Opportunities and challenges of using systematic reviews to summarize knowledge about “what works” in disease prevention & health promotion

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NIH Office Of Disease Prevention
Rockville, Maryland
July 25, 2016

Kay Dickersin's declaration of interests

- Grants and contracts from agencies:
  - NIH-Cochrane Eyes and Vision
  - PCORI-Influence of multiple sources of data on meta-analysis
  - PCORI-Engagement of consumers
  - PCORI-Consumer Summit with G-I-N North America
  - AHRQ-Consumers United for Evidence-based Healthcare Conference Grant
  - FDA-Centers for Excellence in Regulatory Science Innovation (GC Alexander, PI)

Reviews are necessary in health and healthcare

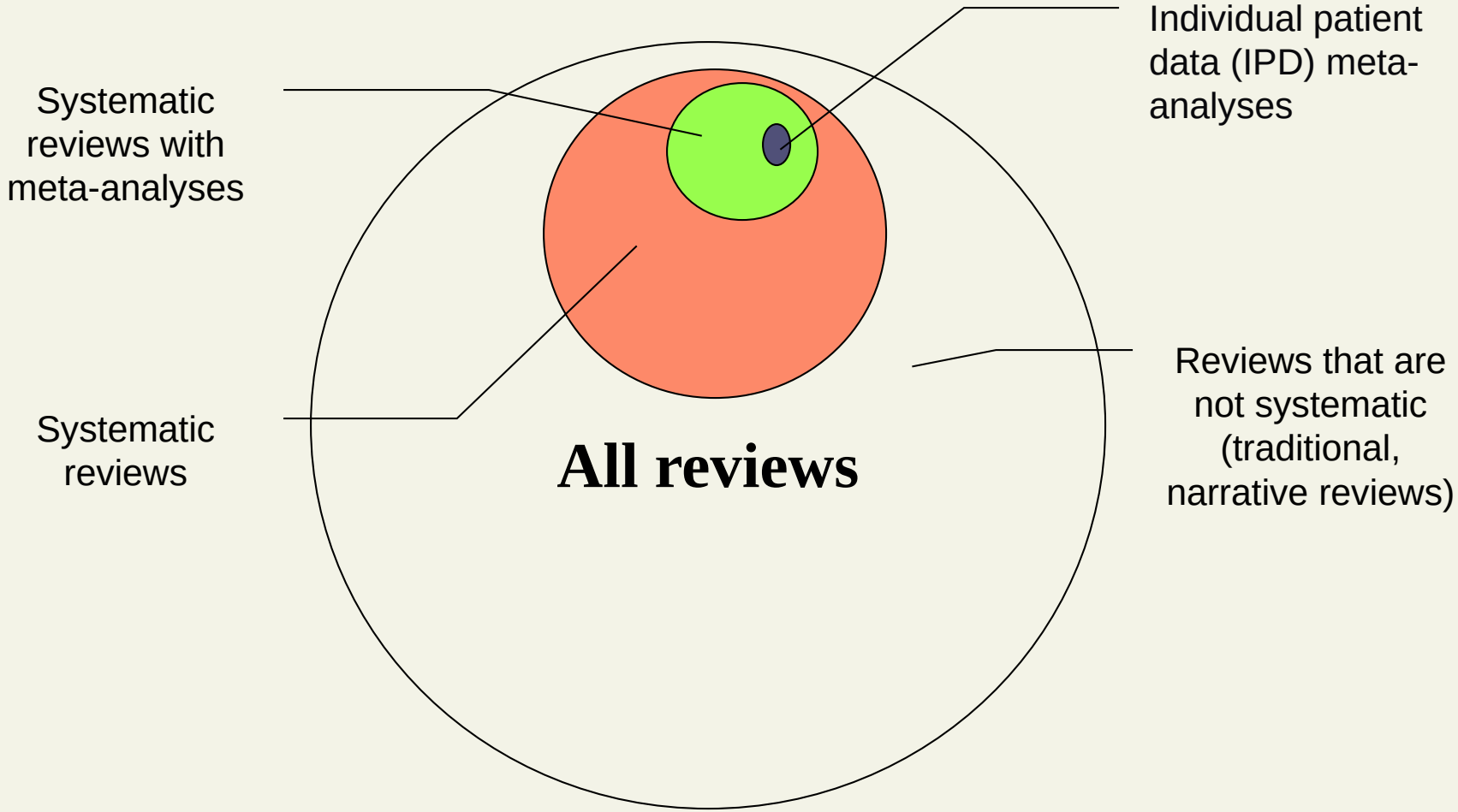
- Systematic reviews of existing research scientifically summarize “what works” at any point in time.
- Reasons for summarizing what works vary (e.g., understanding priorities for research, pursuing answers where there are knowledge gaps, or setting guidelines for care)

What is a systematic review?

- A review of existing knowledge that uses explicit, scientific methods.

- Systematic reviews may also combine results quantitatively (“meta-analysis”)

Types of review articles



Pai M, McCulloch M, Gorman JD, et al. Systematic reviews and meta-analyses: An illustrated, step-by-step guide. *Natl Med J India* 2004;17(2):86-95.

Steps in a systematic review

Step 1 – Gather together your team (content and methods experts)

Step 2 - Write a protocol

- Question, eligibility criteria, search, data abstraction, quality assessment, qualitative and quantitative (if appropriate) synthesis

Step 3 – Collect data (search)

Step 4 – Appraise

Step 4 – Synthesize (qualitative)

Step 6 – Analyze (quantitative)

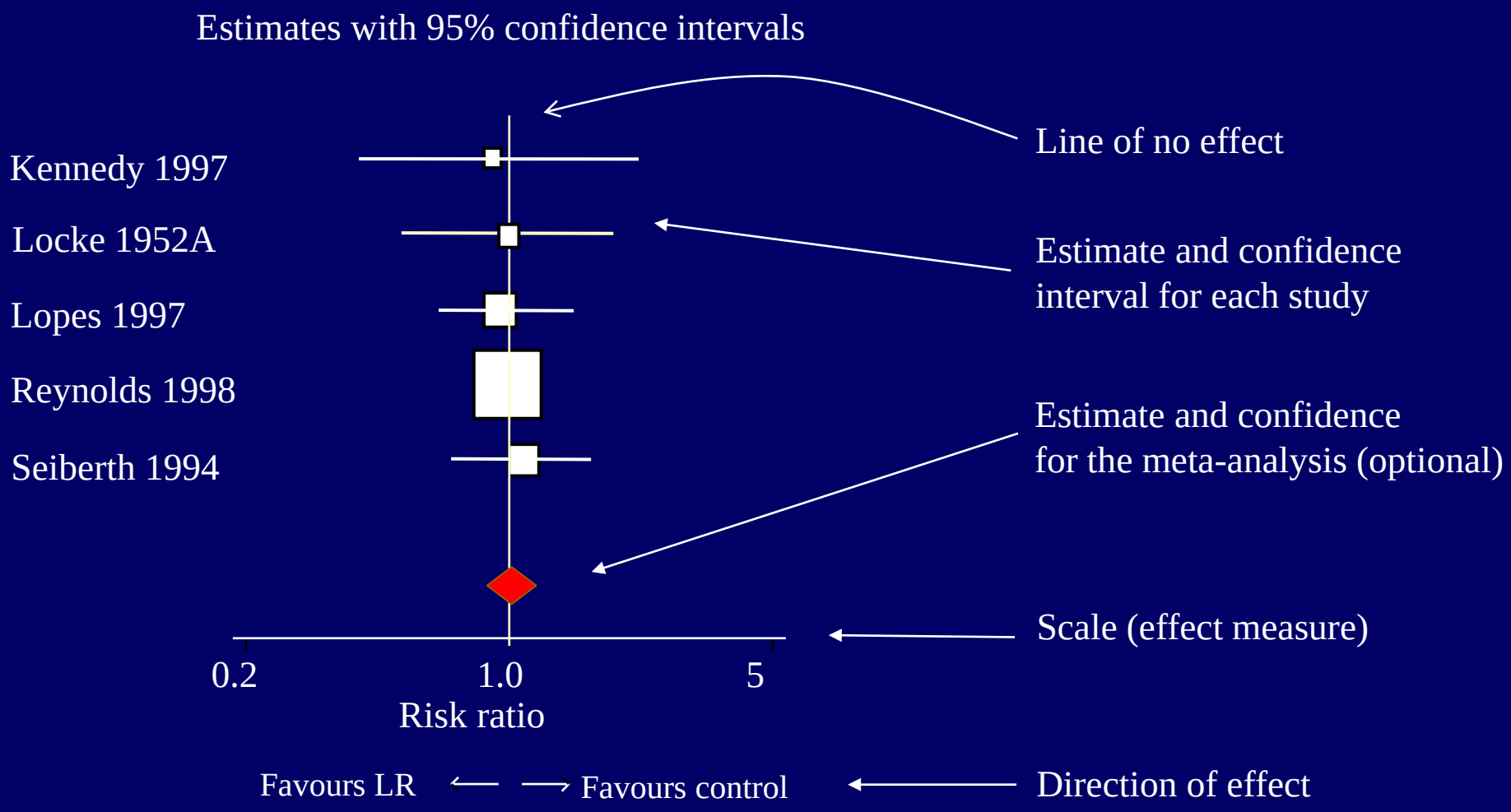
Step 5 – Interpret data and assess limitations

Step 6 – Update review

What meta-analysis can help you do

- Assess strength of evidence
  - To determine whether an effect exists in a particular direction
- Combine results quantitatively
  - To obtain a single summary result
- Investigate heterogeneity
  - To examine reasons for different results among studies

Presentation of a meta-analysis: the forest plot



Many reports summarizing knowledge are “reviews”, but are they systematic reviews?

Human Molecular Genetics, 2014, Vol. 23, No. 12 **3343–3348**
doi:10.1093/hmg/ddu050
Advance Access published on February 11, 2014

A genome-wide association study of intra-ocular pressure suggests a novel association in the gene *FAM125B* in the TwinsUK cohort

Abhishek Nag[1], Cristina Venturini[2], Kerrin S. Small[1], International Glaucoma Genetics Consortium[†], Terri L. Young[3], Ananth C. Viswanathan[4], David A. Mackey[5], Pirro G. Hysi[1]

Glaucoma is a major cause of blindness in the world. To date, common genetic variants associated with glaucoma only explain a small proportion of its heritability. We performed a genome-wide association study of intra-ocular pressure (IOP), an underlying endophenotype for glaucoma. The discovery phase of the study was carried out in the TwinsUK cohort ($N = 2774$) analyzing association between IOP and single nucleotide polymorphisms (SNPs) imputed to HapMap2. The results were validated in 12 independent replication cohorts of European ancestry (combined $N = 22\,789$) that were a part of the International Glaucoma Genetics Consortium. Expression quantitative trait locus (eQTL) analyses of the significantly associated SNPs were performed using data from the Multiple Tissue Human Expression Resource (MuTHER) Study. In the TwinsUK cohort, IOP was significantly associated with a number of SNPs at 9q33.3 ($P = 3.48 \times 10^{-8}$ for rs2286885, the most significantly associated SNP at this locus), within the genomic sequence of the *FAM125B* gene. Independent replication in a composite panel of 12 cohorts revealed consistent direction of effect and significant association ($P = 0.003$, for fixed-effect meta-analysis). Suggestive evidence for an eQTL effect of rs2286885 was observed for one of the probes targeting the coding region of the *FAM125B* gene. This gene codes for a component of a membrane complex involved in vesicular trafficking process, a function similar to that of the Caveolin genes (*CAV1* and *CAV2*) which have previously been associated with primary open-angle glaucoma. This study suggests a novel association between SNPs in *FAM125B* and IOP in the TwinsUK cohort, though further studies to elucidate the functional role of this gene in glaucoma are necessary.

This article reports a meta-analysis. Is it a systematic review?

Why bother with a systematic review?

Many nonsystematic methods are used to synthesize knowledge; most use fewer resources, and in a given field experts believe they know the literature sufficiently to avoid the investment. For example:

- Integrative review
- Realist review
- Narrative review
- Scoping review
- Mixed methods review
- Rapid review

M. Dijkers *KT Update* (Vol. 4, No. 1 – December 2015) [http://ktdrr.org/products/update/v4n1]

Many ways of summarizing what is known

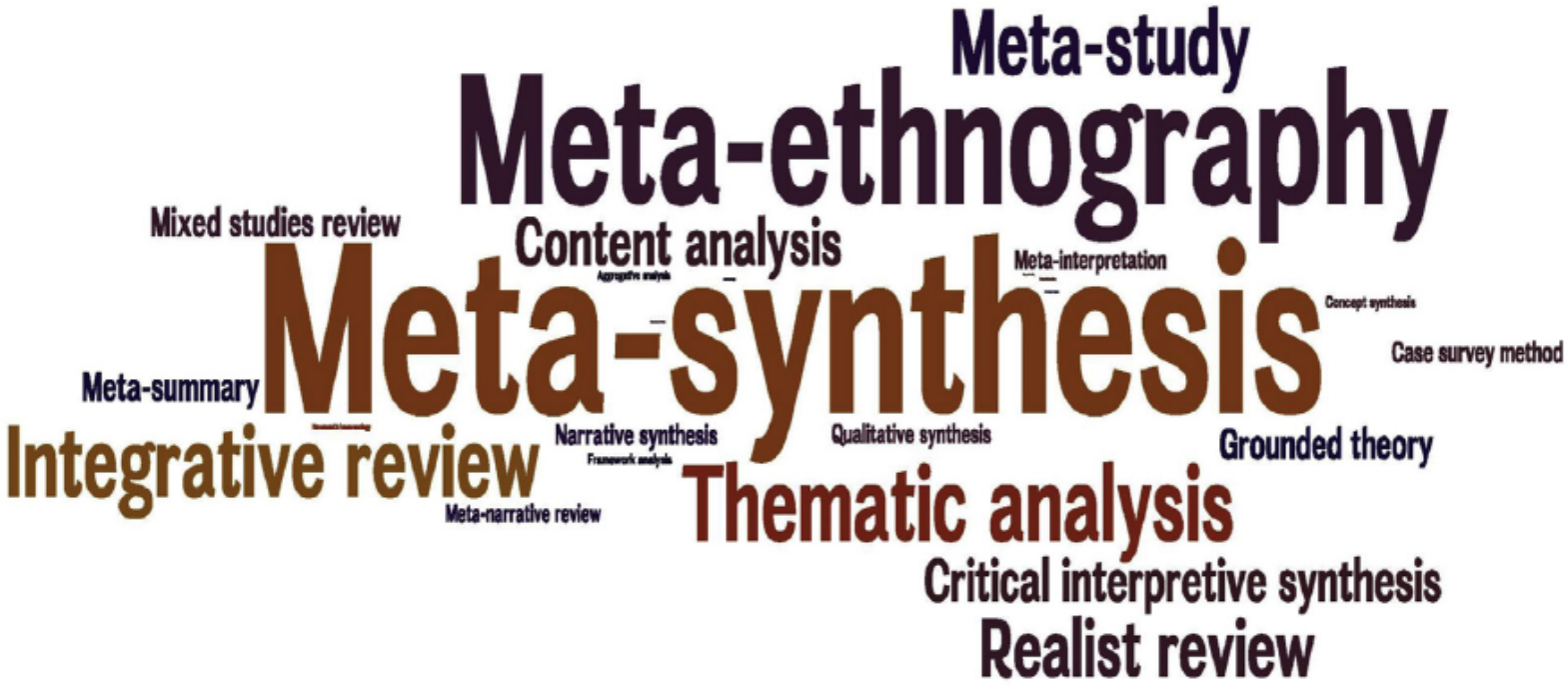


Fig. 2. Word cloud for most frequent knowledge synthesis methods.

2016 Tricco et al J Clin Epi 73: 19e28

There are published standards on how to conduct and how to report a systematic review

Methodological Expectations of Cochrane Intervention Reviews (MECIR)

Methodological standards for the conduct of new Cochrane Intervention Reviews

Version 2.3, 02 December 2013

Jackie Chandler, Rachel Churchill, Julian Higgins, Toby Lasserson and David Tovey

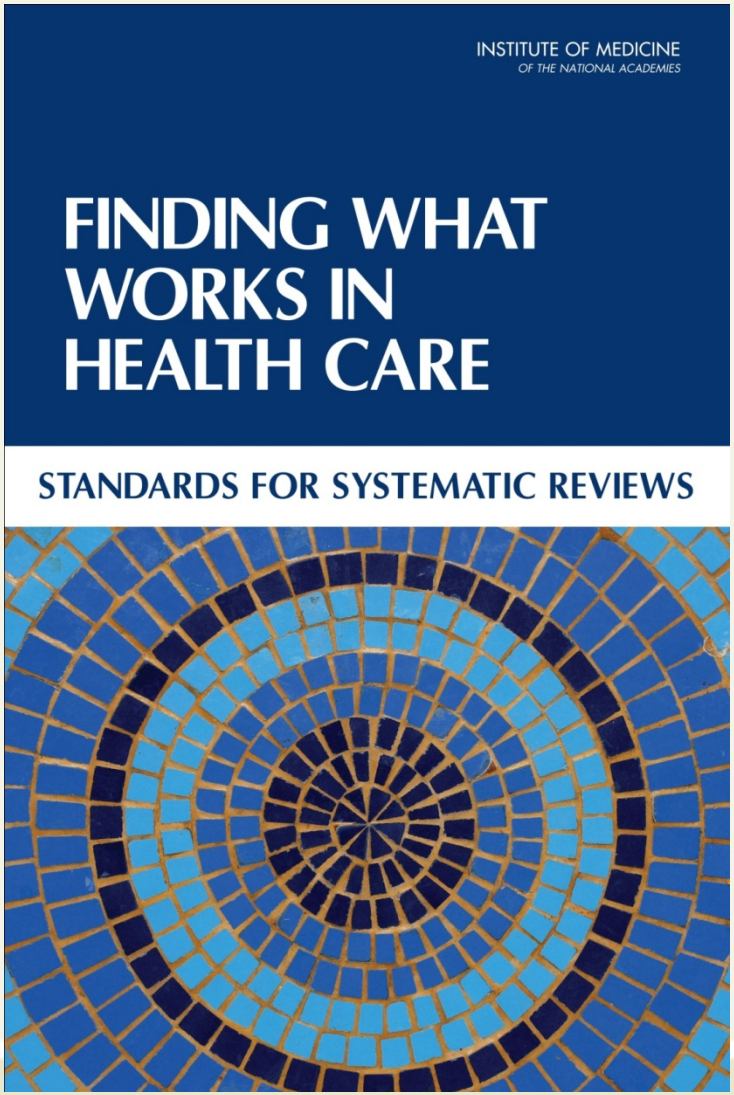
Cochrane Library

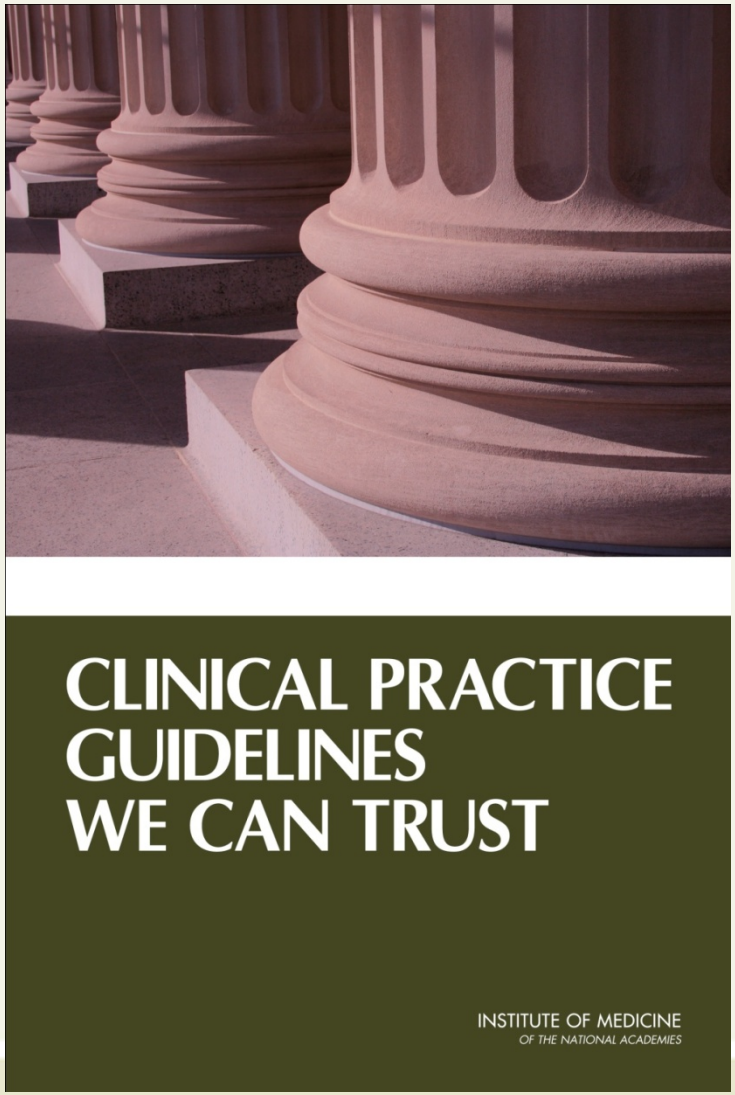
Cochrane Database of Systematic Reviews

Vitamin A supplementation during pregnancy for maternal and newborn outcomes (Review)

McCauley ME, van den Broek N, Dou L, Othman M

IOM - Standards for Systematic Reviews and Guidelines





Why bother with doing or commissioning a systematic review?

What would you feel is acceptable to omit?

Steps in a systematic review

Step 1 – Gather together your team (content and methods experts)

Step 2 - Write a protocol

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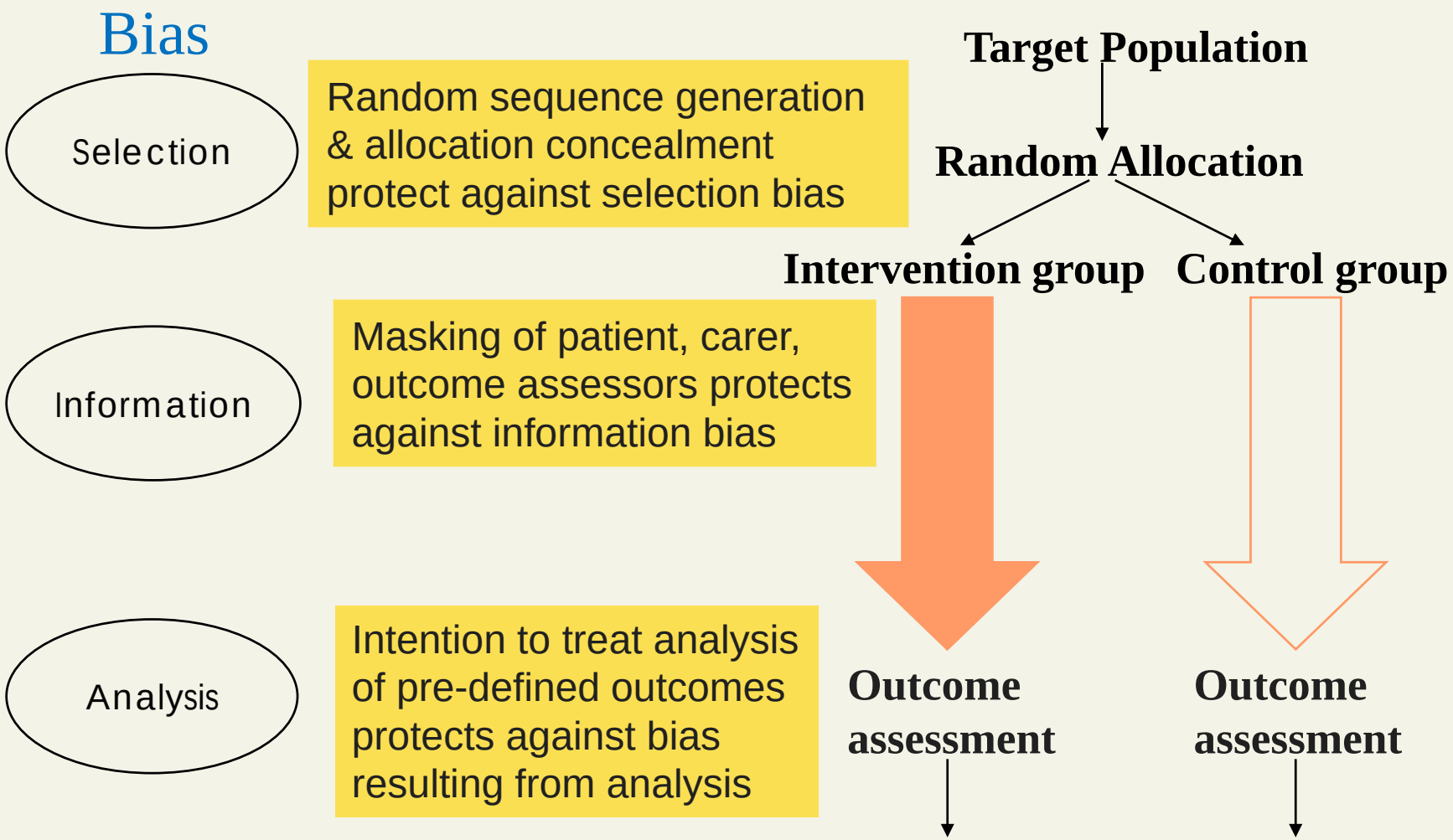
Risk of bias in systematic reviews

- **Bias in the methods used in the included studies**
- Bias in the methods used in the systematic review

Sources of bias in an RCT



Methodological quality of observational studies

- Selection bias
  - Definitions of exposed/unexposed
  - Choice of cases/controls
- Information bias
  - Definition exposure
  - Definition outcome
  - How information obtained
- Analysis

A Cochrane Risk Of Bias Assessment Tool: for Non-Randomized Studies of Interventions (ACROBAT-NRSI)

Edited by Jonathan AC Sterne, Julian PT Higgins and Barney C Reeves
on behalf of the development group for ACROBAT-NRSI

Version 1.0.0, 24 September 2014

Risk of bias in systematic reviews

- Bias in the methods used in the included studies
- **Bias in the methods used in the systematic review (metabias)**

Annals of Internal Medicine | EDITORIAL

Metabias: A Challenge for Comparative Effectiveness Research

Comparative effectiveness research encompasses both individual primary research studies and syntheses of the primary research, typically systematic reviews and meta-analyses. Before accepting the results of either form of study, decision makers must critically assess their methods to identify sources of potential bias.

For primary research, critical appraisal involves close examination of research methods, including design, data, execution, analysis, and interpretation. For meta-analyses, individual studies are examined in the same way, but the collection of studies is also examined for heterogeneity. Studies are deemed heterogeneous if their methods or results differ from one another so much that the studies cannot be regarded as addressing the same scientific question. Factors that produce heterogeneity are typically not regarded as producers of bias, but rather of differences in effect due to variations in populations, interventions, comparisons, outcomes, or settings. Although heterogeneity is related to the characteristics of the individual studies, it is

research have led to heightened concern about these studies, both from journals and systematic reviewers (8–10). This has led some to explore whether industry sponsorship by itself should be considered a bias, or by our criteria, a metabias (11–13).

Reporting biases can be regarded as a mix of procedural biases for individual studies and metabiases. They often elude detection through even the closest examination of an individual study report. They can be found only by comparing study protocols with a published study report or tracking ultimate publication status of an inception cohort of studies. Governments, funders, and the research community have responded to this recognized threat to validity. The most far-reaching remedy to date has been clinical trial registries (14–16). These registries, together with mandates from funders to register trials and protocols before trial onset, allow persons conducting evidence syntheses to detect nonpublication or deviations from prespecified plans for study conduct or analysis (17, 18).

Reporting biases - our biggest challenge in doing a systematic review

Reporting biases introduce selection bias into a systematic review

- Publication bias - unpublished studies have different results from published studies
- Selective outcome reporting – unpublished outcomes have different results from published outcomes
  - Selective reporting of an entire study outcome (e.g., adverse events);
  - Selective reporting of a specific outcome (e.g., selected timepoints or follow-up intervals),
  - Incomplete reporting of a specific outcome (e.g., incomplete reporting of nonsignificant p values, such as p>0.05).

Sources of trial information

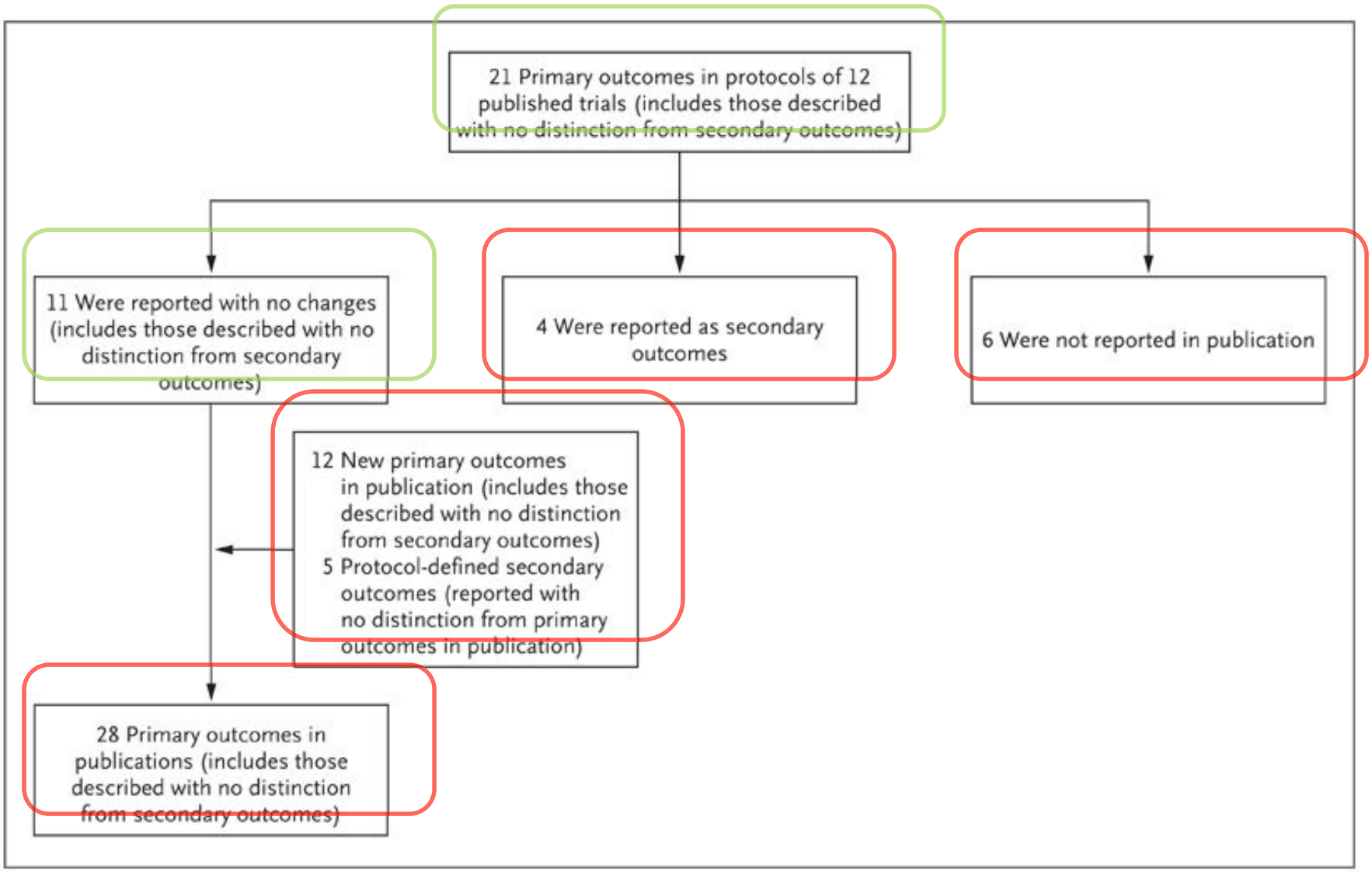
- **Public**
  - Short report (e.g., conference abstract)
  - Journal article (about one or more trials)
  - Results on trial registry (e.g. ClinicalTrials.gov)
  - Information from regulators (e.g. FDA review, label)
  - Trial registration (e.g. ClinicalTrials.gov)
  - Study protocol / statistical analysis plan (e.g., PROSPERO)
- **Non-public (hidden)**
  - Unpublished manuscript (e.g. clinical study report)
  - Individual participant data
  - Grant proposal
  - IRB submission
  - Case report form
  - Metadata (e.g., codebooks, memos)

The Neurontin Story: Selective outcome reporting

- Recognizing that Neurontin earnings were limited with epilepsy, Pfizer did marketing assessment for other applications:
  - Migraine
  - Bipolar disorders
  - Neuropathic pain
  - Nociceptive pain
- Marketing assessments uniformly recommended a "publication strategy" over an "indication strategy"

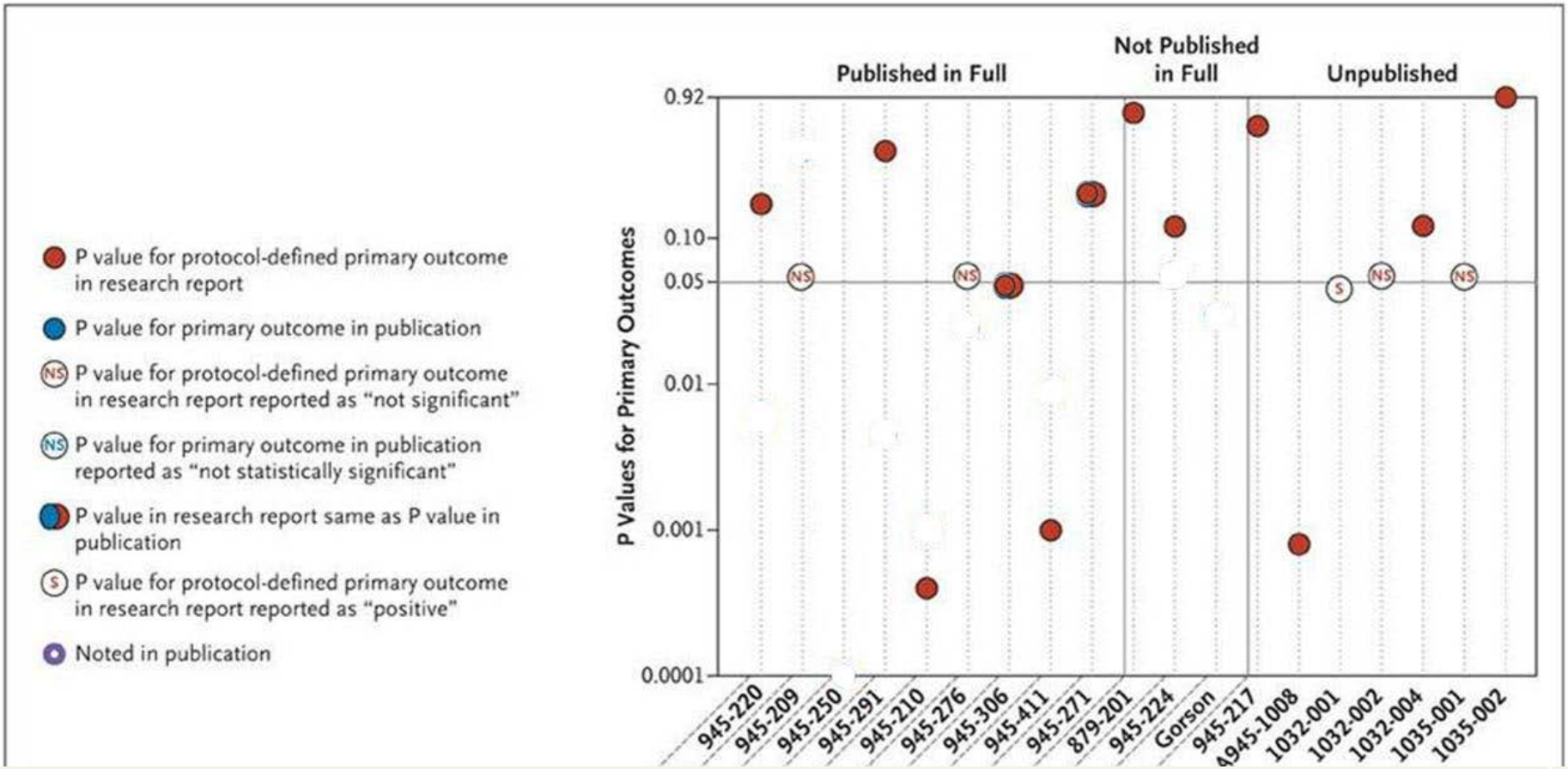
Vedula SS et al. N Engl J Med 2009;361:1963-1971

Number of primary outcomes in research protocols and published reports for 12 clinical trials of off-label uses of gabapentin (bipolar, migraine, neuropathic pain)



Vedula SS et al. N Engl J Med 2009;361:1963-1971

P Values for Protocol-Defined Primary Outcome in Internal Research Report and in Main Publication



Vedula SS et al. N Engl J Med 2009;361:1963-1971

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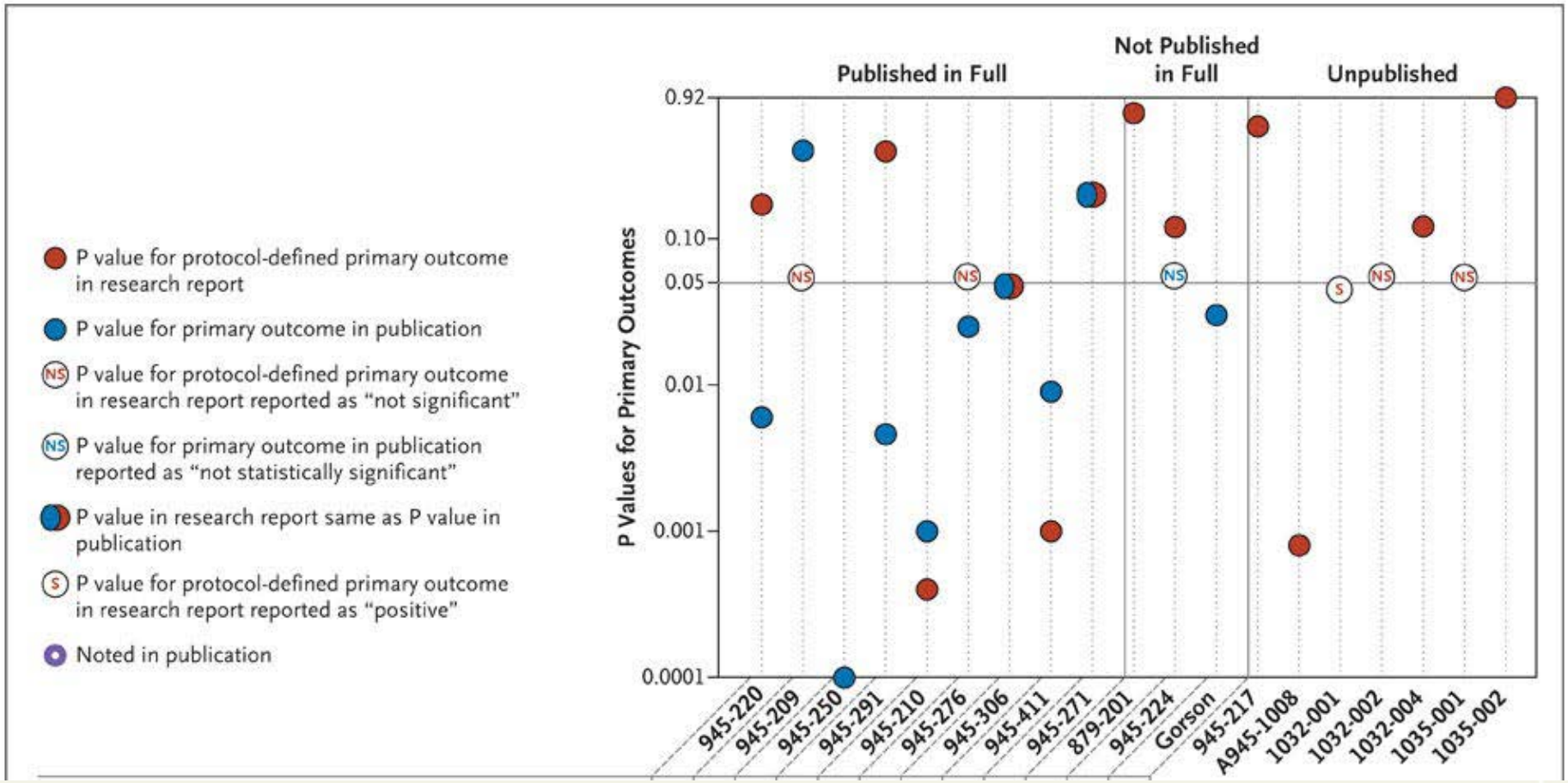
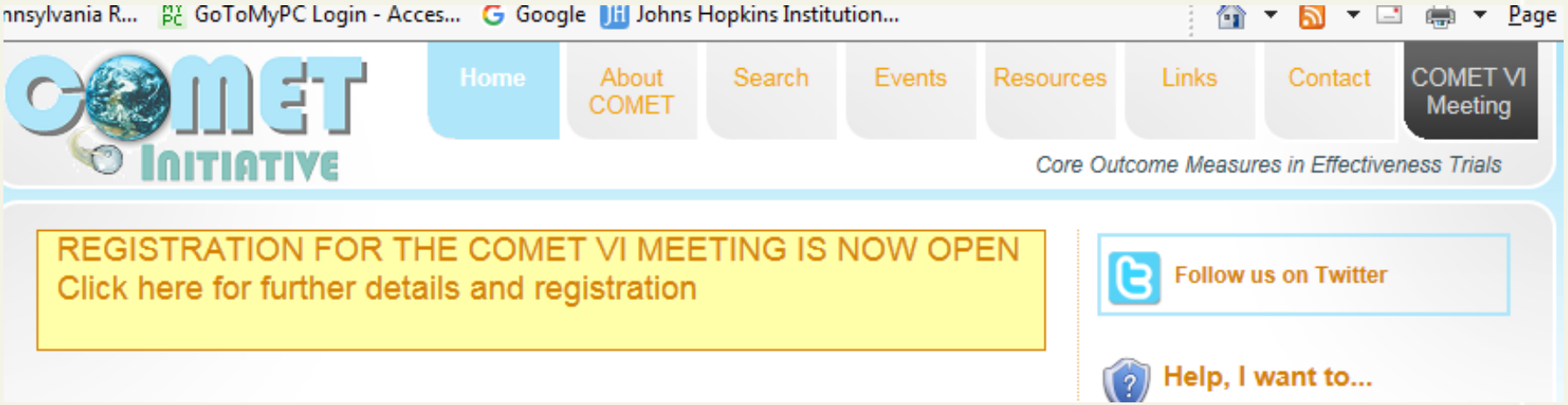
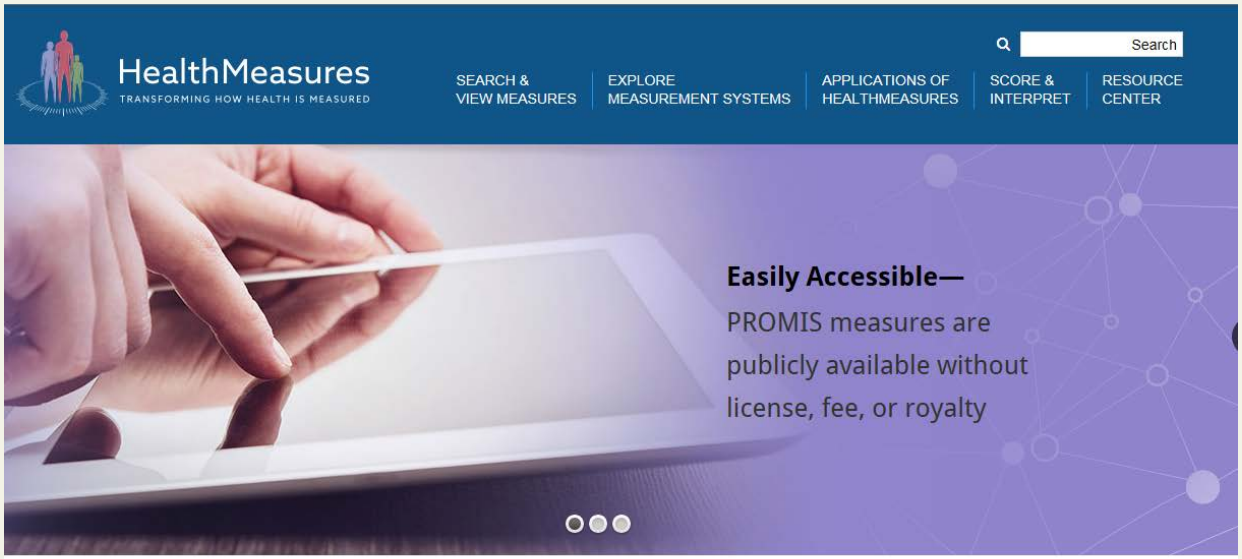


Vedula SS et al. N Engl J Med 2009;361:1963-1971

Development of core outcome measures could help

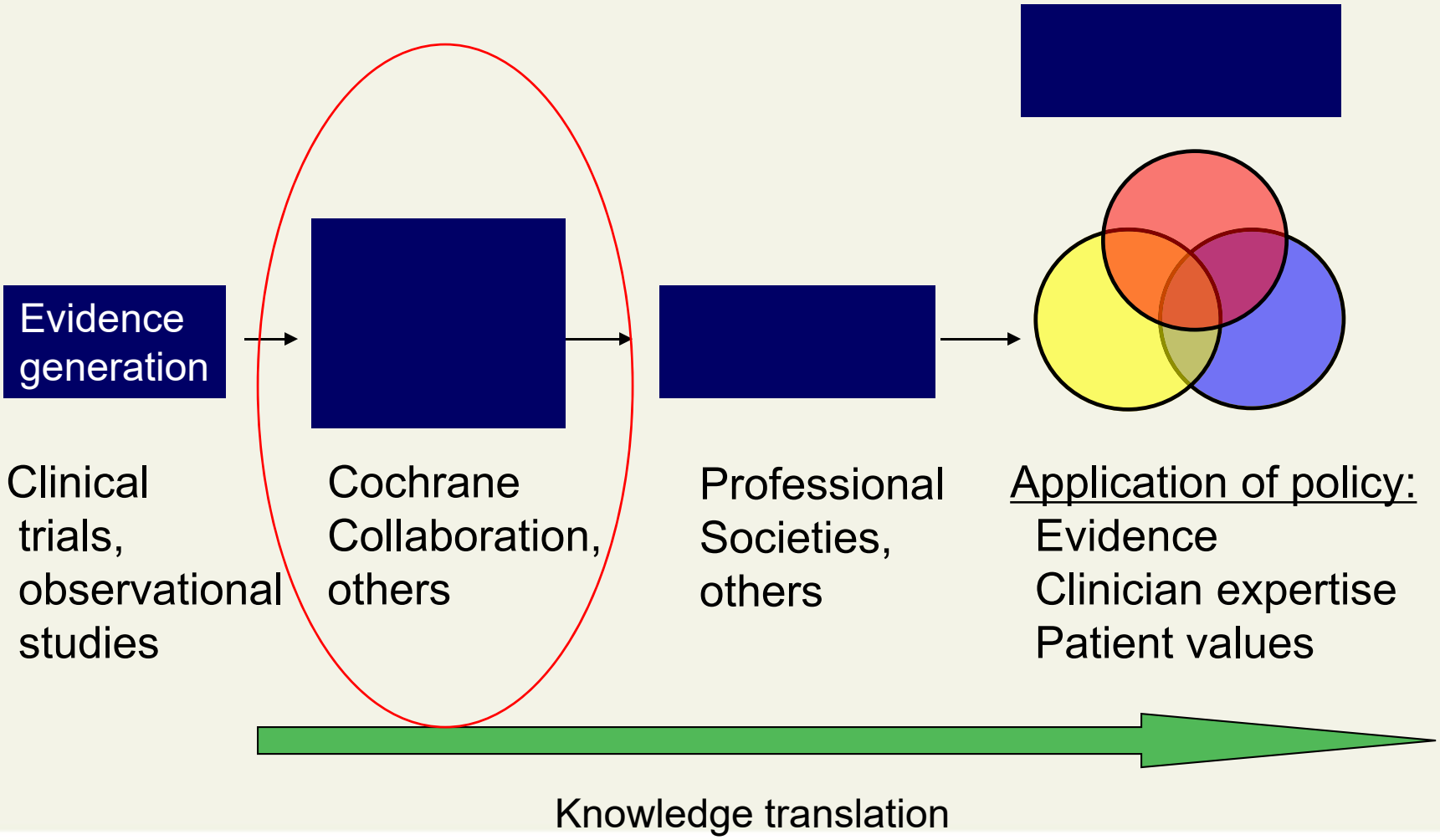




Who is doing systematic reviews?

- Independent authors
- Cochrane Collaboration
- Groups interested in policy (professional societies, governments, payers)
  - US: US Preventive Services Task Force, CDC, AHRQ, EPCs, Blue Cross
  - UK: NICE, Health Technology Assessments
  - Germany: IQWiG
  - Oz: NHMRC
- Funders (next slide)
- Businesses: Hayes, ECRI (contracting to pharma and others)

Knowledge translation:
From clinical research to practice decisions



Do funders require applicants (primary research) to refer to systematic reviews of existing evidence?

NIHR (UK)	**Yes** – It only funds research with a systematic review of existing evidence.
NHMRC (Australia)	**No**
CIHR (Canada)	**Partial** - It encourages (but does not require) conduct of a systematic review in proposals for clinical trials.
NIH (US)	**Partial** - It encourages a 'check of the literature to verify that the proposed project has not been done before', but it doesn't specify whether it has to be a systematic review.
MRC (UK)	**No** - The major grant opportunities do not require a systematic review; the global health clinical trial programme encourages the conduct of a systematic review before request for large-scale clinical trials.

Systematic review of prevalence Baral 2007

OPEN ACCESS Freely available online

PLOS MEDICINE

Elevated Risk for HIV Infection among Men Who Have Sex with M Countries 2000–

Stefan Baral[1,2,3], **Frangiscos Sifakis**[1,2], **F**

1 Department of Epidemiology, Johns Hopkins Bloombe
Rights, Johns Hopkins Bloomberg School of Public Healt
Toronto, Ontario, Canada, **4** Constella Futures Group, Wa

Funding: Publication costs were offset by a Center for Public Health and Human Rights (CPHHR) operating grant. The source of funding did not play a role in the design of the study, analysis of the data, writing of the manuscript, or the decision to submit for publication.

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Dec 1, 2007 (publication date) through Jan 23, 2013*

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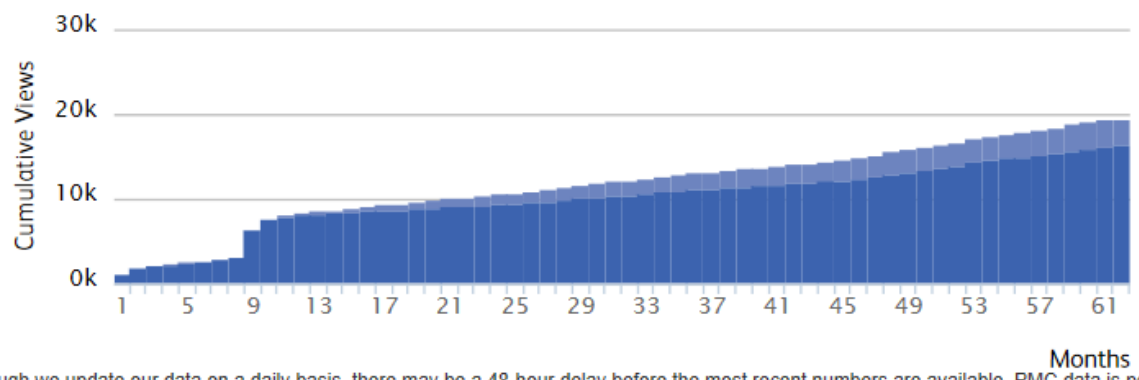


*Although we update our data on a daily basis, there may be a 48-hour delay before the most recent numbers are available. PMC data is posted on a monthly basis and will be made available once received.

Systematic review of possible etiologic association Flegal 2013

Association of All-Cause Mortality With Overweight and Obesity Using Standard Body Mass Index Categories

A Systematic Review and Meta-analysis

Katherine M. Flegal, PhD
Brian K. Kit, MD
Heather Orpana, PhD
Barry I. Graubard, PhD

Importance Estimates of the relative mortality risks associated with normal weight, overweight, and obesity may help to inform decision making in the clinical setting.

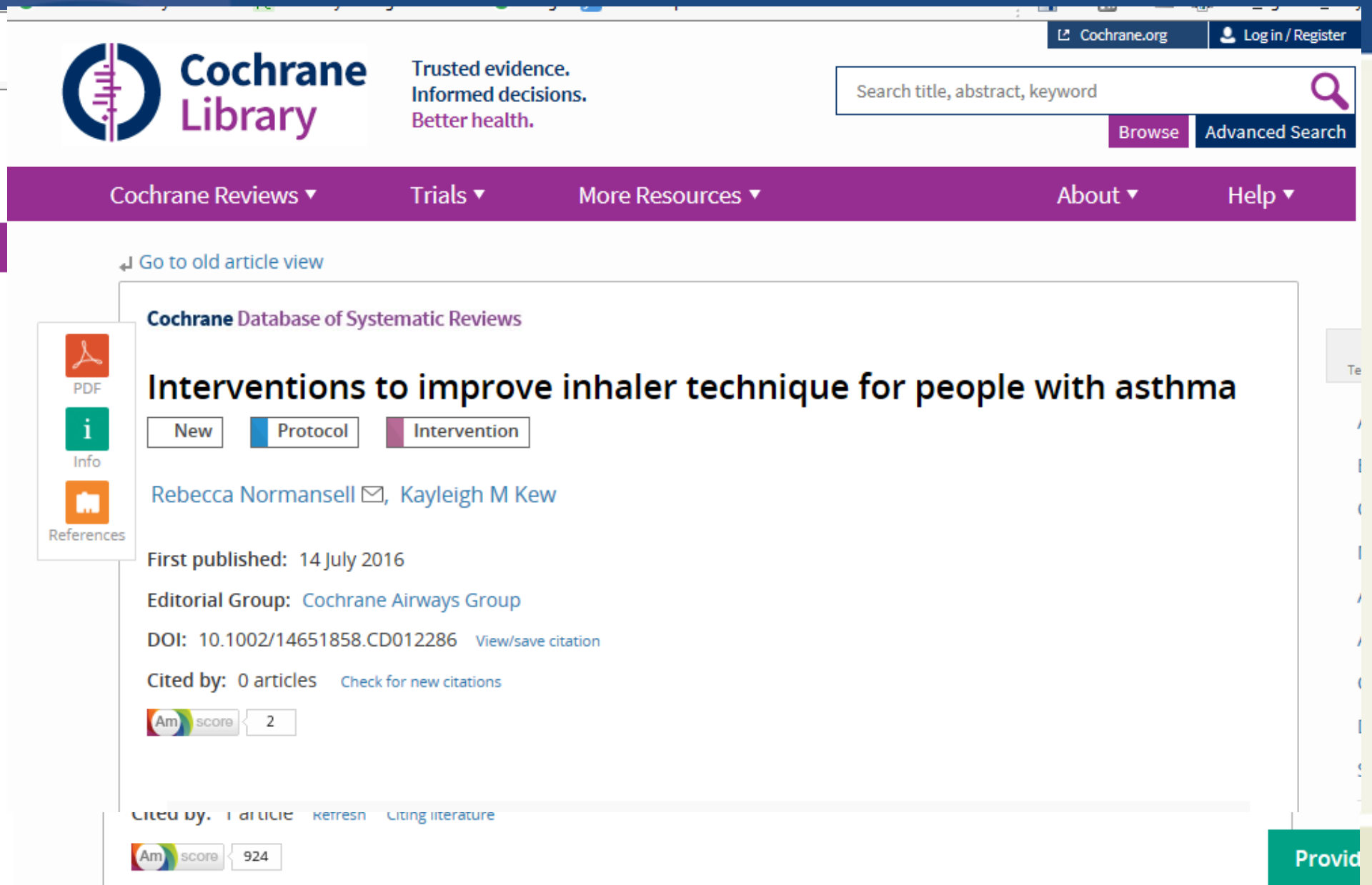
Objective To perform a systematic review of reported hazard ratios (HRs) of all-cause mortality for overweight and obesity relative to normal weight in the general population.

Data Sources PubMed and EMBASE electronic databases were searched through September 30, 2012, without language restrictions.

Study Selection Articles that reported HRs for all-cause mortality using standard body mass index (BMI) categories from prospective studies of general populations of adults were

THE TOPIC OF THE MORTALITY differences between weight categories has sometimes been described as controversial.[1] The appearance of controversy

www.thecochranelibrary.com



http://www.campbellcollaboration.org/library.php

The Campbell Collaboration Library of Systematic Reviews
The Campbell Library

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Published: 01.07.2016
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The Guide to Community Preventive Services
THE COMMUNITY GUIDE
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Community Preventive Services Task Force

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School-Based Health Centers Publications Now Available

New publications feature the effectiveness and economic evidence as well as the Task Force recommendation for school-based health centers in low-income communities.

1 2 3 4

Task Force

2016 Meetings
October 26–27

2017 Meetings

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Text Size: S M L XL

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Adolescent Health	Diabetes	Motor Vehicle Injury	Social Environment
Alcohol - Excessive Consumption	Emergency Preparedness	Nutrition	Tobacco
Asthma	Health Communication	Obesity	Vaccination
Birth Defects	Health Equity	Oral Health	Violence
Cancer	HIV/AIDS, STIs, Pregnancy	Physical Activity	Worksite
Cardiovascular Disease	Mental Health		

Check out the new The Community Guide in BETA now!

Take a look!

What is The Community Guide?

The Guide to Community Preventive Services is a free resource to help you choose programs and policies to improve health and prevent disease in your community. Systematic reviews are used to answer these

http://ies.ed.gov/ncee/wwc/

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The EPA's IRIS Program is using systematic reviews

U.S. ENVIRONMENTAL PROTECTION AGENCY

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IRIS Process

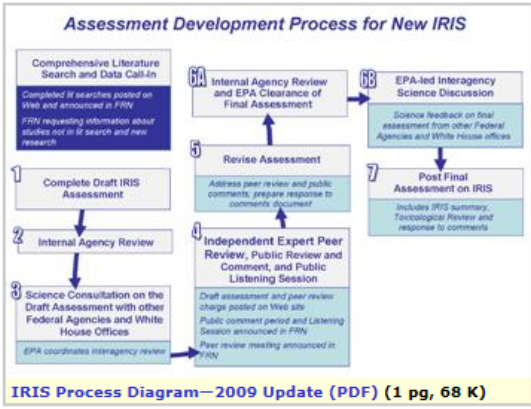
Notice

[11/12] EPA announced a public stakeholders meeting to hear comments on the IRIS Process and Program.

[07/11] EPA announced further improvements to the current IRIS process. July 12, 2011 Press Release.

[05/09] EPA released an update to the IRIS Process. May 21, 2009 Press Release.

The IRIS process consists of the development of a draft Toxicological Review for a chemical; internal and external scientific reviews of the draft document; EPA responses to review comments; and development and posting of an IRIS Summary and final Toxicological Review to EPA's web site. EPA announced revisions to the IRIS process in May 2009 and further revisions in 2011.



IRIS Process Diagram—2009 Update (PDF) (1 pg, 68 K)

2012 Updates

On June 5, 2012, EPA released an IRIS Progress Report to Congress. This report, delivered to Congress on April 20, 2012, provides Congress, stakeholders, and the public with an update on the IRIS Program and EPA's progress toward implementing the recommendations from the National Research Council (NRC), received in April 2011, for improving the development of IRIS assessments.

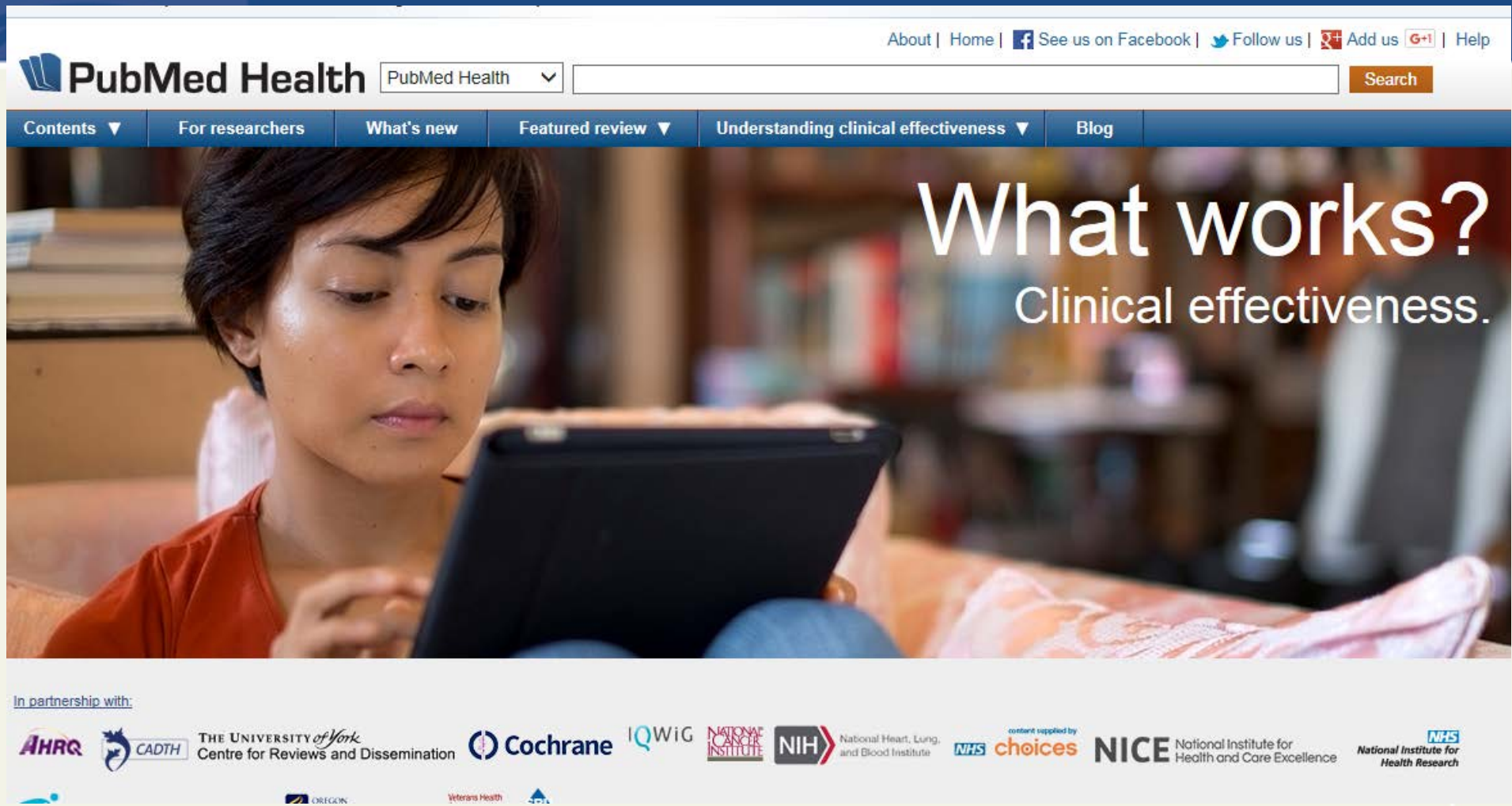
IRIS 2012 Progress Report to Congress

- IRIS Progress Report to Congress – June 2012 (PDF) (29 pp, 1.34MB, about PDF)
- Fact Sheet: Path Forward for IRIS - 2012 (PDF) (2 pp, 54.8 KB, about PDF)
- IRIS Blog post by Becki Clark (Acting Center Director) May 2012

Who is using SRs?

- Clinicians – Underuse and inappropriate use of interventions, prognosis, etiology
- Public health practitioners – Health policy
- Government – Policy (eg, environmental exposures)
- Guidelines producers – Health and healthcare
- Epidemiologists – Incidence, prevalence, etiology
- Payers, purchasers – Especially new health technologies
- Consumers – Appropriate interventions
- Legislators - Public health policy
- Journalists – New results in context
- Educators – Implementation of what works

http://www.ncbi.nlm.nih.gov/pubmedhealth/



Ensuring the quality of published systematic reviews

Ophthalmology

American Academy of Ophthalmology
The Eye M.D. Association

Cochrane Eyes and Vision

Trusted evidence.
Informed decisions.
Better health.

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Associate Editors at Eyes and Vision Journals

- UK Editorial Base
- US Satellite
- Italian DTA Satellite
- CEV Centers for Evidence-Based Medicine
- Our contributors
- Our partnerships
  - Associate Editors at Eyes and Vision Journals
  - Peer Review Training at Eyes and Vision Journals
- Funding and support

We have established partnerships with five major eye journals, whereby a CEV methodologist serves as an editor for systematic reviews at that journal.

The goal of these partnerships is to increase the quality of systematic reviews published in traditional journals so that the evidence base for clinical practice and clinical practice guidelines is as strong as possible. The model was put in place January 2011, when the Ophthalmology Editor-in-Chief named Dr.Tianjing Li as Associate Editor for Systematic Reviews. The Editor-in-Chief (currently Dr. George Bartley) and Dr. Li developed guidance for authors submitting such manuscripts, and have instituted new quality standards. Similar agreements have now been reached with the American Journal of Ophthalmology, Eye, and Optometry and Vision Science.

Augusto Azuara-Blanco - *Eye*

Tianjing Li - *Ophthalmology*

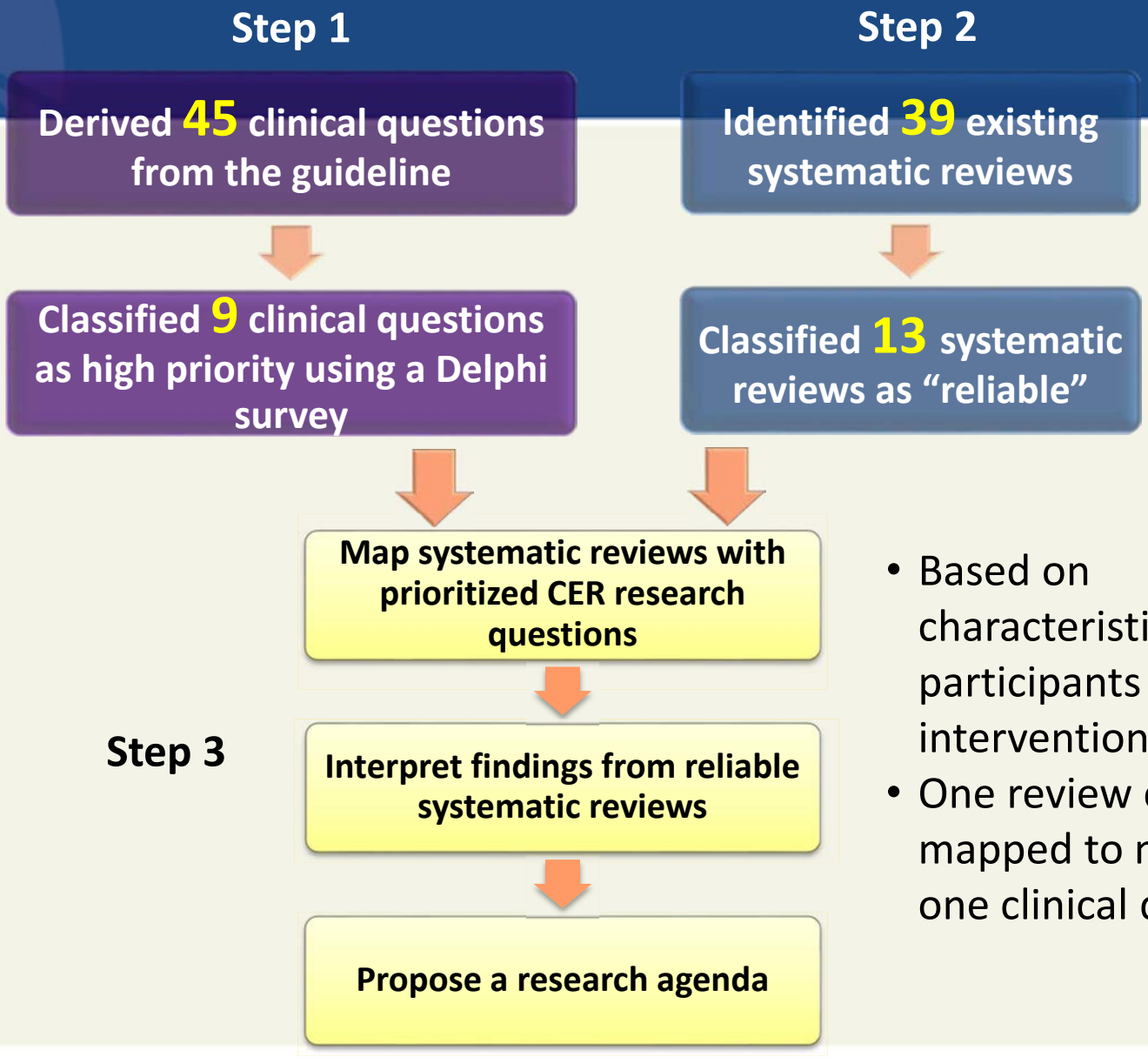
Instructions for Authors

Systematic Reviews and Meta-analyses

Systematic reviews seek to collect and critically assess all evidence that fits pre-specified criteria to answer a clinical question pertaining to the cause, diagnosis, prognosis, prevention, or therapy for a condition. A systematic review may contain a meta-analysis, which uses statistical methods to combine results from similar but independent studies.

Features of a systematic review include “a clearly stated set of objectives with pre-defined eligibility criteria for studies; an explicit, reproducible methodology; a systematic search that attempts to identify all studies that would meet the eligibility criteria; an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias; and a systematic presentation, and synthesis of the characteristics and findings of the included studies (Higgins JPT, Green S (editors). Chapter 1. *Cochrane*

A Model to Set CER Priorities



- Based on characteristics of participants and interventions examined
- One review could be mapped to more than one clinical question

T. Li et al. Annals of Int Med 2012; 156:367

Cochrane Editorial Unit

Cochrane Priority Review List 2015-16

We are pleased to announce the publication of the first Cochrane-wide Priority Review List. The creation of this list represents the achievement of a key milestone for Target 1.1 Prioritisation, a part of Cochrane's Strategy to 2020. In this target we set out a plan to identify about 200 Cochrane reviews, either new titles or reviews requiring updates, that best meet the needs of healthcare and health policy decision makers. The Cochrane Editorial Unit approached this task in two ways: firstly encouraging Cochrane Review Groups to engage with their stakeholders to identify priority reviews in their area, and secondly, identifying a list of research recommendations from national and international organisations in Australia, Canada, Spain, Switzerland, the United Kingdom, and the United States. We hope that publicising the list will act as a stimulus to encourage funders to support production of the reviews.

The level of engagement on this project was high, with about 300 priority review recommendations received from 50 Cochrane Review Groups – significantly more titles than we had hoped to gather. Many of the groups have undertaken engagement activities with external stakeholders, including consumers and health professional groups, so the list reflects those evidence needs. Other titles have been derived from the published research priorities of organisations such as research funders, patient advocacy groups and guideline developers.

This is the first time Cochrane has set priorities across all areas, and we will monitor our success in delivering the reviews. In addition, we recognise that the priority list will need to be refreshed regularly over time, and we will use the learning we have gained through this exercise to ensure that the process is as user-focussed and inclusive as possible in future.

If you would like to contribute in any way to our goal of delivering the reviews through to publication, please contact the Editor in Chief, David Tovey (dtovey@cochrane.org). Please be aware that all titles in the priority list have author teams in place, except for those which have been highlighted.

Download the final Cochrane Priority Review list for 2015-16 (spreadsheet)

Ruth Foxlee, Information Specialist

David Tovey, Editor in Chief

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Created by: Johns Hopkins University

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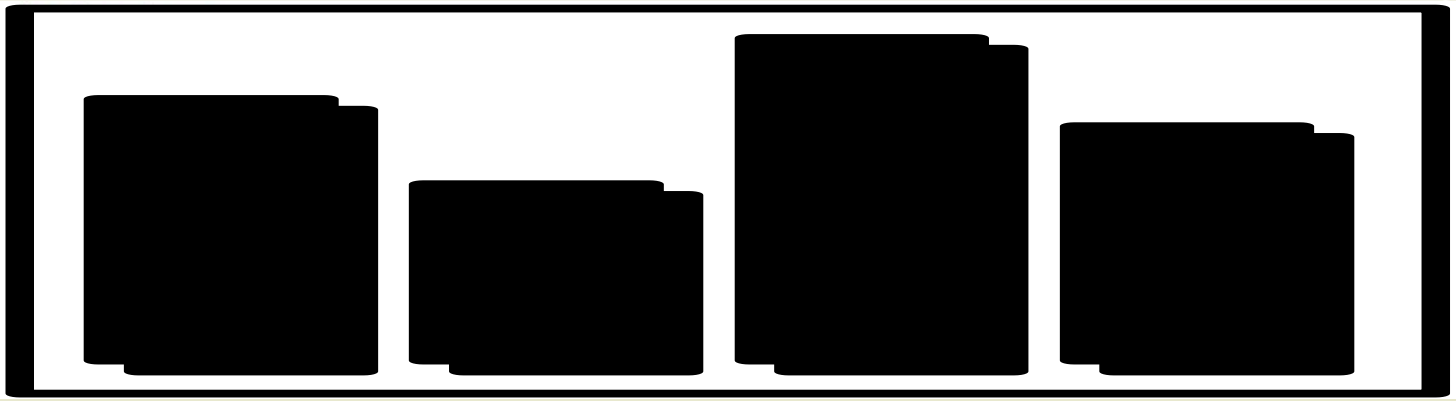

Summary

- Everybody needs formal training and mentoring
- Systematic reviews are transparent and good ones adhere to standards endorsed by the IOM and others
- A lot of groups and individuals are doing systematic reviews but many are doing a “shorter” version that has not undergone scrutiny
- Systematic reviews are used for many things, including priority setting, policy making, clinical practice and public health guidelines
- Cochrane is an international collaboration of over 30,000 contributors from >100 countries producing up-to-date and reliable systematic reviews in prevention, treatment, health promotion, and other topics.

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