt and innovate.

Through this project, a path for establishing FHIR-based registry reporting has been laid out for registry vendors. Whether these vendors are EHR vendors themselves, third party vendors including "app developers" on the EHR app marketplaces, or registry sponsors who are seeking to develop their own reporting tools, the CREDS IG and the POC submission app's open source code base are flexible tools which can be picked up and iterated on to meet the needs of a range of registry use cases. The findings and recommendations in this report are

intended to lay out a clear-eyed assessment of the benefits and challenges of moving towards a FHIR-based model.

Hypothesis 4: Hospitals can benefit from accessing specific CathPCI patient data when it's available at the point of care.

Fully exploring this hypothesis in a proof-of-concept proved beyond the time and manpower constraints of this grant. Given that any implementation of a FHIR-based registry reporting process would require both manual and automated submission, the resulting report would require some custom (registry-specific) work to render in a human-readable, clinically useful format at the point of care. However, the deep dive into the CathPCI data model did yield a noteworthy insight, which is that there are many concepts that, from a cardiologist's perspective are useful to know, which are documented during registry submission but are not otherwise typically captured in clinical systems.

Implications – Recommendations to Stakeholders

Standards and nomenclature developers

The project yielded some summary observations about the nature of data likely to be found in clinical systems versus not. Transactional concepts, which are mostly computable data and are useful in administrative analytics (e.g., case counts, resource utilization) are often found in clinical systems or can be computed from data housed in them. On the other hand, concepts such as performance measures and clinical outcomes, at least as they are conceived in the CathPCI data dictionary, are mostly composite text and largely summative. In other words, they require cognition and judgment, and are more often than not too complex to compute.

As the industry moves toward FHIR-based reporting of performance measures and clinical outcomes across numerous fronts, standards developers should seek to drive consistency in the formulation of such concepts as much as possible. This is no doubt a long-term effort, and one that ONC, as the steward of the Certification Program, can play a key role.

At the same time, standards-developers—particularly HL7 and the track leaders developing new FHIR implementation guides—should be mindful of the fact that, for the foreseeable future, many bulk data use cases, such as registry submission, will require hybrid workflows that include a manual component. This may be required because, as in the case of CathPCI, some data can't be fetched via FHIR, or simply because the submitter requires an opportunity to view, evaluate or even edit the staged data prior to submission. There is nothing in an implementation guide like CREDS (or for that matter MedMorph or UDS+) that forbid additional steps or manual intervention. However, contemplating how these realities could be accommodated will help guide the industry towards its ultimate goal of fuller, real-world automation via FHIR.

Clinical & research registries

The deep dive into the data dictionary of a single registry highlighted the need for clinician-informatician subject matter experts to be at the disposal of registry sponsors. Within each

data model, there are lots of details—e.g., clinical data dictionaries, terminology bindings, what can't be computed. Further these details are changing rapidly with advances in technology and clinical practice.

One way to mitigate the risk of falling too far out of step with these changing details is for registries to embrace native data interoperability. Terminologies alone (SNOMED, LOINC, ICD, etc.) will not result in data liquidity or data liberation. Terminologies are designed for boundary-based (not native) interoperability. But by aligning registry data models as closely as possible to evolving best practices in data governance within clinical systems themselves, registries will come as close as possible to the goal of semantic interoperability.

Even as incremental steps, there are other things registry sponsors can do in support of this goal. One is to begin the process of becoming "FHIR-ready" as ACC has done, by developing the mechanisms to ingest and validate submissions (even partial ones) via FHIR JSON. Sponsors of multiple registries under one roof should also begin the process of harmonizing data dictionaries across internal registries.

HIEs and EHR vendors

From the beginning, the project team set out to develop a FHIR implementation guide that would leverage data from EHRs and HIEs to populate registry submissions. We did so recognizing that CRISP—the representative HIE and the grantee—lacked FHIR capabilities of its own to support the use case as envisioned in the IG. In this sense, CRISP is very representative of HIEs nationally, who have largely focused on high-value use cases dictated by their participants that predominantly leverage HL7 version 2 and version 3 data formats.

While there are approaches for converting these formats to FHIR, they have not been implemented at scale. Instead, the entire interoperability landscape is shifting towards FHIR. As the industry moves through the planned phases of FHIR availability in TEFCA, those HIEs participating in a QHIN will find new ways to support nascent FHIR use cases like registry submission. This project is well-timed to show a path forward.

EHR vendors as a category have more advanced FHIR capabilities than HIEs. This is due in large part to the iterative requirements of ONC's certification program. As this project demonstrated, many of the new FHIR use cases involve bulk data and/or high-throughput transactions which require investment for vendors to effectively support.

Policymakers

Given that most registries are either national or international, the greatest opportunity is likely for national policymakers. For ONC in particular, we recommend maintaining a focus on harmonizing performance measures and clinical outcomes across the broadest spectrum of initiatives possible. This can include coordination with other stakeholders like CMS and remaining committed to collaborations like the Helios FHIR Accelerator for Public Health. Policymakers can also acknowledge the need for hybrid workflows, both transitionally and well into the future, and offer guidance on how they should be implemented to incrementally advance the long-term goal of full FHIR-based automation.

We also believe it's worth noting that most of the stakeholders in clinical and research registries—from submitters to registry sponsors—are mission-driven non-profits. This project begins to demonstrate the targeted strategic investment by policymakers can help to drive innovation in this vital but highly specialized market. We recommend that policymakers continue to make such investments over time to encourage registries' alignment with the broader industry.

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[i] According to the American Medical Association, these are the five things patients and consumers should know about clinical registries (https://www.ama-assn.org/practice-management/digital/5-things-know-about-clinical-data-registries):

1. Clinical data registries record information about patients' health status and the care they receive over time. These registries typically focus on patients who share a common reason for needing care, allowing physicians to see what treatments are available and how patients with different characteristics respond to certain treatments.
2. Different types of registries track specific aspects of care. A registry may focus on a disease or condition, a procedure, or a medical device. The registry defines a patient population, then recruits physicians and other health care professionals to submit data on a representative sample of those patients.
3. Data are used in treatment analyses. Studying attributes of the population in the registry—and finding patterns—can help identify particular outcomes. Because all of the factors that might have an impact on outcomes are not necessarily known at the time of data collection, the data are stored and can be revisited to evaluate previously unrecognized associations.
4. Data are collected via secure online portals or electronic health record (EHR) systems. As data enter the clinical data registry, quality checks are performed to ensure that the data are correct and complete. If something is missing or outside of the expected range, registry staff ask the submitting physician to review and verify the data.
5. Registries help improve health care quality and safety. Registries are used for comparing the effectiveness of different treatments, evaluating different approaches to a procedure, and monitoring the safety of implanted devices. Information from registries is also increasingly employed to ensure that payment is adjusted based on the quality of care provided, or to give patients the information they need to make better choices.

[ii] https://onlinelibrary.wiley.com/doi/full/10.1111/ane.12021

[iii] https://dcri.org/wp-content/uploads/2018/12/Pew-Report-v2018DEC08FINAL3.pdf

[iv] https://www.healthit.gov/topic/2020-leap-health-it-projects#Development