

Good Registry Practice®

Quick Notes



What are characteristics of registries?

- Data are collected in a naturalistic manner.
- Designed to fulfill specific purposes and these purposes are defined before collecting and analyzing data.
- Captures data elements with specific and consistent definitions.
- Data are collected in a uniform manner for every patient.
- Data includes data that are reflective of the clinical status of the patient.
- Some data are collected specifically for the purposes of the registry.

Taxonomy

- Product registries, where the exposure is a product.
- Health services registries, where the exposure is a service such as an encounter, procedure, hospitalization or an episode of care.
- Disease or condition registries, where the exposure is having the condition or disease. These include chronic illness, conditions over more limited time periods (such as an infection) or acute events (such as a myocardial infarction).

Registry Design Questions

- What are the clinical and/or public health questions of interest?
- What types of study designs can be used in registries?
- How do the clinical questions of interest translate into measurable exposures and outcomes?
- What types of patients are needed for study? Is a comparison group needed?
- How should patients be selected for study? Where can the necessary data be found?
- For how long should data be collected, and for how many patients?
- What is the potential for bias, and how does this affect generalizability (external validity)?

What purposes do registries serve?

- Determine clinical, cost or comparative effectiveness of tests or treatments.
- Measure or monitor safety and harm of specific products and treatments.
- Measure or improve quality of care.
- Assess the natural history of conditions and their treatment, including estimating magnitude; determining underlying rates; examining trends over time.

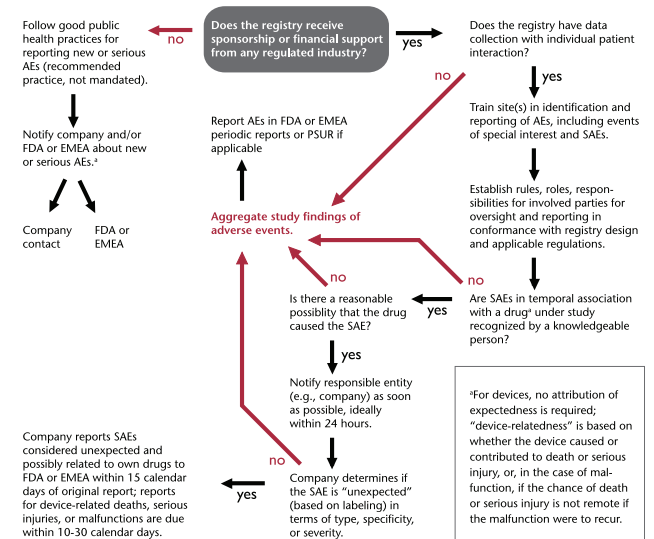
Patient Populations

- Target:** the population to which the study findings are meant to apply.
- Accessible:** subset of target population who are specifically defined and available for study.
- Intended:** members of the accessible population, who are sampled according to the registry design.
- Actual:** people who actually participate in a registry.

Definitions

- 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.
- The patient registry database describes a file (or files) derived from the registry.

Adverse Events



*For devices, no attribution of expectedness is required; "device-relatedness" is based on whether the device caused or contributed to death or serious injury, or, in the case of malfunction, if the chance of death or serious injury is not remote if the malfunction were to recur.

Evidence Quality Checklist

Registry participants

Basic

- Registry participants are similar to target population
- Eligibility confirmed
- For safety studies, train personnel about SAEs
- Completeness of information

Enhanced

- Selection bias evaluated
- External validity described
- Contemporaneous data collected for comparator treatments, if relevant
- Diverse clinical practices represented for registries where practice characteristics may impact outcome

Data elements and data sources

Basic

- Information collected for key exposures, risk factors, and mitigating or protective factors
- Patient outcomes are clinically relevant and clearly defined; validated tools used when available
- Reasonably sufficient follow-up period to capture outcomes of interest

Enhanced

- The exposure data used to support the main hypothesis are as specific as possible (e.g., record branded products where possible)
- Results that can be confirmed by an unbiased observer enhance accuracy and reliability
- Follow-up is sufficient to capture outcomes of interest

Data quality assurance

Basic

- Data are reasonably complete
- Reasonable efforts expended to assure appropriate patients are systematically enrolled, and followed in as unbiased a manner as possible
- Reasonable efforts devoted to minimize losses to follow-up
- Data checks employed using range and consistency checks

Enhanced

- Reproducibility of coding evaluated
- Potential sources of errors (accuracy and falsification) rigorously evaluated and quantified
- Sample of data compared with patient records (safety, effectiveness, and comparative effectiveness studies)
- Reasonably complete follow-up
- Validated analytic tools used for main analysis

Analysis

Basic

- Accepted analytic techniques used
- Explored role and impact of missing data and potential confounding factors

Enhanced

- Follow-up loss characterized at key stages
- Risks and/or benefits quantitatively evaluated, beyond simply statistical significance
- Sensitivity analyses useful to examine effect of testing various assumptions
- If models used, described specific data elements included

Reporting

Basic

- Report describes methods (target population, compliance with regulatory rules/regulations, data collection, transformation of variables and/or construction of composite endpoints, data analysis statistical methods, and description of circumstances that affected data quality or integrity)
- Reported results for all main objectives
- Follow-up time is described so readers can assess impact of observation period on conclusions drawn
- Report includes clear statement of conclusions drawn from analysis of registry's primary and secondary objectives and implications of study results
- Acknowledged authors had meaningful role in design, conduct, analysis, or interpretation of results

Enhanced

- Results' consistency compared and contrasted with other relevant research
- Inferences about causal effects based on variety of factors (inc. strength of association, biases, and temporal relations)

Gliklich RE, Dreyer NA (eds): Registries for Evaluating Patient Outcomes: A User's Guide. (Prepared by Outcome DEClIDE Center [Outcome Sciences, Inc. dba Outcome] under Contract No. HHS290200500351 TO1.) AHRQ Publication No. 07-EHC001-1. Rockville, MD: Agency for Healthcare Research and Quality. April 2007.

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Dreyer NA, Bertagna M, Gliklich RE: Designing and Assessing Registries to Evaluate the Safety of Medical Products, ACRP Monitor, August 2007.