

"Registries for Evaluating Patient Outcomes: A User's Guide, 2nd Edition"

Richard E. Gliklich and Nancy A Dreyer, editors, 2010, 347 pages, Agency for Healthcare Research & Quality, free (electronic edition)

Review by Norman M. Goldfarb

"Registries for Evaluating Patient Outcomes: A User's Guide, 2nd Edition" is a comprehensive and practical handbook for creating and implementing patient registries. The book is clearly written, as illustrated by the following excerpts:

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. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure.

Studies from patient registries and randomized controlled trials (RCTs) have important and complementary roles in evaluating patient outcomes. Ideally, patient registries collect data in a comprehensive manner (with few excluded patients) and therefore produce outcome results that may be generalizable to a wide range of patients. They also evaluate care as it is actually provided, because care is not assigned, determined or even recommended by a protocol. As a result, the outcomes reported may be more representative of what is achieved in real-world practice. Patient registries also offer the ability to evaluate patient outcomes when clinical trials are not practical (e.g., very rare diseases), and they may be the only option when clinical trials are not ethically acceptable. They are powerful tools when RCTs are difficult to conduct, such as in surgery or when very long-term outcomes are desired.

Conversely, patient registries that observe real-world clinical practice may collect all of the information needed to assess patient outcomes in a generalizable way, but interpreting this information correctly requires analytic methodology geared to address the potential sources of bias that challenge observational studies. Interpreting patient registry data also requires checks of internal validity and sometimes the use of external data sources to validate key assumptions (such as comparing the key characteristics of registry participants with external sources to demonstrate the comparability of registry participants with the ultimate reference population). Patient registries, RCTs, other study designs, and other data sources should all be considered tools in the toolbox for evidence development, each with its own advantages and limitations.

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Traditional surveillance systems are intended to continue indefinitely because they are intended to monitor changes in event frequency over time. For example, surveillance systems for epidemic infectious diseases provide early warning about outbreaks and help direct efforts to contain such outbreaks. In contrast, a patient registry is not a true surveillance system, since most are not intended to provide an early warning of a change in outcome frequency. Rather, most patient registries are intended to compile data on outcomes associated with novel treatments, to supplement the sparse data usually available at the time that these treatments are considered for approval by regulatory agencies. For example, a regulatory agency might mandate a patient registry as a condition of approval to supplement safety information that was submitted during the application process.

The book consists of 14 chapters:

- Patient Registries
- Planning a Registry
- Registry Design
- Use of Registries in Product Safety Assessment
- Data Elements for Registries
- Data Sources for Registries
- Linking Registry Data: Technical and Legal Considerations
- Principles of Registry Ethics, Data Ownership, and Privacy
- Recruiting and Retaining Participants in the Registry
- Data Collection and Quality Assurance
- Interfacing Registries with Electronic Health Records
- Adverse Event Detection, Processing, and Reporting
- Analysis and Interpretation of Registry Data To Evaluate Outcomes
- Assessing Quality

Thirty-eight case examples illustrate points in the text. The book is available at <http://www.effectivehealthcare.ahrq.gov>.

Reviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.