Formulating the Review Question & Writing a Protocol

Madhukar Pai, MD, PhD
Associate Professor
Department of Epidemiology & Biostatistics
McGill University, Montreal, Canada
Email: madhukar.pai@mcgill.ca

How are these questions different?

- Do statins improve survival after acute myocardial infarction?

- In patients with first acute myocardial infarction, does early administration of statins lead to higher survival rates as compared to placebo?

How are these questions different?

- Does watching TV cause obesity?

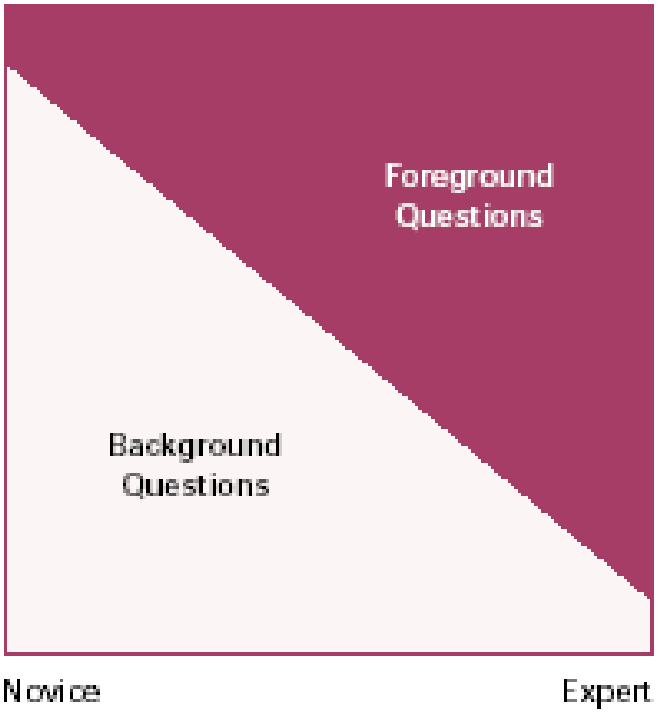
- In school children, is increased TV viewing associated with an increased incidence of obesity measured using body mass index?

How are these questions different?

- Can polymerase chain reaction (PCR) detect TB?

- In adult patients suspected to have pulmonary tuberculosis, is PCR more sensitive and specific than culture?

Foreground (focused) Vs Background (broad) questions



Guyatt et al. Users Guides to the Medical Literature. Chicago: AMA Press, 2002

Why are foreground questions better for reviews & research?

- More likely to get completed and result in a comprehensive review
  - Lead to easier and better searches
  - Lead to clear inclusion/exclusion criteria
  - Lead to better decisions about what data to extract
- More likely to come up with a clear message for the clinician/researcher
- More likely to help the reader to rapidly assess whether the review is relevant to him/her
- More likely to identify questions for future research

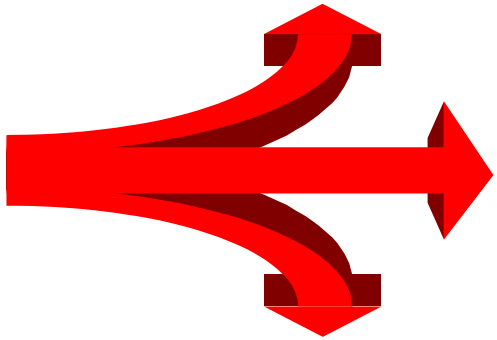
Types of questions (domains)

- Etiology [cohort, case-control]
- Therapy [RCT]
- Prognosis [cohort]
- Harm [cohort, case-control]
- Diagnosis [cross-sectional, case-control]
- Economic [cost-effectiveness analysis, etc.]

  - These domains are usually addressed by different study designs

Architecture of a focused question: a 4-part review question

P - Who is the patient or what problem is being addressed?



I - What is the intervention or exposure?

C – What is the comparison group?

O - What is the outcome or endpoint?

± study design

Richardson et al. The well-built clinical question: a key to evidence-based decisions. ACP Journal Club 1995;A-12

Counsell C. Formulating questions and locating primary studies for inclusion in systematic reviews. Ann Intern Med 1997;127:380-7.

EVIDENCE-BASED PRACTICE Step by Step

Asking the Clinical Question: A Key Step in Evidence-Based Practice

A successful search strategy starts with a well-formulated question.

This is the third article in a series from the Arizona State University College of Nursing and Health Innovation's Center for the Advancement of Evidence-Based Practice. Evidence-based practice (EBP) is a problem-solving approach to the delivery of health care that integrates the best evidence from studies and patient care data with clinician expertise and patient preferences and values. When delivered in a context of caring and in a supportive organizational culture, the highest quality of care and best patient outcomes can be achieved.

The purpose of this series is to give nurses the knowledge and skills they need to implement EBP consistently, one step at a time. Articles will appear every two months to allow you time to incorporate information as you work toward implementing EBP at your institution. Also, we've scheduled "Ask the Authors" call-ins every few months to provide a direct line to the experts to help you resolve questions. Details about how to participate in the next call will be published with May's *Evidence-Based Practice, Step by Step*.

Stillwell et al. AJN March 2010 Vol. 110, No. 3

Templates and Definitions for PICOT Questions[5, 6]

Question type	Definition	Template
Intervention or therapy	To determine which treatment leads to the best outcome	In _____ (P), how does _____ (I) compared with _____ (C) affect _____ (O) within _____ (T)?
Etiology	To determine the greatest risk factors or causes of a condition	Are _____ (P) who have _____ (I), compared with those without _____ (C), at ____ risk for _____ (O) over _____ (T)?
Diagnosis or diagnostic test	To determine which test is more accurate and precise in diagnosing a condition	In _____ (P), are/is _____ (I) compared with _____ (C) more accurate in diagnosing _____ (O)?
Prognosis or prediction	To determine the clinical course over time and likely complications of a condition	In _____ (P), how does _____ (I) compared with _____ (C), influence _____ (O) over _____ (T)?
Meaning	To understand the meaning of an experience for a particular individual, group, or community	How do _____ (P) with _____ (I) perceive _____ (O) during _____ (T)?

Formulation of a therapy question

Intervention

Outcome

Is Zinc effective in treating cold?

Patient/problem

Intervention

In children with common cold, is oral Zinc effective in reducing the duration of symptoms, as compared to placebo?

Outcome

+ RCTs

Comparison

Formulation of an etiology question

Exposure

Outcome

Is smoking a risk factor for tuberculosis?

Patient

Exposure

Are people who smoke regularly at a greater risk of developing pulmonary tuberculosis as compared to those who do not smoke?

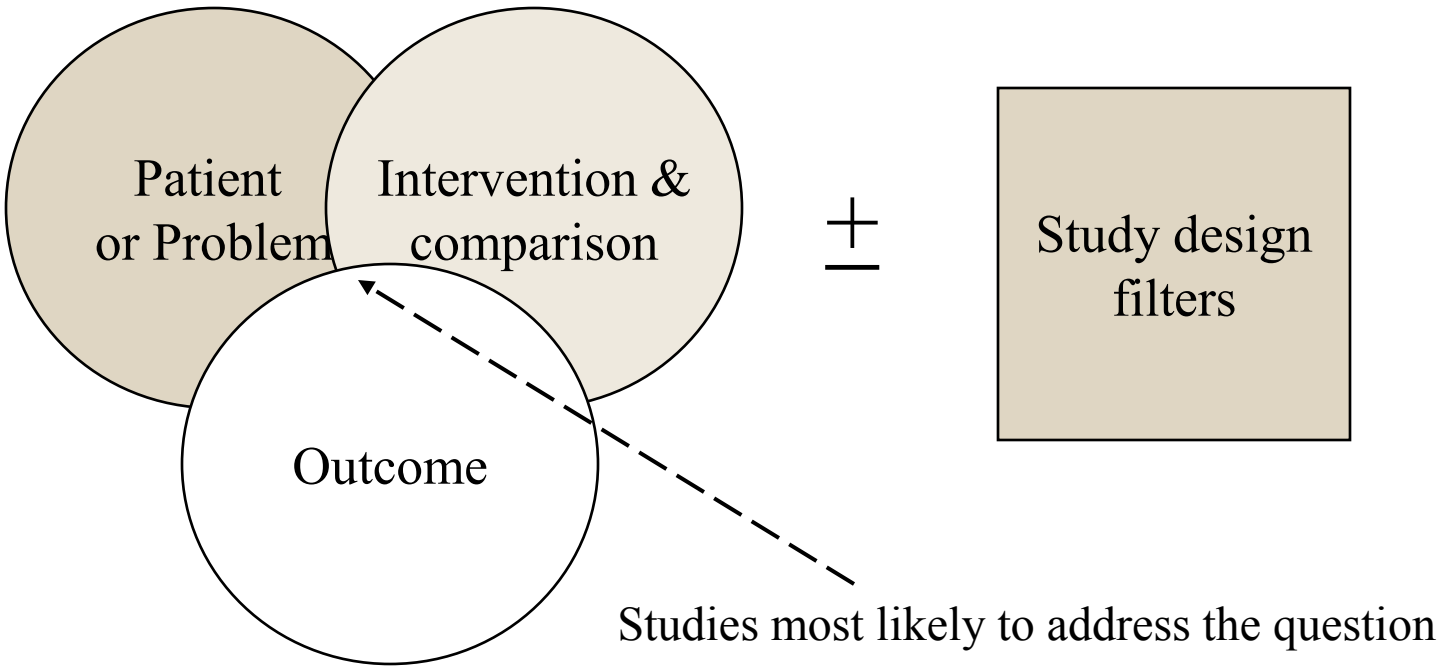
Outcome

+ cohort & case-control studies

Comparison

How a focused question helps in searching for studies

PICO + STUDY DESIGN FILTER



Once a review question is defined

- Search the literature and see if a review has been done already
  - Use sources like the Cochrane Library, DARE database
  - Use Clinical Query in PubMed to identify systematic reviews
- If a review has been done, see if there some way you can improve on it
- If a high-quality systematic review already exists, consider an alternative question!

THE COCHRANE LIBRARY

Independent high-quality evidence for health care decision making

from The Cochrane Collaboration

SEARCH THE COCHRANE LIBRARY

Title, Abstract or Keywords | GO

or try an Advanced Search

HOME | SIGN UP | LEARN | ACCESS | HELP

Notice to all users: The April issue of *The Cochrane library* is now live. **Please note:** there is a delay in the April publication of the *Cochrane Central Register of Controlled Trials* (CENTRAL). We anticipate publication in the next 7 -14 days. Users can still search records published in the January issue. We apologise for any inconvenience this may cause.

BROWSE COCHRANE DATABASE OF SYSTEMATIC REVIEWS

- Anaesthesia & pain control (145)
- Blood disorders (94)
- Cancer (252)
- Consumers & communication (29)
- Dentistry and oral health (107)
- Developmental, psychosocial, and learning problems (70)
- Ear, nose, & throat (92)
- Effective practice/health systems (59)
- Endocrine & metabolic (89)

expand

Other Browse Options

COCHRANE CENTRAL REGISTER OF CONTROLLED TRIALS

Search for trials

BROWSE OTHER RESOURCES

The Cochrane Library has a wide range of resources:

SPECIAL COLLECTIONS


World Malaria Day (25 April 2010)


World Asthma Day (4 May 2010)


Cochrane Evidence Aid: resources for Chile and Haiti earthquakes

View all

EDITORIAL


"Inadequate control despite regular treatment with inhaled corticosteroids." It's a scenario repeated all over the world in surgeries and outpatients departments, anywhere where people with asthma are routinely treated. Health professional and patients are faced with a familiar problem: increase the dose of corticosteroids or add a new agent, such as an inhaled long-acting beta-agonist (LABA). Which is best?...

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HIGHLIGHTED NEW AND UPDATED COCHRANE REVIEWS

- Legislative smoking bans for reducing secondhand smoke exposure, smoking prevalence and tobacco consumption
- Aspirin with or without an antiemetic for acute migraine headaches in adults
- Combined chiropractic interventions for lowback pain
- Indoor residual spraying for preventing malaria
- Self-monitoring and self-management of oral anticoagulation
- Exercise based rehabilitation for heart failure

Centre for Reviews and Dissemination

Search

All these words

Any of these words

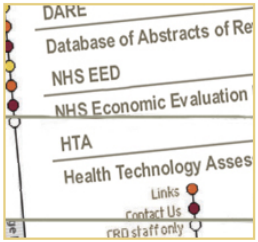
(Searches using AND/OR/NOT combinations override the above)

search

Year published From - restrictions info

10 results per page

All results | DARE | NHS EED | HTA



CRD Databases

DARE contains 15,000 abstracts of systematic reviews including over 6,000 quality assessed reviews and details of all Cochrane reviews and protocols.

NHS EED contains 24,000 abstracts of health economics papers including over 7,000 quality assessed economic evaluations.

DARE and ***NHS EED*** include details of abstracts in the process of being written and these can be 'fast-tracked' on request.

HTA brings together details of over 8,000 completed and ongoing health technology assessments from around the world.

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Tel: +44 (0)1904 321040, Fax: +44 (0)1904 321041, E-mail: crd-info@york.ac.uk

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National Institutes of Health

Search: PubMed Limits Advanced search Help

Search Clear

Welcome to PubMed

PubMed comprises more than 19 million citations for biomedical articles from MEDLINE and life science journals. Citations may include links to full-text articles from PubMed Central or publisher web sites.

Using PubMed

- PubMed Quick Start
- New and Noteworthy
- PubMed Tutorials
- Full Text Articles
- PubMed FAQs

PubMed Tools

- Single Citation Matcher
- Batch Citation Matcher
- Clinical Queries
- Topic-Specific Queries

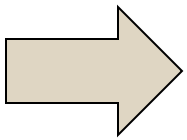
More Resources

- MeSH Database
- Journals Database
- Clinical Trials
- E-Utilities
- LinkOut

NLM/NCBI H1N1 Flu Resources:

- Newest H1N1 influenza sequences
- Submit flu sequences to GenBank
- Latest H1N1 citations in PubMed
- MedlinePlus (consumer health information)
- Enviro-Health links

FLU.GOV
Know what to do about the flu.
VISIT FLU.GOV
SHARE THIS WIDGET



PubMed Clinical Queries

This page provides the following specialized PubMed searches for clinicians:

- Search by Clinical Study Category
- Find Systematic Reviews
- Medical Genetics Searches

Results of searches on these pages are limited to specific clinical research areas. For comprehensive searches, use PubMed directly.

Search by Clinical Study Category

This search finds citations that correspond to a specific clinical study category. The search may be either broad and sensitive or narrow and specific. The search filters are based on the work of Haynes RB

Search Go

Category	Scope
○ etiology	◉ narrow, specific search
○ diagnosis	○ broad, sensitive search
◉ therapy	
○ prognosis	
○ clinical prediction guides	

Find Systematic Reviews

For your topic(s) of interest, this search finds citations for systematic reviews, meta-analyses, reviews of clinical trials, evidence-based medicine, consensus development conferences, and guidelines.

For more information, see Help. See also related sources for systematic review searching.

Search Go

Medical Genetics Searches

This search finds citations and abstracts related to various topics in medical genetics. See the filter table for details.

Search Go

Once you decide to do a review

- Once you decide to do a review, write a short, draft protocol
- Could be 3 – 4 pages long (background, 4-part question (PICO), study designs to be included, and methods)
  - Why?
    - Gets you started!
    - Forces you to read and understand the context
    - Makes you formulate a focused question
    - Makes you plan the search strategy
    - Makes you describe inclusion/exclusion criteria clearly
    - Makes you think about the data you want to collect and the methods you will use to analyze them

Once you write a draft protocol

- Do a quick and dirty initial search of the literature (eg. a simple key word search with PubMed)
- With a few studies, do a pilot
  - Pretend as if you have found all the eligible studies
  - Create data extraction forms and extract data
  - Enter and analyze data using meta-analysis software
- With the pilot study experience, revise the protocol and then start the review

Outline of a full protocol

- Cochrane protocol format*:
  - Background
  - Objectives
  - Criteria for considering studies for this review (PICO)
    - Types of studies (study designs)
    - Types of participants
    - Types of interventions
    - Types of outcome measures
  - Search strategy for identification of studies
  - Methods of the review
    - Eligibility
    - Data collection
    - Assessment of methodological quality
    - Data analysis
  - References

*Cochrane Reviewers' Handbook http://www.cochrane.org/index.htm

Outline of a protocol

- Background
  - Problem statement and importance of the problem addressed
  - Rationale for the review
  - Have there been other reviews on this topic?
    - What did the scoping search find?
  - How will your review be different from others on the same topic?

Outline of a protocol

- Objectives:
  - Precise statement of the primary objective of the review, including the intervention(s) reviewed and the problem addressed.
  - If there are hypotheses for the review (specific theories or suggestions being tested), these should be stated here.

Outline of a protocol

- Criteria for considering studies for this review (PICOT)
  - Types of participants
  - Types of interventions
  - Types of outcome measures
  - Types of studies (study designs)
  - Time period (if relevant)

Outline of a protocol

- Search strategy:
  - What databases and sources will be searched?
  - What will be the time period?
  - What search terms and key words will be used?
  - Will there be language restrictions?
  - How will conference abstracts be handled?
  - Will unpublished data be sought?
  - Who will run the searches?

Outline of a protocol

- Methods:
  - Eligibility:
    - What will the inclusion/exclusion criteria be?
    - Who & how many reviewers will screen the articles for inclusion?
    - How will the reviewers resolve disagreements?

Outline of a protocol

- Methods:
  - Data extraction:
    - Who and how many reviewers will extract data?
    - What data will be extracted?
    - How will the reviewers resolve disagreements?
    - Will inter-rated reliability be measured?

Outline of a protocol

- Assessment of study quality:
  - Who and how many reviewers will assess study quality?
  - What instrument or checklist will be used for quality assessment?
  - How will the reviewers resolve disagreements?
  - Will inter-rated reliability be measured?
  - How will the quality data be used? (subgroup analysis, etc)

Outline of a protocol

- Analysis:
  - What software will be used?
  - How heterogeneity will be evaluated?
  - If a meta-analysis will be done, what model will be used for combining data (random vs. fixed effects)?
  - If heterogeneity is found, what approaches will be used to find reasons for heterogeneity?
  - Will subgroup analyses be done? Meta-regression?
  - Will sensitivity analyses be done?
  - How will quality of studies affect the analyses?
  - How potential publication bias will be evaluated?

Systematic review protocol template

TITLE OF THE REVIEW:

BRIEF BACKGROUND AND RATIONALE FOR THE REVIEW:

REVIEW QUESTION (IN PICOT FORMAT):

CRITERIA FOR CONSIDERING STUDIES FOR THE REVIEW:

Types of studies (designs):

Types of participants:

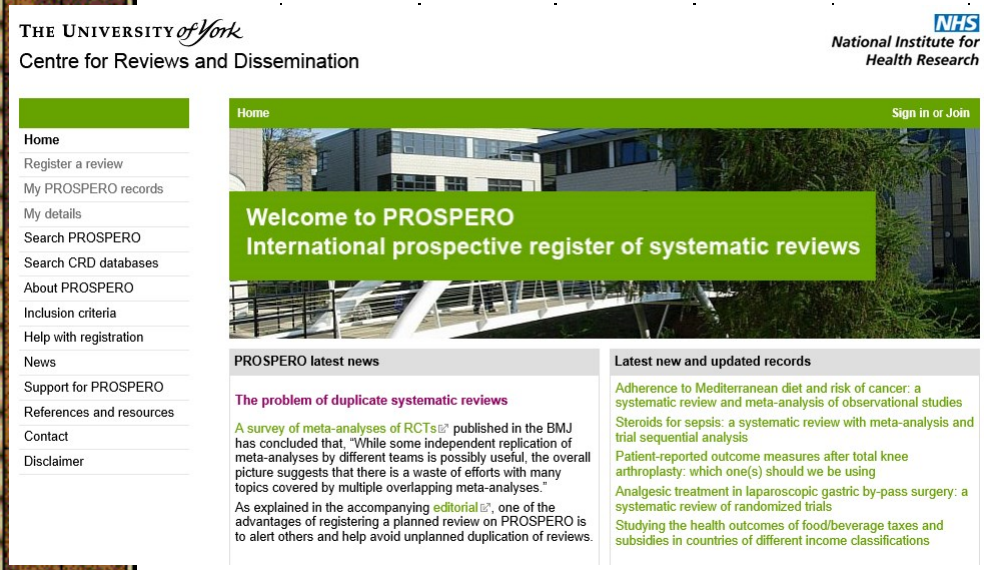
Types of interventions (or exposures):

Types of outcome measures (primary and secondary):

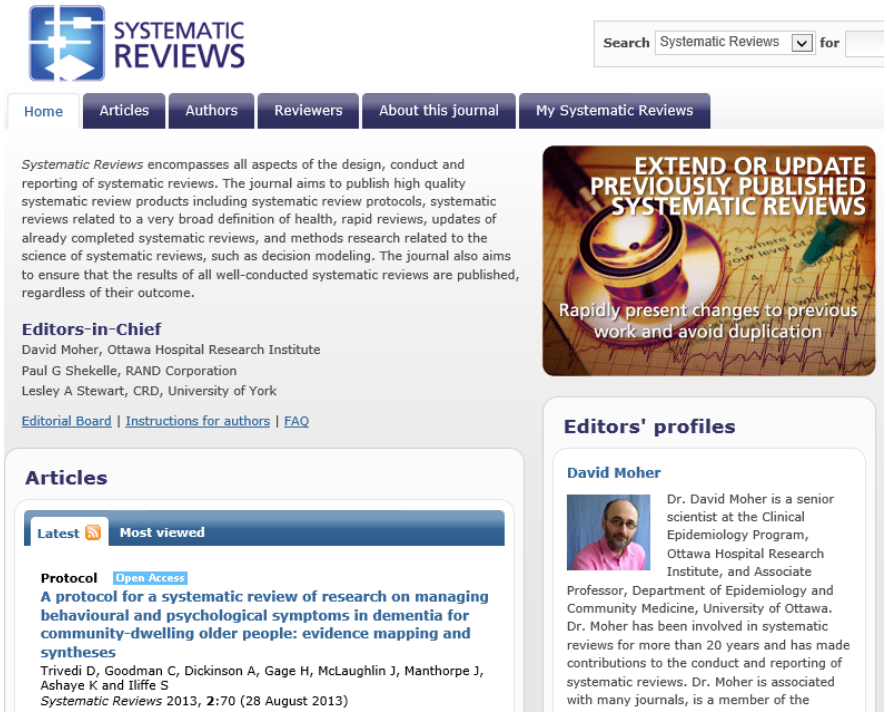
All of you are expected to prepare and present a brief protocol on your own reviews

- Blank template provided in USB key

You could then register your review and publish your protocol



http://www.crd.york.ac.uk/NIHR_PROSPERO/



http://www.systematicreviewsjournal.com/