Registries for Evaluating Patient Outcomes:
An Introduction to the User’s Guide

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Managing Editor
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Ms. Leavy is a Manager, Health Policy at Quintiles and has more than 10 years of experience working with patient registries and health care quality improvement programs. She earned her MPH at the University of North Carolina at Chapel Hill. She has served as the managing editor for the 2007, 2010, and forthcoming 2013 editions of the AHRQ handbook, “Registries for Evaluating Patient Outcomes: A User's Guide.” She is also the author of two chapters and multiple case examples in the guide. In addition to her work on the registries handbook, she has managed several projects to produce in-depth reports on registry-related topics, including reports for AHRQ on developing a registry of patient registries, using registries for comparative effectiveness research, and archiving registry data, and for the FDA on orthopedic device registries. She served as the project manager for the development of the Registry of Patient Registries (RoPR) and managed a project to develop registry standards for PCORI.
Agenda

Introduction to the Registries Guide
- Purpose
- Previous Editions
- Process for Creating the Registries Guide

Organization of the Registries Guide
- Major Topics
- Case Examples

Highlights from the Upcoming 3rd Edition
- New Chapters
- New Case Examples

Q & A
Today’s Webinar Audience

- Academia: 34%
- Biostatistician: 3%
- Clinical Operations: 5%
- Epidemiology: 3%
- Health Economics/Health Outcomes: 0.7%
- Medical Affairs: 1%
- Medical Economics/Health Outcomes: 1%
- Medical Affairs: 1%
- Market Access: 14%
- Medical Economics/Health Outcomes: 6%
- Regulatory Affairs: 32%
- Risk Management: 3%
Polling Questions

A small number of polling questions have been added to today’s webinar to make the session more interactive
Introduction to the Registries Guide
Purpose of the Registries Guide

**Purpose:** Serve as a practical reference for establishing, maintaining, and evaluating the success of registries created to collect data about patient outcomes

As registries continue to evolve, many new methodological and practical issues have arisen. 1st edition (2010) and 3rd edition (planned 2014) were created to address emerging issues identified through:

- Public comment
- Recent publications
- Reported experiences

The Registries Guide is published by the **Agency for Healthcare Research and Quality (AHRQ)** under the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) program (Contract No. HHSA29020050035I).
Publication Timeline

- **Sept 2005**
  - Project award for 1st Edition

- **August 2008**
  - Project award for 2nd Edition

- **Sept 2010**
  - Project award for 3rd Edition


- **April 2007**
  - 1st Edition published

- **Sept 2010**
  - 2nd Edition published

- **Winter 2014 (expected)**
  - 3rd Edition to be published

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3rd Edition Forthcoming
Process for Creating the Guide

Topics Identified
- Topics identified based on public comments received for the previous

New Chapters
- Author and reviewer teams assembled with balanced representation from industry, academia, and government.
- New chapters peer reviewed and posted for public comment.

Original Chapters
- Original authors and reviewers invited to participate. Additions made for new topic areas when necessary.
- Full, revised guide posted for public comment.

Open Call
- Open call for case examples

Senior Editors: Richard Gliklich, MD and Nancy Dreyer, PhD, MPH; Managing Editor: Michelle Leavy, MPH
Multi-Stakeholder Collaboration

Collaborators from Academia, Industry, and Government

- Chapter Contributors
- Peer Reviewers
- Case Examples

1st edition: 23 (Chapter Contributors) + 33 (Peer Reviewers) + 39 (Case Examples) = 95
2nd edition: 38 (Chapter Contributors) + 49 (Peer Reviewers) + 55 (Case Examples) = 142
3rd edition: 64 (Chapter Contributors) + 76 (Peer Reviewers) + 100 (Case Examples) = 240
Use of the Registries Guide

Widely Used as a Reference for Registries

Cited ...
130+ times in the peer-reviewed literature

Cited in...
Cochrane Reviews, Congressional Reports, Institute of Medicine reports, and textbooks as the standard for patient registries

Created in...
Collaboration with 150+ representatives from industry, academia, government, and patients

Translated into...
Chinese and adapted in Korean
Polling Question

• Have you used the Registries Guide in the past?
  - Yes, I frequently use it
  - Yes, I use it occasionally
  - No, I have not used it
Polling Question

• In which format have you used the Registries Guide?
  - PDF/electronic format
  - Printed copy
  - Both electronic and printed formats
  - I haven’t used the Registries Guide
Organization of the Registries Guide
Content Organization – 2nd Edition

I. Creating Registries
• Defining a registry
• Planning steps
• Study design options
• Data elements
• Data sources & linking data
• Legal & ethical considerations

II. Operating Registries
• Recruitment & retention
• Data collection & QA
• Managing adverse events
• Integrating with EHRs
• Analyzing registry data

III. Evaluating Registries
• Defining registry quality
• Research quality
• Evidence quality
## Content Organization – 2nd Edition

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<th>I. Creating Registries</th>
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<td>6. Data Sources for Registries</td>
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<td>7. Linking Registry Data: Technical and Legal Considerations</td>
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<td>8. Principles of Registry Ethics, Data Ownership, and Privacy</td>
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Content Organization – 2nd Edition

Preface describes process for creating the Guide and the organization of the document.

Case examples are included in Chapters 2 –13 to highlight real-world challenges encountered by registries.

Executive Summary offers concise description of each chapter’s contents.

References are listed at the end of each chapter and supplemental material can be found in the appendices.
Highlights from the Upcoming 3rd Edition
Volume 1

I. Creating Registries
II. Legal and Ethical Considerations for Registries
III. Operating Registries

Volume 2

IV. Technical, Legal, and Analytic Considerations for Combining Registry Data with Other Data Sources
V. Special Applications in Registries
VI. Evaluating Registries
New Chapters – 3rd Edition

I. Creating Registries

1. Patient Registries
2. Planning a Registry
3. Registry Design
4. Data Elements for Registries
5. Use of Patient-Reported Outcomes in Registries
6. Data Sources for Registries

II. Legal and Ethical Considerations for Registries

7. Principles of Registry Ethics, Data Ownership, and Privacy
8. Informed Consent for Patient Registries
9. Protection of Registry Data
New Chapters – 3rd Edition

III. Operating Registries

10. Recruiting and Retaining Participants in the Registry
11. Data Collection and Quality Assurance
12. Adverse Event Detection, Processing, and Reporting
13. Analysis, Interpretation, and Reporting of Registry Data to Evaluate Outcomes
14. Modifying and Stopping Registries

IV. Technical, Legal, and Analytic Considerations for Combining Registry Data with Other Data Sources

15. Interfacing Registries With Electronic Health Records
16. Linking Registry Data with Other Data Sources to Support New Studies
17. Managing Patient Identity across Data Sources
18. Analysis of Linked Registry Datasets
New Chapters – 3rd Edition

V. Special Applications in Patient Registries

19. Use of Registries in Product Safety Assessment
20. Rare Disease Registries
21. Pregnancy Registries
22. Quality Improvement Registries
23. Registries for Medical Devices
24. Public-Private Partnerships

VI. Evaluating Registries

25. Assessing Quality
Preview of New Chapters (5, 8, 9)

Chapter 5
Use of Patient-Reported Outcomes in Registries
- Discusses the role that PROs play in registries
- Addresses factors in selecting and using these types of measures

Chapter 8
Informed Consent for Patient Registries
- Discusses how informed consent for patient registries differs from that of clinical trials
- Offers suggestions for creating informed consent documents that address the unique aspects of registries

Chapter 9
Protection of Registry Data
- Reviews the legal protections available for data about providers, manufacturers, and health plans contained in registries
Preview of New Chapters (14, 17, 18)

Chapter 14
Modifying and Stopping Registries
- Examines the process of modifying an existing registry
- Reviews considerations for determining when to end a registry

Chapter 17
Managing Patient Identity across Data Sources
- Reviews the options and strategies for linking patient information stored in multiple databases without the use of full personal identifiers

Chapter 18
Analysis of Linked Registry Datasets
- Addresses issues that should be considered when analyzing combined or linked registry data
- Examines issues related to using registry data to support secondary research studies
Preview of New Chapters (20, 21, 22)

- **Chapter 20 (Rare Disease Registries)**
  - Discusses the increasing interest in using registries to study rare diseases.
  - Reviews the related challenges in design, recruitment, retention, and analysis.

- **Chapter 21 (Pregnancy Registries)**
  - Examines the value of registries for understanding the effects of medication used during pregnancy.
  - Discusses challenges related to design, recruitment, analysis, and dissemination of results.

- **Chapter 22 (Quality Improvement Registries)**
  - Examines the ability of registries to support efforts to improve quality of care through the use of specialized tools and reports.
Preview of New Chapters (23, 24)

Chapter 23
Registries for Medical Devices
- Addresses the unique aspects of medical devices that must be considered in the development and analysis of a device-based registry

Chapter 24
Public-Private Partnerships
- Provides a review of public-private partnership models for supporting registries
- Discusses major considerations for planning and operating a registry using this type of model
New Case Examples – 3rd Edition

• Case examples include:
  > 16 international registries
  > 8 medical device registries
  > 4 public-private partnerships
  > 6 rare disease registries
  > 9 quality improvement registries
  > 5 pregnancy registries… and more!

64 Examples total
34 New case examples
Polling Question

• Which topic areas in the 3rd edition of the Registries Guide are of most interest to you (select all that apply)?
  - Fundamentals of design, operation, and analysis
  - Evaluation criteria
  - Legal and ethical considerations
  - Data linkage
  - Public-private partnerships
  - Patient reported outcomes
  - Special applications for registries (quality improvement, pregnancy, rare diseases, medical devices)
  - Technology challenges (EHR integration, managing patient identities)
For more information…

Printed and electronic copies of the 3rd edition will be available in early 2014

Visit the AHRQ website for updates, to order a free printed copy, or to download the electronic version: effectivehealthcare.ahrq.gov

Other Questions?

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Thank you

Questions?