Frequently Asked Questions about Clinical Data Registries

August 2014

Completed by the National Quality Registry Network (NQRN®)

The PCPI Foundation and the National Quality Registry Network disclaim any liability for use or non-use of this document. The PCPI does not provide medical, legal, financial, or other professional advice and users are encouraged to consult a professional for such advice.
Acknowledgements

The National Quality Registry Network (NQRN®) wishes to thank the following authors for contributing content to this FAQ:

Seth Blumenthal, MBA, American Medical Association
Carrie Bosela, RN, Society for Vascular Surgery®
Mythreyi Chatfield, PhD, American College of Radiology (ACR®)
Raymond Fang, MSc, MASc, American Urological Association
Danica Marinac-Dabic, MD, PhD, U.S. Food and Drug Administration
Sarah Murphy, American Orthopaedic Association
Becky Schierman, MPH, American Academy of Neurology®
Introduction

About the FAQ

This document contains questions and answers about planning and development for clinical data registries. The ordering of the questions presents a suggested approach to the planning process.

About the NQRN

The National Quality Registry Network (NQRN®) is a voluntary network of organizations operating registries and others interested in increasing the usefulness of clinical registries to measure and improve patient health outcomes.

The NQRN seeks to:

- Establish and disseminate leading practices for registries
- Support a learning network to accelerate registry development, growth & use
- Develop resources for the clinical registry industry

The NQRN succeeds when stakeholders view NQRN-affiliated registries as the best source of trustworthy data for clinically enriched quality and efficiency of care information, and when information from registries is used for meaningful performance assessment & improvement, comparative effectiveness research, and accountability programs (payment & public reporting).

The NQRN provides value to a variety of stakeholders. For consumers it promotes registries as a source of accurate information for timely decision making. For registry steward organizations it seeks to increase the breadth of data available within registries, both from existing and linked data sources, improving the availability of accurate, credible and timely feedback reports. For health plans, the NQRN promotes registries as valuable sources of performance information to improve the quality and efficiency of service delivery, as well as the effectiveness of reimbursement programs.

The NQRN is led and staffed by the American Medical Association-convened Physician Consortium for Performance Improvement® (PCPI®).

Please visit nqrn.org to access the latest NQRN resources for registries.
Frequently Asked Questions for Early Phase Clinical Registries

1. **What is a registry?**

   **Answer:**
   A clinical data registry records information about the health status of patients and the health care they receive over varying periods of time. Clinical data registries typically focus on patients who share a common reason for needing health care. They allow health care professionals and others to see what treatments are available, and how patients with different characteristics respond to various treatments. This information can be used to inform patients and their health care professionals as they decide the best course of treatment and to improve care for patients in the future. Information from registries may also be used to compare the performance of healthcare providers with regard to their outcomes and resource use.

   (More information in NQRN.org -> Resources -> “What is a Clinical Data Registry?” and AHRQ user’s guide, 3rd Ed., executive summary p.1 & chap. 1, p.1)

2. **What is the focus of the registry going to be? It can be broad, or very specific.**

   **Answer:**
   Determination of registry focus involves several tradeoffs. Registries may be created to investigate a disease or condition, the results of a procedure, to track the performance of a device, or for other purposes. It is important early in the registry development process to identify patient health outcomes of greatest importance and to mark them as primary or secondary study goals (endpoints). The primary endpoint is an important determinant of the population size needed for the registry data to be useful, especially for research. This exercise has immediate value in establishing proper focus, but also helps later in designing a data model that appropriately balances the cost of data acquisition with the expected value of the new dataset.

   A registry’s focus should align with the interests of organizations and practitioners the registry plans to target for participation. It is helpful to plan for both a primary and secondary base of participants. The primary user base is the set of participants that the registry will be principally designed for, and the secondary user base includes others who may be interested in the registry data, especially as the database matures. This planning can help with prioritizing which data elements to initially include in the dataset. Data elements supporting primary endpoints and other elements of interest to the primary user base may be included in a core dataset. Secondary endpoints and elements potentially of interest to secondary users can then be added as resources allow, or at a later date.
Typically data elements are included parsimoniously in order to conserve data collection resources. However, if resources allow, an alternative approach is to find efficient ways to collect as much data as possible in the hope that previously unknown associations can be identified. With this broader focus, supplemental use of existing data and automated extraction from other health information systems become increasingly important for success.

Within the above broad categories of investigation, focus can be further defined in terms of scope (Table 1) and factors influencing scope (Table 2).

### Table 1: Scope

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>The number of data elements, submitters and patients, along with the complexity of the data elements. This is a tradeoff between the burden of data collection and the ultimate analytical power of the resulting dataset.</td>
</tr>
<tr>
<td>Setting</td>
<td>The components of the health care delivery system that will submit data to the registry (e.g., hospital, practitioner or patient).</td>
</tr>
<tr>
<td>Richness of the data needed</td>
<td>The data needed could be simple (e.g., height &amp; weight) or a complex set of symptoms and measurements.</td>
</tr>
</tbody>
</table>

### Table 2: Scope Influencers

<table>
<thead>
<tr>
<th>Influencer</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>Scope determination should weigh initial and ongoing registry costs against the potential value of the resulting dataset as it matures.</td>
</tr>
<tr>
<td>Legal and environment</td>
<td>Regulatory requirements, reimbursement considerations, research interests or public health policy can influence scope due to their importance in determining the usefulness of the dataset.</td>
</tr>
<tr>
<td>Ease of data acquisition</td>
<td>Scope determination is impacted by the ability to collect the necessary data in sufficient quantity, quality and detail (e.g., automated extraction from other health information systems v. manual data entry)</td>
</tr>
</tbody>
</table>

Recognizing that needs may change after data collection has begun, it is important to anticipate the work involved to preserve data integrity when making changes to the data set after initial collection has begun.

(More information in AHRQ user’s guide, 3rd ed., chap. 2, p.29-30)
3. Who are the key people to include on registry teams?

Answer:
To begin registry development, several teams should be considered and assembled. First, an executive or steering committee should be convened that performs a strategic oversight role. Then, a registry core team can be created that in the beginning, performs detailed design and later, oversees daily operations. In addition to the core team, team members may be brought in ad-hoc such as medical product developers, finance and legal experts. Building the stakeholder council separate from the registry development team preserves its independence so that it can serve as a sounding board for the development of the registry. This council can counter any “groupthink” that may develop among the core development team. At an appropriate stage in the development of the registry organization, various committees can then be formed (see Q.4).

A registry core team may be composed from the following groups as needed to meet the purpose of the registry:

- Health care practitioners working in the registry scope area
- Other scientists
- Patients affected by the disease or condition under study
- Epidemiologists
- Database developers
- Project managers
- Ambassadors / champions
- Measure developers

Because of the preponderance of registries and associated costs to hospitals and practices, it is very important to develop relationships with potential participating organizations. One way to accomplish this is to recruit ambassadors who represent both small and large facilities and practices. These ambassadors can then work to gather appropriate feedback and engage participation in the registry.

(More information in AHRQ user’s guide, 3rd ed., chap. 2, p.31-32, 33-34)
4. **What legal and governance structures are used for registries?**

**Answer:**
Various legal and governance structures can be created for clinical registries, taking into consideration existing organizational structure, as well as the mission and activities of the registry. Depending on the registry's activities, one or more entities may be appropriate. Conversely, a single entity can support multiple registries.

Legal structures to consider:
- Corporation
  - For-profit
  - 501(c)(3) not-for-profit
  - 501(c)(4) not-for-profit
  - 501(c)(6) not-for-profit
- Partnership of two or more organizations
- Joint venture of two or more organizations

You should confer with your legal advisor who can assist you in evaluating a variety of taxation and other consideration when considering legal structures.

The governance structure may benefit from inclusion of the stakeholders who are connected to the mission and activities of the registry, and support the purpose of the registry (see Q.3). These stakeholders could be included in the governance body such as the board of directors, or the in committees to advise the governance body.

Committees to consider forming to advise the governance body:
- Oversight, executive or steering
- Advisory board e.g., for vendors or scientists
- Measures & reporting
- Standards
- Research & publications
- Technology

**Legal advisors should always be consulted to address specific needs and to ensure that all applicable Federal, State, and local laws are followed.**

(More information in AHRQ user’s guide, 3rd ed., chap. 2, p.34-36)
5. **What are good funding sources for a new registry? How might those funding sources need to change to sustain the registry after initial growth?**

**Answer:**
When seeking funding for a registry, the first consideration should be to determine who may benefit from the data to be collected. Will the registry be funded by existing membership dues, or will it be expected to cover its costs by charging additional fees to participating organizations? Appropriate fee structures should be determined depending on if the participation fee is at the individual or organization level.

Grants from federal agencies and from philanthropic organizations offer opportunities for seed funding, although this funding often covers only a small part of the startup costs for a registry. Securing funding for the successful launch and build-up to a critical mass of participants may require partnership and/or investment from multiple funding sources.

When seeking initial investments, it must be assured that there is a sound business plan for ongoing sustainability of registry operations. Without such a plan, investors will be less likely to participate. In planning for financial sustainability it is helpful to consider the increased usefulness of the registry as it grows in scale and scope. The plan may anticipate ways to monetize a more mature dataset including charging for advanced reporting or analytical services.

(More information in AHRQ user’s guide 3rd ed., chap. 2, p.32-33)
6. What organizations support the registry industry?

**Answer:**
The following are some of the organizations that provide support to the registry industry (Table 3).

**Table 3: Organizations Supporting Registries**

<table>
<thead>
<tr>
<th>Organization</th>
<th>Focus</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Quality Registry Network (NQRN®)</td>
<td>Clinical registries</td>
<td>nqrn.org</td>
</tr>
<tr>
<td>AMA-convened Physician Consortium for Performance Improvement® (PCPI®)</td>
<td>Performance measures</td>
<td>physicianconsortium.org</td>
</tr>
<tr>
<td>National Quality Forum (NQF)</td>
<td>Measures endorsement</td>
<td>qualityforum.org</td>
</tr>
<tr>
<td>International Consortium for Health Outcomes Measurement (ICHOM)</td>
<td>International measure alignment</td>
<td>ichom.org</td>
</tr>
</tbody>
</table>
7. How to create an executive summary that helps a registry describe its value proposition to a non-technical audience?

Answer:
Messaging about the value proposition of a registry needs to consider its audience(s) - organizations providing the financial support to begin a registry project, as well as organizations and individuals recruited to submit and use the registry information.

Registries have many uses that can benefit different audiences:
- Benchmarking and monitoring of quality improvement activities
- Evaluating if patients are receiving recommended treatments
- Comparing the effectiveness of different treatments and procedures
- Supporting clinical trials
- Monitoring the safety of drugs and devices
- Collecting information reported by patients about their health status & care
- Identifying knowledge gaps to support education
- Supporting accreditation, certification and licensing
- Providing information to adjust payment

As the above uses show, registry participation can be beneficial for a variety of different organizations or individuals, who may in turn be willing to pay participation fees. For organizations, submission to registries can support performance improvement activities with clinically relevant and credible data, as well as facilitate payment and compliance with quality assurance mandates. For health care professionals, participation may present a valuable opportunity to participate in relevant scientific endeavors, interact with respected opinion leaders, obtain practice pattern and/or outcome information, and satisfy other data needs such as submission to accountability programs. Registries can also provide toolkits and other knowledge resources that can be used directly to improve performance. These can be valuable incentives for participation in addition to analysis and reporting of the registry data.

After a value proposition has been determined, an executive summary can be created with a paragraph structure similar to the following:
- Summarize the ultimate goal of the registry and the services that will be offered to help participating organizations.
- Describe the registry’s governance model
- Describe how the registry data will be collected and reported (summary level detail)
- Describe current activity, if any, in terms such as of number of sites or groups participating, number of procedures reported, etc.
- Explain the value proposition for patients, health care professionals or the contracting entity to participate in the registry. (How will this registry improve patient care, safety and reduce the cost of care?)
8. How to decide what to outsource to a vendor?

Answer:

Decisions about what to outsource to a vendor depend on many factors. Considerations for outsourcing include:

- In-house staff availability and expertise – does it exist today, and if not, can this be achieved through training or staffing changes?
- Budget impact from performing work in-house v. outsourcing
- Convenience and flexibility
- Data submission – how data will be collected from other information systems such as electronic health records or billing systems

Example responsibilities that can be performed in-house or outsourced to a vendor:

- Management of data security needs
- Physical environment/security provision
- Data element specification
- Data analysis activities or preparing data for analysis e.g., calculating measures, generating benchmark comparisons
- Management of regulatory and legal requirements
- Extraction of data from information systems to the registry
- Submission of data to outside organizations
- Measure development

If a decision is made to outsource, additional costs need to be considered beyond what the vendor charges. In-house staff will need to work with vendors to provide information and coordinate between the vendor and other stakeholders. This cost of person-hours needs to be taken into consideration when making decisions about outsourcing.

(More information in NQRN.org -> Resources -> “Registry Vendor Assessment”)

9. How to prioritize what electronic health records to support?

Answer:
Considerations for prioritizing electronic health record (EHR) support include:

- The popularity of certain EHRs in the registry’s disease area or primary participants location,
- The ability of the EHR to collect all of the needed data, and
- The ease of transmitting data from the EHR to the registry

There are several models for achieving interoperability between an EHR and a registry including data push, pull or direct export. In prioritizing EHR support, it is important to understand if/how each EHR supports these models.

Interoperability may be achieved through participant exports – the data push model. Working from a uniform specification published by the registry, participants create the data export according to the specification and then deliver it to the registry through a secured internet gateway. The specification may be written using standards from organizations such as Health Level 7 (HL7®), Integrating the Healthcare Enterprise (IHE) and the Clinical Data Interchange Standards Consortium (CDISC®).

With the data pull model, data capture software, developed in-house or through a vendor, is placed on the network at each participating site. Using read-only access to the EHR, the data capture software periodically queries the EHR for data to input to the registry. This software then transmits the data to the registry through a secured internet data gateway. The software may need to be customized for each EHR vendor and for each new participating site.

In the direct export model, the registry staff works with EHR vendors directly to certify their support for the registry’s published specification. This may be easier to accomplish if certain EHRs are popular in the registry’s specialty or if participants are advocating for ease of participation.

Regardless of the method chosen, integration work may require additional time and resources the first time the registry integrates with a particular vendors’ EHR. Subsequent integrations may become more routine and less costly. Additionally, resource planning should take into account expected future changes to the registry dataset. Changes may require additional expenses to update integration specifications or software or may require participants to update their EHR.

(More information in AHRQ user’s guide, 3rd ed. chap. 15, p.3-20)
10. What assurances do participants need in order to share protected health information?

Answer:
The Common Rule and HIPAA Privacy Rule regulate human subjects research and the use of protected health information (PHI). These rules permit the disclosure of PHI to external parties including registries for health care operations, payment and research. Conditions and requirements differ based on the data elements disclosed and their uses. In order for registry participants to willingly share PHI, most will want to understand what is permitted under these rules, and then understand what data elements need to be collected including the rationale for including them in the dataset. Participants will then want to know how data will be stored, used and reported.

Common Rule

The Common Rule is federal law, administered by the Office for Human Research Protections, that codifies ethical principles for research involving human subjects. It outlines the provisions for Institutional Review Boards (IRBs), patient informed consent and assurances of compliance.

HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act (HIPAA), administered by the Office of Civil Rights (OCR), includes Privacy, Security and Breach Notification Rules. HIPAA regulates the uses and disclosures of PHI. PHI may be used or disclosed only as expressly permitted by the Privacy Rule, or with the individual’s written authorization. Where use or disclosure is permitted, requirements differ based on the purpose of the use or disclosure.

Considerations for how HIPAA and the Common Rule apply to registries include:
• Will the registry be used for health care operations?
• Will the registry be used for research?
• Will existing or new data be used for research?
• Will individually identifiable data on patients be collected?
• What individuals and entities will need to access the data?
• What future uses of the registry data may be anticipated?

Legal advisors should always be consulted to address specific issues and to ensure that all applicable Federal, State, and local laws are followed.

11. What are the limitations and benefits of abstraction v. electronic extraction?

Answer:
Electronic extraction of data to the registry from other health information systems is recommended for its increased speed, accuracy and scalability over manual abstraction (Table 5).

Table 5: Limitations and Benefits of Abstraction v. Electronic Extraction

<table>
<thead>
<tr>
<th>Method</th>
<th>Limitations</th>
<th>Benefits</th>
</tr>
</thead>
</table>
| Manual abstraction and data entry via a secure web portal | • Cost of data entry resources including the costs of increased data entry burden on health care practitioners  
• Slow speed of data entry  
• Human error and variation in interpretation of the data  
• Abstraction from multiple information systems  
• Need to train and validate performance of multiple abstractors across all participating organizations | • Human observation at entry  
• Human interpretation and translation into a structured format of information from the EHR/information system  
• Data entry resources can serve as quality improvement advocates in the submitting organization |
| Automated submission of data via a secure connection | • Cost to connect the registry to the EHR or other health information systems  
• Challenge of translating data from one system to another automatically in a way that preserves the original meaning of the source data  
• Lack of standardized data definitions | • Reduced cost for data entry resources including reduction of data entry for practitioners  
• Automated, rules-based extraction of data to the registry from EHR and other information systems allowing data collection to more efficiently increase in scale and scope over abstraction.  
• Elimination of human error in abstraction and data entry  
• Shortening of data lead times  
• Facility to achieve bidirectional connectivity where the registry may also be used to update data in other information systems as well as extract data  
• Can automatically send updates |

(More information in AHRQ user’s guide, 3rd ed., chap. 6, p.129-139, chap. 15, p.3-20)
12. How do registry stewards obtain buy in to build a critical mass of participants in the first year or two?

Answer:
For registries where participation is voluntary and there is no direct industry or regulatory incentive for participating, the value proposition for participation may differ depending on the registry’s development phase.

A mature registry can sustain itself by deriving value from its large and comprehensive database. A registry in the early phases cannot yet rely on this; however it can add value through rapid feedback, benchmarking, clinical decision support, and access to guidelines or quality improvement programs. Through these activities, an early phase registry can add value to its early participants. As the registry matures, this value proposition can be enhanced to take advantage of the increasing power of the collected data for activities such as comparative effectiveness research or clinical trials support.

To build participation, organizations in the early phase of registry development can use strategies such as marketing the value of participating in quality improvement activities, and of opportunities for practitioner leadership. Recruiting physician leaders who will become champions, and give testimonials and presentations on behalf of the registry is an important component of these strategies. Participation in registry activities that bring its community of researchers together can provide access to expertise that can help impact practice in the short term. The value of these relationships can increase over time along with that of the growing dataset. Registry participation may also deliver improved reputational value to participants through public recognition of their association with the registry’s sponsoring organization, maintenance of certification & meeting reporting requirements.

Despite their smaller initial datasets, new registries can still provide access to useful data through reports with quick turnaround. This can be augmented through expertise and opportunity for performance improvement from QI, education activities or materials, and toolkits. Educational materials can be part of a QI program or made available for use based on needs identified from analysis of the submitted data.

(More information in AHRQ user’s guide, 3rd ed., chap. 10)