Real-World and Late Phase Research

Patient Registries

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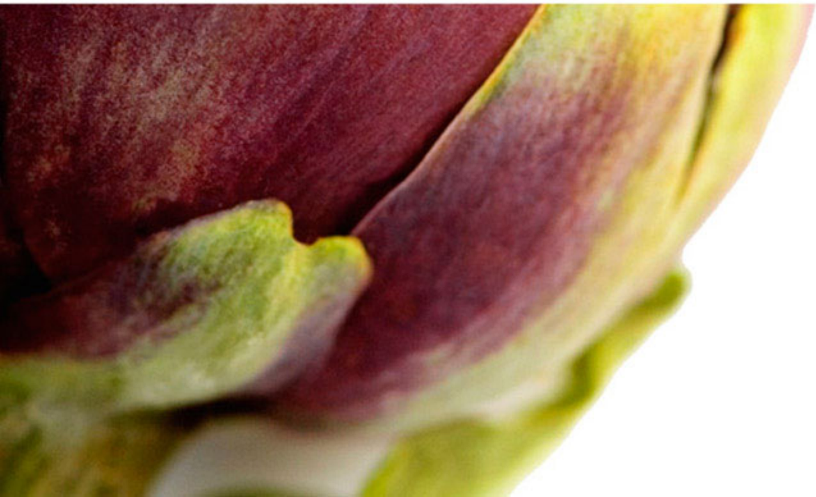
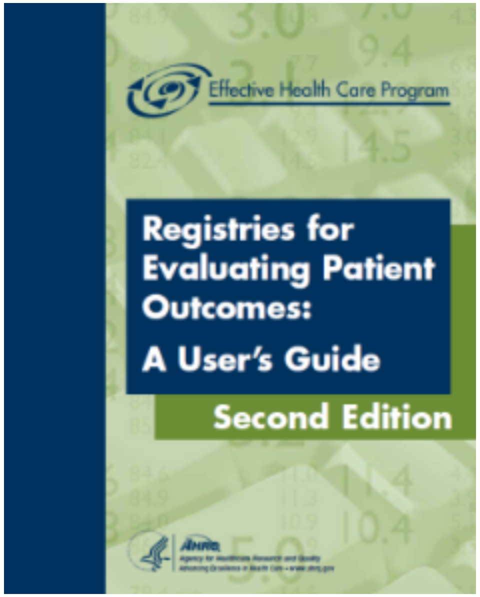


clinical | commercial | consulting | capital

Overview

- **Background**: Definition, Ideal Registry for PCOR, Existing Registries and Suitability for PCOR,
- **Accomplishments**: Key Achievements with respect to PCORI goals
- **Expansion and Growth Potential**: Characteristics Suitable for Expansion, Expansion Example, How PCORI might Use/ Extend Existing Registries
- **Barriers**: What PCORI can do to Extend the Model Broadly
- **Additional**
  - Registry Standards (Draft)
  - Registry of Patient Registries

Definition of Patient Registry



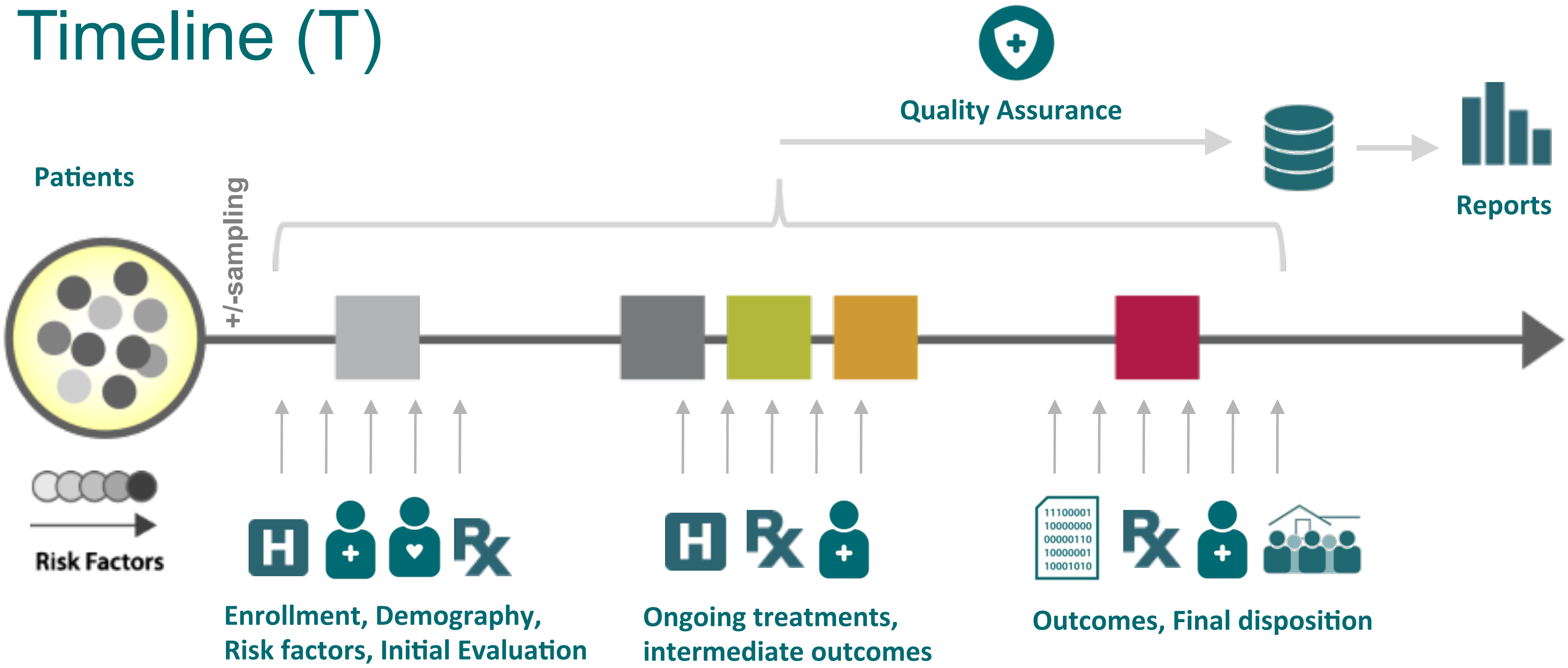
Effective Health Care Program

Registries for Evaluating Patient Outcomes:
A User's Guide
Second Edition

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 a predetermined scientific, clinical, or policy purpose(s).

Gliklich RE, Dreyer NA: Registries for Evaluating Patient Registries: A User's Guide: AHRQ publication No. 07-EHC001. Rockville, MD. April 2007

Timeline (T)



Quality Assurance

Patients

Reports

Risk Factors

Enrollment, Demography, Risk factors, Initial Evaluation

Ongoing treatments, intermediate outcomes

Outcomes, Final disposition

The Ideal Registry for PCOR

- Collects uniform, clinically rich data including risk factors, treatments and outcomes at key points for a particular disease or procedure
- From multiple sources (doctors, patients, hospitals) and across care settings (practices, hospitals, home)
- Leverages HIT systems through interoperability and data sets from other sources through linkage
- Uses standardized methods to assure representative patient sample, data quality (accuracy, validity, meaning, completeness) and comparability (risk adjustment)
- Provides rapid or real-time feedback/ reports at patient and population levels to facilitate care delivery, coordination, quality improvement, and quality reporting (to third parties)
- Can change in response to changing information or needs or addition of new studies
- Maintains high levels of participation by providers and patients and a sustainable business model
- Can be randomized at the site or patient level for certain sub-studies

Registries that have higher likelihood to constitute **long-term infrastructure** are those with at least one purpose being QI. They also have additional benefits in terms of communicating and disseminating PCOR findings.

Inputs: Obtaining data

- **Identify/enroll representative patients** (e.g. sampling)
- **Collect data from multiple sources and settings** (providers, patients, labs, pharmacies) at key points
- **Use uniform data elements and definitions** (risk factors, treatments and outcomes)
- **Check and correct data** (validity, coding, etc.)
- **Link data from different sources at patient level** (manage patient identifiers)
- **Maintain security and privacy** (e.g. access control, audit trail)

Outputs: Care Delivery and Coordination

- **Provide real-time feedback with decision support** (evidence/guidelines)
- **Generate patient level reports and reminders**(longitudinal reports, care gaps, summary lists/plans, health status)
- **Send relevant notifications to providers and patients** (care gaps, prevention support, self management)
- **Share information** with patients and other providers
- **List patients/subgroups** for proactive care
- **Link** to relevant patient education

Outputs: Population Measurement and QI

- **Provide population level reports**
  - real-time/rapid cycle
  - risk adjusted
  - include standardized measures
  - include benchmarks
  - enable different reports for different levels of users
- **Enable ad-hoc reports** for exploration
- **Provide utilities to manage** populations or subgroups
- **Generate dashboards** that facilitate action
- **Facilitate 3rd party quality reporting** (transmission)

Registries today vary by **organization**, **condition** and **type**. They exhibit different strengths and limitations. They are more prevalent and sustained in certain conditions.

Types of Organizations	Condition	Registry Type	Example Strength	Example Limitation
Professional society	Heart failure Surgical care	Hospitalization Procedure & Hospitalization	High participation Strong quality assurance methods including audits	Limited follow-up Cannot obtain data across settings
Patient advocacy organization	Cystic fibrosis	Disease	High participation	Not interoperable with HIT systems
Integrated delivery system	Diabetes	Disease	Extensive care delivery and care coordination functionalities	Accessible population too limited for PCOR
Individual hospital	Orthopedics	Procedure	Collects nationally standardized data elements	Non-representative sampling methods
Regional/ Community	Arthritis Orthopedics	Disease	Data from doctors and patients Representative sampling	Limited quality assurance Very low participation
Government entity	Stroke Cancer	Hospitalization Disease	Mandated participation	No risk adjustment No outcomes data
Manufacturer	Acute coronary syndrome Liposome storage diseases	Drug Disease	Strong methods High follow-up rates Use of PROs	May not be sustained Potential conflicts of interest for PCOR

Key Achievements

Example relevant achievements and ability to meet core electronic data model requirements for PCOR

Achievements

Patient Care

- AHA GWTG registries reduce healthcare disparities.

Research

- STS, ACC NCDR and AHA GWTG have produced hundreds of peer reviewed publications

Clinical Guidelines

- NCCN registry assesses and reports on guidelines

Policy

- ACC NCDR ICD registry has been utilized for Coverage under Evidence Development

New Quality Measures

- STS registry, ACS NSQIP and AHA GWTG have all developed nationally recognized measures

American Academy of Ophthalmology Ophthalmic Database, RIGOR (www.aao.org)
Agency for Healthcare Research and Quality RIGOR (www.ahrq.gov)
American Heart Association Get With the Guidelines (www.heart.org)
American College of Cardiology NCDR®, PINNACLE (www.cardiosource.org)
American Collgeof Gastroenterology GiQuic (www.gi.org)
American College of Surgeons NSQIP, NCD, Bariatric (www.facs.org)
American Society of Plastic Surgeons TOPS (www.plasticsurgery.org)
Cystic Fibrosis Foundation (www.cff.org)
National Comprehensive Cancer Network (www.nccn.org)
Society of Thoracic Surgeons (Database www.sts.org)

Ability to meet core requirements for EDM

Large, diverse populations from usual care

- Available from most national society and patient organization driven registries

Complete capture longitudinal data

- CFF registry captures longitudinal data at set intervals

Patient reported outcomes (PROs)

- PROs routinely captured in RIGOR, ASPS TOPS, and CFF registry

Patient and clinician engagement

- Patients and clinicians represented in CFF and ACS registries governance

Linkage to health systems for dissemination and automation

- AHA GWTG and ACS NSQIP provide real-time feedback to health systems; ASPS uses retrieve form for data capture (RFD) to integrate registry with EMRs

Capable of randomization

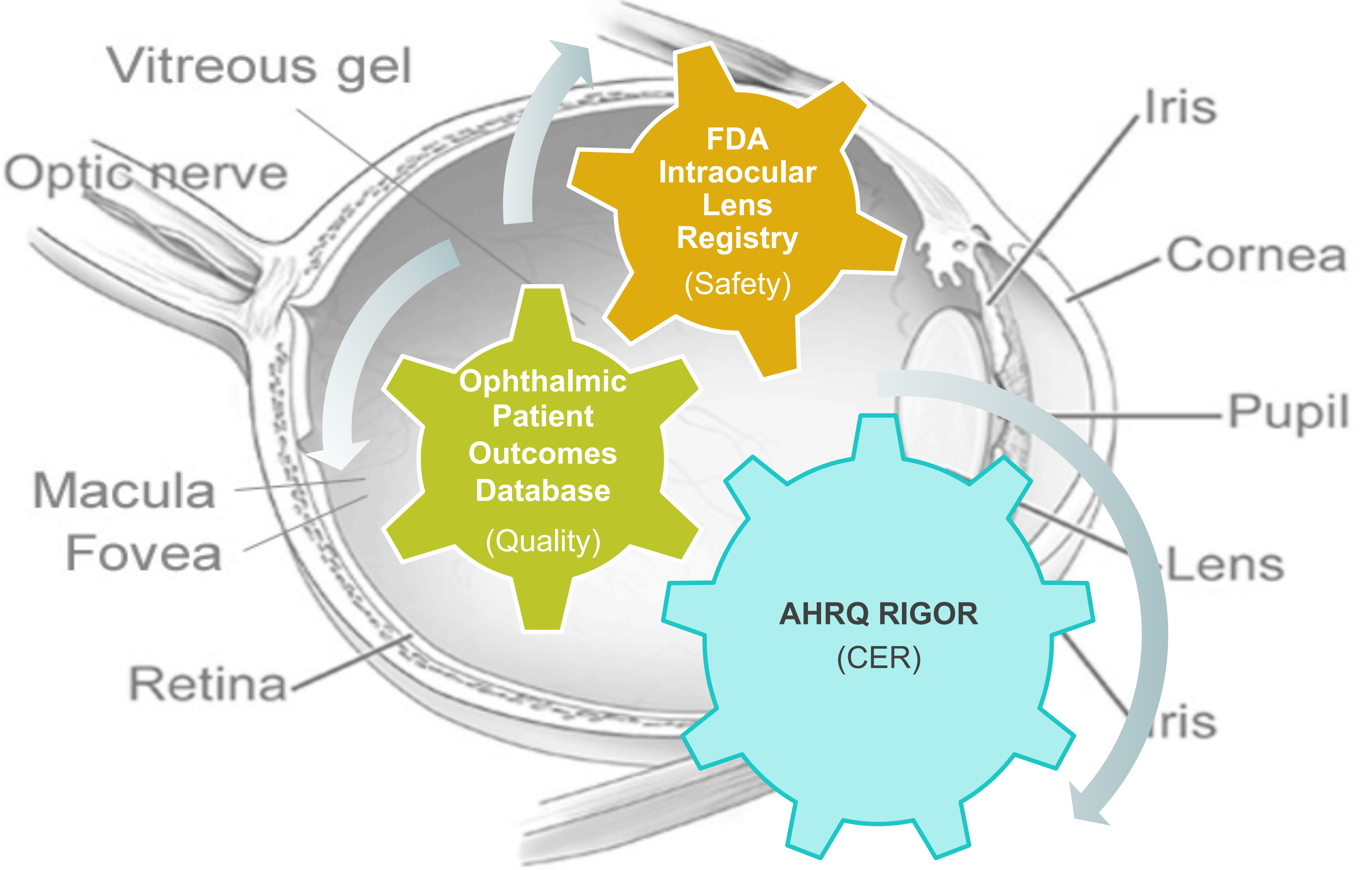
- AHA registries have incorporated randomization for sub-studies

Registries with **strong geographic reach**, **high participation**, **modifiable data collection systems** (including PRO and randomization) and **sustainable business models** are best options.

These attributes vary significantly by condition and by specific registry.

Types of Organizations	Conditions	Can Model address PCORI's goals?	Barriers
Professional society	various	Large, diverse populations from usual care settings, PRO capacity, Patient and clinician engagement, affordable, linkage to health systems, capable of randomization	Many societies in early stages of developing programs, only some are of sufficient infrastructure to scale and those are in a limited number of disease areas. Vary in quality
Patient advocacy organization and communities	various	PRO capacity, patient and clinician engagement, affordable, linkage to health systems possible, capable of randomization	Limited number of groups have active registries in place today. Those that do vary in quality and extensibility of architecture
Integrated delivery system	various	Complete capture of longitudinal data, PRO capacity, patient and clinician engagement, linkage to health systems	Would need to be linked to other IDNs using common data standards in federated networks to meet goals
Regional/ Community	various	Large, diverse populations from usual care settings, PRO capacity, patient and clinician engagement, linkage to health systems, capable of randomization	Limited number of community efforts and participation within communities typically varies
Government entity	various	Large, diverse populations from usual care settings, PRO capacity	Most programs are funded for limited duration and may not be sustainable

Expansion Potential: Example



FDA Intraocular Lens Registry
(Safety)

Ophthalmic Patient Outcomes Database
(Quality)

AHRQ RIGOR
(CER)

How PCORI might use/extend existing registries

National registry examples in a range of conditions and procedures

Registry Examples	Large, diverse popoulations from usual care settings	Complete capture of longitudinal data	Ability to contact patients for study specific PROs	Patient and clinician engagement in data governance	Linkage to health systems	Capable of randomization
American Heart Association (Get With the Guidelines Stroke, Heart Failure, Resuscitation)	Yes	No Extend with linkage	Not routine Has been used in substudies, ePRO capable	Yes	Yes	Yes
American College of Cardiology (NCDR, PINNACLE)	Yes	Mixed Extend with linkage			Yes	
Cystic Fibrosis Foundation Registry	Yes	Yes	Yes	Yes	Yes	Yes
American Society of Plastic Surgeons (TOPS)	Yes	Longitudinal, focused	Yes, ePRO		Yes	Yes
AHRQ (RIGOR) with AAO, Quintiles Outcome	Yes	Longitudinal, focused	Yes, ePRO	Mixed	Yes, practices	Yes
American College of Surgeons (NSQIP, Bariatric, NCD)	Yes	Mixed Extend with linkage	Mixed	Mixed	Yes	Yes
American College of Gastroenterology (GIQuic)	--	No Extend with Linkage	Not routine, systems capable		Yes	Yes

What can PCORI do to extend the model more broadly?

Data elements and definitions not standard for most conditions	•Promote core data set development for PCOR through multi-stakeholder collaboratives
Data is not easily collected across care settings or long-term	•Advance patient identity management solutions (e.g. secure anonymized patient ID linkages)
HIT systems not yet interoperable with registries	•Leverage interoperability solutions (e.g. HITSP TP-50) for registries and EHRs as part of meaningful use
Lack standardized methods for sampling, data quality and risk adjustment	•Specify acceptable methods and quality assurance requirements for use of data for PCOR*
Linkage of data from different sources limited by inconsistent methods and HIPAA concerns	•Promote standardized approaches for linkage •Seek clarification of linkage issues under HIPAA from HHS, address access issues such as to death indices
Participation is highly variable and related to incentives and interpretation of rules	•Leverage registries with high participation rates. •Work with HHS (HIPAA and Common Rule) with respect to increasing efficiency of IRB and consent requirements for core registry and PCOR within existing registries
Not all registries have sustainable business models	•Focus on registries with sustainable models

Additional

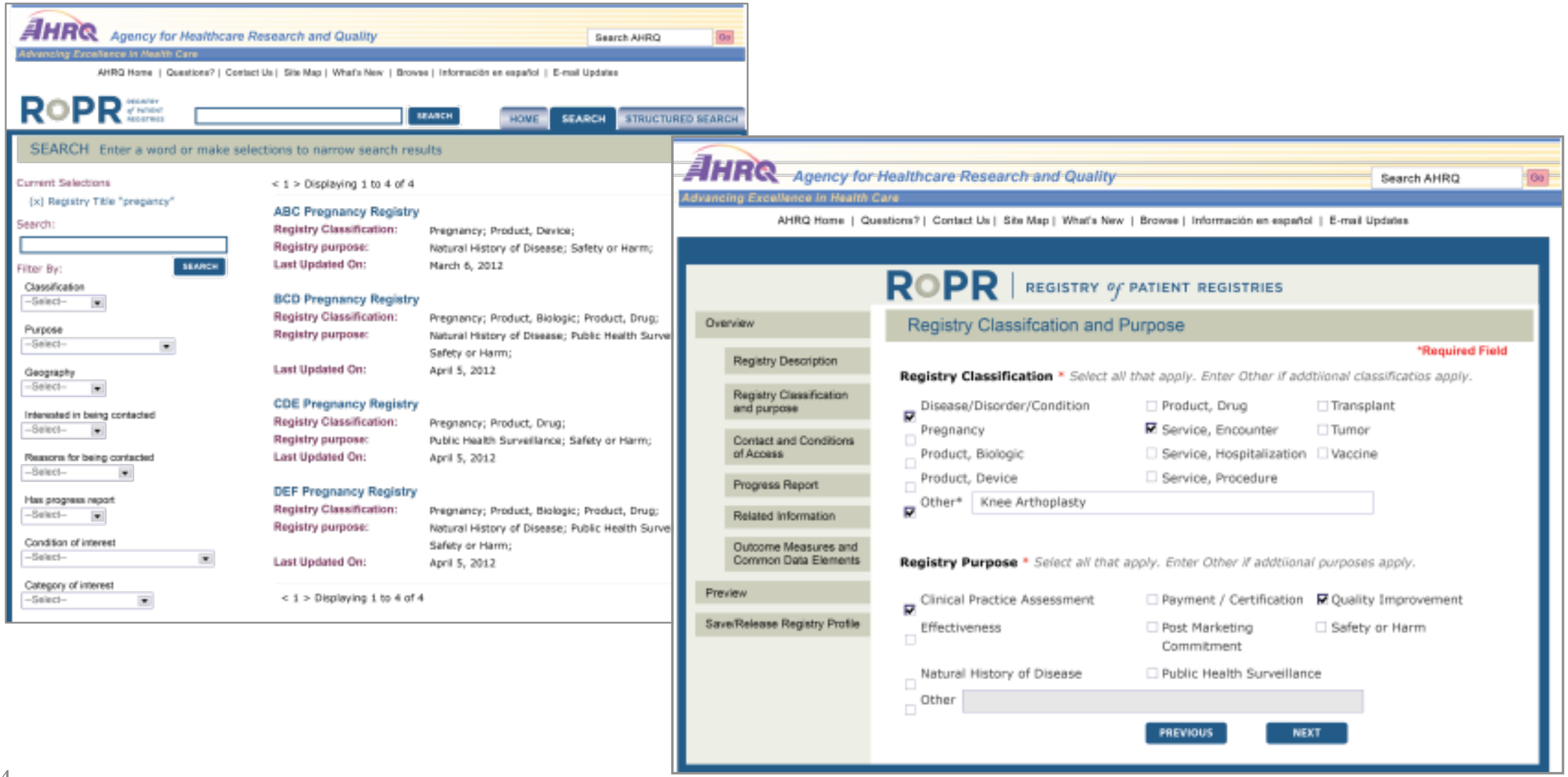
Standards for Data Registries

From PCORI Draft Methodology Report

- Develop a Formal Study Protocol
- Measure Outcomes that People in the Population of Interest Notice and Care About
- Describe Data Linkage Plans, if Applicable
- Plan Follow-up Based on Registry Objective(s)
- Describe Data Safety and Security
- Take Appropriate Steps to Ensure Data Quality
- Document and Explain Any Modifications to the Protocol
- Collect Data Consistently
- Enroll and Follow Patients Systematically
- Monitor and Take Actions to Keep Loss to Follow-up to an Acceptable Minimum
- Use Appropriate Statistical Techniques to Address Confounding

Where to Find Registries?

- Registry of Patient Registries (RoPR)
    - > AHRQ, Outcome DEcIDE in collaboration with NLM



SEARCH Enter a word or make selections to narrow search results

Current Selections
[x] Registry Title "pregancy"

Search:

Filter By:
Classification --Select--
Purpose --Select--
Geography --Select--
Interested in being contacted --Select--
Reasons for being contacted --Select--
Has progress report --Select--
Condition of interest --Select--
Category of interest --Select--

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ABC Pregnancy Registry
Registry Classification: Pregnancy; Product, Device;
Registry purpose: Natural History of Disease; Safety or Harm;
Last Updated On: March 6, 2012

BCD Pregnancy Registry
Registry Classification: Pregnancy; Product, Biologic; Product, Drug;
Registry purpose: Natural History of Disease; Public Health Surve
Safety or Harm;
Last Updated On: April 5, 2012

CDE Pregnancy Registry
Registry Classification: Pregnancy; Product, Drug;
Registry purpose: Public Health Surveillance; Safety or Harm;
Last Updated On: April 5, 2012

DEF Pregnancy Registry
Registry Classification: Pregnancy; Product, Biologic; Product, Drug;
Registry purpose: Natural History of Disease; Public Health Surve
Safety or Harm;
Last Updated On: April 5, 2012

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Registry Classifcation and Purpose

*Required Field

Registry Classification * *Select all that apply. Enter Other if addtional classificatios apply.*

☑ Disease/Disorder/Condition
☐ Pregnancy
☐ Product, Biologic
☐ Product, Device
☑ Other* Knee Arthoplasty
☐ Product, Drug
☑ Service, Encounter
☐ Service, Hospitalization
☐ Service, Procedure
☐ Transplant
☐ Tumor
☐ Vaccine

Registry Purpose * *Select all that apply. Enter Other if addtiional purposes apply.*

☑ Clinical Practice Assessment
☐ Effectiveness
☐ Natural History of Disease
☐ Other
☐ Payment / Certification
☐ Post Marketing Commitment
☐ Public Health Surveillance
☑ Quality Improvement
☐ Safety or Harm