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Patient Registries and ME/CFS: Introduction

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What is a 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 one or more **predetermined** scientific, clinical, or policy **purposes**

Registry Goals

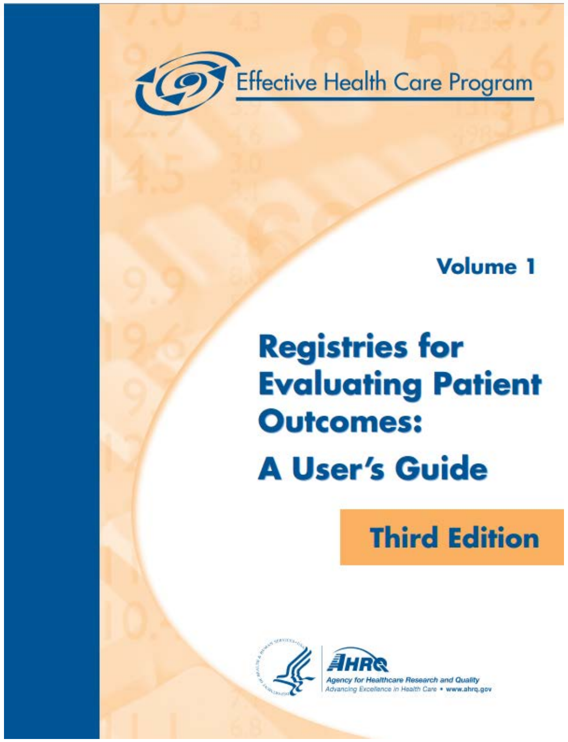
- **Improve quality of care for <u>individual</u> patients**
  - Tracking and reminders for individual patients
- **Improve quality of care <u>across</u> the health care system**
  - Tracking and reminders for processes in the health system
  - Tracking outcomes over time such as hospital readmission rates
- **Research**
  - Understanding disease progression
  - Postmarket studies of new drugs and devices
  - Comparative effectiveness of clinical and process interventions

Models

- **Bio-Banks**
  - CFIDS SolveCFS BioBank
  - NIH Lipkin samples NOT-AI-13-005
- **EHR-based**
  - Registries Module
- **Patient Reported**
  - PatientsLikeME
- **Federated Model**
  - NDAR

One size does not fit all!

Registries Guide



Effective Health Care Program

Volume 1

Registries for Evaluating Patient Outcomes:

A User's Guide

Third Edition

AHRQ
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April 2014

- Handbook for establishing, maintaining and evaluating registries.
  - Volume 1: creating registries, legal and ethical considerations for registries, and operating registries.
  - Volume 2: technical, legal, and analytical considerations for combining registry data with other data sources, and special applications in patient registries.

- www.effectivehealthcare.ahrq.gov/ registries-guide-3.cfm.
  - PDF and **eReader** version
- To order printed copy: email **AHRQPubs@ahrq.hhs.gov** **AHRQ Publication No. 13(14)-EHC111**

First Published in 2007

- Collaborative effort with broad multi-stakeholder involvement
  - industry
  - academia
  - health plans
  - physician societies
  - government
- Peer reviewers
- Public comment

- Example driven:

  3rd edition features 34 new case examples (total of 64) including:

  - 16 international examples
  - 8 device registries
  - 4 public-private partnerships
  - 6 rare disease registries
  - 9 quality improvement registries
  - 5 pregnancy registries

Registry of Patient Registries (RoPR)

https://patientregistry.ahrq.gov

- Create online repository of info on patient registries
- White papers: e.g., expired registries and collaborative online work space
    - ▶ registries development
    - ▶ forum for methods
    - ▶ research project workspace
- Develop a framework and prototype syntax for definitions of outcomes

Challenges in Developing an Outcome Measures Framework

- Stakeholders identified 4 major challenges:

Variation in:

1. Type of outcome measure
2. Outcome measure definitions
3. Timeframe

and

4. User burden

Final White Papers posted: June 3, 2014.

www.effectivehealthcare.ahrq.gov, then search for “Registry”

Summary Points

- Registries are an important tool to understand diseases and the outcomes of health interventions
- Coordination and interoperability are key to leverage the investment in registries

Today..

- Begin the conversation on potential benefits of leveraging the power of registries to enhance quality of care and research for ME/CFS Patients.