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Hierarchy of evidence

Objectives

Hierarchy of evidence

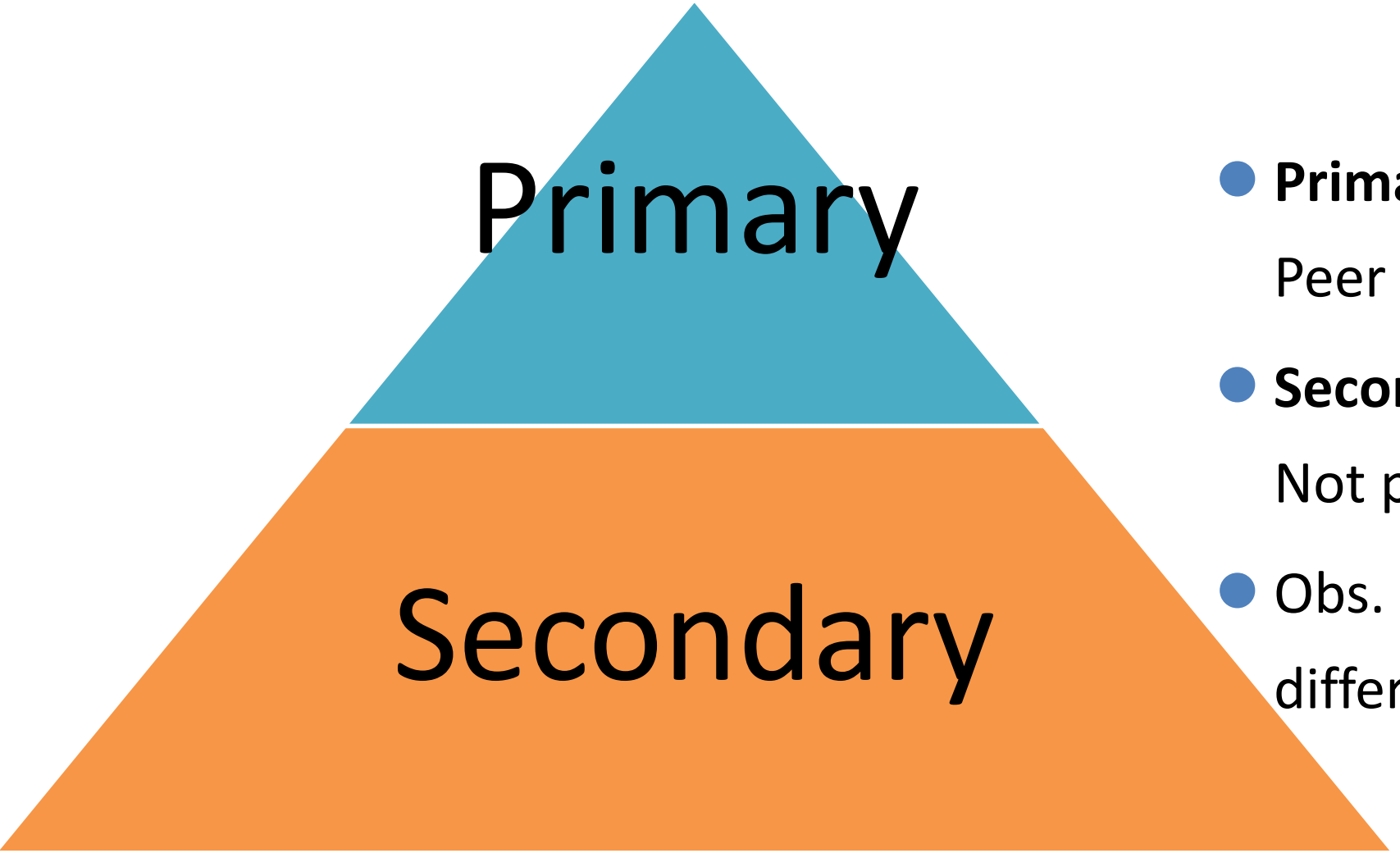
Validy of the studies

Hierarchy of evidence (hierarchy of study quality) - Evaluating the truthfulness of study types

What we should read?

- Books?
- Studies?
- Reviews?

Medical literature

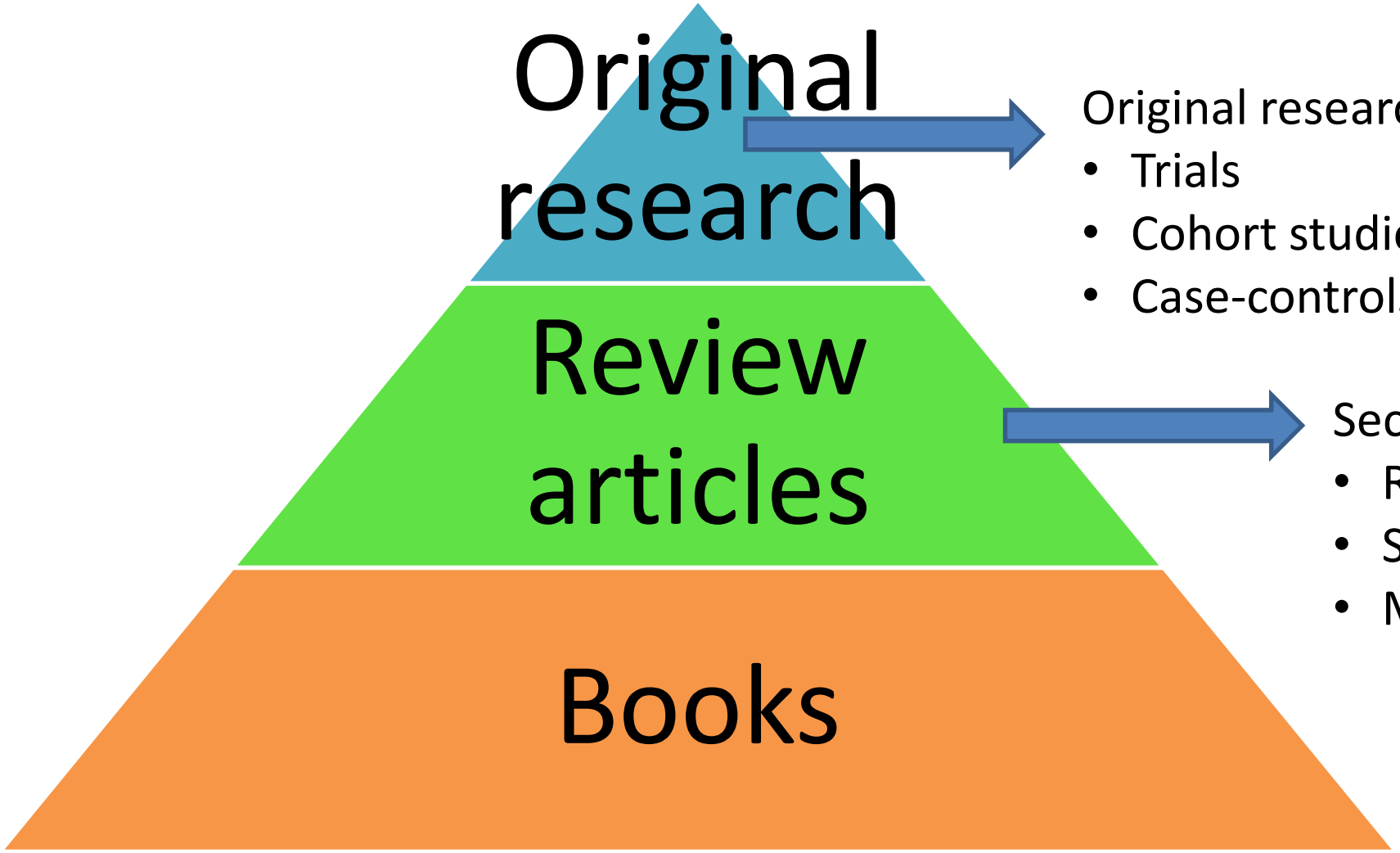


- **Primary literature:**

  Peer Reviewed journal articles
- **Secondary literature:**

  Not peer reviewed
- Obs. Secondary studies is different

Levels of **Peer Reviewed** Information



Original research
- Trials
- Cohort studies
- Case-controls studies

Secondary research
- Review
- Systematic review
- Meta-analysis

Valid studies

- valid studies
  - free from errors,
  - perfect
- ! The conclusions in a valid studies are not necessarily true
  - They are more or less close to the truth
- ! we will choose to read
- first of all valid studies that are
  - closest to the truth
- If we do not find such studies
  - valid studies less close to the truth.

valid studies that are closest to the truth

- ?
  - Hierarchy of evidence

Hierarchy of evidence

Yetley EA, MacFarlane AJ, Greene-Finestone LS, Garza C, Ard JD, Atkinson SA, et al. Options for basing Dietary Reference Intakes (DRIs) on chronic disease endpoints: report from a joint US-/Canadian-sponsored working group. Am J Clin Nutr. 2017 Jan;105(1):249S-285S.

Hierarchy of evidence

scientific investigations designed to understand the underlying biological, physical, or chemical processes that cause an effect

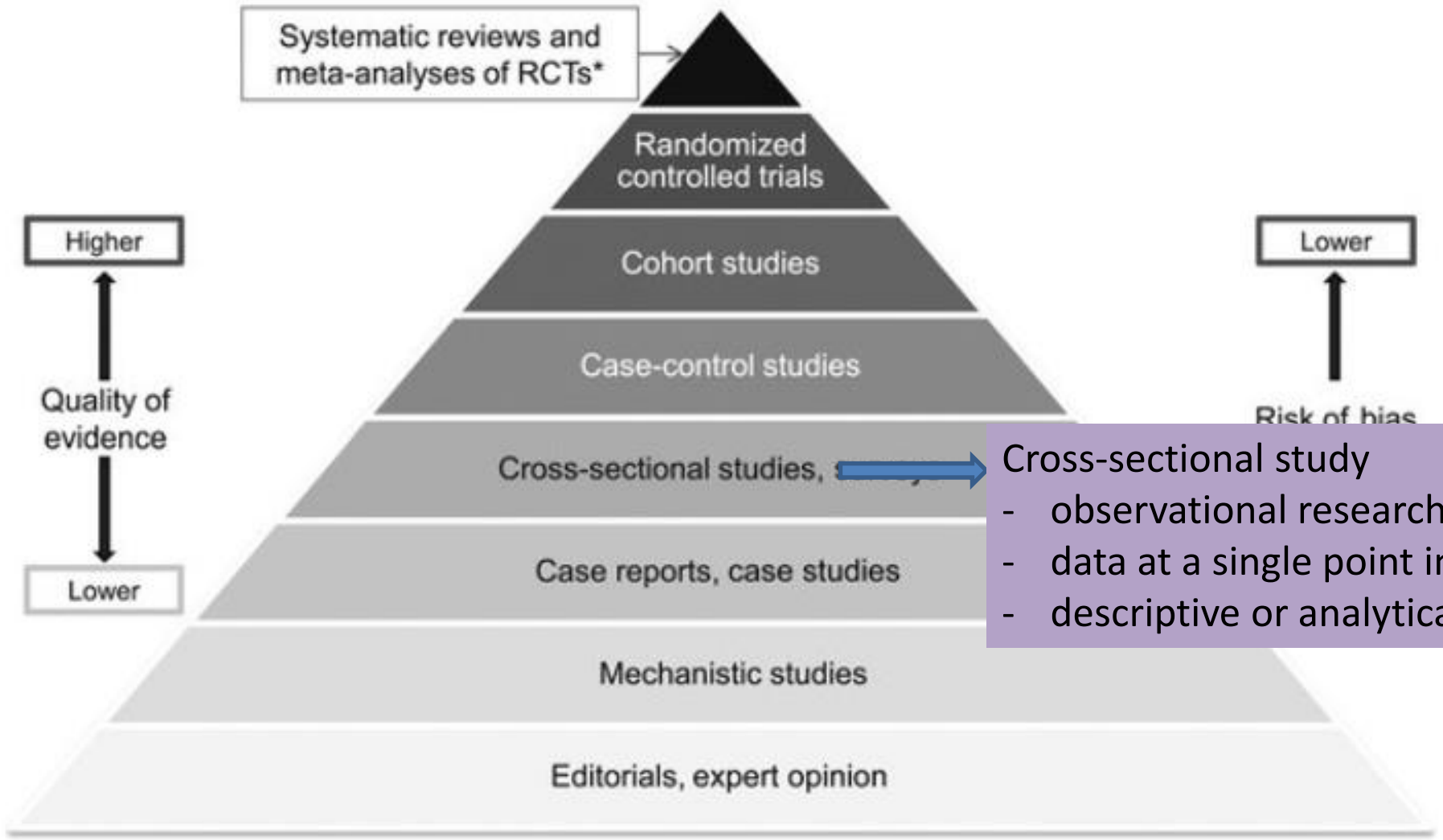
Yetley EA, MacFarlane AJ, Greene-Finestone LS, Garza C, Ard JD, Atkinson SA, et al. Options for basing Dietary Reference Intakes (DRIs) on chronic disease endpoints: report from a joint US-/Canadian-sponsored working group. Am J Clin Nutr. 2017 Jan;105(1):249S-285S.

Hierarchy of evidence

descriptive analyses - unique, complex, or new situations in detail.
Case report - a single case
Case study – a series of cases

Yetley EA, MacFarlane AJ, Greene-Finestone LS, Garza C, Ard JD, Atkinson SA, et al. Options for basing Dietary Reference Intakes (DRIs) on chronic disease endpoints: report from a joint US-/Canadian-sponsored working group. Am J Clin Nutr. 2017 Jan;105(1):249S-285S.

Hierarchy of evidence



Cross-sectional study
- observational research method
- data at a single point in time
- descriptive or analytical

Yetley EA, MacFarlane AJ, Greene-Finestone LS, Garza C, Ard JD, Atkinson SA, et al. Options for basing Dietary Reference Intakes (DRIs) on chronic disease endpoints: report from a joint US-/Canadian-sponsored working group. Am J Clin Nutr. 2017 Jan;105(1):249S-285S.

Hierarchy of evidence

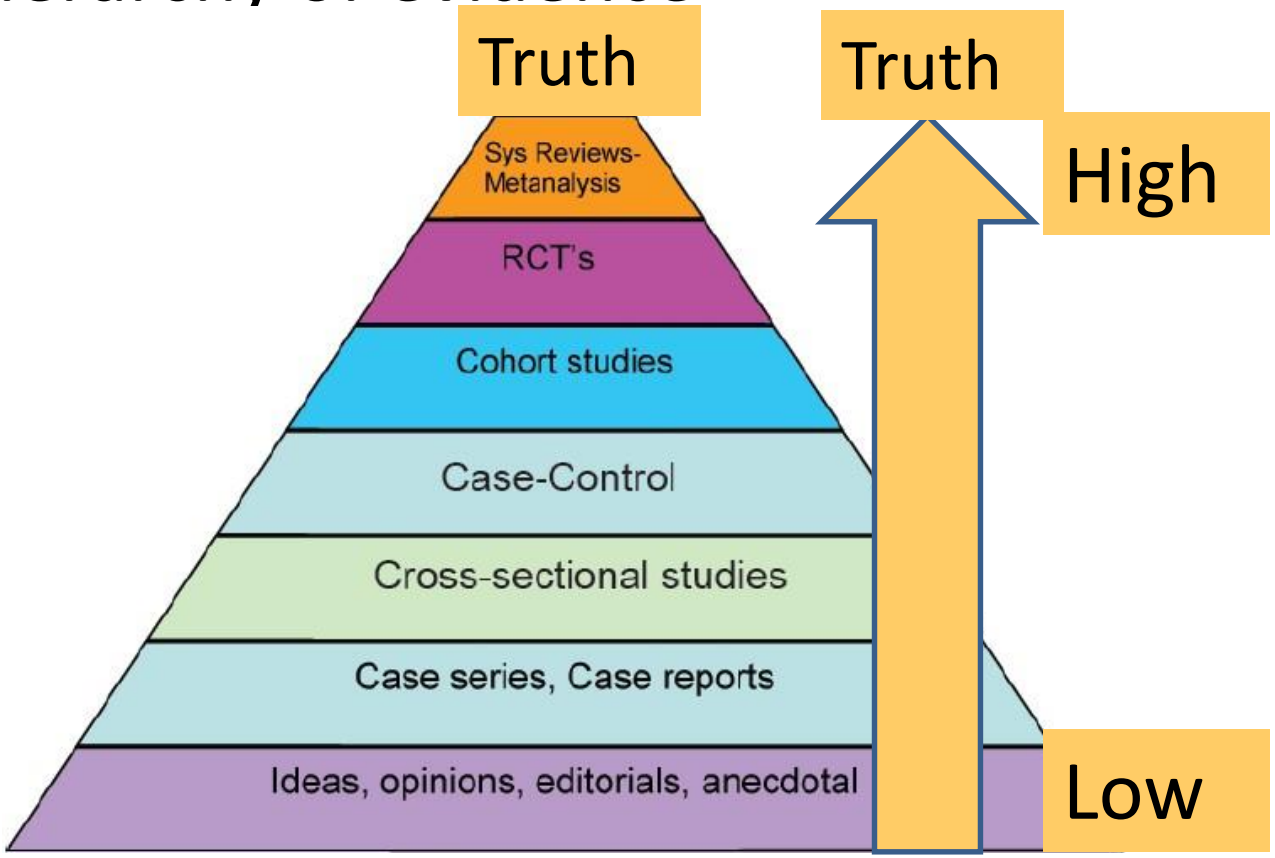
Survey - a method of gathering information, opinions, or data from a specific group of people, typically using questionnaires or interviews.

Yetley EA, MacFarlane AJ, Greene-Finestone LS, Garza C, Ard JD, Atkinson SA, et al. Options for basing Dietary Reference Intakes (DRIs) on chronic disease endpoints: report from a joint US-/Canadian-sponsored working group. Am J Clin Nutr. 2017 Jan;105(1):249S-285S.

Hierarchy of evidence

The closer a study is to the truth

- the higher it is in the hierarchy of evidence

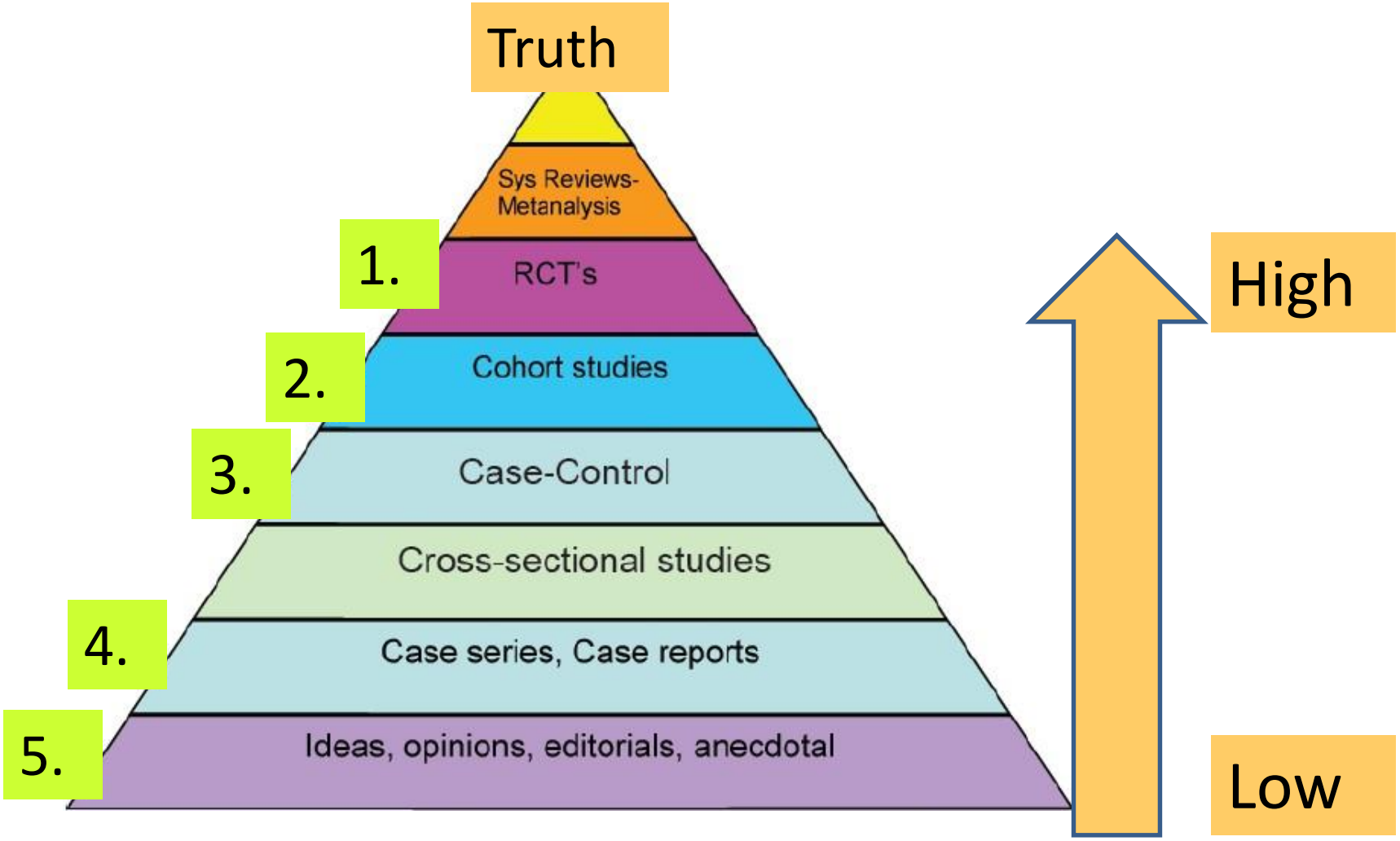


Hierarchy of evidence

- numbering from 1 to 5,
- with subclasses (type 1a, 1b).
- 1 - studies closest to the truth,
- …
- 5 - studies furthest from the truth

- If we know the hierarchy of study types
  – we know what to read.

Hierarchy of evidence



Hierarchy of evidence

Therapeutic studies/adverse reactions/etiology/prevention

- **1**
  - 1a: systematic reviews of randomized controlled trials
  - 1b: randomized controlled trials
- **2**
  - 2a: systematic reviews of cohort studies
  - 2b: cohort studies (including low-quality randomized controlled trials)
- **3**
  - 3a: systematic reviews of case-control studies
  - 3b: case-control studies
- **4**
  - 4: case series (or low-quality cohort or case-control studies)
- **5**
  - 5: Expert opinion

taken from: Centre for Evidence-Based Medicine, adapted, simplified for educational purposes

Hierarchy of evidence

- **Prognostic studies**
- **1**
- 1a: systematic reviews of cohort studies
- 1b: cohort studies with follow-up >80%
- **2**
- 2a: systematic reviews of retrospective cohort studies (case-control studies)
- 2b: retrospective cohort studies (case-control studies)
- **3**
- 3 – none
- **4**
- 4: case series (or low-quality cohort studies)
- **5**
- 5: Expert opinion

taken from: Centre for Evidence-Based Medicine, adapted, simplified for educational purposes

Valid studies

- Validity evaluation
  - Essential criteria
  - Secondary criteria

Valid studies

- Validity evaluation
  - Essential criteria
  - Secondary criteria

A study is valid if the essential validity criteria are met

Each validity criteria that is not met lowers the quality of the study

Therapeutic studies /adverse reactions /etiology /prevention

- **Essential criteria in validity evaluation**
  - treatments randomly assigned
  - treatment allocation concealed
    - *person who made the randomisation*
    - *participants*
    - *investigators*

    } didn't know about the treatment
  - subjects followed enough time for the treatment effect become visible

Therapeutic studies /adverse reactions /etiology /prevention

- **Essential criteria in validity evaluation**
  - enough patients left in the study
    - withdrawal/ quitting rate < 20%
  - analysis was of the “intention to treat” type
    - subjects analyzed as if they took the treatment correctly
  - controlled
    - treatment compared to
      - placebo
      - or reference treatment
      - or another treatment

Therapeutic studies /adverse reactions /etiology /prevention

- Secondary criteria in validity evaluation
  - followed group and the control one are comparable
    - known factors that may influence the desired result
      - !!! The samples are comparable = the known factors which may influence the results are evenly distributed among the groups
      - In case they are not evenly distributed

        →their effect may be controlled with statistics
        - stratification
        - regression

        → their effect on the results → eliminated
    - unknown factors that may influence the desired result
      - Randomization's purpose - to make the compared samples as similar as possible

Therapeutic studies /adverse reactions /etiology /prevention

- Secondary criteria in validity evaluation
  - blind method used in case of
    - Patients
      - the patient doesn’t know which treatment he/she receives
    - Doctors who treat
      - the doctor who treats doesn’t know which treatment he/she gives
    - Investigators who observe the result
      - the investigator who observes the result doesn’t know who received a certain treatment
  - the study is negative
    - There aren’t any significant statistical differences between the compared ($p>0.05$)
  - if the study is negative
    - power of the study is big enough
      - sample size is big enough

Prognostic studies

- Essential criteria in validity evaluation
  - representative studied sample
  - clearly defined studied sample
    - using inclusion
    - exclusion criteria
  - well defined illness stage

Prognostic studies

- Essential criteria in validity evaluation
  - In a cohort study
    - patients were included before the development of the expected results
      - i.e. before the disease/death
    - subjects followed for a period of time long enough
      - so that the effects may occur
    - enough subjects left in the study
      - withdrawal/ quitting rate < 20%

Prognostic studies

- Secondary criteria in validity evaluation
  - results evaluated using the blind method
    - investigator who observes the result doesn't know who was exposed
  - objective criteria for the results
  - comparable groups
    - known factors which may influence the prognostic equally distribute among the samples
    - if the groups are not comparable
      - the influence of factors where adjusted using statistics
        - » stratification
        - » regression
    - Through control their effect on the results is eliminated

Diagnostic studies

- Essential criteria in validity evaluation
  - acceptable reference test
    - is the best diagnostic test or among the best ones used for the desired aspect
  - the new and standard tests were independently evaluated
    - different investigators evaluated the 2 tests
  - the blind method was used
    - neither the new test's investigator, nor the standard test's one knew about the other's results
  - test evaluated on a sufficient number of patients
    - similar to what happens in real practical cases: including subjects in stages of disease
      - initial
      - medium
      - severe
    - subjects with similar pathologies

Diagnostic studies

- Secondary criteria in validity evaluation
  - standard test applied no matter of the new test's outcome
  - appling the tests was detailed enough so that they may be replicated
    - the ways of executing the test were describes
      - the patient's preparations for the test
      - contraindications / precautions for the test
      - precautions after the test
      - risks or uncomfortable issues for the patient who is subjected to the test

Thank you!