How to find, filter, and format Evidence-based Information on the Benefits and on the Risks of Medicines

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Disclosure

I am a general practitioner and a clinical pharmacologist,
with many interests,
but no conflicts of interests,

Board member / co-founder of :

- CEBAM : Belgian Centre for Evidence-Based Medicine
- CDLH : Cebam Digital Library of Health
- EBMPracticeNET : Belgian Platform for Guidelines

Senior advisor of :

- Belgian Centre of Pharmaco-therapeutic Information

A discrepancy in pharmaceutical information

Evidence-based information on efficacy

Based on Randomized Controlled Trials

Synthesis extremely well developped since 1990

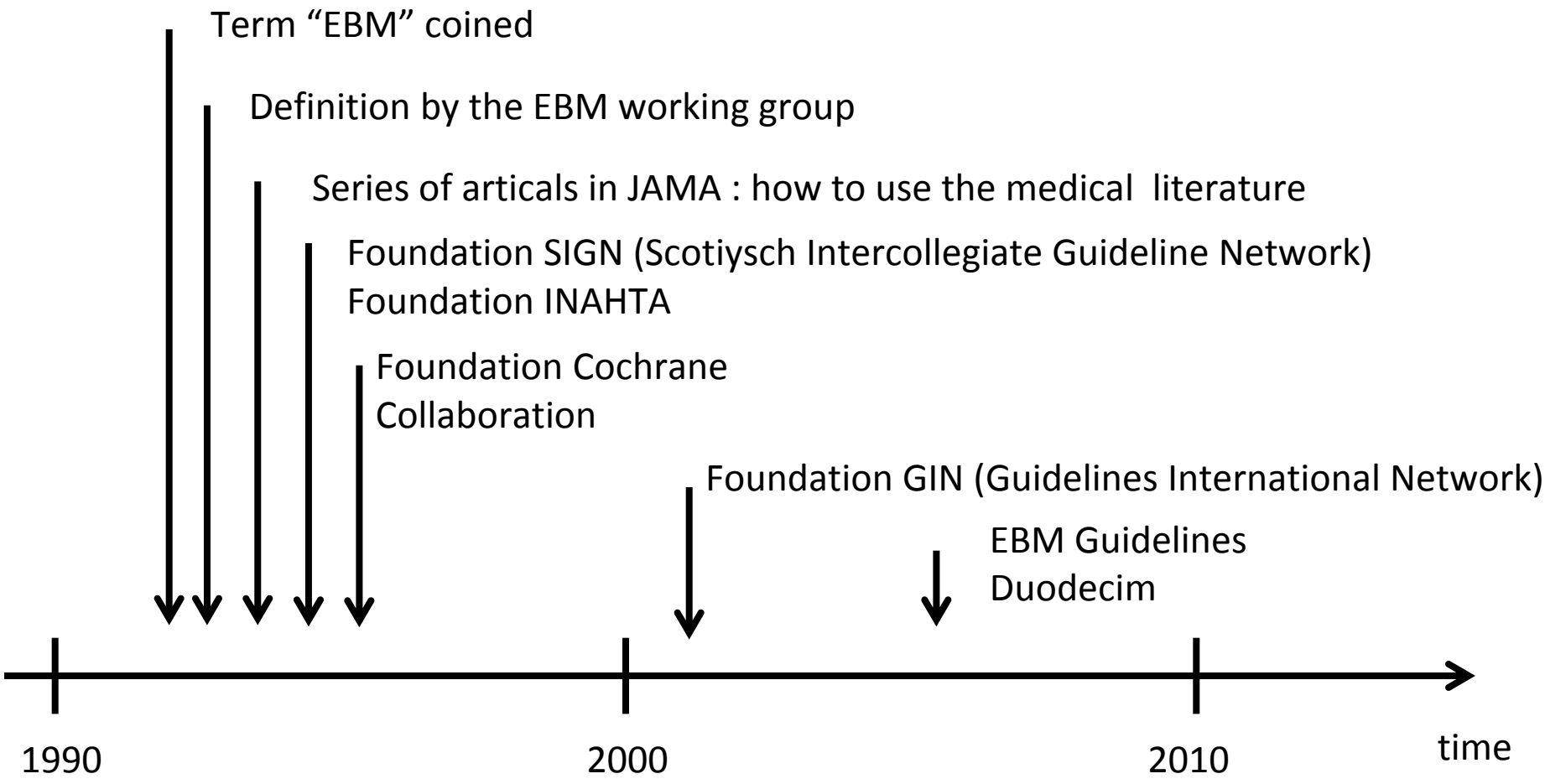
Evidence-based information on patient Safety

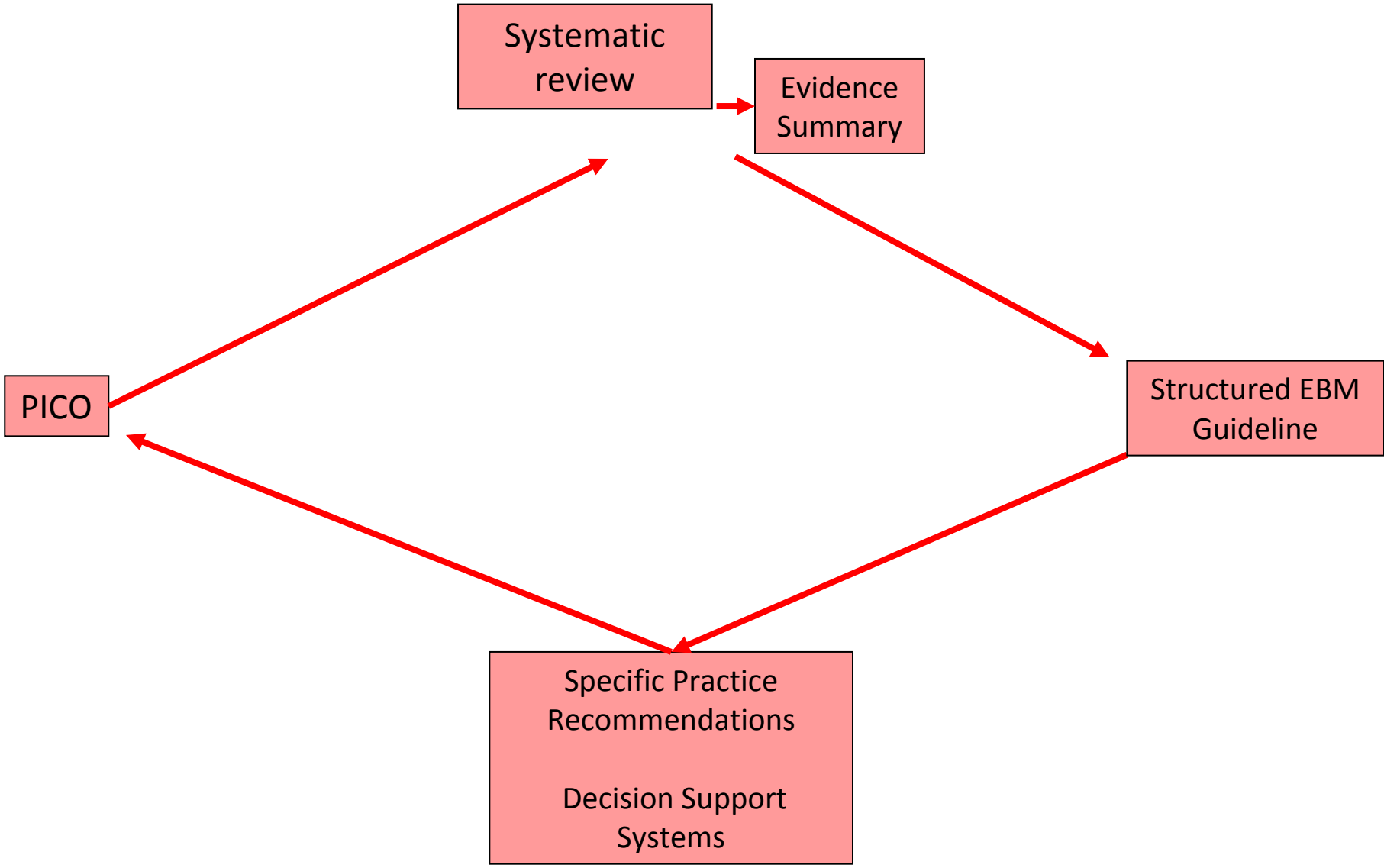
Based on anectdotical pharmacovigilance and observational pharmaco-epidemiology

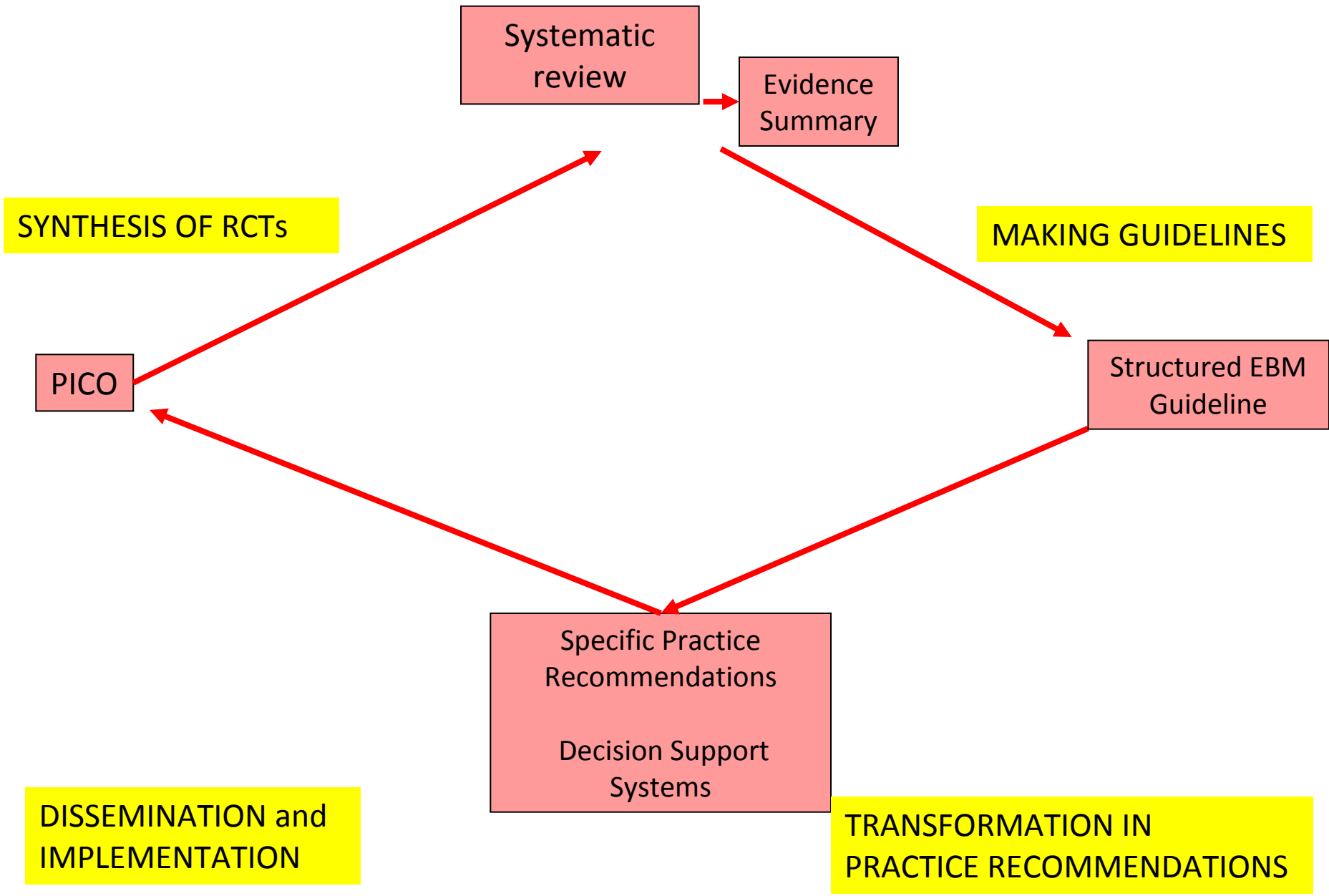
Still in its infancy

Evidence on efficacy of medication

Timeline EBM : international (1992 – now)




Systematic review
Evidence Summary
PICO
Structured EBM Guideline
Specific Practice Recommendations
Decision Support Systems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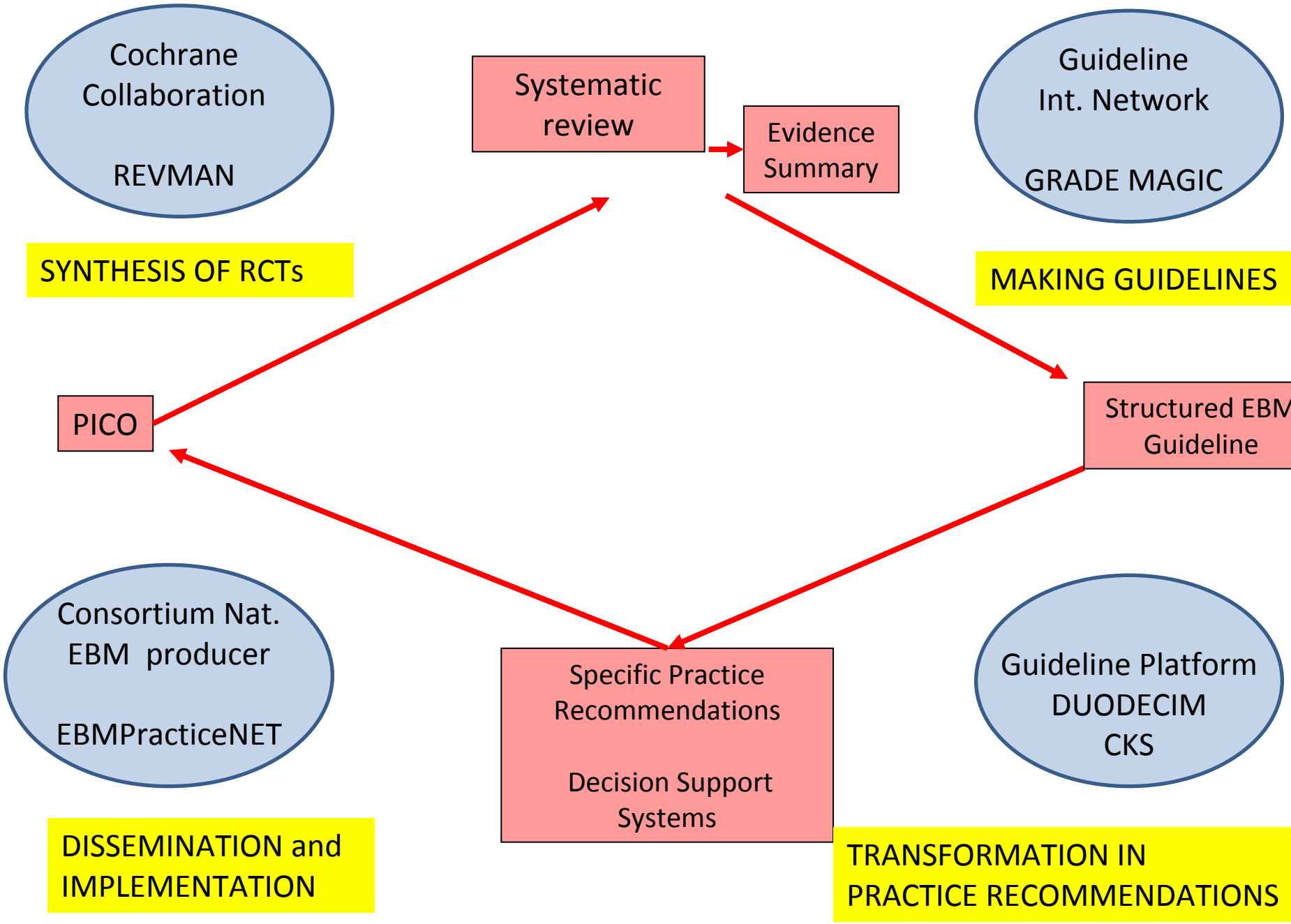
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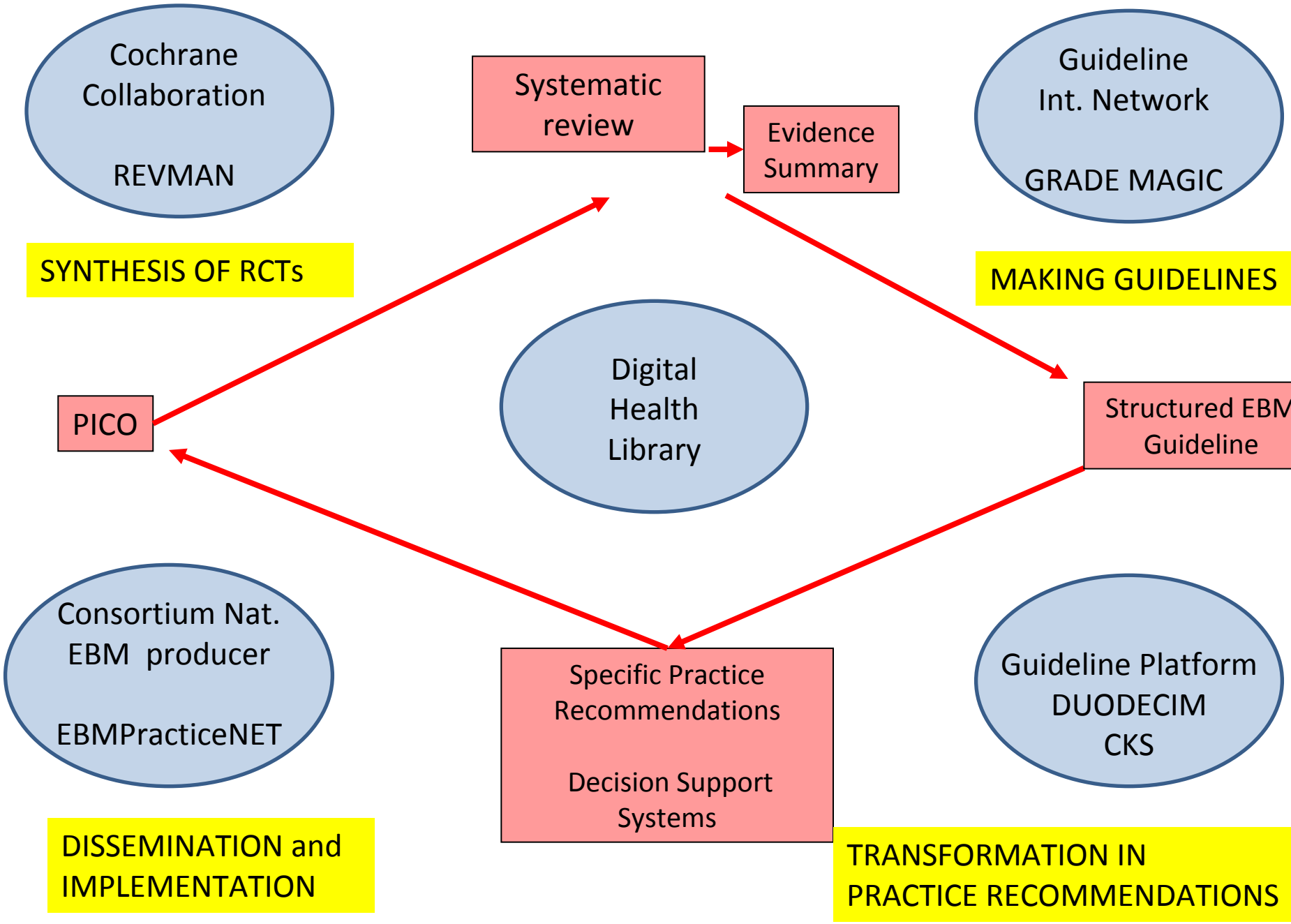
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An example of aggregation of high level evidence on efficacy in guidelines on behavioral problems in dementia

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Ageing Research Reviews

journal homepage: www.elsevier.com/locate/arr

Review

Systematic appraisal of dementia guidelines for the management of behavioural and psychological symptoms

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ABSTRACT

Background: Within the treatment of dementia, management of behavioural and psychological symptoms (BPSD) is a complex component.
Purpose: We wanted to offer a pragmatic synthesis of existing specific practice recommendations for managing BPSD, based on agreement among systematically appraised dementia guidelines.

And for evidence on patient safety ?

Find evidence :

For each the relevant topics, what are the relevant sources of information ?

- SPC
- National drug Information Centre
- Handbooks
- Bibliographic indexes
- Trustworthy sites
- Exhaustive electronic resources,
  to be integrated in EHR systems

Filter evidence :

- Which information items will be integrated

  in electronic decision support systems ?
  (Senator, Prima)
  in audit of pharmaceutical quality ?
  (Beers, ACOVE, Phebe, Bednurse, Stopp-Start)

- Only those that are clinically and epidemiologically relevant ?

  To be determined by which method and which cut-off ?

Format evidence :

- How will we integrate the selected information items (clinically and epidemiologically relevant) into structured knowledge bases ?

- How good will the rule-based studies work in the environment of the EHR ?

- How will we present alerts and remarks to the clinicians ?

An example

Identification of medications with a clinically important anticholinergic profile

Eur J Clin Pharmacol
DOI 10.1007/s00228-013-1499-3

PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

Systematic review of anticholinergic risk scales in older adults

Carlos E. Durán · Majda Azermai · Robert H. Vander Stichele

Background

- Anticholinergic (muscarin) side effects :
  - peripheral adverse effects (dry mouth, dry eyes, constipation, blurred vision and increased heart rate)
  - central adverse effects (Dizziness, sedation, confusion, delirium and even cognitive impairment)
- Medications with anticholinergic side-effects in many therapeutic areas
- Related with serious negative outcomes on the older adults
- Several attempts were made to produce reliable lists of anticholinergic drugs, with a gradation of potency.
- Considerable variation exists in the methodology of anticholinergic risk scale development.

Objective

- To systematically review existing anticholinergic risk scales and
- to develop a uniform list of anticholinergic drugs with differentiation in anticholinergic potency.

Method

- We searched the literature for anticholinergic scales, expressing the potency of selected medications
- Only scales based on a validation study were included
  - (relation with (clinical) outcome)
- Congruence between the potency estimation of the selected scales was examined.
- For drugs with a concordant potency estimation, the result was accepted and reduced to a potency estimation varying from 0 to 2 (no, low and high potency)
- When the estimation of anticholinergic potency was discordant, a handbook (Martindale) was used as gold standard.

Results

- 454 articles screened, 62 studies selected,
- 7 risk scales included

47 high potency anticholinergic drugs
53 low potency anticholinergic drugs

All classified in the Anatomical Chemical Therapeutic Classification

80 drugs mentioned in at least one scale,
but no consensus and no confirmation in Martindale

Further work

Link potency to dosage

- Mimimal effective dosis
- Normal dose
- Dose adapted for the elderly
- Maximum dose

Build an analytic algoritm to assess medication lists

Validate in a clinical study

General Conclusion

The methodology to filter and format

clinically and epidemiologically relevant

evidence-based information

on safety of medication

is its infancy.

Progress might come rapidly.