

Institute of Medicine Standards for Systematic Reviews

Christopher H Schmid
Tufts University

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Disclosures

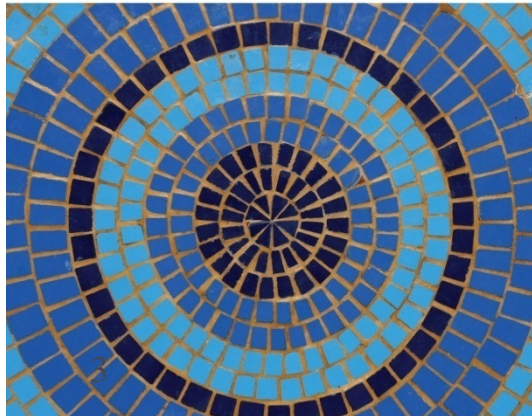
- ▶ Member of Tufts Evidence-Based Practice Center
- ▶ Member, External Advisory Board, ECRI
- ▶ Co-Convener, Cochrane Combining Multiple Interventions Methods Group
- ▶ Editor, *Research Synthesis Methods*
- ▶ Funded by Agency for Healthcare Research and Quality and Patient Centered Outcomes Research Institute (PCORI) for methodological and standards development of systematic reviews
- ▶ Member of IOM Committee on Standards for Systematic Reviews

Finding What Works in Health Care Standards for Systematic Reviews

Institute of Medicine (IOM)



STANDARDS FOR SYSTEMATIC REVIEWS



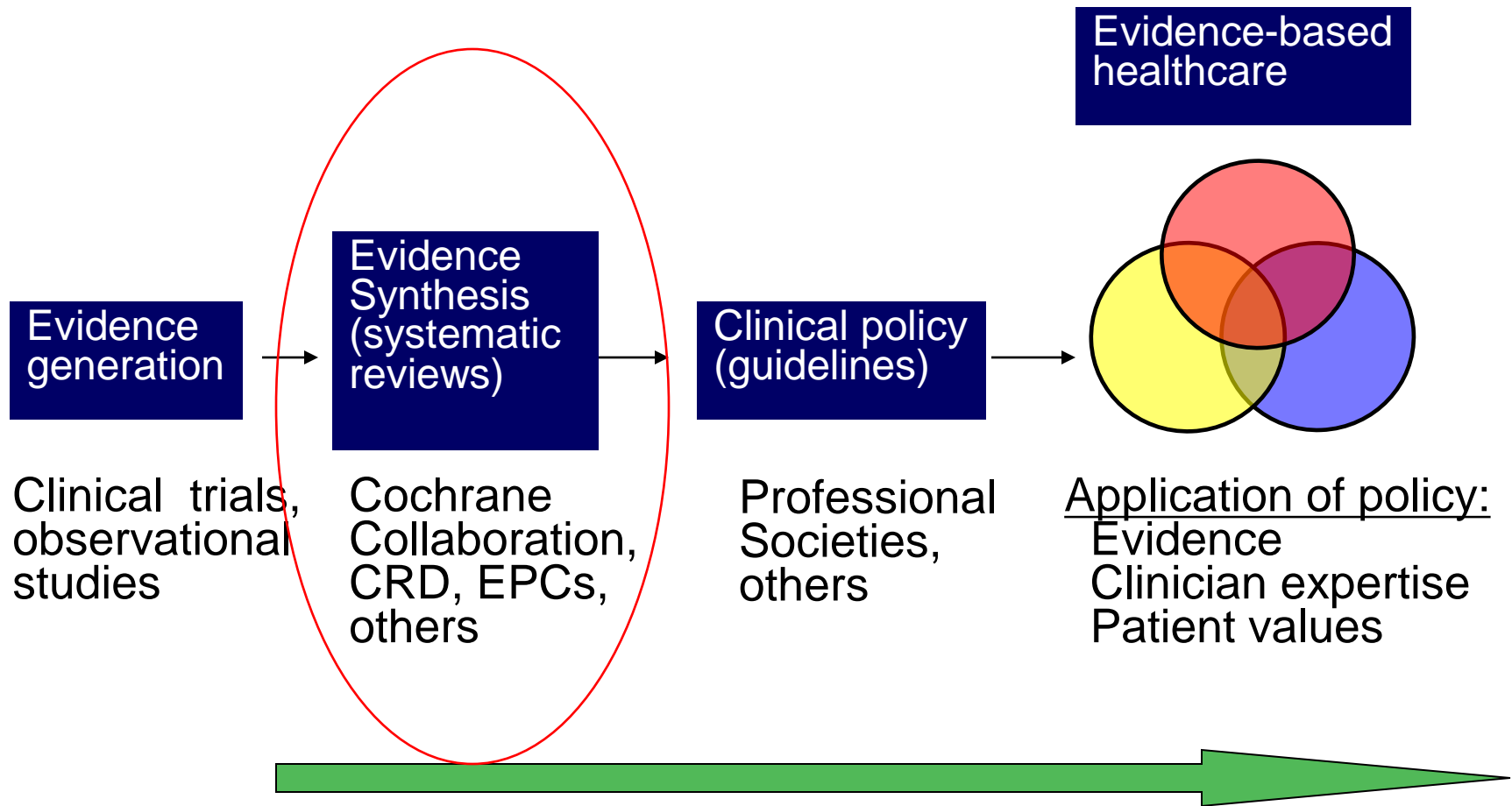
For more information about
the report please go to

www.iom.edu/srstandards

or

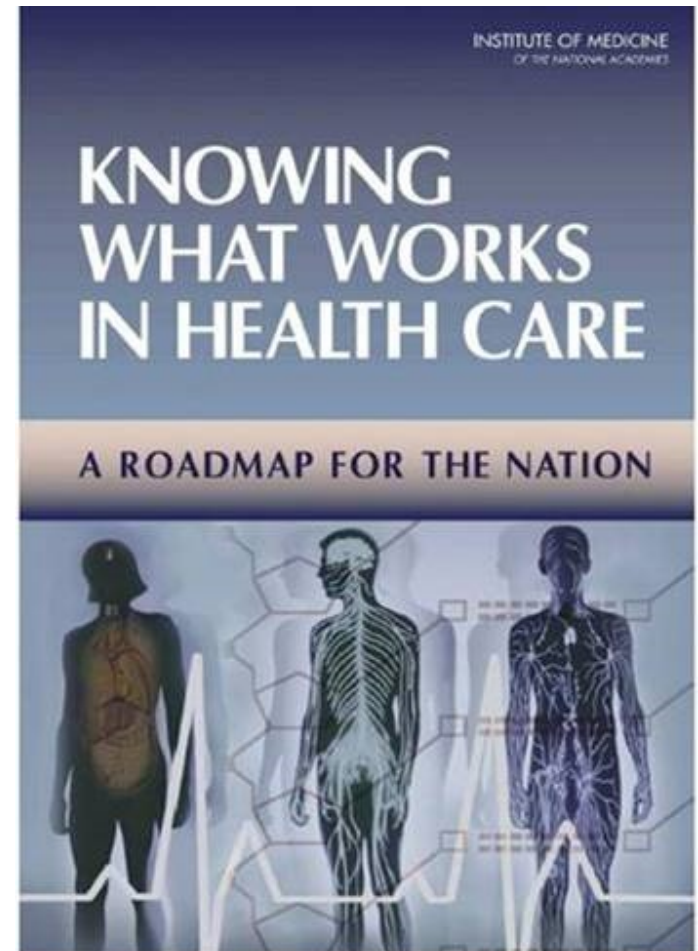
www.nap.edu

Knowledge translation: From clinical research to practice decisions



Background

- ▶ In 2008 IOM issued the report *Knowing What Works in Health Care: A Roadmap for the Nation*
 - ▶ Recommended that methodological standards for systematic reviews (SRs) and Clinical Practice Guidelines be set
 - ▶ Recommended new entity with authority to produce systematic reviews of comparative effectiveness
 - ▶ Set priorities, fund, manage systematic reviews
 - ▶ Develop common language and standards



Congressional Mandate

- ▶ IOM report followed by *Medicare Improvement for Patients and Providers Act of 2008* mandated two independent IOM studies:
 - ▶ Develop standards for conducting SRs
 - ▶ Develop standards for trustworthy CPGs
 - ▶ ...to ensure that SRs and CPGs “are objective, scientifically valid, and consistent.”
- ▶ IOM Committees formed in 2009
- ▶ Reports of the two committees were released together on March 22, 2011

IOM Definition of Comparative Effectiveness Research

- ▶ Generation and synthesis of evidence that compares benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve delivery of care
- ▶ Purpose is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels

Charge to IOM Committee on Standards for Systematic Reviews of Comparative Effectiveness Research

Recommend methodological standards for systematic reviews of comparative effectiveness research on health and health care

- Assess potential methodological standards that would assure objective, transparent, and scientifically valid systematic reviews of comparative effectiveness research
- Recommend a set of methodological standards for developing and reporting such systematic reviews

Patient-Centered Outcomes Research Institute (PCORI)

- ▶ US health care reform created nonprofit public/private Institute for establishing and implementing healthcare research agenda
 - Governing board includes NIH and AHRQ directors
- ▶ Methodology committee
 - Charged with developing and improving science and methods of CER
 - IOM report establishes blueprint for systematic review methods

Patient-Centered Outcomes Research Institute (PCORI)

- ▶ PCORI to award contracts to outside entities (including AHRQ and NIH) to manage funding and conduct research
 - Clinical trials, systematic reviews, observational studies (including patient registries)
 - Investigator-initiated research in methods development
- ▶ Identify and analyze national research priorities, evidence and gaps, relevance and economic effects

IOM Committee

- ▶ 15 Member committee
 - ▶ Doctors
 - ▶ Epidemiologists
 - ▶ Statisticians
 - ▶ Consumer advocates
 - ▶ Industry stakeholders
 - ▶ Healthcare organization stakeholders
 - ▶ Academic stakeholders

Some Background: What is a Systematic Review?

- Scientific investigation focusing on a specific question and using explicit, preplanned scientific methods to identify, select, assess, and summarize similar but separate studies
- May or may not include a quantitative synthesis of results from separate studies (meta-analysis)

Systematic reviews can be used to...

- Inform patient and clinician healthcare decision making
- Inform development of clinical practice guidelines
- Inform primary research agendas and funding by highlighting gaps in existing evidence

IOM Study Scope

Inside scope:

- Systematic reviews designed to inform everyday healthcare decision making, especially for patients, clinicians and other healthcare providers, and developers of clinical practice guidelines
- Publicly funded
- Therapeutic medical or surgical interventions

Outside scope:

- Academic systematic reviews
- Diagnostic tests, disease etiology or prognosis, systems improvement, or patient safety practices

Key Audiences for IOM Standards

- Agency for Healthcare Research and Quality Effective Health Care Program
- Patient-Centered Outcome Research Institute Methodology Committee
- Centers for Medicaid and Medicare Coverage Advisory Committee
- Drug Effectiveness Research Project
- National Institutes of Health
- Centers for Disease Control and Prevention
- U.S. Preventive Services Task Force.

Definition of a Standard

- ▶ A process, action, or procedure for performing systematic reviews that is deemed essential to producing scientifically valid, transparent, and reproducible results
- ▶ A standard may be supported by:
 - ▶ scientific evidence
 - ▶ reasonable expectation that standard helps achieve anticipated level of quality in a systematic review
 - ▶ broad acceptance of practice in systematic reviews

Balancing Report Objectives

- ▶ Intended audience: PCORI, groups funded by US Government to produce systematic reviews, those producing clinical practice guidelines
- ▶ Many constituencies to satisfy, including consumers
- ▶ National and international principles and practices (e.g., EPCs and Cochrane)
- ▶ Evidence should support standards set
- ▶ No mention of cost-effectiveness

Constituencies and IOM Processes to Obtain Cross-section of Stakeholder Perspectives

- ▶ Stakeholders
 - ▶ Producers of CPGs
 - ▶ Producers of US government evidence reports (mainly AHRQ)
 - ▶ Clinical professional societies
 - ▶ Consumer organizations
 - ▶ Healthcare payers
 - ▶ National and international users
- ▶ Open and closed meetings of IOM committee
- ▶ White papers commissioned for committee

Study Methodology

The committee developed its standards based on:

- Available research evidence
- Expert guidance from the:
 - ▶ AHRQ Effective Health Care program
 - ▶ The Centre for Reviews and Dissemination (U York, UK)
 - ▶ The Cochrane Collaboration
 - ▶ GRADE Working Group
 - ▶ PRISMA
- Committee's assessment criteria

Committee Assessment Criteria

- ▶ Acceptability (credibility)
- ▶ Applicability (generalizability)
- ▶ Efficiency
- ▶ Patient-centeredness
- ▶ Scientific rigor
- ▶ Timeliness
- ▶ Transparency

The Committee Recommended 21 Standards and 82 Elements of Performance

Elements of performance are essential components of a standard that should be followed for all publicly funded SRs of CER

Steps in Systematic Review Process

- ▶ Define objectives and identify necessary players to ensure user and stakeholder input
- ▶ Gather evidence
- ▶ Assess evidence
- ▶ Report evidence
- ▶ Describe future needs

8 Standards to Initiate Systematic Review Process

Encompass following elements:

- Establish team with appropriate expertise/experience in content, methods, searching
- Ensure user and stakeholder input
- Manage bias and conflict of interest
- Confirm need and formulate topic for review using analytic framework
- Develop protocol and submit for peer review

6 Standards to Find and Assess Individual Studies

Encompass following elements:

- Conduct up-to-date comprehensive systematic search with librarian using multiple databases
- Address potential biased reporting of results by searching unpublished sources and multiple languages contacting researchers and sponsors
- Screen and select studies using multiple screeners
- Document search precisely
- Extract data using standard forms and multiple extractors
- Critically appraise quality of individual studies for risk of bias, relevance of populations, interventions and outcomes; fidelity of implementation of interventions

4 Standards to Synthesize Body of Evidence

Encompass following elements:

- Assess body of evidence for risk of bias, consistency, precision, directness, reporting bias, dose-response, confounding, strength of association and level of confidence in estimates
- Conduct qualitative synthesis to describe characteristics of studies, strengths and limitations, flaws and relevance to questions posed
- Conduct quantitative analysis, if needed, to address heterogeneity, uncertainty and sensitivity of conclusions to study assumptions

Standard 4.4 If conducting a meta-analysis, then do the following

- ▶ Required elements
- ▶ 4.4.1 Use expert methodologists to develop, execute, and peer review the meta-analyses
- ▶ 4.4.2 Address the heterogeneity among study effects
- ▶ 4.4.3 Accompany all estimates with measures of statistical uncertainty
- ▶ 4.4.4 Assess the sensitivity of conclusions to changes in the protocol, assumptions, and study selection (sensitivity analysis)

3 Standards for Final Report

- Prepare final report using structured format (like PRISMA)
- Peer review draft report using third party
- Publish final report ensuring free public access

Changing Standards

The Standards must be considered provisional pending better empirical evidence about their scientific validity, feasibility, efficiency, and ultimate usefulness in medical decision making

Recommendations

1. Sponsors of SRs of CER should:
 - Adopt appropriate standards for the design, conduct, and reporting of SRs
 - Require adherence to the standards as a condition for funding
2. The Patient-Centered Outcomes Research Institute and the Department of Health and Human Services (HHS) agencies (directed by the secretary of HHS) should collaborate to improve the science and environment for SRs of CER.

Primary goals of this collaboration

- Develop training programs for researchers, users, consumers, and other stakeholders to encourage more effective and inclusive contributions to SRs of CER
- Systematically support research that advances the methods for designing and conducting SRs of CER
- Support research to improve the communication and use of SRs of CER in clinical decision making

Primary goals of this collaboration

- Develop effective coordination and collaboration between U.S. and international partners
- Develop a process to assure that standards for SRs of CER are regularly updated to reflect current best practice
- Use SRs to inform priorities and methods for primary CER