STUDY DESIGNS: A CONUNDRUM!

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Structure

- Importance
  - *Why this topic?*
- Taxonomy
  - *Broad categorization*
- Examples
  - *Illustrating with 'real-life' examples!*
- Strengths & limitations
  - *What can (& cannot) they do?*
- Choosing a study design
  - *Broad guidelines*

Importance

Study design

- Basic ANATOMY of any study!

Anatomy determines the physiology!

Importance

Study design

- 'influences' what research question (RQ) can be answered!

Anatomy determines the physiology!

Example…

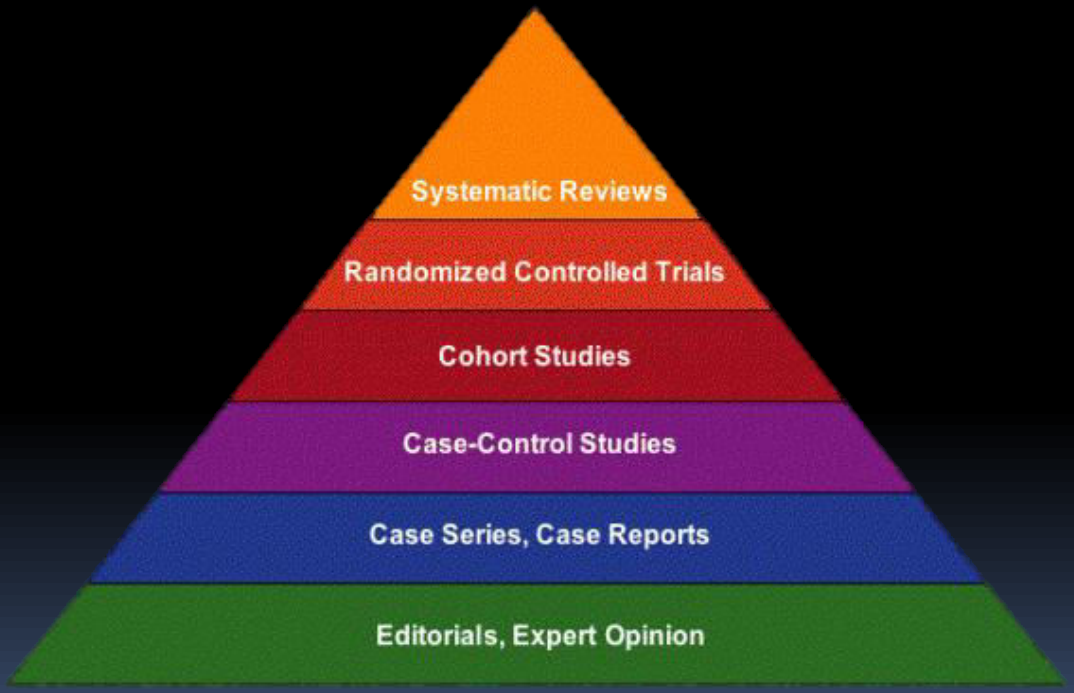
RQ

- Does **exclusive breastfeeding** in first 6 months of life improve **IQ** in healthy infants?

Can I do RCT?

Importance

2. Level of evidence



All are equal but some are more than equal!

Importance

3. Rejection of manuscript

- Confusion in study design – common reason for rejection
- Notorious:
  - RCT vs. non-/quasi-randomized trial
  - Case-control vs. cohort

Do NOT expect to be accepted!

Taxonomy & classification

Taxonomy

Explanation of terms

1. Exposure/intervention

- "Condition that you expect to make subjects do better or worse"

- Example:
  - Does kangaroo mother care (KMC) reduce pain after IM vitamin K injection in preterm neonates?

"Factor that differentiates the 2 groups"

Taxonomy…

Explanation of terms

2. **Outcome**
   - "the EFFECT of treatment/condition that you expect to make difference"
- Example:
  - Does KMC reduce pain after IM vitamin K injection in preterm neonates?

Can 'death' be an 'Exposure'?

Taxonomy…

Explanation of terms

3. **Random allocation**
   - "each participant has EQUAL chance of going into EITHER of the treatment groups"
- Method:
  - Tossing a coin

Is allocation by day of birth 'random'?

Classification

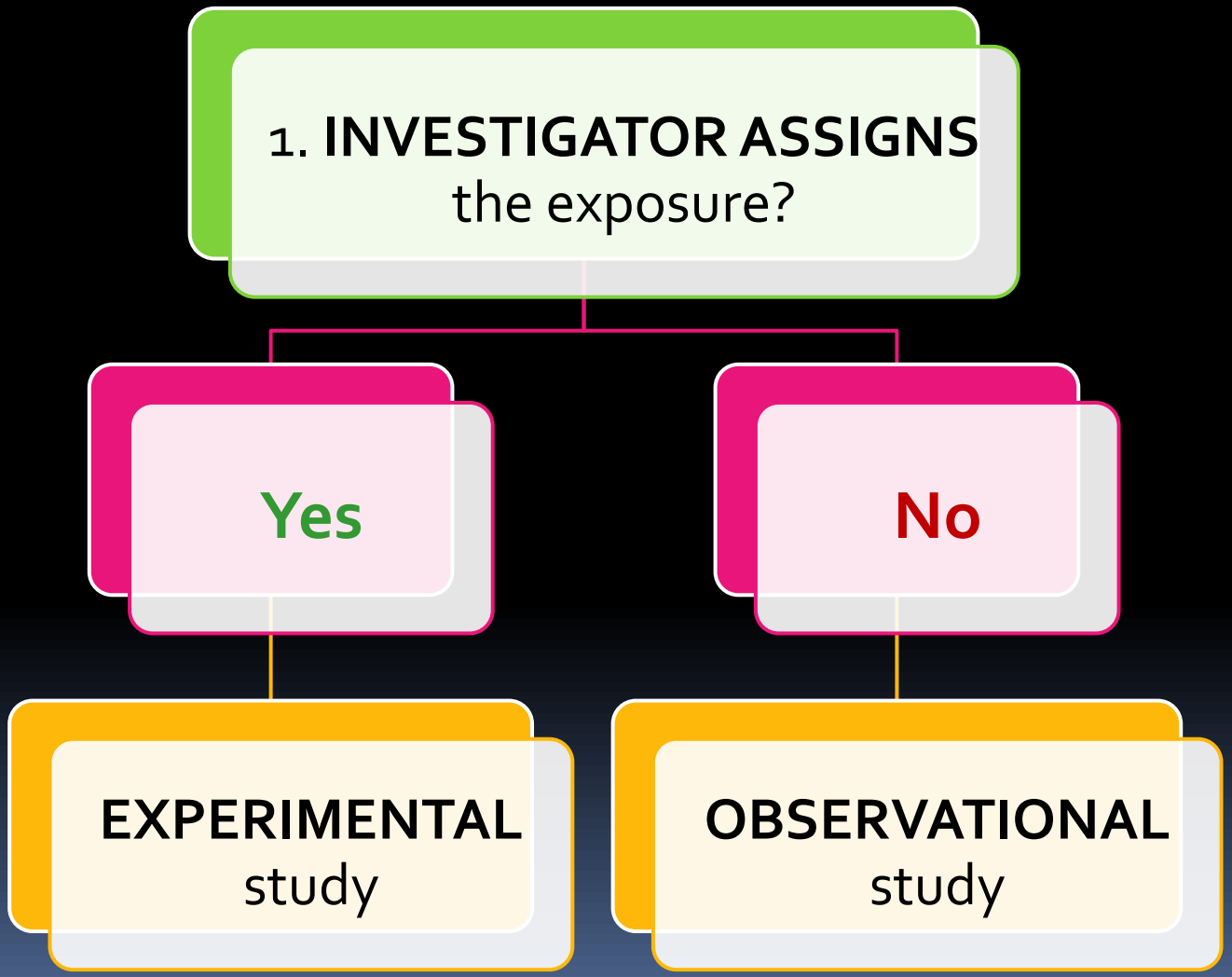
Broad categorization*

1. Experimental study
2. Observational study
   - Descriptive
   - Analytical

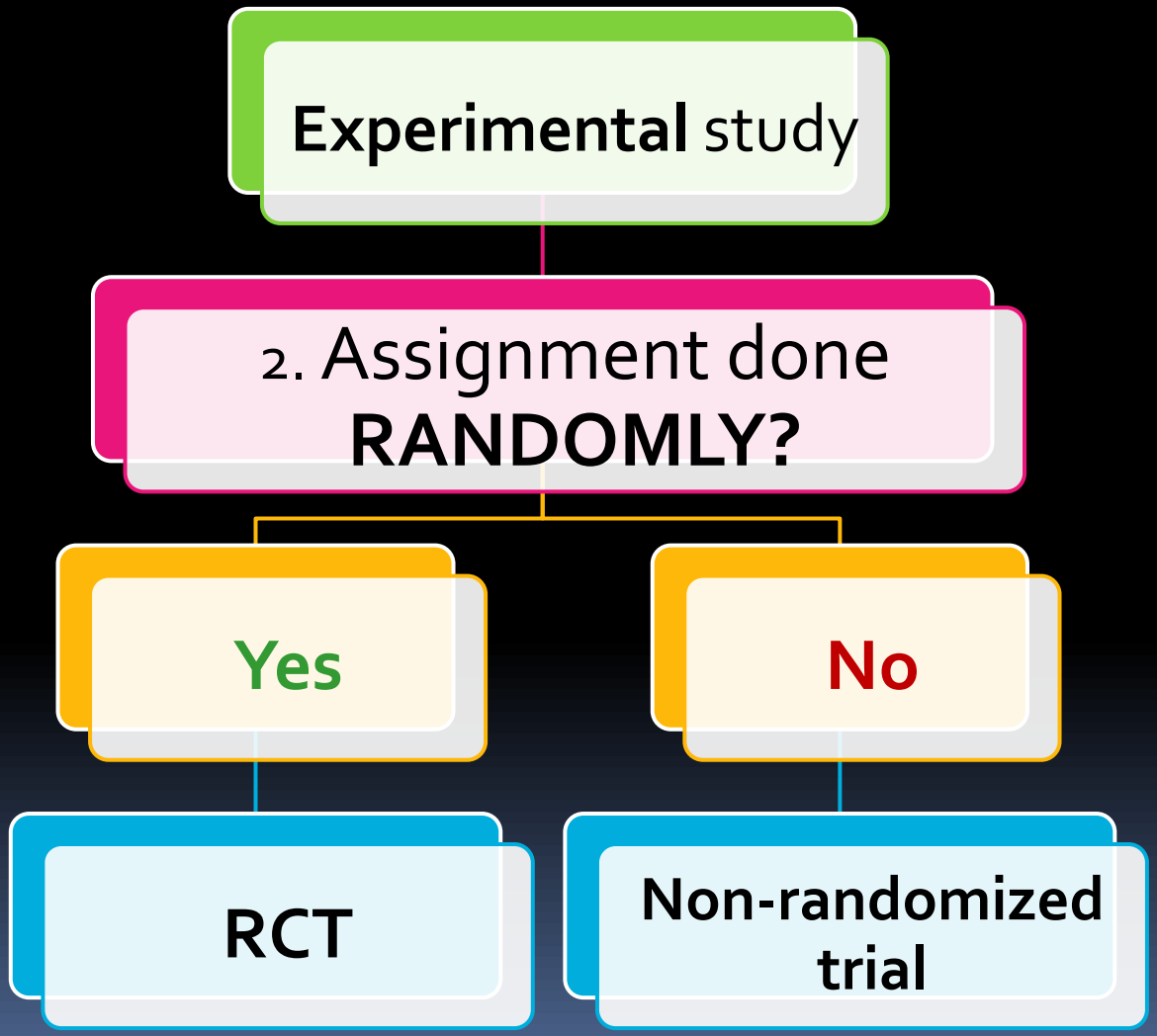
Based on 4 questions!!!

**Grimes, Schulz; Lancet 2002*

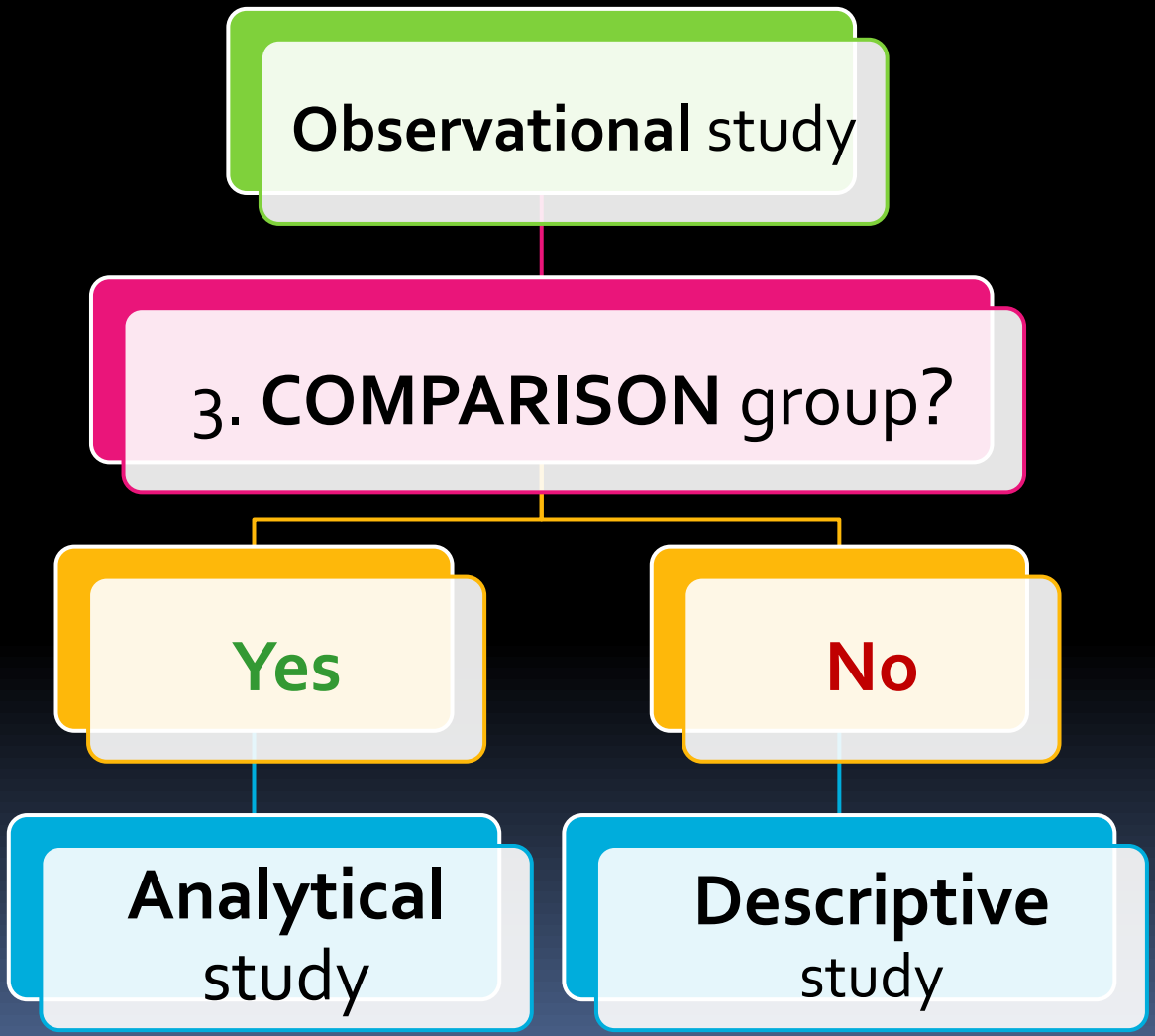
Classification



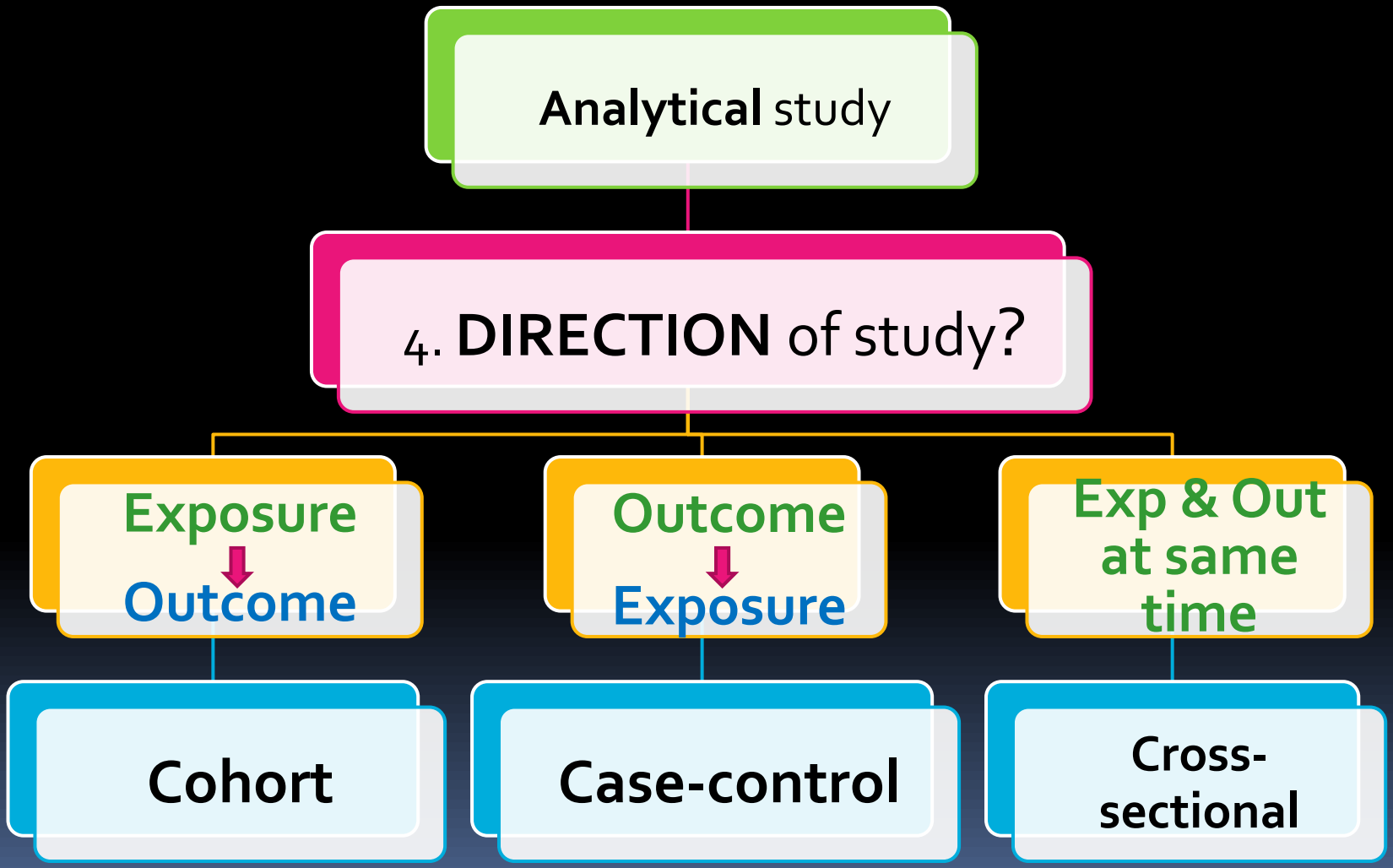
Classification…



Classification…



Classification…



Examples

Classification…

Descriptive study

1. Case report
2. Case series
3. Descriptive cohort
4. Survey

Classification…

Case studies

- Case report /case-series
- Describes in-depth characteristics of a unit
  - Unit: patient, health centre or community
- Helps generate hypothesis
- E.g. Neonatal ARF due to maternal enalapril ingestion

Slide courtesy: Agarwal R

Classification…

Others

1. Evaluation of diagnostic test
   - For a ‘new’ test/investigation
2. Before-and-after study
3. Retrospective cohort

Classification…

Evaluation of diagnostic test

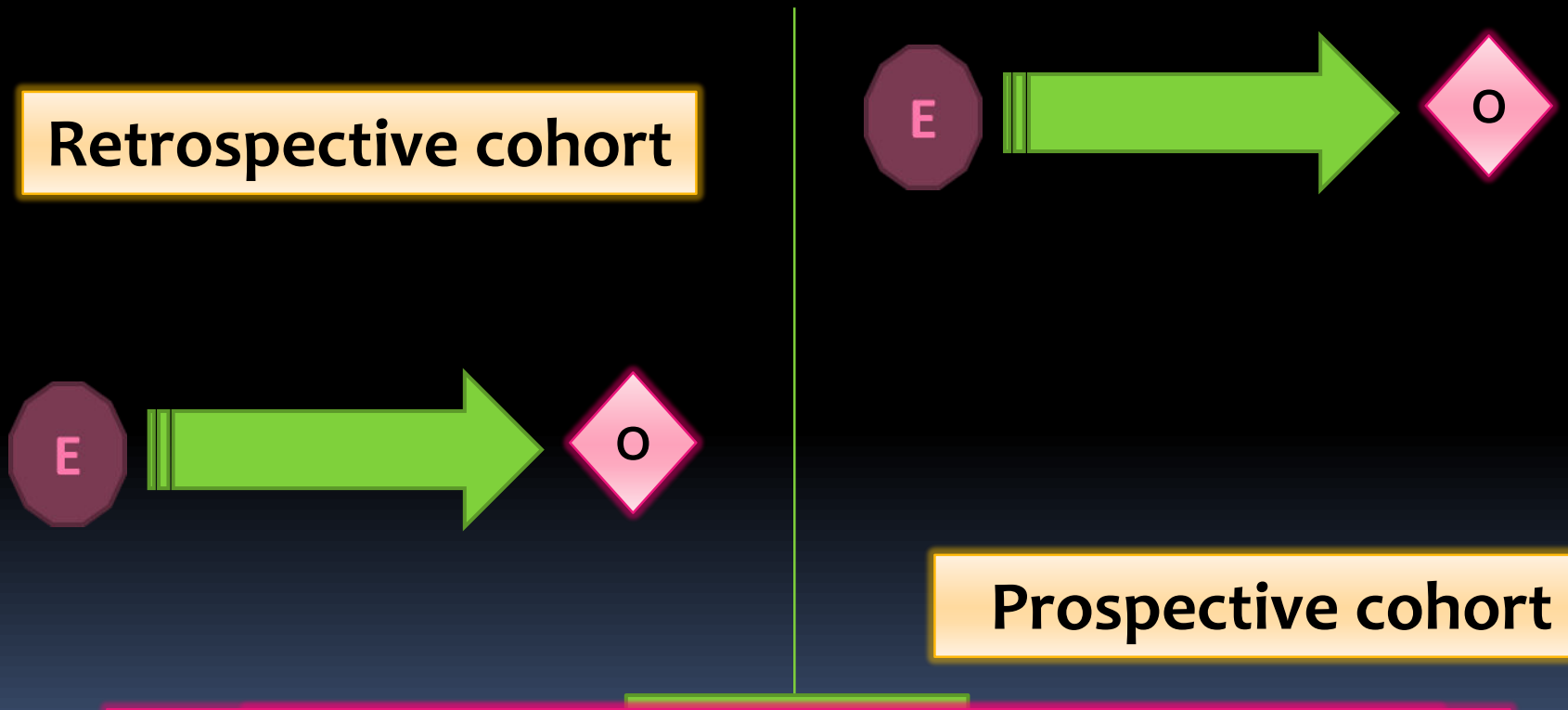
- Lab test or clinical criteria
- Apply the test AND gold standard in ALL participants
- Compare performance of the test against gold standard
- E.g. performance of sepsis screen against blood culture

Classification…

Before-and-after study

Classification…

Retrospective cohort



Courtesy: Agarwal R

Example 2

Exposure!

Outcome!!

Does surfactant therapy reduce neonatal mortality in preterm infants?

Scenario 1

- You describe 10 PT babies who were given surfactant
  - Clinical course
  - Complications and
  - Mortality

Case-series!

NB: Association CANNOT be determined

Scenario 2

- You observe next 100 PT babies admitted to NICU
- Record how many receive surfactant and how many do not
- Follow-up till discharge/death

Cohort study!

Scenario 3

- You retrieve records of 2015
- Select records 100 PT babies
- Note how many received surfactant and how many did not
- Note the outcome for all

Retrospective cohort!

Scenario 4

- You retrieve records of 2015
- Select records of 50 PT babies who died and another 50 PT babies who survived
- Retrieve information on surfactant treatment

Case-control!

Scenario 5

- Your unit does not have surfactant facility
- Record outcomes of 50 PT babies for 3 months
- Introduce surfactant after 3 mo
- Record the outcomes of 50 PT for next 3 mo

Before-and-after study!

Strengths & limitations

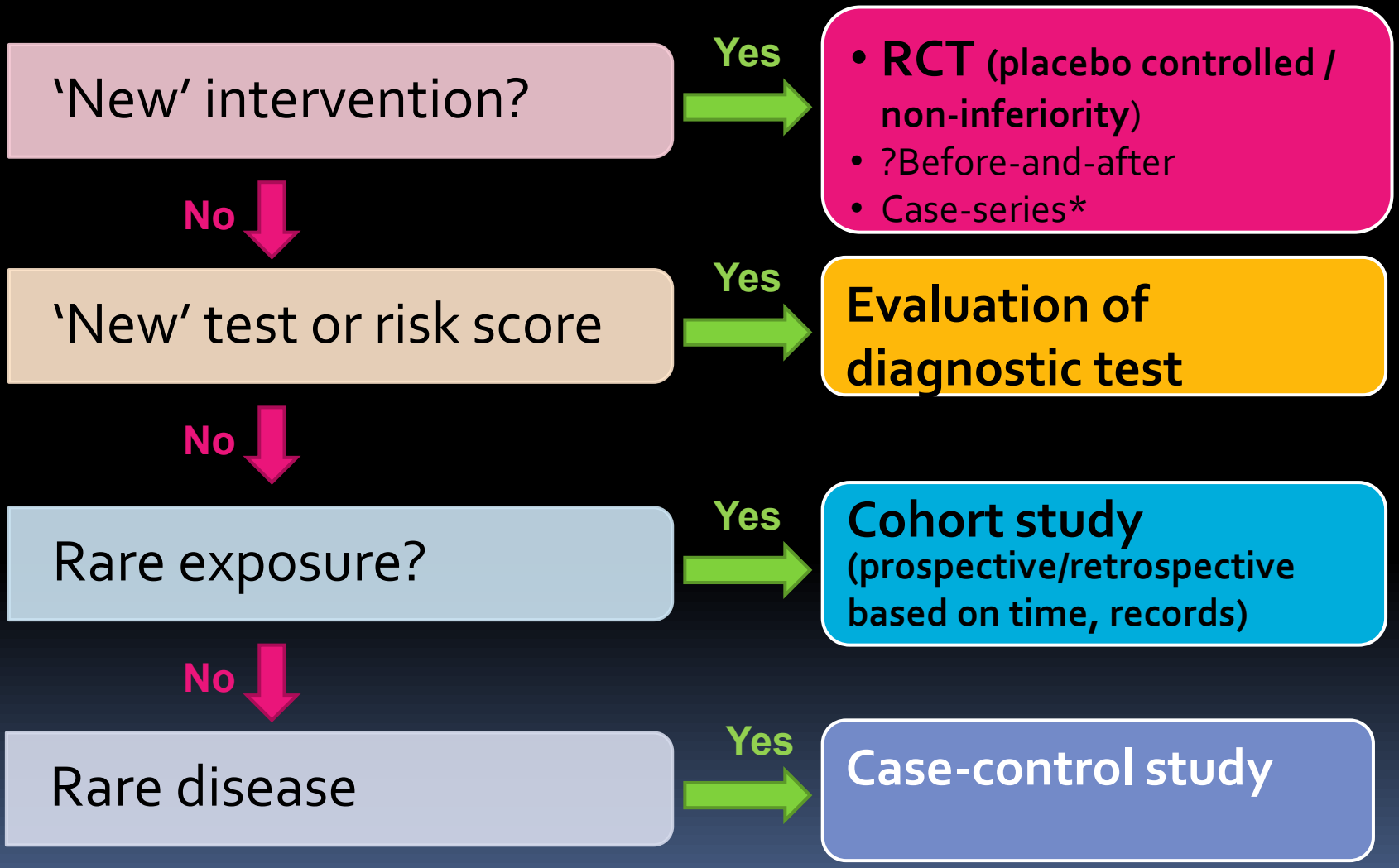
In brief!

Design	Strengths	Limitations
Case studies	Cheap & easy; Description	No analysis; Biased reporting
Cross sectional	Prevalence; Hypothesis generation	No temporal relationship
Case control	Less costly & quick; For rare diseases; Multiple risk factors	Recall bias; selection bias
Cohort	Cause and effect relationship; For rare risk factors; Multiple outcomes	Time consuming; Costly
Experimental	Causality	Expensive; ethics; difficult

Courtesy: Agarwal R

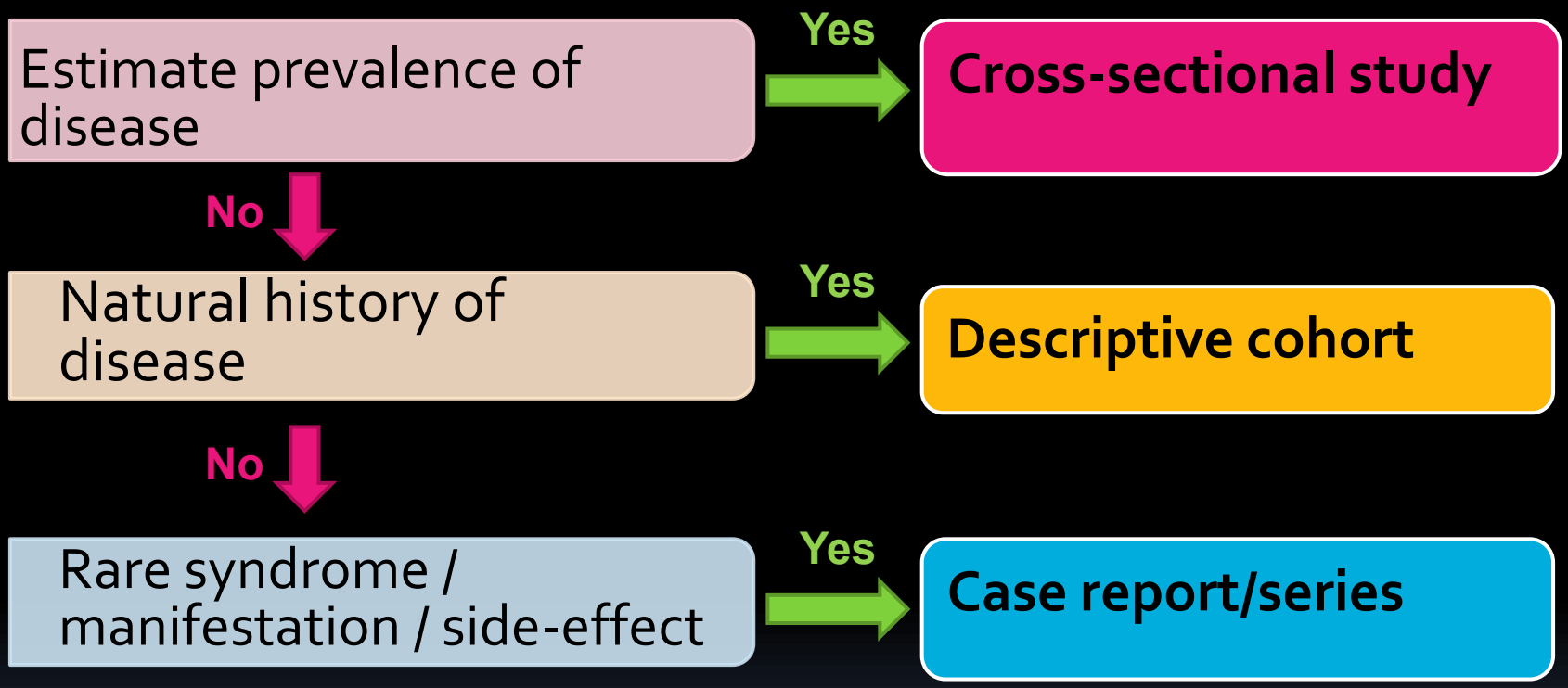
Guidelines

Guidelines



*Untested drug; as a first step

Guidelines


Estimate prevalence of disease
Yes
Cross-sectional study
No
Natural history of disease
Yes
Descriptive cohort
No
Rare syndrome / manifestation / side-effect
Yes
Case report/series