



Council of Medical
Specialty Societies

CMSS Primer

**for the Development and Maturation of
Specialty Society Clinical Data Registries**



For Specialty Societies and Organizations Developing
and Advancing Clinical Data Registries

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I. INTRODUCTION

When the Council of Medical Specialty Societies (CMSS) was founded in 1965, CMSS established a goal to improve the quality of care delivered in the United States. Fifty years later, the first strategic priority of the modern CMSS is to facilitate a culture of performance improvement in practice. In the current environment of medicine and health care, clinical data registries (CDRs) offer the best promise to fulfill that goal.

Specialty society CDRs pre-date the 2001 publication of the Institute of Medicine's *Crossing the Quality Chasm*,¹ the report that is often credited with ushering in the modern focus on quality in health care. By then, four specialty societies had introduced CDRs for their specialists to measure and improve the care of their patients, including the American Society of Reproductive Medicine in 1980, the Society of Thoracic Surgeons in 1989, the American College of Surgeons in 1990 (*although the first surgical registry can be credited to Dr. Ernest A. Codman's collection of "End Results" more than 100 years ago*), and the American College of Cardiology in 1998.

Today, there are more than 120 CDRs, 90% of which are offered by specialty societies.² Registries are evolving from requiring manual data entry to extracting data directly from electronic health records (EHRs). Practice performance is reinforced by seeing improvement over time. Frequent feedback on performance allows clinicians to compare themselves with peers as well as with national benchmarks. Thus, in contrast to one-time quality improvement projects, CDRs create an ongoing process of measuring, reporting and improving the quality of care that clinicians provide. CDRs are the modern specialist's best tool for creating a culture of performance improvement in practice.

CMSS would like to recognize and thank the more than 70 specialty society representatives who comprise the CMSS Registries Component Work Group, Chaired by Paul Pomerantz, MBA, CAE, Chief Executive Officer of the American Society of Anesthesiologists. In addition, CMSS acknowledges the skillful facilitation of the subgroup of the Registries Component Group that led the efforts to research and write the CMSS Registry Primer, and the coordination of this Registry Primer by Rebecca J. Swain-Eng, MS, CAE, Swain Eng and Associates, LLC. But most of the credit goes to the CEOs of the CMSS member specialty societies who, under the leadership of Allen Lichter, MD, CEO of the American Society of Clinical Oncology (ASCO), recognized the promise of registries and committed to collaboratively facilitating their development and maturation, resulting in measurable improvements in care.

*-Norman B. Kahn Jr., MD, Executive Vice-President and CEO
Council of Medical Specialty Societies*

CMSS plans to update this Primer when new relevant information becomes available. The next update is scheduled for May 2016. CMSS would welcome your input, feedback and questions on this Primer. Please contact mailbox@cmss.org.

II. OVERVIEW AND PURPOSE OF REGISTRY PRIMER

“Data really powers everything that we do.” – Jeff Weiner

“Information is the oil of the 21st Century, and analytics is the combustion engine”

– Peter Sondergaard, Gartner Research

“Hiding within those mounds of data is knowledge that could change the life of a patient, or change the world.” – Atul Butte, Stanford School of Medicine

Although physicians and their professional societies may be foremost positioned to define best practices, many have not yet played a major role for the development of clinical data registries (CDRs) that are critical for providing the data to support best practices. There are many hurdles to overcome with registry development and implementation that can appear daunting to those just starting out.

The Council of Medical Specialty Societies (CMSS) is focused on building a culture of performance improvement in medical practice. In order to demonstrate that physicians are improving the care they provide, data is needed. There are laborious ways of tracking patient outcomes by hand to gather this data, but the simplest, easiest way is by using a CDR that can meet multiple purposes for quality improvement, maintenance of certification, pay for performance and more.

In 2013, CMSS made a strategic move to place registries at the top of its priorities. CMSS had the foresight to realize that its membership needed additional resources to help in the education around registries and the development and implementation of organizational registries. CMSS held its first Registry Summit in 2014 and its second Registry Summit in 2015. Both Registry Summits attracted leaders from across the nation in registry development and implementation, legal protections, data analytics, and each hosted a unique registry vendor showcase. CMSS continues to grow its registry efforts with webinars, collaborations with several national organizations, meetings, and advocacy efforts that have proven to be beneficial and invaluable to societies developing or updating their CDRs.

The purpose of this Registry Primer is to educate practicing physicians, leaders and staff of specialty societies, national medical boards, registry organizations, and other organizations with current information on:

- Special issues for specialty societies about CDRs;
- Business of CDRs;
- Brief descriptions of the key players in CDRs;
- Overview of data standards for CDRs;
- Overview of quality measures, quality improvement in registries;

This Registry Primer is intended to serve as background and a resource guide on clinical registry development and implementation for those that are new to this area and those organizations that are interested in remaining current on new and emerging issues. It is not intended to be an exhaustive document of all the information related to clinical data registries nor is it meant to compete with any documents the Agency for Healthcare Research and Quality (AHRQ), National Quality Registry Network (NQRN®), or other organizations have developed on registries. Rather it is intended to be a dynamic document that will be updated periodically with the most current information on registries to aid specialty societies and others with the development, maintenance and update of CDRs.

III. SPECIAL ISSUES FOR SPECIALTY SOCIETIES ABOUT CLINICAL DATA REGISTRIES

PREFACE: WHY REGISTRIES ARE IMPORTANT FOR HEALTHCARE SPECIALTY SOCIETIES

Specialty society CDRs have been gathering and analyzing clinical data in a variety of specialty areas for nearly 40 years. Most of this work started with manual chart abstraction, and that technique is still widely employed. However, as clinical data becomes all electronic, CDRs will play an increasingly important role in the healthcare system. There are two major outputs from registries: 1) monitoring the quality of medical care, and 2) generating new clinical knowledge that will lead to improved patient care and outcomes.

Monitoring the Quality of Care

Monitoring and improving the quality of clinical care is a clinician responsibility and cannot be delegated to the insurance industry, Federal agencies, or for-profit data companies. Not only are those organizations ill equipped to understand the nuances of clinical care, they generate most of their quality data by extrapolating from administrative claims. Professional society run CDRs trump these efforts because their data comes directly from the clinical record, and the findings are not inputted from claims data.

Furthermore, running a first-rate CDR creates a vehicle whereby specialty society members can not only improve the quality of the care they provide, but also satisfy most, if not all, the demands about to be placed on them by the [Center for Medicare and Medicaid Services \(CMS\) Merit-Based Incentive Performance System \(MIPS\)](#), an essential feature of CMS payment reform. In fact, there is little chance that payment reform, whether through [MIPS or Alternative Payment Models \(APMs\)](#), can succeed without a rigorous quality monitoring and improvement program as exemplified by our registries. All new payment models have incentives built in, whether intentional or unintentional. Clinicians must assure patients and the public that they are monitoring the quality of care and minimizing the impact of any unintended incentives. Finally, public reporting of physician and other clinicians' performances are here to stay. These reports come from a host of groups using mostly administrative claims or a very limited set of performance measures. By using registry data, clinicians can make public reporting far more accurate and meaningful.

Generating New Knowledge

Clinicians have long lived within a world where clinical research trials (CRTs) are separate and distinct from routine clinical care. While formal CRTs are critically important and will continue to be an essential part of medicine, they have serious limitations. CRTs are often cumbersome, costly to perform and time intensive. CRTs often eliminate a large segment of the patient population with the condition being studied due to exclusion criteria, which leads to huge gaps in knowledge about the excluded patients.

It is estimated less than 21% of clinical decisions are based on solid clinical trial data. Clinicians often use the results of the clinical trials and apply them "off label" to treat patients based upon the results of trials they never would have qualified for either due to age, co-morbidities or both.³ There must be a way of filling the gaps in knowledge rapidly and in a cost-effective manner. The solution to filling the knowledge gap may be accomplished by the development and implementation of a robust clinical CDR.

Today, with most clinical encounters being recorded electronically, it is feasible to aggregate data on large numbers of patients, normalize the data, and analyze the results of de-identified datasets. In this fashion, clinicians can make new observations and draw conclusions over a broad range of topics with speed and agility. Of course, there are limitations inherent in observational data and some findings that will need to be verified in formal clinical trials. However, the health system and implementation of EHRs have evolved to the point where new knowledge can be generated as a byproduct of routine clinical care. This is the promise of CDRs leading up to the so-called Institute of Medicine's Learning Health Care System.⁴

The Big Picture

Today, with more and more clinical data being incorporated directly into EHRs or recorded electronically, clearly these data will be aggregated, analyzed, and used in various ways. The question is not whether this will happen, but rather who is going to do this and how are they going to do this. Many believe it is imperative that the clinician community should be leading this work. If clinicians back away leading efforts on how and when EHR data is used, for-profit organizations will take the lead; be they payers, drug distributors, big-data analytics companies, government agencies, or other organizations.

As clinicians face the future of medicine in a rapidly changing world, the group that has the most accurate and actionable data will have the greatest power over the specialty and the profession. That group should be the medical profession itself as represented by the professional societies who are devoted to supporting their members for the ultimate good of the patients they care for. This is a pivotal moment. If clinicians fail to act, others certainly will. Clinicians face the possibility of looking back at this decade from the time that they actually lost control of their own clinical data. Clinicians must not allow that to happen. **Through the support of robust specialty society clinical data registries, clinicians can shape the future of their specialty and medicine.**

-Allen Lichter, MD, CEO, American Society of Clinical Oncology (ASCO)

A. DEFINING THE PURPOSE OF THE REGISTRY

A **clinical data registry** (CDR) is an organized data system that collects uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease or condition, and that serves one or more predetermined scientific, clinical, or policy purposes.⁵

“DETERMINE AND ALIGN THE CDR’S PURPOSE WITH THE ORGANIZATION’S NEEDS”

Developing a CDR is a major initiative for any medical specialty society or other organization to undertake. It requires a significant investment in staff and volunteer time, substantial financial support, and considerable attention to the CDR governance and management. Societies should be knowledgeable about the requirements and the internal resources needed for a CDR before they commit to building one. The first step to understand if a CDR is right for the society or organization is to determine the purpose(s) of the registry. The reason for developing the registry and how the CDR will be used should be core to and align with the mission, vision and strategic objectives of the sponsoring society or organization.

Early registries were established for specific purposes. For instance, the Society of Thoracic Surgeons implemented its National Database in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. The Society of Interventional Radiology established the Fibroid Registry for Outcomes Data (FIBROID) in 2000 to collect high-quality data on uterine artery embolization.

In recent years, the most significant driver of registry development and updates by medical specialty societies has been the growing linkage of quality reporting with payment and pay for reporting programs like the Centers for Medicare and Medicaid Services (CMS) Physician Quality Reporting System (PQRS). The 2014 Medicare Payment Rule created a new avenue for quality reporting, the Qualified Clinical Data Registry (QCDR). The QCDR option allows the society to develop and test measures in their QCDR, participate in pay for reporting programs using their specialty specific measures, including measures that are not individually formally approved by CMS, and transmit data directly from the QCDR to CMS or other deemed entities. (More information available in Section VII. Quality Measures and Quality Improvement in Registries). Additionally, in 2015 the repeal of SGR and implementation of MACRA gives societies more latitude to develop and report on quality measures in their QCDRs to meet the requirements for MIPS. (More information available in Section IV. Business of Registries, Regulatory Issues). Lastly, many clinicians have reported feeling more comfortable reporting data to their specialty society registry than directly to a public entity (i.e. CMS).

Each organization must decide the purpose and scope of their CDR to meet the organizational needs and answer the specific questions that they would like to address.

The ability to collect large amounts of electronic medical record information has made it possible to develop registries for multiple purposes. Still clarity about purposes will drive the investment, design, and operation of the registry.

PURPOSES OF A CDR (Non-Exhaustive List)

- Measuring or monitoring patient safety or harm
- Benchmarking and quality improvement activities, including those in support of American Board of Medical Specialties (ABMS) Maintenance of Certification Part IV
- Meeting of quality reporting requirements from accrediting organizations such as The Joint Commission
- Public reporting of clinical performance
- Monitoring the effectiveness of specific treatments or devices

- Studying the prevalence and incidence of specific conditions or diseases and population surveillance
- Describing the natural history of a condition or disease
- Health services and health policy research, such as variations and discrepancies in care; impact of care redesign or development of bundled payment strategies.
- Identification of education and performance gaps (to support member education needs)
- Determine effectiveness or cost-effectiveness of treatments/services or medical products or devices
- Comparative Effectiveness Research (CER)
- Clinical decision support tool development
- Monitoring of overall specialty trends and valuing the care the specialty provides

Several societies have had positive experience with registries as a source of non-dues revenue from a number of activities. These include Federal research grants and industry sponsored studies. In order for the society to sustain its energy and investment, the registry will need to serve a clear strategic purpose and meet member needs.

B. CHECKLIST OF ITEMS TO CONSIDER BEFORE STARTING A NEW REGISTRY

The creation of a registry will take several years and significant funding. Organizations starting out now will need to think out in terms of 2-3 years before the registry is live. The first stage is the “planning” phase during which you will need to consider whether the society is prepared to support the registry in the long term. The Agency for Health Care Research and Quality (AHRQ) has developed a [Registries for Evaluating Patient Outcomes: A User's Guide: 3rd Edition](#)⁶ that provides a wealth of information useful for societies and other organizations interested in starting or updating a CDR. The AHRQ document includes “Steps in Planning a Registry” that organizations may find helpful to understand what is needed to start a CDR.

Before committing to starting a registry a society should:

1. articulate the purpose of the registry;
2. determine if a registry is an appropriate means to achieve the purpose;
3. identify key stakeholders; and
4. assess the feasibility of a registry.⁶

The assessment of feasibility may include the following⁷:

- ✓ **Target Population:** specific disease or treatment, age, etc.
- ✓ **Scope of Study:** participation of specific geographic areas, length of time patient is followed, hospital vs. non-hospital, etc.
- ✓ **Identification and Engagement of Stakeholders:** Professionals, insurance companies, CMS, industry, sponsors, etc. It is recommended that the society assemble a planning committee with representatives of the key stakeholders. This planning group should be as broadly representative as possible, but should include individuals with knowledge of health information technology, large databases, quality improvement, and observational research. This group should include also representation of the society Board of Directors (BOD) and should report directly to the CEO or to the BOD.
- ✓ **Feasibility to Execute and Operationalize the Registry:** Do the data already exist? If so, is the quality of the data sufficient to answer the related research questions? Data collection via electronic remote database access vs. paper, patient generated data vs. research professional involvement, Community based hospitals vs. university-based hospitals, etc.
- ✓ **Funding:** Can you afford to maintain a registry/ repository? Development of a realistic budget that encompasses every aspect of development, execution, and finalization of the registry, confirmation that funding exists, inclusion of various funding partners who may be stakeholders, etc.
- ✓ **Internal Staff Support:** Identify a society staff champion/project leader. This should be an individual with sufficient bandwidth, leadership stature (i.e., direct report to the CEO, motivation and experience to lead the project and knowledge to oversee the development).
- ✓ **Registry Guidance and Regulations:** Consider designation of experienced staff or retention of a consultant to guide the effort. Obtain knowledgeable legal counsel to review issues and considerations related to organizational structure as well as HIPAA and other regulatory compliance issues.
- ✓ **Market Research:** Determine if the market can support your CDR.
- ✓ **Study Closure:** For studies that do not have a finite sample size, having clarity to determine when enough data has been collected.

The BOD or membership of a society might require additional information before giving final approval for a CDR.

Additional considerations in planning a CDR are:

5. Determine who will be on your CDR team staff
6. Establish your CDR Governance and Oversight Plan
7. Define the Scope and Rigor of the CDR
8. Define the Data Set, expected Patient Outcomes and Target Population(s) of the CDR
9. Develop a Study Plan or Protocol
10. Develop a Full CDR Project Plan

The BOD may also request a formal **Business Case** or **Business Plan**. A Business Case is different from a Business Plan in that although it has the same core pieces of the Plan, it may not include additional extensive studies such as environmental scans, feasibility studies, financial risk analyses, vendor market surveys, etc. (More information available in Section IV. Business of Registries and forthcoming in future versions of this Primer.)

C. GETTING BUY-IN WITH THE BOARD OF DIRECTORS

For Specialty Societies, Board of Directors' buy-in is among the most critical elements of success. In addition to the items identified above, there are several elements to achieving this.

- First, identify key champions on the BOD. These will be knowledgeable and forward thinking people who will have the credibility to help lead the BOD through the process of discovery, evaluation, strategy development, resource allocation and implementation.
- Second, determine how you will educate the BOD. Groups have used outside speakers, benchmark data, case studies and other information to make the business case.
- Third, assume that BOD buy-in will take several meetings. Society leaders should plan for generative discussions, without BOD action, that will allow BOD members to discuss openly the advantages, risks, and investments associated with the registry.
- Finally, BODs respond well to data. A draft CDR feasibility study should be presented to the BOD for review.

D. BUILDING THE MEMBER VALUE PROPOSITION

Medical societies are reporting that registries have resulted in an improved member value proposition. Retention and new membership rates have increased for specialty societies with registries. Registries provide member value in the following ways:

- Quality reporting through a Qualified Clinical Data Registry (QCDR);
- Support of quality improvement activities that quality for American Board of Medical Specialties (ABMS) Maintenance of Certification Part IV activities (More information to come on this area in future versions of the Primer);
- Resources for practice benchmarking including efficiency, case mix and quality;
- Demonstrate the value of the specialty by providing information that can be applied to the American Medical Association's Relative Value Scale Update Committee (RUC) and Relative Value Units toward physician compensation;
- Lastly, registries may become a source of non-dues revenue that can help reduce reliance on membership dues and obviate the need for regular dues increases.

E. REGISTRY GOVERNANCE WITHIN A SPECIALTY SOCIETY

Specialty societies most often incorporate a registry directly into the functions of their organization. However, in some cases, a registry may be established as a separate non-profit organization. The latter may be appropriate if the legal structure provides improved legal or tax protections. In addition, some registries have developed a separate structure to allow for a governance structure that allows for the engagement of multiple stakeholders including patient advocates, related medical specialties and providers, and industry. In any case, legal counsel should be consulted to determine which legal structure best fits the registry.

Regardless of the legal structure, the sponsoring organization should consider a committee structure that will support the integrity and reputation of the registry. Committee considerations include:

Executive or Steering Committee: This committee will provide overall oversight to registry development and operations.
Data Definitions Committee: This committee will assure consistency in definition of data items within the specialty, between specialties and with vendors.
Data Quality Committee: This committee will establish processes for auditing of data and oversee improvement strategies.
Vendor Advisory Committee: This committee will work with vendors to provide a voice in the development of appropriate standards.
Data Access, Use and Publication Committee: This committee will set standards and processes for how data can be requested, by whom and in what format. Typically, data use committees will review and approve requests for data by outside organizations.
Registry Science Committee: Epidemiology and biostatistics expertise specific to the subtleties of patient registries and observational research is very important in the design, implementation, and analysis of registry data. ⁶

REGISTRY STAFF SUPPORT

The needed internal and external staff to support the CDR will depend upon the size and needs of the registry. In general, the registry team should include staff or experts in the following roles⁶:

Project Management: Manage the day-to-day activities and the overall CDR project. May include Executives, Mid-Level and/or administrative staff
Subject Matter Expert: Clinical Experts relevant to the subject(s) and purpose(s) of the CDR
Registry Science Staff/Experts: E.g. epidemiologist, biostatistician, health outcomes researcher, economist, other scientists as applicable to the CDR
Data Collection and Database Management Staff/Experts: Oversee database administration and security
Legal Issues/Patient Privacy Experts: Provide guidance on legal and HIPAA related issues
Quality Assurance Experts: Provide guidance on data elements issues and quality of data in CDR

IV. BUSINESS OF CLINICAL DATA REGISTRIES

A. BUILDING THE REGISTRY BUSINESS CASE AND BUSINESS PLAN

A typical CDR business case outline may look something like the one below. The CMSS and NQRN® are currently working on a joint project to define a business case and examples to be presented in the next version of this Primer, expected to be released in May 2016.

Business Case

- I. Executive Summary
- II. Purpose
 - a. Define data set, patient outcomes and target population
 - b. Fit with Society Mission, Vision and Values
- III. Key Stakeholders
- IV. Benefits for:
 - a. Members and Society
 - b. Clinicians
 - c. Specialty
 - d. Patients
- V. Assess feasibility of CDR
 - a. Funding
 - b. Landscape
 - c. Other
- VI. Risk Management/Mitigation
- VII. Consequences of NOT starting a CDR
- VIII. Overview of Registry Team
- IX. Overview of Governance and Oversight Plan
- X. Draft Timeline

BUSINESS PLAN

All the above items in Business Case, but in much more detail.

- XI. Scope and Rigor Needed
- XII. Study Plan and Protocol
- XIII. Project Plan

In Version 2 of the CMSS Registry Primer expected out in May 2016 more specific information will be made available on building the Registry Business Plan along information from the NQRN® on the Business Case, models of Business Cases and Business Plans and other tools to aid societies with the development or updating of their registry business cases and plans.

B. SELECTING THE REGISTRY PLATFORM AND OTHER VENDORS

In 2014, the (NQRN®) released a registry vendor assessment tool. The document describes a process and a set of tools that may help registry stewards select registry vendors that will best meet their organization needs. NQRN® Registry Vendor Assessment: <https://download.ama-assn.org/resources/doc/cqi/x-pub/nqrn-registry-vendor-assessment.pdf>

C. CDR REGISTRY VENDOR INFORMATION AND DATA

Over the past three years, the CMSS has connected with many specialty societies and other organizations which are actively engaged in running or are seriously considering developing a CDR. These interactions have led to many opportunities to learn from these groups about their registry vendor needs, what the ideal registry would look like, and how CMSS can best assist its members with CDRs. In addition, in 2015 the CMSS conducted an informal survey of CMSS member societies with CDRs about registry vendors. The aggregated results of this survey are found below (n=10 out of the 25 CMSS members known to have CDRs in 2015. Response rate 40%).

Based upon multiple sources of information these are the vendors that CMSS is currently aware of that specialty societies are using for their CDRs. Readers are encouraged to contact CMSS with additional vendor resources they are aware of to be added to future versions of this Primer.

Registry Vendors (in alphabetical order)

Adverttek www.adverttek.net

FigMD* www.figmd.com

Liaison Technologies* www.liaison.com

Quintiles* www.quintiles.com

Premier (formerly CE City)* www.premierinc.com

REDCap <http://project-redcap.org/>

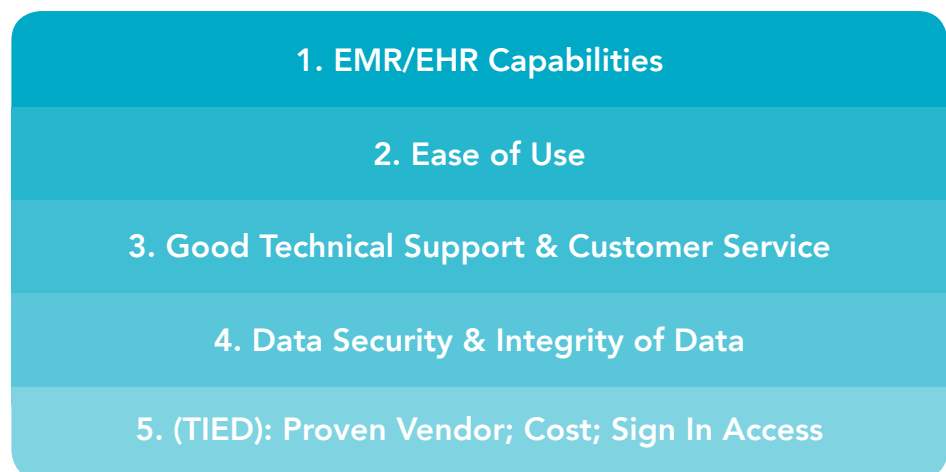
Specialty Society as the Vendor (society may serve as their own registry vendor)

One of the top priorities for many specialty societies in selecting a registry vendor is the ability for a vendor to be able to accept data directly from an EMR (2015 CMSS Vendor Survey). The respondents indicated with (*) are known to be able to accept data directly from an EMR.

The top five priority needs, as indicated by the 2015 CMSS Vendor Survey, for specialty societies in selecting a vendor for a CDR were:

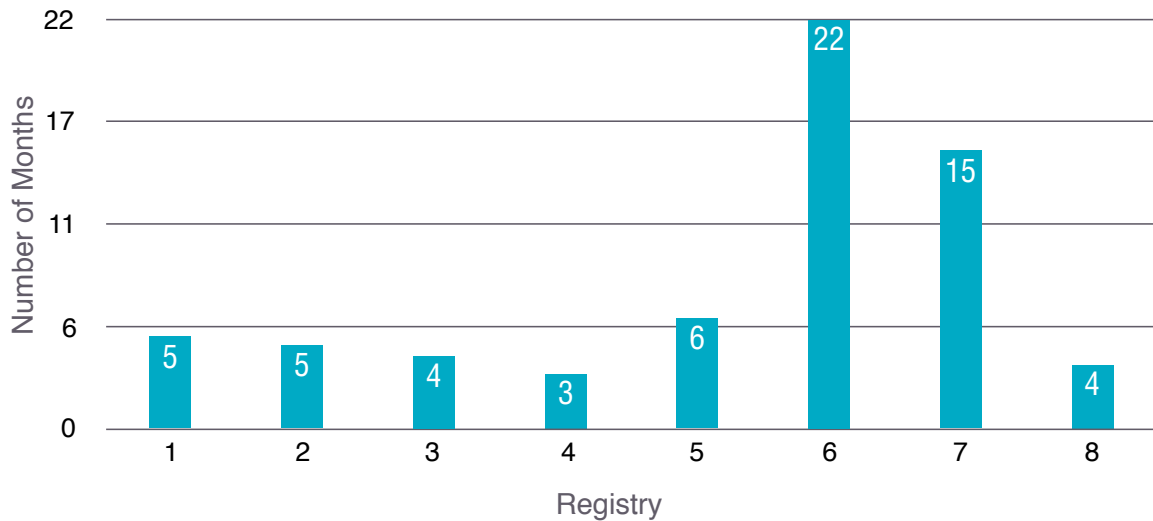
1. EMR/EHR Capabilities
2. Ease of Use
3. Good Technical Support & Customer Service
4. Data Security & Integrity of Data
5. (TIED): Proven Vendor (Track Record); Cost; Sign In Access

The top five priority needs for specialty societies in selecting a vendor for a clinical data registry were:



SOCIETIES WERE ASKED, "HOW MANY MONTHS DID IT TAKE FROM CONTRACT SIGNING TO HAVING YOUR REGISTRY UP AND RUNNING WITH ENTERING YOUR FIRST PATIENT DATA (OUTSIDE OF ANY PILOT TESTING)?"

Months to Start Entering Data Into CDR from Contact Signing
(Ave. 7.9, Min 3, Max 22 months)

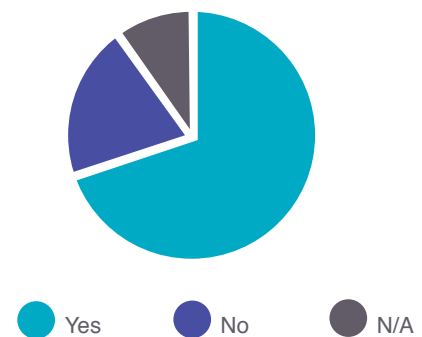


OTHER FEEDBACK FROM THE SURVEY

- Majority of respondents indicated that the vendor had a dashboard to track stages of practice enrollment, but two indicated that this would be a nice add on and another indicated this was not possible.
- Societies were asked about vendor support for technical issues and implementation of the registry with society, sites, and participants. Weekly calls with the vendor were the most commonly used way to assess any implementation issues, participant satisfaction and answer any questions. **Technical support offered by the registry is key to society and registry participant satisfaction. The vendors all interact directly with the participants to answer technical questions about the vendor registry software, technical issues, or implementation questions.**
- **Approximately 70% of the respondents indicated that their registry could accept data directly from an EMR or EHR.** Other societies indicated that their registry could accept data in other formats as needed (50% of respondents) as automated data entry or CDR (20% of respondents, respectively); semi-automated data entry, Manual (data) entry (only) or Different formats (XLS, CVS, FHIR), or Flat files (10 % of respondents, respectively).

- **HIE/EHR Incorporation into the Registry was the highest rated item on a scale of 1-10 (Mean 9.8) for importance by the respondents to the survey.** Ongoing (technical support), vendor organizational profile and total cost were the next highest rated items of importance to the respondents (Mean: 9.5, 9.5, 9.3, respectively).

Registry Accept Data Directly from EMR/EHR



D. FINANCING A REGISTRY

There are several different funding opportunities available to support the development, implementation or sustainability of CDRs. It is recommended that organizations review the specific information that can be found on pg. 26 of the [AHRQ Registries for Evaluating Patient Outcomes website](#).

Categories of Financial Support for CDRs (Non-Exhaustive List)

- *Membership/Society Support*
 - Dues or special assessment
 - Enrollment fee
- *Medical Society Foundation*
- *Private Grants and Philanthropic Grants*: Non-profit organizations may wish to support the mission and vision of the CDR.
- *Sale of Registry Data/Services*
 - Academic Researchers
 - Data Request Portals (DRP)
 - Newer option for dissemination CDR data through a DRP. More information available via a webinar presented by CMSS and Prometheus Research in November 2015. [Link to Webinar](#).
- **Public Private Partnerships** including those with corporations, pharmaceutical companies, foundations, government, health plans, private funding or device manufacturers.
- *Foundations*: Nonprofit disease foundations may be interested in a registry to track the natural history of the disease of interest as well as the impact of therapeutic interventions.
- *Federal Grants/Government*: Federal agencies, such as the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), (CMS), (AHRQ), U.S. Food and Drug Administration (FDA), and State agencies.
- *Health plan providers*: Health plan providers may be interested in funding a registry.
- *Patient Advocacy groups*: Patients may be able to contribute funding to focus on rare diseases or patient subgroups of interest for more common conditions.
- *Private funding*: Private philanthropic individuals or charitable foundations and trusts may have an interest in CDRs.
- *Device/Product manufacturers*: Product manufacturers may be interested in studying the natural history of the disease for which they have (or are developing) a product, or demonstrating the effectiveness and/or safety of existing products or assisting providers in evaluating or improving quality of care.
- *Professional society/pharmaceutical industry "hybrids"*: Situations may exist in which a product manufacturer funds a registry designed and implemented by a professional society to gain insight into a set of research questions.
- *Multiple sponsors*: Registries may meet the goals of multiple stakeholders, and such stakeholders may have an interest in sharing the funding.

E. AMERICAN ACADEMY OF OPHTHALMOLOGY CASE STUDY:

HOW TO BUILD A FINANCIALLY SUSTAINABLE REGISTRY-IRIS REGISTRY WITH AAO WILLIAM RICH MD III

There are two approaches to establishing a long-term revenue stream: a participant fee based revenue stream and a second approach that leverages aggregate data. In the first model, the registry charges an initial participation fee to each professional and annual charges for collecting the data and calculating measures. While this is a more predictable model, there is empiric evidence that societies that adopt this approach have had great difficulty in recruiting and maintaining participants.

The second approach encourages physician participation by not charging fees to the professionals or the practice. The prerequisite attributes for a successful model include:

- **Support of the society leadership**
- **A small, knowledgeable registry governing body**
- **A vendor with a record of accomplishment of successfully working with professional societies whose registry's goals have been achieved**

Robust participation of physicians from as many of the society's subspecialists as possible. The value proposition of the registry and its ability to meet the regulatory and professional improvement goals of physicians must be repeatedly communicated to the membership. The registry design and principles should be mentioned at meetings, to subspecialty leadership, in the trade press, to public policy leaders and industry once a unified communications message is adopted.

Meaningful measures must be developed and implemented to address conditions or interventions of importance to the profession, boards, patients, society, researchers and industry. The measures and the accompanying data points are resources that are key to a successful financial strategy.

Informatics and analytical tools to evaluate the collected aggregate data. In this second model, the revenue stream is dependent on the ability of the registry to develop several core abilities. First, a system must be implemented to evaluate the quality, validity and quantity of the data collected. The capability to do the analytics to answer clinical, epidemiologic, surveillance and research questions is a necessary requirement.

It is critical that the registry form a small group to evaluate the submitted projects for scientific importance and the ability of the registry to answer proposed questions. Are all the required data points for a proposal captured in the EHR? If not, how feasible is it to begin collecting the new inputs? What are the resources /costs to do so?

Program Management. Most professional societies can develop the previously mentioned infrastructure capabilities. What the societies often lack is the business expertise to evaluate a project, awareness of all the needed inputs and associated costs, and develop a feasible timeline for delivery of the registry. Societies may decide to engage a consultant with experience with registry development and management, business case or plan development, and/or industry and government contracts to work with them to evaluate whether or not a registry will meet the organizational needs and if the organization is appropriately prepared to develop a registry. There may be value and a return on organizational investment with hiring a consultant if a society does not have the resources internally. The society will still need to have internal staff oversight assigned to manage the registry program both at the Executive level and at the programmatic staff level. The staffing needs will vary dependent upon the size and scope of the registry program.

HOW HAS THIS WORKED OUT FOR THE AAO'S IRIS REGISTRY-INTELLIGENT RESEARCH IN SIGHT?

IRIS launched on April 1, 2014 with a goal of contracting with 2200 ophthalmologists and reporting on eighteen million patients by January 2018. As of August 7, 2015 IRIS had contracted with six thousand ophthalmologists, integrated with over 26 different EHRs and reported on measures for over 13.1 million patients and extracting data from 44.1 million visits.

There is value in this aggregated data. The AAO has contracted with two separate applicants who responded to a Center for Disease Control (CDC) proposal to evaluate ophthalmic disease prevalence. The AAO is negotiating contracts with industry to develop an analysis of the natural course of a dry macular degeneration.

Negotiations are proceeding with a diagnostic manufacturer and pharmaceutical companies to look at comparative effectiveness of topical drugs. The AAO has not developed the infrastructure to evaluate research proposals from members and academic centers, but hopes to do so by next year. The decision to charge AAO members for the use of IRIS as a research tool has not been decided, but will be influenced by the success of the business model.

In summary, all new professional societies' registries have entered the quality measurement arena with understandable trepidation stoked by uncertain funding models. The success of ACC and STS give us hope. The CMSS will continue to be the forum where strategies and ideas are shared.

F. SUMMARY OF REGULATORY ISSUES AFFECTING REGISTRIES AND LINKS

Registries must comply with applicable privacy and security regulations. Depending on the data being collected, the use and disclosure of such data and the jurisdictions of the registry as well as the data recipient, registries should consider addressing the following:

- **Health Insurance Portability and Accountability Act of 1996 (HIPAA)**⁸ and **Health Information Technology for Economic and Clinical Health Act (HITECH – part of the American Recovery and Reinvestment Act of 2009)**⁹
- **Common Rule**¹⁰
- State Laws: Privacy and Breach Notifications; Common Law
- Food and Drug Administration: Regulations, Medical Device Reporting

- European Union Data Protection Laws
- State Laws and Regulations
- Food and Drug Administration regulations

There are several great resources available that summarize the current regulatory and legal landscape for CDRs. For example, the AHRQ Registries for Evaluating Patient Outcomes: A User's Guide, 3rd edition also provides useful information on this topic.⁶ There are two new documents that came out in 2015. The first is the [Physician Clinical Registry Clinician Coalition's Guidance on Legal Challenges and Regulatory Obligations for Clinical Data Registries](#)¹¹ that was released in February 2015 and the second is NQRN's [Application of HIPAA and Common Rule to Clinical Registries](#) released in December 2015.¹² Please review the above resources for more information on legal and regulatory topics related to CDRs.

Recent changes with the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015,¹³ which permanently repealed the Medicare Sustainable Growth Rate (SGR), also affects CDRs. Effective January 1, 2019, MACRA replaces and consolidates the existing CMS PQRS, Meaningful Use (MU) and Value-based payment modifiers (VM). It creates the Merit-based Incentive Payment System (MIPS). MIPS will merge these various measurement and reporting tools with claims-based financial considerations. There is also a new clinical practice improvement part included. A provider's "MIPS score," rated on a scale from 0 to 100, will dramatically influence a Medicare reimbursement payment each year. The four areas of consideration to be scored will be 30% by VBM-measured resource use (claims data), 30% by VBM-measured quality (PQRS data), 25% by Meaningful Use (EHR data), and 15% by a new "clinical practice improvement" part. The 2019 Medicare reimbursement will be based on the 2017 data and MIPS score. Each eligible professional's MIPS score and individual category scores will be made publicly available on the [Medicare Physician Compare website](#),¹⁴ including a comparison of the ranges of scores for EPs across the country.

Ineligible providers are those that elect to participate in an "alternative payment model" (APM) under MACRA and providers enrolling in Medicare for the first time during the performance year. In addition, providers who do not service a minimum number (to be determined) of Medicare patients do not need to participate in MIPS.

For CDRs that are Qualified Clinical Data Registries (QCDR), they can continue to self-nominate measures through their QCDR, group practices can report through QCDRs, and the QCDRs will be able to help eligible providers comply with the new requirements for clinical improvement projects. **The value of the QCDR for the specialty society and QCDR participation has increased dramatically with the implementation of MACRA and MIPS. Specialty societies should be prepared to support their CDRs/QCDRs business models with these changes in the regulatory environment.** The final rules/regulations are expected to be rolled out by CMS in April 2016. For the most up-to-date information on MACRA and MIPS and also the Alternative Payment Models (APMS) please go to the [CMS website](#).¹⁵

G. REGISTRY DATA USE POLICIES

1. General Issues

As medical specialty societies consider the development and maintenance of CDRs they should anticipate a broad set of possible uses for the data collected, among these will be interest from the academic research community. CDRs represent a particular opportunity for academic and health services researchers interested in retrospective observational studies, patterns of care analyses, comparative effectiveness research, outcomes assessments, or identifying specific patient cohorts to support study or trials designs. While a broad range of data resources are available from federal agencies, payers and industry,^{6,16,17} society developed and supported CDRs are discipline-specific in nature and thus particularly well positioned to support specific lines of clinical inquiry which may not necessarily be supported via other available data resources.

CDR data has significant utility, including detecting trends within specific populations, research, hypothesis generation, and improving quality of care. The information gleaned from registry data is crucial in making clinical insights and in enhancing and improving the quality of patient care. However, it is important to ensure that data collection and use comply with secure and ethical guiding principles.

The collection and use of CDR data for quality measurement and performance improvement typically does not require informed consent from patients. A CDR may not legally be required to offer an opt-out option to patients, but may determine after input from patients, patient advocates, and the clinical community to offer an opt-out option to patients. A CDR must set up a process to maintain and foster a culture of secure and ethical use of data.

As outlined below, a legal framework aligned to comply with federal regulations guiding appropriate use of patient data (Health Insurance Portability and Privacy Act (HIPAA)⁸/ Health Information Technology for Economic and Clinical Health (HITECH) Act) is necessary. This framework should include securing and maintaining appropriate Institutional Review Board (IRB) protocols within which registry operations are conducted. The specialty society should establish policies guiding data sharing or release. This may include an application and review process to ensure that proposed uses of data are not only clinically or scientifically sound, but also that the data held in the registry are adequate to address the study question(s) proposed and that the proposed study methodology is sound.

CDRs whose data support academic research projects should be prepared to provide documentation to researchers. This information would include, but not necessarily be limited to:

- general information describing the data source,
- description of the data reporting sources and any standards utilized in the preparation or transmission of the data to the society's data repository,
- itemizing the fields or variables included in the data and the code values and descriptions,
- specific analytic notes, which may inform the researcher's use of particular fields or sets of fields.

Society sponsored CDRs need to demonstrate that they provide high data quality by either securing some form of commercial data certification or adopting and adhering to uniform data standards recognized by the research community. For example, the North American Association of Central Cancer Registries (NAACCR) promulgates data standards for cancer registries across the United States and Canada.¹⁸ CDRs may choose to publish methodological reviews of the data collected by the registry on an ongoing basis to promote data quality, which increases the research value of the society's data assets.

Specialty societies should have a sustainable infrastructure in place to support:

- a. the management and review of data requests,
- b. explicit process to ensure documentation of IRB review and determination of any research uses of registry data,
- c. the secure distribution of data files to specific recipients, and
- d. a monitoring mechanism to ensure that applicable data use agreements are adhered to and appropriate citations are attributable to the society's data.

This can be done through a Data Access, Use and Publications Committee as specified earlier.

Specialty societies should be prepared to promote a transparent infrastructure to facilitate data access, produce high quality registry data, and demonstrate effective utilization of their data assets while maintaining that IRB/human subject issues (if applicable) have been addressed. Among the medical societies that may serve as vanguard examples of the successful engagements of the academic research community are the American College of Cardiology,¹⁹ the American College of Surgeons with its Cancer,²⁰ National Surgical Quality Improvement Program® (NSQIP),²¹ and Trauma²² registries, and the Society of Thoracic Surgeons.²³ Each of these societies have implemented data sharing programs and engaged the research community.

2. Contractual Issues

CDRs must comply with data use agreements according to contractual agreements they have with parties who supply data for the CDR. CDRs may want to create contractual obligations for any downstream recipients of the data from the CDR. These contractual obligations will depend on the nature of the data collected, the proposed data uses and disclosures of such data, and the applicable laws and regulations relative to such collection, use and disclosure. CDRs should also consider which (if any) obligations arising from upstream agreements they may need to pass downstream to data recipients.

The types of agreements that should be considered include, but are not limited to the following:

- **Master Services Agreements**
- **Data Use Agreements/ Data Sharing Agreements**
- **Business Associate Agreements**
- **Confidentiality/Non-disclosure Agreements**

The types of contractual obligations that are important to consider include, but are not limited to the following:

- Adequate data protection
- Confidentiality
- Limitations on use and disclosure of data

- Data breach reporting and notification
- Prohibitions on re-identification
- Limitations on liability
- Intellectual property rights

Intellectual property (“IP”) rights around CDR data use should be focused on what types of rights are necessary for the registry to function. CDRs should consider what types of IP rights should be retained to protect proprietary aspects of the registry business. Depending on these IP needs, registries may need to evaluate Federal as well as state law to determine the IP landscape.

3. Legal Issues

Data Governance and Policy Issues:

A CDR must maintain an active data governance program, which includes a dedicated and knowledgeable individual who can oversee the development of the registry’s data use policies and procedures, and ensure that use of and access to data are in line with organizational needs, institutional approvals, applicable laws and regulations, and responsible data use standards. The development of internal policies and processes that promote a commitment to responsible, secure, and ethical data use are critical. A CDR should carefully evaluate its participants, their data needs, and consider whether the following policies and processes are necessary:

- **General Participation Policies** – General policies that outline guidelines for participation in the registry are important. Policies specify whether the participant or the CDR will maintain intellectual property over and ownership of the CDR data. These general policies should outline data retention and disposal practices and the approach to terminating participation in the registry.
- **Data Governance Policies and Processes** – Outline what type of data will be collected, under what circumstance(s) data will be disclosed to third parties, provision of limited data sets, circumstances for redacting data, and methods by which data will be de-identified.
- **Data Request/Access Policies and Processes** – Outline a process by which data may be requested for legitimate research, academic, health care operations, or legal purposes. Issues to address include provision(s) of data reports to third parties – to whom and under what circumstance(s) – and guidelines surrounding publications and advertisements that include CDR, as the use of CDR for these purposes may imply endorsement from the Registry or its responsible organization.
- **Data Quality Policies and Processes** – Maintaining adequate data quality is always of concern to a registry. Issues with and ways to improve data completeness, accuracy, validity, correctness, and consistency should be noted. Attention should be paid to CDR data quality reporting, especially if the CDR is focused on improving patient care, registry participant or clinician performance or other healthcare quality outcomes.
- **Audit and Compliance Policies and Processes** – Outline an audit and compliance policy to ensure that registry participants adhere to the registry’s guidelines for secure data collection, patient notification regarding registry participation, and appropriate use of the registry. A CDR should be able to monitor for and identify any red flags. A process for responding to compliance issues should be in place, including specifying sanctions that the registry may impose in response to compliance issues.

Liability and Litigation Issues:

CDRs may be subject to liability based on published CDR data or data analyses if such publications led to patient harm caused by erroneous data or data reports. CDRs affiliated with multi-stakeholder organizations may also risk violating antitrust laws if registry data or reports are used to limit competition of products in the health care market.

CDRs must consider to what extent the data they collect, use and disclose is subject to legal discovery. If a CDR is implicated in a legal dispute, requests may be made under subpoena or otherwise in the discovery phase of litigation. CDRs should evaluate the following to determine what rights and obligations they have in such instances:

- [The Federal Rules of Civil Procedure](#)²⁴
- [The Patient Safety Organization \(“PSO”\) Act](#)^{25, 26}
- Peer review laws
- Contractual protections regarding confidentiality and cooperation

Resources for Further Information

[CDC’s Training Module on Data Use](#)²⁷

[AHRQ’s Report on Informed Consent for Registries](#)⁶

V. KEY PLAYERS AND LINKS TO EXISTING RESOURCES.

There are many moving pieces and players in the world of CDRs and it is often difficult to know where to begin and who to contact when one is just starting a registry. For reference, this Primer lists the topic resources organizations should be aware of and their websites. This list is non-exhaustive and will be updated periodically to ensure it is up to date.

- a. [Agency for Health Care Research \(AHRQ\) Registries for Evaluating for Patient Outcomes 3rd Edition: User's Guide⁶](#)
This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. This a comprehensive set of documents with many case studies.
- b. [AHRQ Registry of Patient Registries \(RoPR\)](#)
This system contains registry specific information intended to promote collaboration, reduce redundancy, and improve transparency among registry holders.
- c. [National Quality Registry Network[®] \(NQRN[®]\) and NQRN[®] Collaboration Portal](#)
NQRN[®] is a national voluntary network of medical specialty associations with patient registries and databases designed to support performance improvement and innovation in health care. Its aims are to improve patient experience of care, improve health of the population and reduce cost of quality health care.
- d. [Patient-Centered Outcome Research Institute \(PCORI\)](#)
PCORI is focused on determining which of the many healthcare options available to patients and those who care for them work best in particular circumstances. Their mandate is to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions. They fund comparative clinical effectiveness research, or CER, as well as support work that will improve the methods used to conduct such studies.
- e. [National Institute of Health \(NIH\)'s Patient Reported Outcomes Measurement Information System \(PROMIS\)](#)
Patient Reported Outcomes Measurement Information System (PROMIS) is a system of highly reliable, precise measures of patient-reported health status for physical, mental, and social well-being. PROMIS tools measure what patients are able to do and how they feel by asking questions. PROMIS' measures can be used as primary or secondary endpoints in clinical studies of the effectiveness of treatment.
- f. [American Board of Medical Specialties \(ABMS\)](#)
Through the NQRN[®], ABMS has promoted the development of clinical registries to measure and improve patient health outcomes.
- g. [Health Level 7 \(HL7\) International](#)
HL7 Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 is supporting efforts to increase interoperability and is working with registries and specialty societies to do so.
- h. [Health Information Management System Society \(HIMSS\)](#)
HIMSS North America has thousands of volunteers that work to improve the quality, cost-effectiveness, access, and value of healthcare through IT. HIMSS is collaborating with CMSS on several joint efforts in 2016.
- i. [National Care Quality Alliance \(NCQA\)](#)
The NCQA is a private nonprofit organization that works to improve health care quality through measurement, transparency and accountability. They have experience with registries (including maintaining a registry for PQRS), developing clinical quality and patient experience measures and validating data.
- j. [Physician Clinical Registry Coalition \(PCRC\) Guidance on Legal Challenges and Regulatory Obligations for Clinical Data Registries Feb. 2015.](#)
Summary of guidance on legal challenges and regulatory obligations for clinical data registries.
- k. [American College of Surgeons Quality In Training Initiative](#)
The ACS maintains several registries that qualify for the CMS PQRS such as the Surgeon Specific Registry. The ACS runs many quality programs with individual clinical registries including the ACS NSQIP (National Surgical Quality Improvement Program), Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program, National Accreditation Program for Breast Centers, the National Cancer Data Base, ACS NSQIP Pediatric, and the Trauma Quality Improvement Program.

I. [Society of Thoracic Surgeons National Database](#)

Cardiothoracic surgeons established the database in 1989 as an initiative for quality improvement and patient safety.

m. [Accreditation Council for Graduate Medical Education \(ACGME\)](#)

The ACGME aims to improve the population health and health care through the assessment and advancement of graduate medical education. The ACGME maintains several data collection systems designed to aid in the assessment of each program, the sponsoring institutions and the resident experience in necessary clinical encounters. The accreditation data system enables bidirectional communication between the ACGME and sponsoring institutions and the residency programs. The ACGME Surveys are used to monitor the training environment and clinical education of residents. The Resident Case Log System is maintained by the ACGME to catalog the resident experience in required clinical encounters.

n. [Office of the National Coordinator Interoperability Roadmap](#)

The Roadmap, shaped by stakeholder input, lays out a clear path to catalyze the collaboration of stakeholders who are going to build and use the health IT infrastructure. The goals of the Roadmap are to build upon and shore up the existing foundation of health IT, move quickly to short-term success, and lay out a longer-term set of drivers, policy, and technical components that will achieve the outcomes necessary to achieve its vision.

VI. DATA STANDARDS AND DATA ANALYTICS FOR REGISTRIES

Accurate and reliable data are integral to many health IT initiatives. According to the International Organization for Standardization (ISO): “The increased use of data processing and electronic data interchange heavily relies on accurate, reliable, controllable, and verifiable data recorded in databases. One of the prerequisites for a correct and proper use and interpretation of data is that both users and owners of data have a common understanding of the meaning and descriptive characteristics (e.g., representation) of that data.”²⁸ Specialty society CDR developers must understand and utilize the basic data standards and analytics for registries as described below in order to correctly and properly use the registry data for the benefit of their registry participants, society members and their specialty.

A. MODELS FOR DATA ACQUISITION

There are two broad approaches for acquiring data for a CDR: 1.) re-using data collected manually or electronically as part of routine clinical care, or 2.) collecting new data specifically for the registry. These new data can come from a number of sources, including patient reported data (e.g. medical history, family history), patient reported outcomes (e.g., quality of life, symptoms, functioning), claims data, EHR data, clinician input, medical records, monitoring devices, linkages to other sources and utilities. The source of data for the CDR needs to be taken into consideration when designing the registry. More information is available in the [AHRO Registries for Evaluating Patient Outcomes: A Users Guide. 3rd Edition. Chapter 4. Data Elements for Registries.](#)⁶

There are a number of basic steps to collecting data from EHR settings for registries.²⁹ These include data access, data definition, data transfer, and data transformation. Additional steps for analysis might include record linkage, algorithms, and data quality assessment. Detailed documentation and local workflows must be documented for all of these steps. Experienced registry vendors should be able to address some of these issues. In addition, consultation with data and informatics experts can improve the society’s understanding of the nature and limitations of registry data that came from healthcare systems.

B. DATA ELEMENT STANDARDIZATION FOR INTEROPERABILITY AND HARMONIZATION ACROSS REGISTRIES

Basing CDR measures on standard **data element definitions** can enable similar interpretation of a quality measure, for example, by team members. However, this is challenging to implement in registries that are using data directly from EHRs, as the decisions regarding what is collected in EHRs are driven by business considerations, including the use of mandated coding systems, such as Current Procedural Terminology (CPT) and the International Classifications for Disease (ICD), for reimbursement. Although these data can provide information about health service utilization and patient co-morbidities or disease severity, most CDRs will require additional disease-specific data to address specific quality and registry questions. In addition to common codes, there also needs to be agreement on the data element definitions used at each site. For example, what constitutes an MI or an admission for Heart Failure?

A number of specialty societies develop data element lists for categories of care. Basing registry measures on EHR standard data elements or claims data is another way of ensuring similar interpretation of the measure by team members, sites, different providers, different providers and other different regulatory or payer organizations. More information

on data elements from AHRQ is [found here](#).⁶ The [NIH Common Data Element \(CDE\) Resource Portal](#) has research data elements developed or endorsed by different institutes and centers of the NIH.³⁰ This important resource is expected to grow over time. Developers of registries are encouraged to check the NIH NLM CDE for relevant data elements used in research before developing new ones. The NLM also oversees disease specific CDE's such as those for neurological conditions such as [Parkinson's disease and epilepsy](#).³¹ There are many other CDEs available such as the National Cancer Institute's [common data elements for cancer care](#).³² Registry developers should also be cognizant of emerging data standards for EHR data collection (described later) and leverage these to reduce data entry burden for registries, and to ensure harmonization and interoperability across registries.

In addition, the use of standardized data elements and terminology are critical to ensure consistent data collection across departments or facilities. For example, specialty societies develop data element lists for categories of care and patient outcomes. Because there are many uncoordinated efforts related to data elements and assessment instruments, registry developers are encouraged to do a thorough search for data elements, beginning with medical specialty societies, and research data element repositories, such as those hosted by NIH and [CDISC SHARE](#).³³ A single central repository for clinical data elements does not yet exist, but the CMSS has identified this need. This gap will likely be filled by the EHR-related standards development organizations like Health Level 7 (HL7) or by the NIH or another federal agency.

The CMSS would like to promote efficiencies in data elements across specialties with the ultimate goal to enable health care organizations to collect a limited set of important data that can support the automated population of multiple specialty registries. The CMSS is currently collaborating with standards and informatics experts and organizations, including from NQRN®, American Medical Informatics Association (AMIA), Health Information Management System Society (HIMSS) and HL7, to maximize efficiencies for registry design and use across medical specialties and healthcare organizations. Interested readers should contact the CMSS to participate in future activities related to the identification of standard data elements. The CMSS will amend this Primer as specific standards and related resources emerge.

C. INTEROPERABILITY AND HEALTH INFORMATION EXCHANGE-EHR DATA COLLECTION

EHR systems currently collect data on the patient's history, conditions, procedures, and responses, thus these systems are the ideal sources of data to populate a registry. However, in reality, the data collected in EHR systems are not necessarily comprehensive or complete. A recent review has shown the quality of EHR data may be unreliable and not valid.³⁴ In addition, few data elements are standardized across all EHR systems. These include how codes for diagnosis (ICD-10 codes), procedures (CPT and ICD-10) and problems (ICD-10-CM or SNOMED CT) are utilized in the different EHR systems. Medication history, laboratory results and other patient history are stored in structured data fields in the EHR. However, there are many different non-standardized structured data fields across the different EHR systems that make it difficult or impossible to extract the data into one CDR from multiple EHR systems. Unstructured data fields, such as physician narratives or notes, require the use of natural language processing software to extract important clinical concepts from these notes into a reference terminology such as SNOMED CT for analysis.

Two models can be used to include EHR or data from multiple sites into a registry. A **federated query model** supports queries from the registry to clinical sites, who in turn run the queries and then return aggregate level results to the registry. This federated approach allows the data to remain at each host institution, and therefore the host institutions are more agreeable to participation. A number of national networks use this model, including [PCORnet](#),³⁵ [HCSRn](#),³⁶ and [OHDSI](#),³⁷ as well as the [FDA's Mini-Sentinel drug safety surveillance program](#).³⁸ If a federated query approach is not used, then the alternatives require that the data transfer from the local EHR systems or data repositories to the registry. These data must be queried, and these queries will depend upon the scope of the registry. Patients might be queried by condition (e.g., COPD, T2DM) or procedure using specified logic and standardized coding systems. The informatics community refers to these EHR-based queries as **computable phenotypes**. Currently, there is no single consolidated repository for computable phenotypes, making it difficult to find all definitions that already exist, and hindering the sharing of definitions between user groups. Health services researchers and quality assessment groups (i.e. NQF, NCOA, CMS and AHRQ) provide computable phenotypes on a number of websites.³⁹⁻⁴⁵ Biomedical researchers from various research networks are beginning to place their EHR-based logic, including approaches for NLP, on the Phenotype Knowledgebase website.⁴⁴ Background information on clinical phenotyping and the standardization of EHR-based condition definitions can be found in the NIH Health Care Systems Research Collaboratory's Living Textbook of Pragmatic Clinical Trials.⁴⁵

All of the official versions of vocabulary value sets contained in the 2014 Clinical Quality Measures are publicly available on the [NLM Value Set Authority Center](#)⁴⁶ (VSAC), developed in collaboration with the **Office of the National Coordinator for Health Information Technology** (ONC) and CMS. The value sets provide lists of the numerical values and individual names from standard vocabularies used to define the clinical concepts (e.g. diabetes, clinical visit) used

in the quality measures. The content of the VSAC should grow to accommodate value sets for other use cases, as well as for new measures and updates to existing measures. As medical specialty societies develop new measures using standardized coding systems, they should strongly consider using the VSAC as a source for distributing and standardizing these specifications. The NLM also maintains a [Data Element Catalog](#), which includes all data element names (value set names) required for capture in (EHR) technology certified under the 2014 Edition of the ONC Standards and Certification Criteria.⁴⁷

The ONC has developed an **Interoperability Roadmap**, shaped by stakeholder input, that lays out a path to catalyze the collaboration of stakeholders who are going to build and use the health IT infrastructure.⁴⁸ The Roadmap includes standards, certification, privacy/security and other components. It also makes the appeal for consistent formats/ semantics and accurate patient matching. For CDRs that means that there will be increasing national data for standards registries. There is the possibility for an expansion of regulatory data being extracted automatically from EHRs. Several registry organizations are also working on developing and disseminating data standards.

D. DE NOVO REGISTRY DATA COLLECTION

Other important data, particularly patient-generated health data (e.g., health history, treatment history, biometric data, symptoms, lifestyle choices), and patient-reported outcomes, can be collected in other ways. Physicians, nurses, or registry staff can manually abstract data collected in EHRs (either as structured or non-structured data). Providers might be asked to provide assessments of patient status or procedure details that are not routinely collected, and hence a new data form, either electronic data collection interface or paper form to be entered later, must be employed. A number of surveys and research data collection products can be used. Patient and family reported data are increasingly valued in research and quality measurement efforts. This is a dynamic area and registry developers are encouraged to consider applying standard approaches and publicly funded tools, such as the Patient Reported Outcomes Measurement Information System ([PROMIS](#)),⁴⁹ and deliberately search for condition-specific and relevant standard measures.

E. VALIDATION OF THE DATA CAPTURE PROCESS

There is currently no standard for assessing or reporting the quality of data extracted from EHRs, but some researchers are calling for the routine publication of data quality assessment results with reports of research results.⁵⁰ A recent informatics review article identifies **five dimensions of data quality** (completeness, correctness, concordance, plausibility, and currency).⁵¹ They further identify seven broad categories of **methods for data quality assessment**: comparison with gold standards, data element agreement, data source agreement, distribution comparison, validity checks, log review, and element presence. Registry developers should assess as many of the CDR data quality aspects as possible. CDR data quality can be assessed in the same manner as EHR data for observational research. CDRs should maintain an association of data values to transformation algorithm, as well as the association of original data values to new or changed values to ensure traceability of data. They also suggest version control and periodic testing for transformation algorithms, and the archival of data documentation.

As part of the registry data acquisition process, data quality assurance procedures should be employed. These include double data entry if applicable, range and validation checks on final data, record counts, and random audits. Clearly defined data collection procedures and training manuals will support whatever process is employed. To support consistency of data collection across sites, the documentation of registry procedures across sites should be centrally reviewed and harmonized where possible.

An understanding of the workflows and operational aspects of data cleaning, storage and maintenance at each clinical site that may affect the availability, completeness, and meaning of the data is imperative for CDRs. For example, if one facility performs a procedure in-house they will have a record of the procedure in their data repository while another organization that receives the referral case as an independent facility may not have access to the procedure data or may receive data that is incomplete or even incompatible with their EHR system. Similarly, the data may undergo a number of processing steps before it is stored in an organizational repository. For example, laboratory values from bedside analyzers may be lumped in the warehouse with results from institutional and contract labs, which may affect how the values are interpreted. Additionally, data definitions can change over time as changes in the source systems are made and new systems are brought on line or as new data sources are brought into a data warehouse. These variations can affect the meaning of the data, and affect the interpretation of registry reports.

F. ASSESSING THE QUALITY OF DATA COLLECTION OF OUTCOME DATA ELEMENTS AND RELATED STANDARDS

There is an increasing awareness and appreciation for the fact that many measures of healthcare quality are influenced by the activities of many medical specialties and types of clinicians (e.g., nursing, medical, nutrition, educators). These “team” based measures are then relevant to the quality improvement activities of each care area and the EHR promises

to be an important platform for the computation and display of these measures across an organization. The AHRQ-sponsored *Team Care Measures Atlas* presents a [Conceptual Framework of Team-Based Primary Care](#) that identifies areas that are important to effective functioning of primary care teams and also provides an inventory of [48 instruments](#) that can be used to measure team-based primary care for purposes of quality improvement, evaluation, and research.⁵² Other medical specialties are defining specific outcomes measures using combinations of existing EHR and claims data, as well as developing new data elements.

The challenge for data collection is that there are multiple different sources for the data, within and across institutions. To support accurate interpretation of data – across departments or organizations, it is important to specify the source of data collection. For example, medication data can be collected from prescription orders from the Computerized Physician Order Entry (CPOE) systems, actual prescriptions filled (and billed) by pharmacies, administration data collected from bar-coded medication administration systems in inpatient units or directly from patient reports on patient portals, questionnaires, or as part of medication reconciliation processes occurring at a patient encounter. For data to be comparable, the source of data collection must be specified and enforced (ideally) as part of the registry design, or be explicitly represented to ensure that data are aggregated and interpreted properly.

VII. QUALITY IMPROVEMENT AND MEASURES IN REGISTRIES

A. QCDR FOR REGISTRIES

The QCDR is a CMS defined entity that can support the CMS PQRS participation by submitting quality measure data for Eligible Providers (EPs). This entity was created in the [American Taxpayer Relief Act of 2012](#) (commonly referred to as the fiscal cliff bill, 112th Congress, HR 8)⁵³ and 2014 was the first year in which QCDRs were operational. QCDRs provide an opportunity for EPs to use quality measures in use in clinical practice registries to meet reporting requirements.

Traditionally, CMS quality reporting programs had relied on a CMS-approved list of measures that could be performed using claims, EHRs, or traditional registries. These mechanisms were limited by what was feasible and not all physician groups had an adequate mix of measures to choose from in order to demonstrate their quality or monitor quality improvement. QCDRs were a way to overcome some of these limitations. By using existing quality improvement registries as a PQRS reporting mechanism, more measures may be offered to providers without a full approval and specification process for CMS and data could be collected by a variety of means supported by the QCDR.

In order to be approved as a QCDR, a registry must self-nominate annually. The reporting criteria for EPs are specified in the fee schedule final rule and posted on the [CMS QCDR page](#).⁵⁴ The criteria specify, among other things, the number and types of measures a QCDR may support. For example, for 2016, QCDRs may include no more than 30 non-PQRS registry measures. In addition, QCDRs must include 9 individual measures (PQRS and non-PQRS measures) that span at least three National Quality Strategy domains and should also include two outcomes-based measures. The criteria are specified annually. QCDRs are featured prominently as a mechanism for participation in the Merit Based Incentive Payment System (MIPS) specified in the Medicare and CHIP Reauthorization Act (MACRA) legislation.

Since QCDRs are seen as primarily in existence for quality improvement, with PQRS reporting as one of its ancillary functions, QCDRs are held to a higher standard than traditional reporting registries. QCDRs are expected to collect data on all patients, not just Medicare patients. QCDRs need to report to EPs at least quarterly to provide timely feedback to facilitate improvement. Currently random samples of patients are not acceptable, and successful participation requires submission of data for at least 50% of an EP's applicable patients for each measure. A complete list of requirements for 2016 are available on the [2016 PQRS: QCDR Criteria Toolkit](#)⁵⁵ including:

- 2016 QCDR Criteria - Provides guidance to prospective QCDRs on successfully completing the self-nomination process to become a 2016 QCDR.
- 2016 QCDR Data Validation Plan Criteria - Assists entities interested in participating as a QCDR with the process of submitting a data validation plan that meets the requirements as outlined by CMS in the 2016 Medicare Physician Fee Schedule (MPFS) final rule.

The NQRN[®] website also offers helpful documents and webinars on QCDRs that is available on the [NQRN website](#),⁵⁶ including a [QCDR guide](#).⁵⁷ In addition, in May 4, 2016 NQRN[®] will be holding an in-person QCDR Meeting and training in Chicago, IL on the QCDR. More information will be on the NQRN[®] website when it is available.

B. BUILDING IN QUALITY IMPROVEMENT MEASURES INTO THE REGISTRY

Registries may be developed specifically for quality improvement, or registries that are in existence for research or other purposes may be used for quality improvement. Registries may include all patients or a scientifically random sample of patients for a provider, team, or institution. This allows for the aggregation of data to characterize each provider's performance relative to peers. Provider performance may be characterized using measures of patient outcomes in response to a particular aspect of care, or using measures of the extent to which guidelines were followed in the delivery of care.

Quality improvement (QI) measures in registries must provide actionable information to their participants. There is a movement towards the increasing use of outcome measures, particularly for reporting programs. However, outcomes are not always available, directly attributable to specific providers, or measured in standardized ways. Any QI measures implemented using registry data must use standardized data elements, and must be developed based on evidence. If there is evidence-based support for links between patient outcomes and certain process-based measures, such as measures of adherence to guidelines, these process measures can help providers identify how to improve their practice quality.

Quality improvement requires the ability for participants to use the registry results and comparisons to develop and implement quality improvement plans. Measures must be easy to understand and unambiguously defined. Any comparisons provided must be fair and relevant. This requires comparing at the appropriate level – facility or physician, for appropriate time periods – one year, one quarter, multiple years as appropriate, and comparing with appropriate groups of peers – within region or national or to other facilities of similar type (e.g., cancer center). In addition, where possible, measures must be risk-adjusted for fair comparisons to peers.

The [AHRQ Registries for Evaluating Patient Outcomes 3rd edition](#)⁶ identifies certain additional requirements in registry planning and measure development that are specific to quality improvement registries. QI registries need local champions as early adopters to drive adoption and help engage team members at the institution in the activity. QI registries need a wider variety of funding models in order to be sustainable. As quality improves and new evidence becomes available, registries must be able to incorporate new measures and phase out measures that are no longer relevant. Sometimes, the manner or definitions by which data are collected may need to change – registries need to be nimble at implementing the changes and have continuous documentation of such changes to allow comparisons over time.

Registry participation has additional effects on quality improvement beyond the measures used. The data collection and submission process for registries typically leads to closer examination of data maintained within a facility or provider's records. Exposing data to an external entity often motivates providers to improve the quality of the data maintained for patients, and the transparency offered by registries makes it easier for registry participants to identify and remedy gaps in data quality. Registry participants form learning networks, often in the form of user groups, and can help each other translate registry results into practical quality improvement.

C. SELECTION OF MEASURES FOR THE REGISTRY

Measure selection for QI registries needs to balance multiple uses and needs – identifying gaps in quality and performance that can be used by providers to improve care quality, and meeting other needs for providers, such as reporting quality measures to payers or regulatory bodies.

The NQF recommends four [criteria for selecting measures](#),⁵⁸ and uses these criteria when reviewing and endorsing measures: importance of measurement, scientific acceptability, usability and relevance, and feasibility. The [National Priorities Partnership](#)⁵⁹ and the [National Quality Strategy](#)⁶⁰ help identify areas of importance with evidence of gaps that can be addressed by measurement. Measures need to be consistent and reproducible, and meaningfully related to quality of patient care to be scientifically valid. Providers must be able to use the measures for quality improvement, and other stakeholders must be able to use measures to identify good quality. Measures must be implemented with available data without the undue burden of collecting or extracting the data for measurement.

Different kinds of measures may be selected within registries for different purposes.

- **Process measures** that monitor if the provider performed the right activities, potentially consistent with guidelines, to benefit patient care: These quality measures (QMs) are generally fairly easy to act on for providers.
- **Outcome measures** that monitor the results of care on each patient: These QMs are often used in accountability measures by payers and regulatory bodies.
- **Patient experience** measures that measure how patients perceive the care they receive: These QMs are increasingly in use for accountability.

- **Structural or system** measures that identify aspects of the infrastructure used to provide care: These QMs are used to identify system-level gaps that may need to be addressed to make improvements in outcomes.

Typically, QI registries may include all four kinds of measures with different measures used for different purposes.

Many of the criteria used for measure selection also inform measure development – importance, scientific validity, usability and feasibility. Registry measures must identify gaps and variability in care and develop measures to address the gaps.⁶¹ Where other measures exist, it is preferable to use existing measures for consistency. If the exact specifications of an existing measure are not replicable, attempts must be made to harmonize registry measures with existing measures.

Measure development for registries generally follows the same process as measure development for claims or other mechanisms. There must be a link to an expected outcome with a strong evidence base to support the development of the measure. Measures must address priority areas, use scientific evidence and stakeholder consensus, be appropriately specified and tested, and reviewed and approved by relevant governance bodies.⁶ The measure should address a gap or variation in care and have the potential for improvement. Additionally, the measure should not duplicate any existing measure and if needed, should be harmonized with any existing measure(s). Lastly, the data collection must be feasible to collect and the measure must be feasible to implement.

The 2016 CMS Quality Strategy Goals⁶² include:

Goal 1: Make care safer by reducing harm caused in the delivery of care

Goal 2: Strengthen persons and their families as partners in their care

Goal 3: Promote effective communication and coordination of care

Goal 4: Promote effective prevention and treatment of chronic disease

Goal 5: Work with communities to promote best practices of healthy living

Goal 6: Make care affordable.

Measures that can address any of these goals are highly encouraged. CMS states that measures should be patient-centered and outcome oriented whenever possible. CMS also states that measures from each of these six domains can be used to form a core set of measures.

The Institute of Medicine has also developed what they call a core measure set, the **IOM Vital Signs**.⁶³ The IOM Vital Signs aim to improve measurement efficiency and ensure a focus on outcomes. There are 15 standard categories across population health, quality, cost and engagement domains. These measures are very general in nature and not specialty specific, but can be applied across different registries. The benefit of using the IOM Vital Signs measures is that you can compare quality measure results across registries and across other data systems.

There are many other sets of measures to choose from that may be applicable to your society or may meet your society's needs. Many of these measures may be found on the [CMS website](#),⁶⁴ through the [National Quality Measures Clearinghouse](#)⁶⁵ or may be available on other specialty society websites. More information on the measure development landscape and important current information is also available in the [2014 CMSS Quality Primer, 3rd Edition](#).⁶⁶

D. MEASURE DEVELOPMENT FOR REGISTRIES

The data collection opportunities in registries offer additional opportunities for measure development. With CDRs, there may be enriched data collection opportunities that allow for continuous and informed measure refinement compared to claims. Registries collect data from participants on an ongoing basis (as opposed to claims data, for instance, that capture data at one point in time to facilitate payment). This may allow development of measures that require data collection over longer periods. QI registries generally rely on data already collected within a facility. Using available registry facility data simplifies testing of measures, adjustments to measures, if needed, retesting measures at a lower cost, and implementing measures compared to using other mechanisms.

QI registries tend to have all the data associated with a particular type of care or for patients with a particular kind of disease. This makes registry data supportive of the development of composite measures that combine multiple measures to provide an overall characterization of care. These are particularly important for public reporting to patients and referring physicians when comparing different providers.

GLOSSARY

Business associate: is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information. He/she may also be a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate.

Business Associate Agreements (BAA) serves the purpose of obtaining satisfactory assurance that the Business Associate will appropriately safeguard any PHI received from the Covered Entity. With this agreement in place, the exchange of information between the Covered Entity and the Business Associate will meet HIPAA requirements without disruption of the business arrangement. BAAs include Health Information Organizations, E-prescribing Gateways, personal health record vendors, as well as entities that provide data transmission services for PHI and that require routine access to such PHI. The HIPAA Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information. The business associate contract also serves to clarify and limit, as appropriate, the permissible uses and disclosures of protected health information by the business associate, based on the relationship between the parties and the activities or services being performed by the business associate.

CDISC Shared Health and Clinical Research Electronic Library (SHARE): cornerstone of the CDISC technical roadmap, is a global electronic repository for developing, integrating and accessing CDISC metadata standards in electronic format.

Clinical data registry (CDR) is an organized data system that collects uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease or condition, and that serves one or more predetermined scientific, clinical, or policy purposes.

Coding System: a set of terms for a particular domain and corresponding codes to enable computerize capture and exchange of data.

Confidentiality/Non-disclosure Agreements: A confidentiality agreement is a contract governing the obligations of the parties who receive and/or disclose confidential information.

Computable phenotype: A computable phenotype is a clinical condition, characteristic, or set of clinical features that can be determined solely from the data in EHRs and ancillary data sources and does not require chart review or interpretation by a clinician. These can also be referred to as EHR condition definitions, EHR-based phenotype definitions, or simply phenotypes.

Data Element Catalog: The Data Element Catalog identifies data element names required for capture in Electronic Health Record (EHR) technology certified under the 2014 Edition of the Office of the National Coordinator for Health Information Technology (ONC) Standards and Certification Criteria.

Data element (definition): the unit of data being queried, exchanged, or analyzed, which includes a descriptive name that represents the concept being described plus a specified value set and other descriptive metadata, such as a definition.

Data Use Agreement: A data use agreement (DUA) is a contract that governs the transfer of data outside the context of the research agreement. When the organization enters into a DUA it shares, receives or transfers de-identified data, limited data sets or fully identifiable data.

Disease or patient registries: collections of secondary data related to patients with a specific diagnosis, condition, or procedure. A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care.⁶

FDA Mini Sentinel Program: Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to create an active surveillance system - the Sentinel System - to monitor the safety of FDA-regulated medical products.

Health Insurance Portability and Accountability Act of 1996 (HIPAA): The HIPAA Privacy Rule regulates the use and disclosure of Protected Health Information (PHI) held by "covered entities" (generally, health care clearinghouses, employer sponsored health plans, health insurers, and medical service providers that engage in certain transactions).

HCSRN: The HCSRN brings together the research departments of some of the nation's best and most innovative health care systems. Collectively, the HCSRN represents over 1,900 scientists and research staff with methodological and content expertise from an array of disciplines including epidemiology, economics, disparities, outcomes and quality assessment, trials, genomics, and more.

Health Information Technology for Economic and Clinical Health Act (HITECH-part of the American Recovery and Reinvestment Act of 2009): Federal privacy regulations promulgated under the HIPAA and were modified by the HITECH to specifically apply to the use and disclosure of certain individually identifiable health information for research and other purposes.

Master Services Agreements: A negotiated agreement containing global contract terms that may be applied to specific studies.

Metadata: descriptive data about objects, including data objects. Metadata are data about data, such as version, author, concept, identifier, data type, definition, and preferred label for a particular data element in a data collection system or form.

National Library of Medicine Value Set Authority Center (NLM VSAC): The VSAC provides downloadable access to all official versions of vocabulary value sets contained in the 2015 Clinical Quality Measures (CQMs). Each value set consists of the numerical values (codes) and human-readable names (terms), drawn from standard vocabularies such as SNOMED CT[®], RxNorm, LOINC and ICD-10-CM, which are used to define clinical concepts used in clinical quality measures (e.g., patients with diabetes, clinical visit).

Office of the National Coordinator for Health Information Technology (ONC): The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration's health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care. ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS).

OHDSI (Observational Health Data Sciences and Informatics): The Observational Health Data Sciences and Informatics (or OHDSI, pronounced "Odyssey") program is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics.

PCORnet: PCORnet, the National Patient-Centered Clinical Research Network, is an innovative initiative of the Patient-Centered Outcomes Research Institute (PCORI). It is designed to make it faster, easier, and less costly to conduct clinical research than is now possible by harnessing the power of large amounts of health data and patient partnerships.

Public Private Partnerships: a broad term that refers to any partnership in which at least one entity is a public agency (e.g., a government entity) and at least one other entity is a private organization. The scope can range from partnerships at the local level, including local and regional health agencies, to national and international health agencies and other private institutions or organizations (e.g., professional associations, patient advocacy groups). In a research context, a partnership implies some joint collaboration to achieve a common scientific goal. Partners may contribute intellectual capital, funding, data, or other services.

Value set: the set of possible values, categories, or responses (and their codes) that are associated with a particular data element often derived from established vocabularies or data standards.

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REFERENCES

1. IOM (Institute of Medicine) Washington, D.C: National Academy Press; 2001. Crossing the Quality Chasm: A New Health System for the 21st Century
2. NQRN Registry Inventory 2015. <https://download.ama-assn.org/resources/doc/cqi/x-pub/nqrn-national-clinical-registry-inventory.pdf> Accessed 11/18/15.
3. Radley DC, Finkelstein SN, Stafford RS. Off-label prescribing among office-based physicians. Arch Intern Med. 2006 May 8; 166(9):1021-6
4. Smith I, Mark D, [et al.] editors. Best care at lower cost: the path to continuously learning health care in America/ Committee on the Learning Health Care System in America, The Institute of Medicine; ISBN 978-0-309-26793-2
5. Gliklich RE, Dreyer NA, eds. Registries for Evaluating Patient Outcomes: A User's Guide. (Prepared by Outcome DEClDE Center [Outcome Sciences, Inc. dba Outcome] under Contract No. HHS29020050035I TO1.)
6. Gliklich RE, Dreyer NA, Leavy MB, editors. Registries for Evaluating Patient Outcomes: A User's Guide [Internet]. 3rd edition. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 Apr. 2, Planning a Registry. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK208631/>
7. Niemyski P. The what, when and how of clinical registries. (white paper) Posted November 2015. <http://boston-biomedical.com/the-what-when-and-of-clinical-registries/>
8. Part C of Title XI of the Social Security Act, 42 USC §§ 1320d to 1320d-9 , and section 264 of the Health Insurance Portability and Accountability Act of 1996, 42 USC §1320d-2 note ; 45 CFR Parts 160 and 164.
9. American Recovery and Reinvestment Act of 2009, 41 U.S.C. § 17934 (2014)
10. See United States Dep't of Health and Human Servs., Federal Policy for the Protection of Human Subjects ('Common Rule'), <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> Accessed 12.01.2015.
11. Physician Clinical Registry Coalition's Guidance on Legal Challenges and Regulatory Obligations for Clinical Data Registries, February 2015. Physician Registry Coalition <http://www.ppsv.com/assets/attachments/221.PDF>
12. National Quality Registry Network. Application of HIPAA and Common Rule to Clinical Registry. December 2015. <https://download.ama-assn.org/resources/doc/cqi/x-pub/nqrn-application-hipaa-cr-registries.pdf>
13. H.R. 2: Medicare Access and CHIP Reauthorization Act of 2015, Pub Law 114-110
14. Medicare Physician Compare Website <https://www.medicare.gov/physiciancompare/> Accessed 12.28.15

15. Centers for Medicare and Medicaid Services: The Merit-Based Incentive Payment System (MIPS) & Alternative Payment Models (APMs): <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html> Accessed. 12.01.2015
16. CMS Data Navigator <https://www.cms.gov/research-statistics-data-and-systems/research-statistics-data-and-systems.html> Accessed 12.18.15
17. NIH Data Sharing Repositories https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html Accessed 12.28.15
18. North American Association of Central Cancer Registries <http://www.naaccr.org/> Accessed 12.28.15
19. National Cardiovascular Data Registry <http://cvquality.acc.org/NCDR-Home.aspx> Accessed 12.28.15
20. American College of Surgeons NCDB Participant Use Data File <https://www.facs.org/quality-programs/cancer/ncdb/puf> Accessed 12.28.15
21. American College of Surgeons National Surgical Quality Improvement Program® <https://www.facs.org/quality-programs/acs-nsqip> Accessed 12.28.15
22. American College of Surgeons National Trauma Data Bank Data Sets <https://www.facs.org/quality-programs/trauma/ntdb/datasets> Accessed 12.28.15
23. Society of Thoracic Surgeons National Database <http://www.sts.org/quality-research-patient-safety/research> Accessed 12.28.15
24. The Federal Rules of Civil Procedure, 2016 Edition <https://www.federalrulesofcivilprocedure.org/> Accessed 12.28.15
25. Patient Safety Act amended the Public Health Service Act (42 U.S.C. 299et seq.) by inserting new sections 921 through 926, 42 U.S.C. 299b-21 through 299b-26.
26. Patient Safety Rule <https://psa.ahrq.gov/legislation> Accessed 12.28.15
27. NETS Module 11: Uses of Cancer Registry Data <http://www.cdc.gov/cancer/npcr/training/nets/module11/> Accessed 12.28.15
28. ISO/IEC 11179-4:2004(en)Information technology — Metadata registries (MDR) — Part 4: Formulation of data definitions <https://www.iso.org/obp/ui/#iso:std:iso-iec:11179:-4:ed-2:v1:en> Accessed. 12/21/15
29. Zozus MN, Richesson RL, Walden A, et al. Research reproducibility in longitudinal multi-center studies using data from electronic health records. The AMIA Joint Summits for Clinical and Translational Research. Submitted September 2015.
30. National Institutes of Health Common Data Element Resource Portal <https://www.nlm.nih.gov/cde/> Accessed 12.28.15
31. NINDS Common Data Elements <https://commondataelements.ninds.nih.gov/#page=Default> Accessed 12.28.15
32. National Cancer Institute NCI Wiki CTEP Common Data Elements <https://wiki.nci.nih.gov/display/caDSR/CTEP+Common+Data+Elements> Accessed 12.28.15
33. CDISC SHARE <http://www.cdisc.org/cdisc-share> Accessed 12.28.15
34. Chan KS, Fowles JB, Weiner JP. Review: electronic health records and the reliability and validity of quality measures: a review of the literature. Med Care Res Rev. Oct 2010;67(5):503-527
35. The National Patient-Centered Clinical Research Network <http://www.pcornet.org/> Accessed 12.28.15
36. Health Care Systems Research Network <http://www.hcsrn.org/en/> Accessed 12.28.15
37. Observational Health Data Sciences and Informatics The Observational Health Data Sciences and Informatics (or OHDSI, pronounced "Odyssey") program is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics. <http://www.ohdsi.org/> Accessed 12.28.15

38. FDA Mini Sentinel Project <http://www.mini-sentinel.org/> Accessed 12.28.15
39. National Quality Forum Measure Evaluation Criteria 2015. http://www.qualityforum.org/Measuring_Performance/Endorsed_Performance_Measures_Maintenance.aspx. Accessed 12.29.2015
40. CMS. Chronic Conditions Data Warehouse. © 2015 NewWave-GDIT, LLC <http://www.ccwdata.org/index.htm>. Accessed 12.29.2015.
41. CMS. eCQM Library. 2015. https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/ecqm_library.html Accessed 12.29.15
42. National Care Quality Alliance (NCQA). Healthcare Effectiveness Data and Information Set (HEDIS) Measures. 2015; <http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx> Accessed 9.28.15.
43. Healthcare Cost and Utilization Project (HCUP). Clinical Classifications Software (CCS) for ICD-9-CM. 2013; <http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp>. Accessed 12.29.15
44. Vanderbilt University. PheKB. 2012; <http://www.phekb.org/>. Accessed 12.29.15
45. NIH Health Care Systems Research Collaboratory. Electronic Health Records-Based Phenotyping. In Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials. Available at: <http://sites.duke.edu/rethinkingclinicaltrials/ehr-phenotyping/> Accessed 10.19.15.
46. Value Set Authority Center <https://vsac.nlm.nih.gov/> Accessed 12.29.15
47. National Library of Medicine Data Element Catalog <https://www.nlm.nih.gov/healthit/dec/> Accessed 12.29.15
48. The Office of the National Coordinator for Health Information Technology. Connecting Health and Care of Nation. A Shared Nationwide Interoperability Roadmap. Final Version 1.0 2015. <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf> Accessed 12.21.2015
49. Patient Reported Outcomes Measurement Information System (PROMIS) www.nihpromis.org Accessed 12.29.15
50. Kahn MG, Brown JS, Chun AT, et al. Transparent reporting of data quality in distributed data networks. EGEMS (Wash DC). 2015 Mar 23;3(1):1052. doi: 10.13063/2327-9214.1052. eCollection 2015.
51. Weiskopf NG, Weng C. Methods and dimensions of electronic health record data quality assessment: enabling reuse for clinical research J Am Med Inform Assoc 2013 1:20(1): 144-51.
52. Shoemaker SJ, Fuda KK, Parchman M, Schaefer J, Levin J, Hunt M, Ricciardi R. Atlas of Instruments to Measure Team-based Primary Care Report. Prepared by Abt Associates under Contract # HHS 290.2010.0004I, Task Order #5. AHRQ Publication No. 14-0063-EF. Rockville, MD: Agency for Healthcare Research and Quality. September 2014. Available at: <http://primarycaremeasures.ahrq.gov/team-based-care/> Accessed 12.29.15.
53. H.R.8 - American Taxpayer Relief Act of 2012 112th Congress (2011-2012) <https://www.congress.gov/bill/112th-congress/house-bill/8/text> Accessed 12.29.15
54. CMS Qualified Clinical Data Registry Reporting <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/qualified-clinical-data-registry-reporting.html> Accessed 12.29.15
55. CMS Quality Clinical Data Registries Criteria Toolkit http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016QCDR_Criteria_Toolkit.zip Accessed 12.29.15
56. National Quality Registry Network www.nqrn.org Accessed 12.21.15
57. NQRN QCDR Guide <https://download.ama-assn.org/resources/doc/cqi/x-pub/nqrn-guide-qcdr-2015.pdf> Accessed 12.09.2015
58. National Quality Forum. ABCs of Measurement. http://www.qualityforum.org/Measuring_Performance/ABCs_of_Measurement.aspx Accessed 12.29.15
59. National Quality Forum. National Priorities Partnership. https://www.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx Accessed 12.29.15

60. National Quality Strategy <http://www.ahrq.gov/workingforquality/index.html> Accessed 12.29.15
61. NQRN® webinar on the Basics of Measure Development for Registry Use 7.23.15- <http://www.ama-assn.org/resources/doc/cqi/x-pub/nqrn-lp-webinar-072315.pdf>. Accessed 12.29.15
62. CMS Quality Strategy 2016 <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf> Accessed 12.28.15.
63. Institute of Medicine Vital Signs Core Metrics for Health and Health Care Progress http://iom.nationalacademies.org/~media/Files/Report%20Files/2015/Vital_Signs/VitalSigns_RB.pdf Accessed 12.1.2015
64. CMS. Quality Measures. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/index.html?redirect=/QUALITYMEASURES/> Accessed 12.21.2015
65. National Quality Measures Clearinghouse (NQMC) <http://www.ahrq.gov/cpi/about/otherwebsites/qualitymeasures.ahrq.gov/index.html> Accessed 12.29.15
66. CMSS Quality Primer, 3rd Edition, 2014 <http://cmss.org/> Accessed 12.01.2015