Study design

Clinical studies

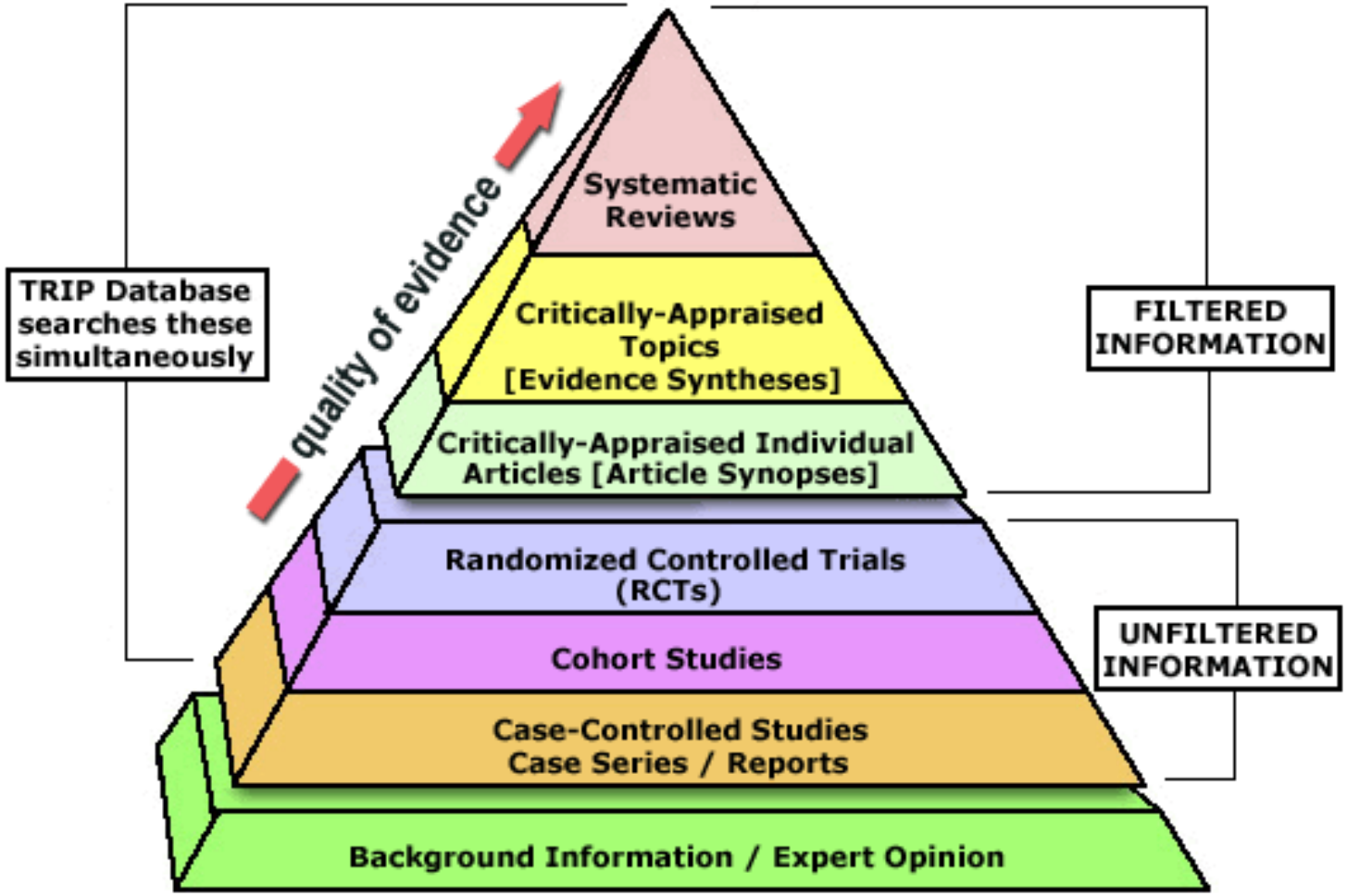
Study design

Qualitative

- Subjective
- Inductive
- Process oriented

Quantitative

- Objective
- Deductive
- Outcome oriented

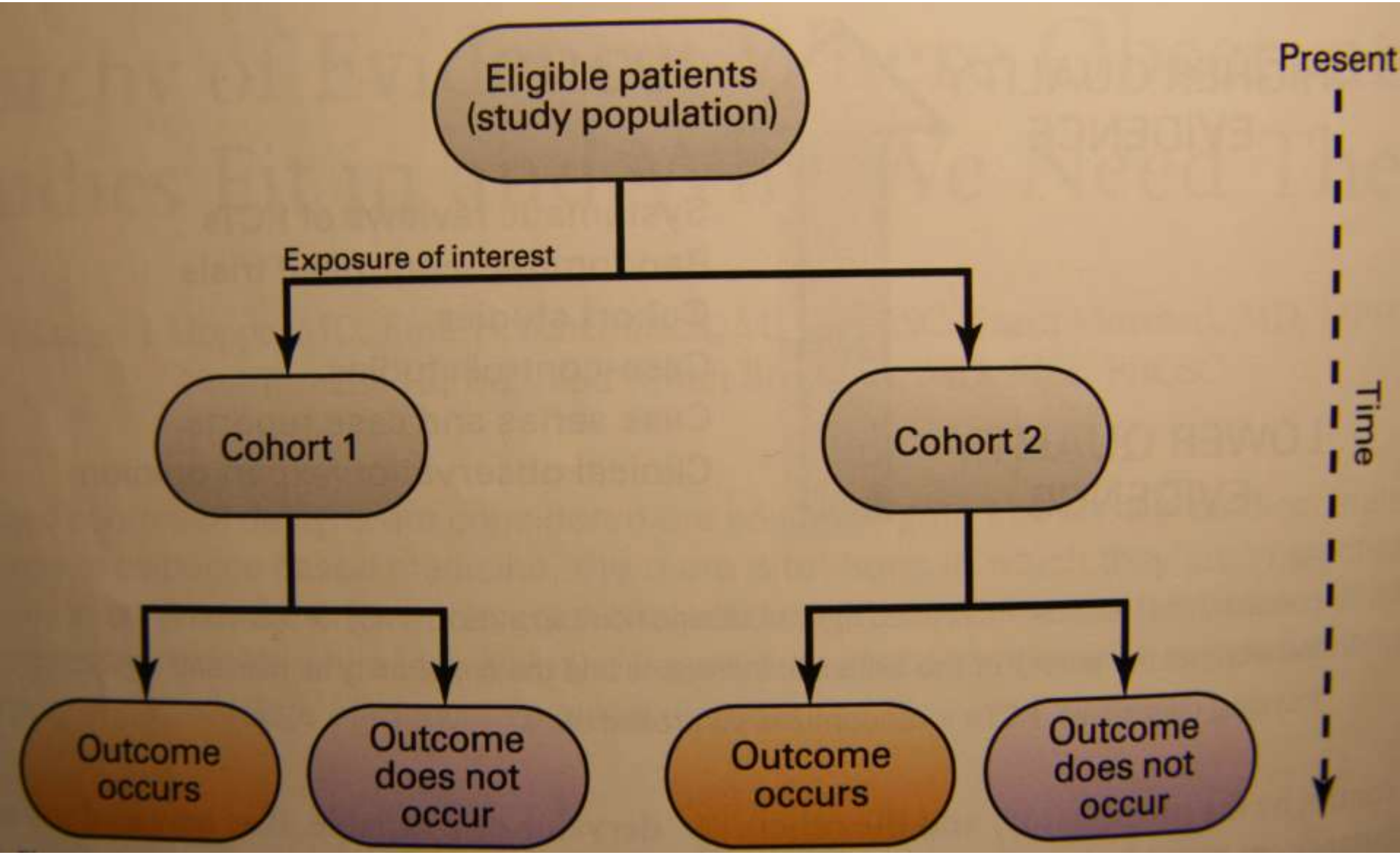


David Lawrence Sackett, ClinicalEpidemiology, McMaster University

Study question

- Does delay in surgical treatment influence mortality following hip fractures?

Moran et al, JBJS(Am). 2005;87:483-9


Eligible patients
(study population)
Present
Exposure of interest
Time
Cohort 1
Cohort 2
Outcome
occurs
Outcome
does not
occur
Outcome
occurs
Outcome
does not
occur

	Mortality - Yes	Mortality - No	Total
Cohort 1 (>4 days)	**a**	**b**	**a+b**
Cohort 2 (<4 days)	**c**	**d**	**c+d**
Total	**a+c**	**b+d**	

$$\text{Relative Risk} = \frac{a/(a+b)}{c/(c+d)} \qquad (2.4)$$

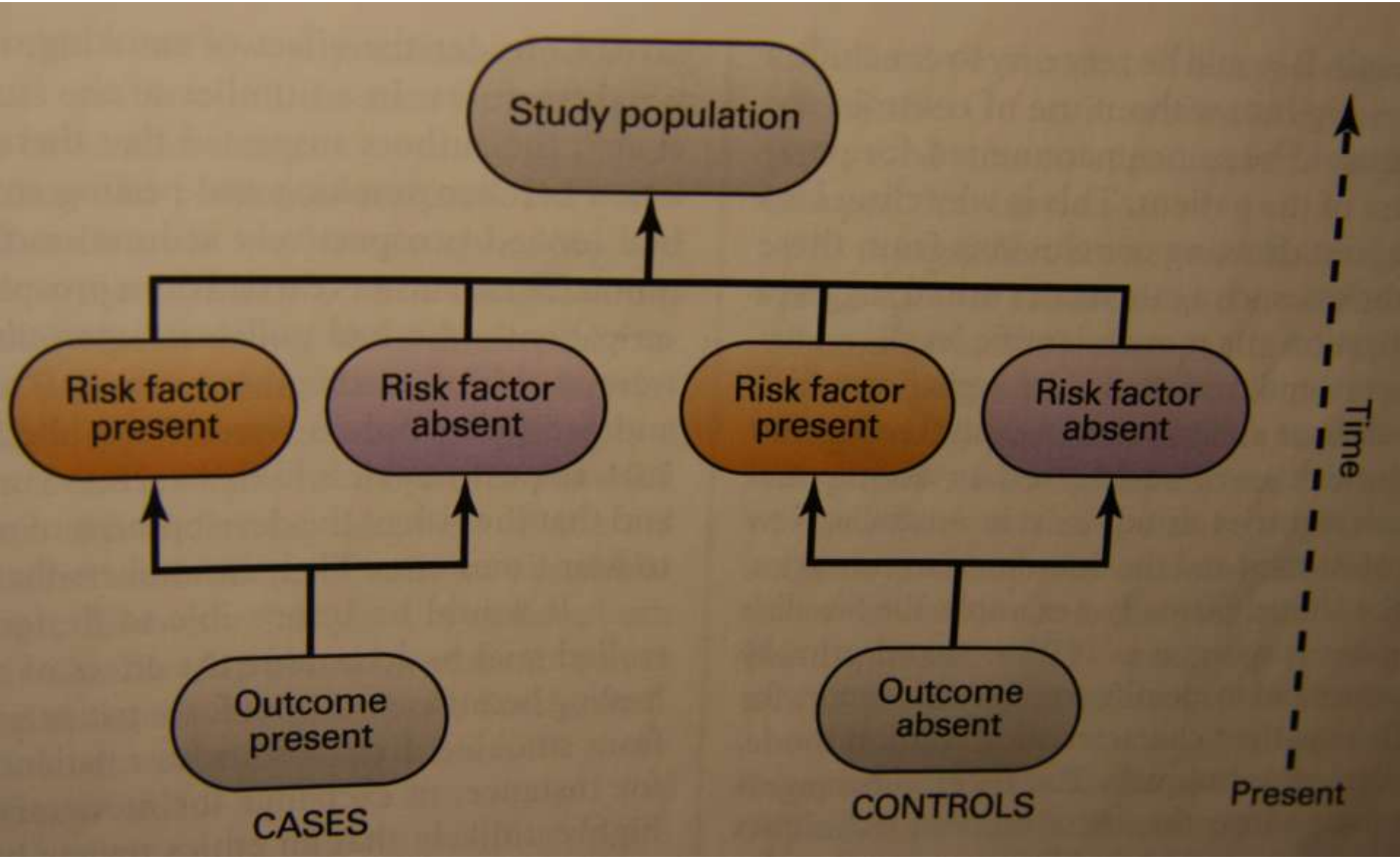
Study questions

- Identify risk factors for surgical site infection following spinal surgery

  Olsen et al, JBJS(Am). 2008;90:62-9

- Association between concentration of fluoride in drinking water and hip fracture

  Hillier et al, Lancet. 2000;355:265-9


Study population
Risk factor present
Risk factor absent
Risk factor present
Risk factor absent
Outcome present
Outcome absent
CASES
CONTROLS
Time
Present

	Infection -Yes	Infection - No	Total
Diabetes - Yes	**a**	**b**	**a+b**
Diabetes - No	**c**	**d**	**c+d**
Total	**a+c**	**b+d**	

Odds ratio: ad / bc (3.5)

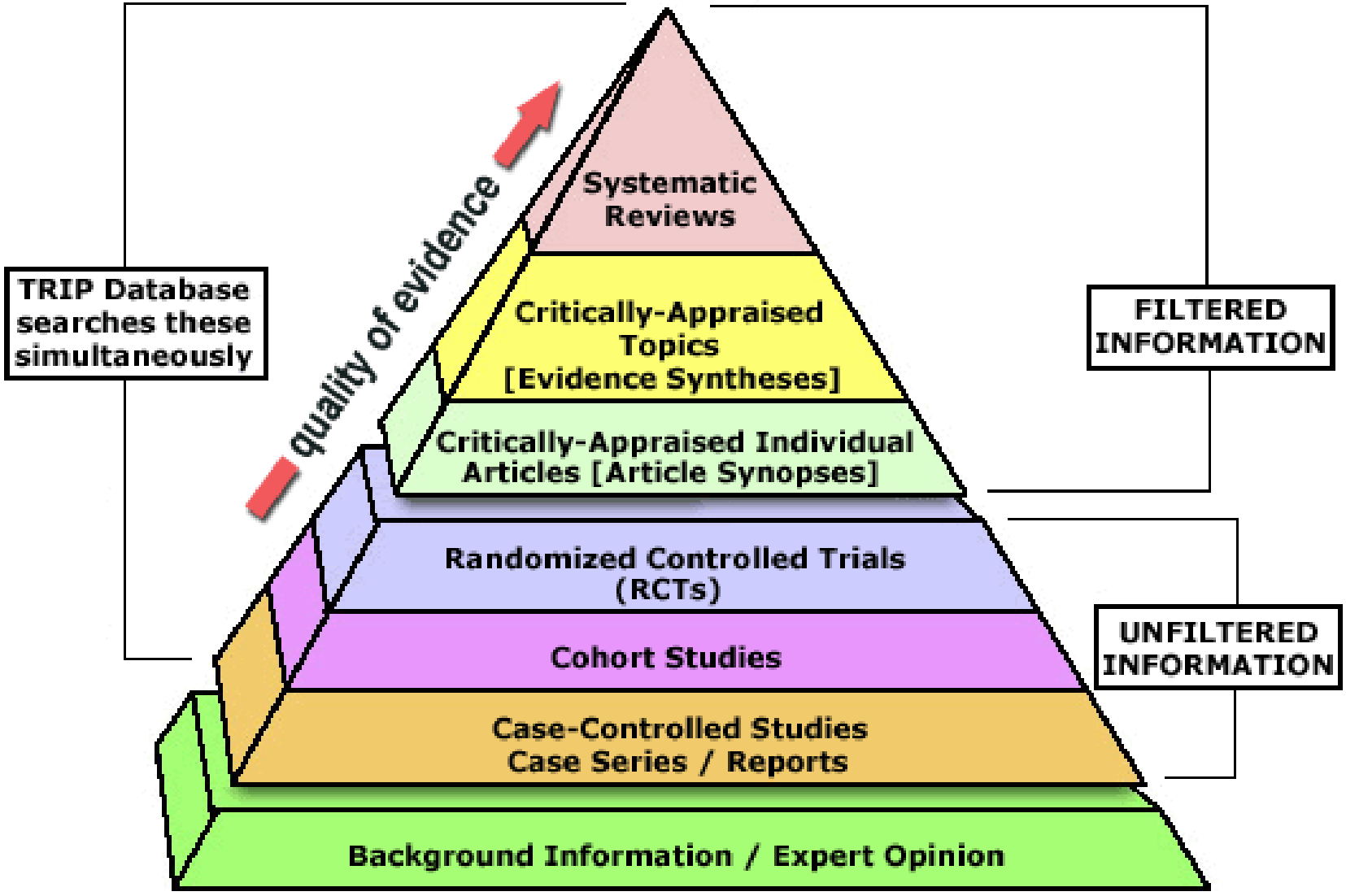
Study design

Observational

- Cohort study
  - Prospective
  - Retrospective – *concurrent or historic controls*
- Case control study
- Case series / surveys / registers
- Cross sectional
- (Longitudinal)

Occupation & OA in hip and knee

- 250,217 Blue collar workers
- 1980 Swedish census
- Same occupation 1960 & 1970 census
- Followed for hospital care for hip or knee OA from discharge registry 1981 - 1983



Study design

Experimental

- RCT
  - Single-blind
  - Double-blind
  - Non-blind

- Non-randomised trial (quasi-experiment)

RCT

- In most areas of life we want to know ‘What Works’
  - Is arthroscopic surgery better than open surgery?
  - Are doctors better than nurses at pre-operative assessments?

- The best way of answering the ‘What Works’ question is the RANDOMISED TRIAL.

What randomisation does

- It controls for the unknown unknowns and known unknows. By forming two groups using random allocation ensures that the characteristics of the groups are balanced so that the only thing that differs is the intervention.
- Differences in outcomes can then be attributed to the intervention.

Common confounders

- Temporal change
- Regression to the mean

Temporal Change

- Most people get better or worse irrespective of any medical attention.

- Any intervention or treatment mixed up with these temporal changes is difficult to disentangle.

Regression to the mean

This is a GROUP phenomenon and occurs when the group are measured with an inexact measurement tool and then remeasured. Those individuals with ‘extreme’ values will have a high probability of regressing towards the mean on the second measurement.

Good research question: clear and specific

- Clinical clarification:
  Who (are the patients)?
  What (is the intervention)?
  Why (are you trying to do this)?

- Practical clarification:
  Where (is it possible to do this)
  When (is it feasible)
  How (can you implement it)?

Clarified research question

- ✓Aim (general terms)
- ✓Hypothesis (specific terms)
- ✓Novelty?
- ✓Why does it matter?
- ✓How will patients benefit?

Method

- P – participants
- I – interventions
- C – comparators
- O – outcomes
- S – study design / sample size / stats

CONSORT

(Consolidated standards of reporting trials)

Evidence based minimum set of recommendations for reporting of RCTs

- Checklist
- Flowchart

http://www.consort-statement.org

Summary

- EBM pyramid and Sackett levels of evidence
- Systematic reviews of good quality RCTs
- RCTs
- Role of non-randomised studies in Orthopaedic surgery