



Community Led Data Collection and Patient Registries



Defining a patient registry



- “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).”
- a collection—for one or more purposes—of standardized information about a group of patients who share a condition or experience.
- Community led vs Research led
 - patients and family members “power” the registry by managing or controlling the collection of the data, the research agenda for the data, and/or the translation and dissemination of the research from the data.
- Data collection
 - Structured or unstructured way to collect data

<https://www.ncbi.nlm.nih.gov/books/NBK164514/>

https://www.ncbi.nlm.nih.gov/books/NBK164513/pdf/Bookshelf_NBK164513.pdf

Purpose of registries



- There are 4 main purposes for keeping registries
 - (1) describing the natural history of disease,
 - (2) determining clinical and/or cost-effectiveness,
 - (3) assessing safety or harm, and
 - (4) measuring or improving quality of care.

Types of registries



- Patients in a registry are typically selected based on a particular disease, condition (e.g., a risk factor), or exposure.
- Classification are based on how the populations for registries are defined.
- Three general categories with multiple subcategories and combinations account for the majority of registries that are developed for evaluating patient outcomes.
 - **Product Registries**
 - **Health Services Registries**
 - **Disease or Condition Registries**
 - **(combinations)**

Product registries



- The patient is exposed to a health care product, such as a drug or a device
- The exposure may be brief, as in a single dose of a pharmaceutical product, or extended, as in an implanted device or chronic usage of a medication.
- Examples
 - A registry for all patients who receive an implantable cardioverter defibrillator, a registry of patients with hip prostheses, or a registry of patients who wear contact lenses are all examples of device registries
 - British Society for Rheumatology established a national registry of patients on biologic therapy
 - Registries for thalidomide, clozapine, and isotretinoin.

Health Services Registries



- One purpose might be to evaluate the health care service with respect to the outcomes (individual clinical encounters, such as office visits or hospitalizations, procedures, or full episodes of care).
- Examples include registries enrolling patients undergoing a procedure (e.g., carotid endarterectomy, appendectomy, or primary coronary intervention) or admitted to a hospital for a particular diagnosis (e.g., community-acquired pneumonia).

Disease or Condition Registries



- Disease or condition registries use the state of a particular disease or condition as the inclusion criterion.
- In disease or condition registries, the patient
 - may always have the disease (e.g., a rare disease such as cystic fibrosis or Pompe disease, or a chronic illness such as heart failure, diabetes, or end-stage renal disease) or
 - may have the disease or condition for a more limited period of time (e.g., infectious diseases, some cancers, obesity).

Different forms and formats



- They may be operated by a single organization or by a collaborative of multiple organizations.
- PRs may also pursue a specific research question or conduct ongoing data collection to answer a variety of existing and emerging research questions. Several PPRs have biobanks, or repositories, where patients can provide samples of blood or tissue to be used in research.

Concerns



- only a small minority of patients with sufficient education and ability are able to participate
- Bias due to type of patient?
- Lack of standardization in data collection
- Potential competition for registered patients across registries
- Meta analysis across registries may be challenging or impossible if multiple registers are used
- Issues of patient consent and rights violations relative to tissue samples submitted to biobanks

Elements of Successful Community Led Registries and Research Networks



1. Well-designed technology
2. Recruitment, encouragement, and gratitude for participation
3. Collaborative relationships with researchers
4. Partnerships with a broad range of stakeholders.

Creating a Community Led Registry



Table 1. Advantages and disadvantages of PPR models

Pathway	Advantages	Disadvantages
Create a stand-alone PPR	<ul style="list-style-type: none"> • More focus on what is important to affected individuals • More control of design to meet needs • More control of data, including use and sharing • Potentially higher participation rates • More opportunities to promote the organization 	<ul style="list-style-type: none"> • Higher costs • More resources needed for promotion • Sole responsibility for data management and use
Join a PPRN	<ul style="list-style-type: none"> • Lower costs • Greater promotion of the network across populations • Reduced fracturing of patient sample • Greater ability to do research across conditions or address concomitant conditions 	<ul style="list-style-type: none"> • Less autonomy/control of design • Less ownership of data • Potentially less brand or name recognition^a

Abbreviations: PPR = patient-powered registry; PPRN = patient-powered registry network.

^aSome PPRNs allow member organizations to maintain their identity and brand, eliminating this disadvantage.

Data Standards

