TLV

TANDVÅRDS- OCH

LÄKEMEDELSFÖRMÅNSVERKET

HTA/payers' perspective on significant benefit

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EMA Workshop, December 7, 2015

Cost-effectiveness is about comparing, and that is why we are here

Compared to

Cost & Benefit
New treatment

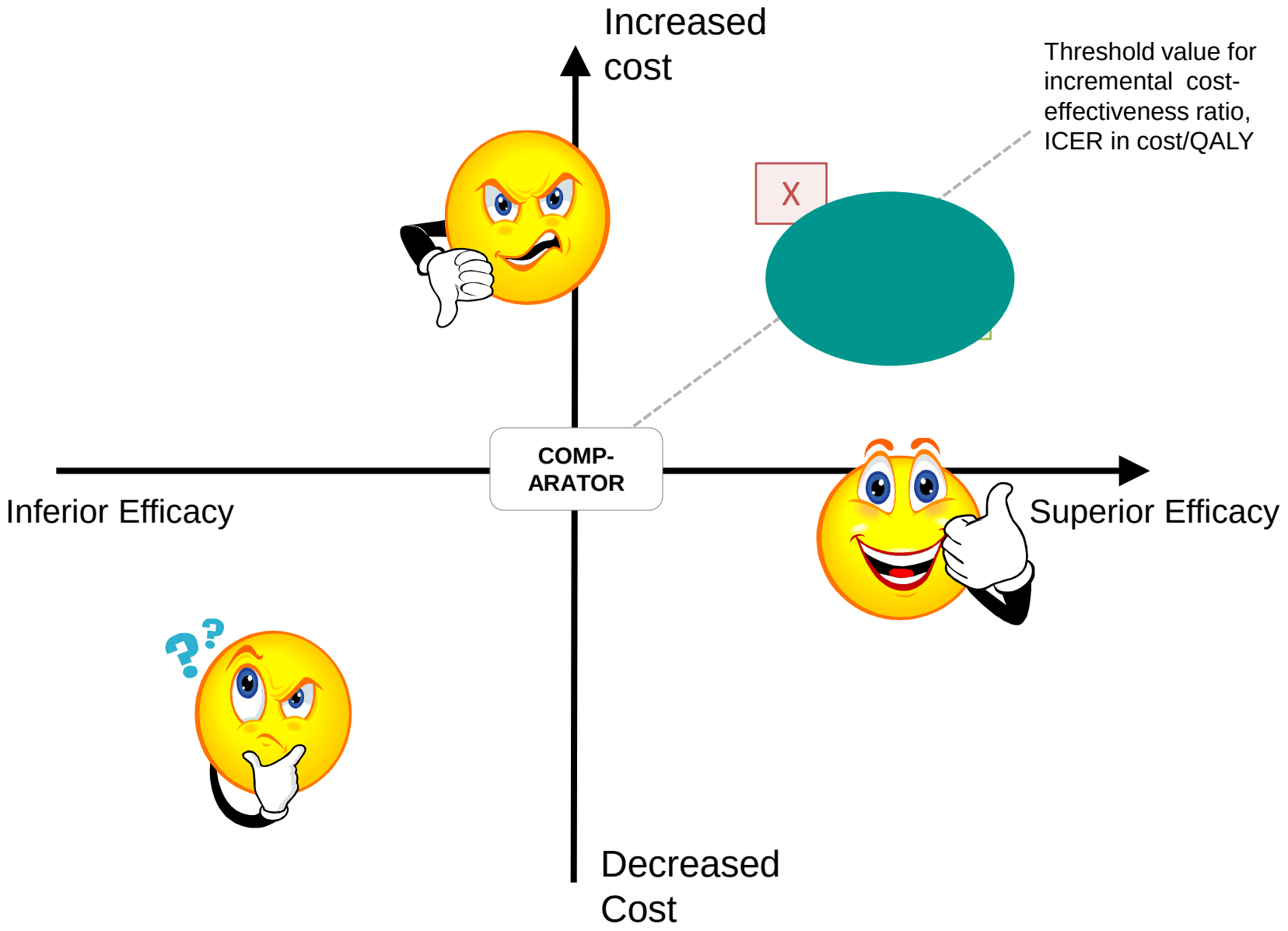
Cost & Benefit
Old (or no)
treatment

Two key questions

- How to choose the most relevant comparator?
  - Strictly after label?
  - Depending on clinical use?
- How to prove significant benefit?
  - Is it truly significant?
  - Indirect comparisons?

Why is the choice of comparator of importance?

- If applying for a premium price, the company must prove that the new product has a significant benefit compared to the existing therapy.
- If no significant benefit can be proven, a higher price may (should?) not be approved.
- $ICER = \frac{Cost_1 - Cost_2}{Efficacy_1 - Efficacy_2}$
- Given the above, if a company still requests a premium price patients may (should?) be prescribed the comparator.


Increased cost
Threshold value for incremental cost-effectiveness ratio, ICER in cost/QALY
X
COMP-ARATOR
Inferior Efficacy
Superior Efficacy
Decreased Cost

Significant ”**label”** benefit

- Decision makers sometimes use a comparator that does not possess an identical approved indication.
  - This is often debated, but may be justified if it’s based on scientific standards and established clinical experience.
- Does an approved indication per se translate to significant benefit?
- How shall such benefit be measured?
- Which parameters are most relevant for an HTA agency or a payer when chosing comparator?
  - Cost effectiveness?
  - Clinical relevance?
  - Usage volume in market?
  - Strength of evidence?
  - Approved indication?
  - Reimbursement status?

Two key questions

- How to choose the most relevant comparator?
  - Strictly after label?
  - Depending on clinical use?
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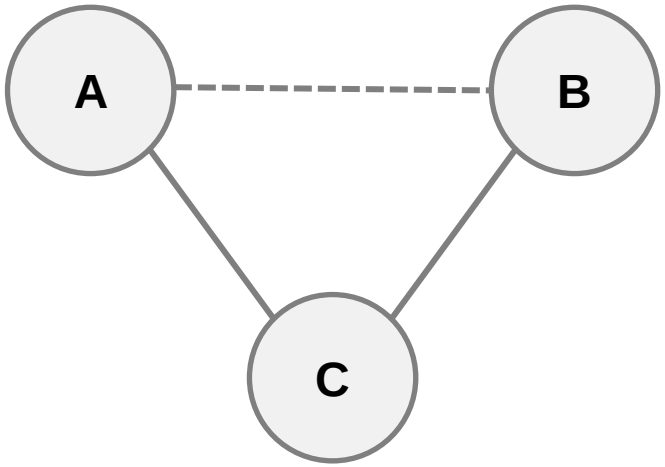
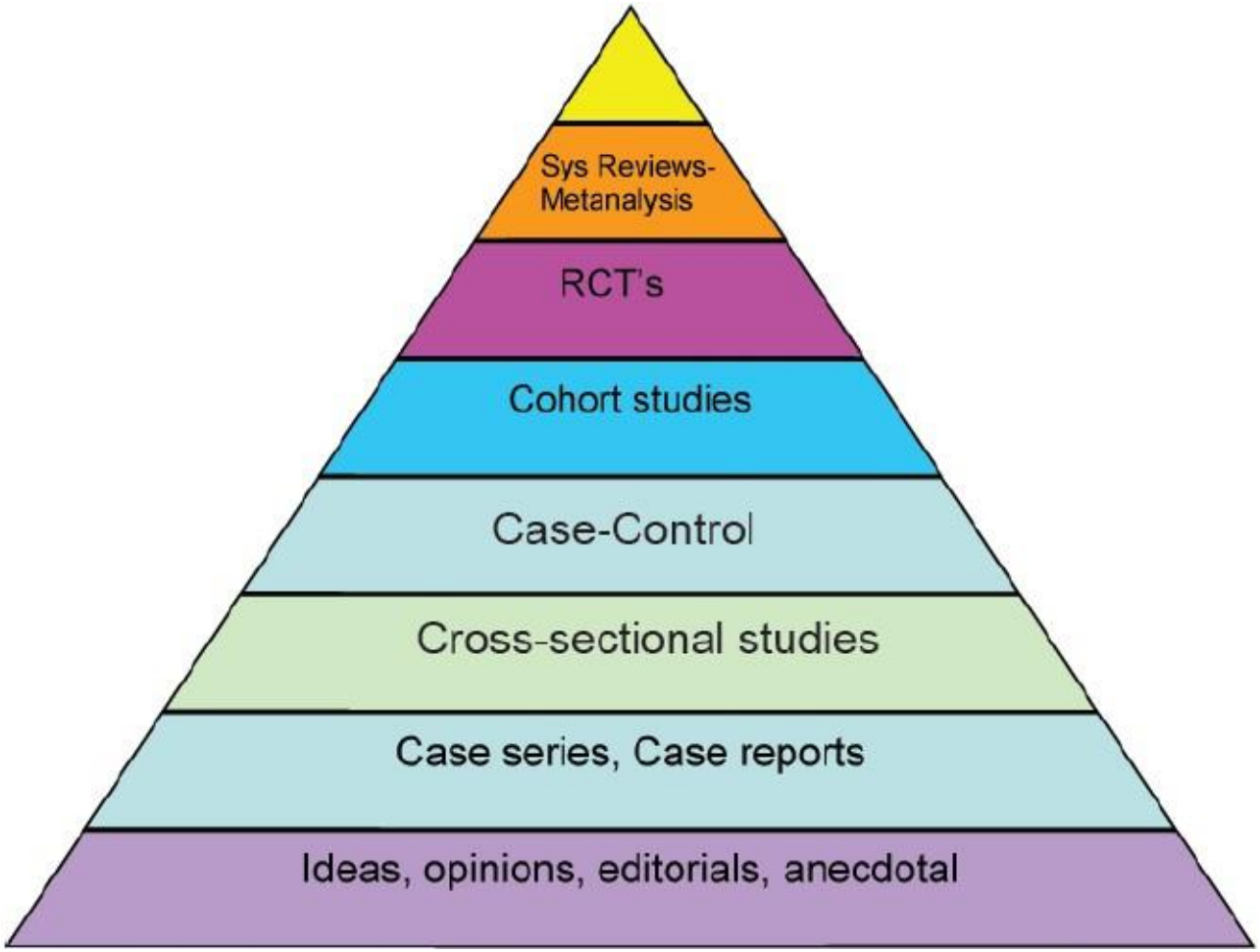
Use of indirect comparisons

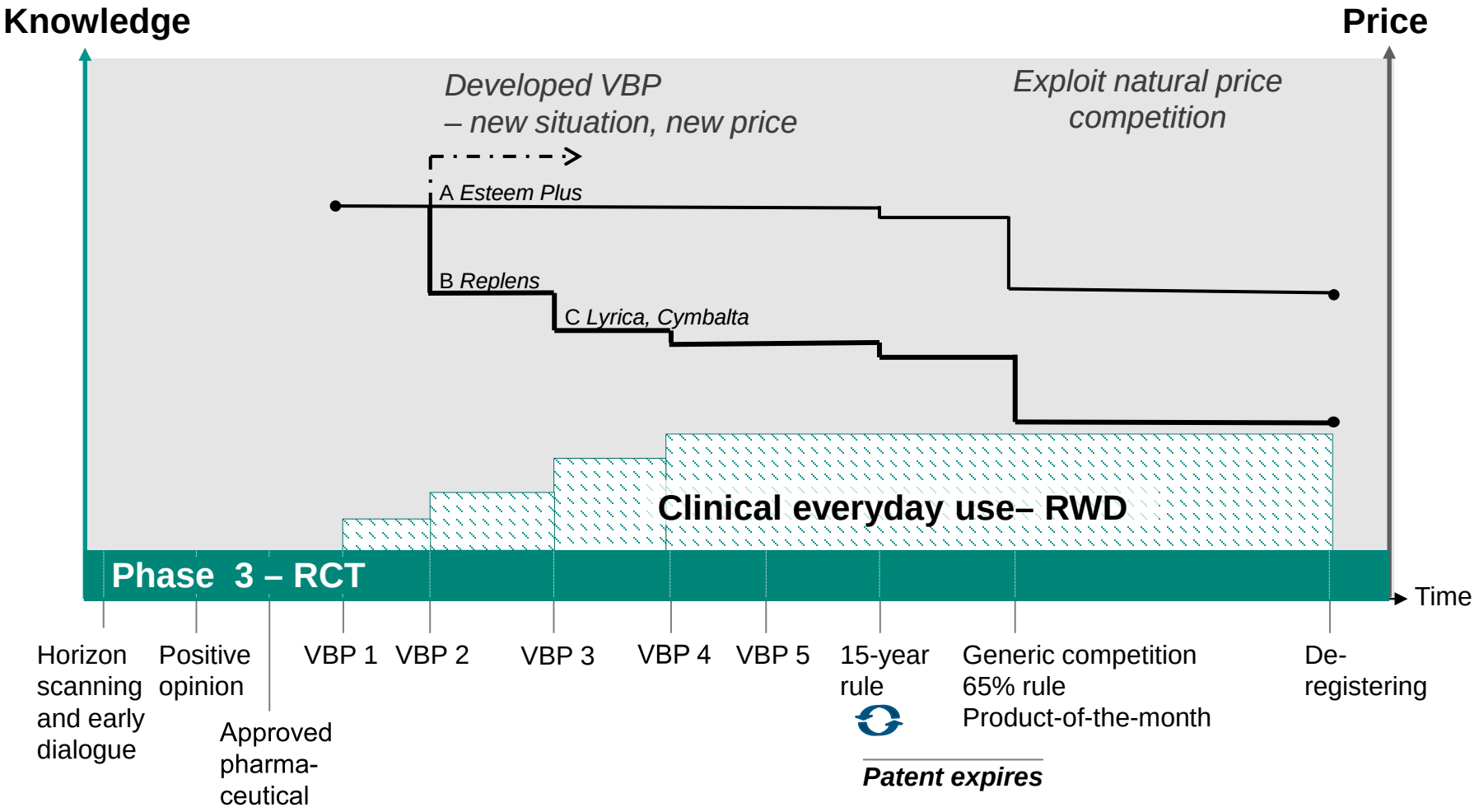
- When head to head studies comparing the new and the old therapy are not available, indirect comparisons may be used. (This can also occur for two new therapies.)



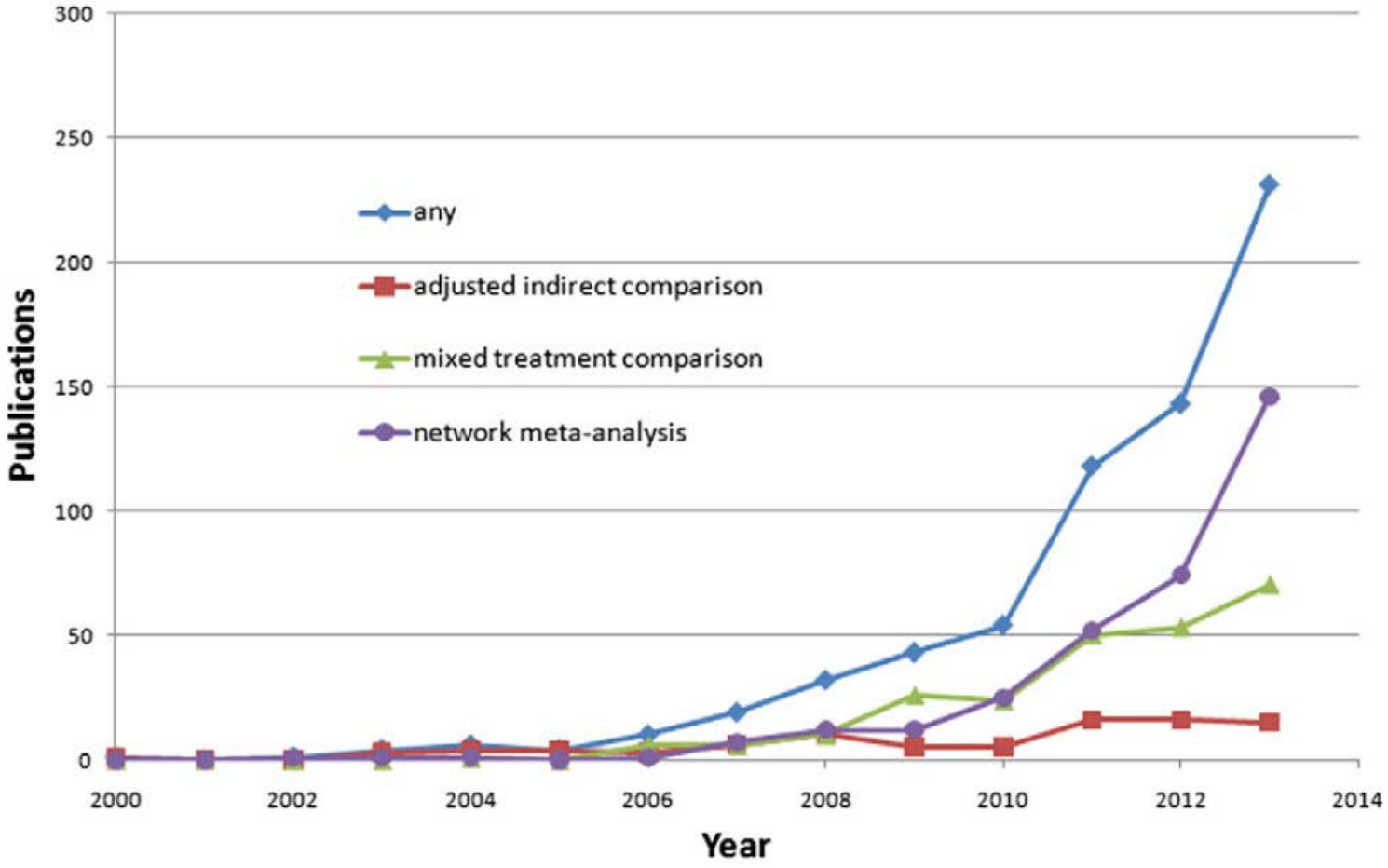
Desired evidence



Value Based Pricing during the Life Cycle

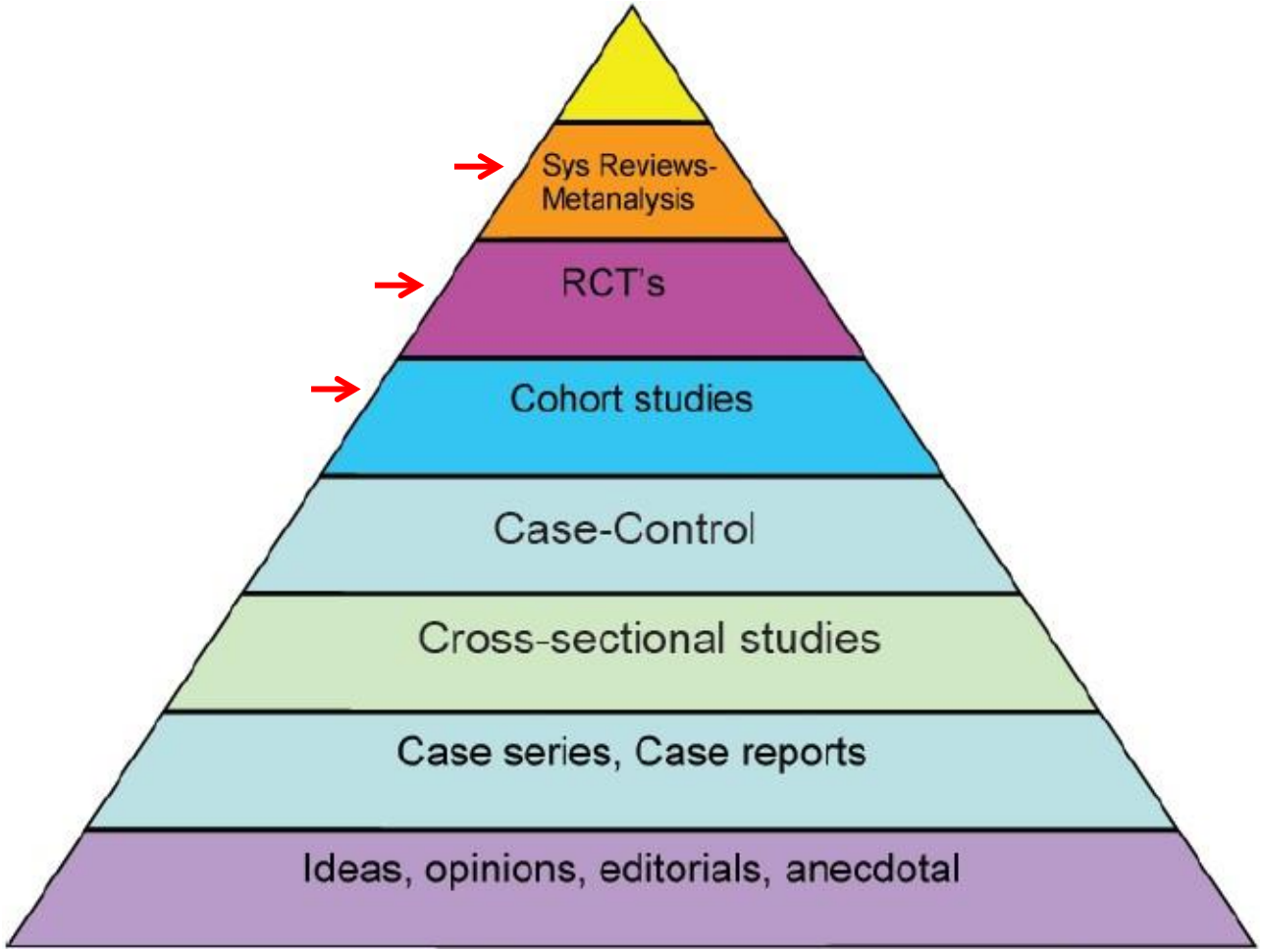


Available evidence



Source: TLV search on PubMed

Where to place indirect comparisons in the traditional evidence hierarchy?



Reasonable requirements on indirect comparisons (IC)

- When available, head to head studies and direct comparisons should be used.
- If possible, all comparisons should be based on systematic reviews.
- When background data allows, the least complicated method for IC should be used.
- The individual studies included in the IC must be properly described.
- IC must allow evaluation of the transitivity assumption.
- IC must include sensitivity analyses.
- Requirements for, and the handling of, IC should be described in a handbook or equivalent.
- Staff shall be properly trained for handling IC.

Examples from reimbursement decisions

- Adempas, compared to sildenafil for CTEPH (chronic trombo embolic pulmonary hypertension)
- Quetenza, compared to amitriptylin for peripheral neuropatic pain
- Strattera, compared to methylphenidate for ADHD in adults

- Premalex, for premenstrual dysforic syndrom was compared to no treatment, in spite of a widespread use of generic SSRIs.

Thank you for your attention!

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