Research Design

Einas Al-Eisa, MSc, PhD

“Because science carries us toward an understanding of how the world is, rather than how we wish it to be, its findings may not in all cases be immediately comprehensible or satisfying. It may take a little work to restructure our mindsets. When we shy away from it because it seems too difficult (or because we’ve been taught so poorly), we surrender the ability to take charge of our future.”

Carl Sagan:

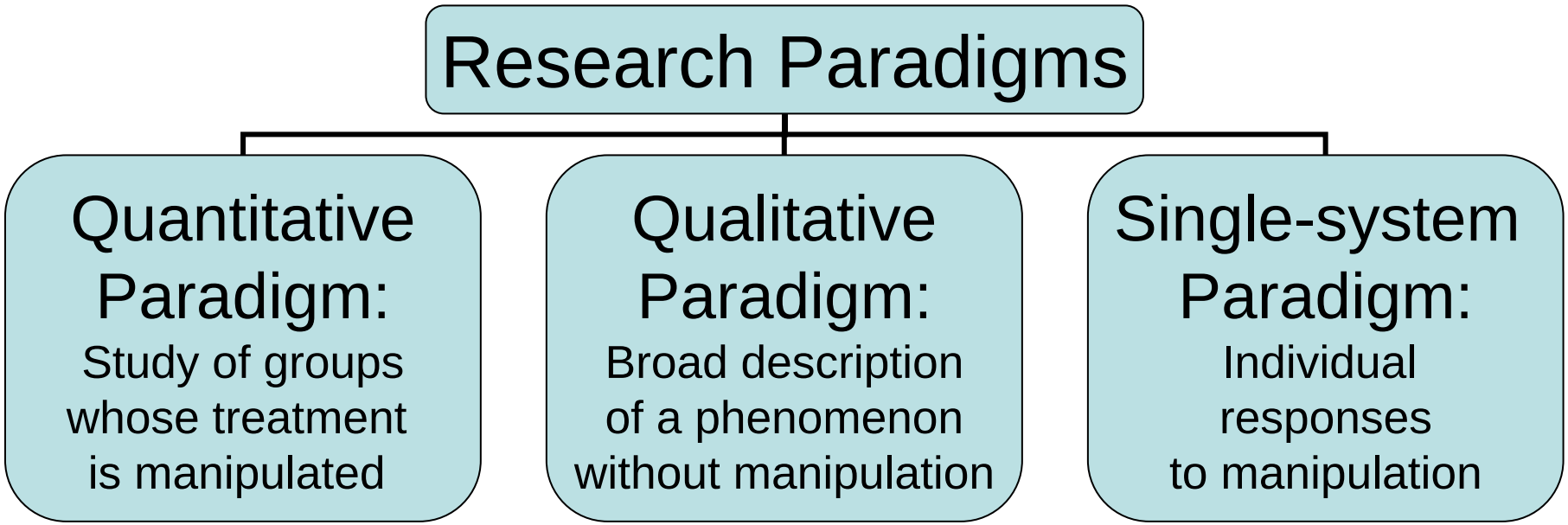
“The Demon-Haunted World: Science as a Candle in the Dark”

Research design

- = the process in which the investigators determine how they can best answer their research questions

- Research problem ⟶
  Research design ⟶
  Data analysis

Methods of obtaining knowledge



Paradigm **versus** **Methods**

The assumptions & beliefs that guide the researcher

The actions taken by the investigators as they implement the research

Quantitative paradigm assumptions

1. There is a single objective reality
2. The investigator & subject are **independent**
3. **Generalizability** of findings is **possible**
4. **Cause and effect** relationship
5. **Value free** (investigator opinion, social norms)

Qualitative paradigm assumptions

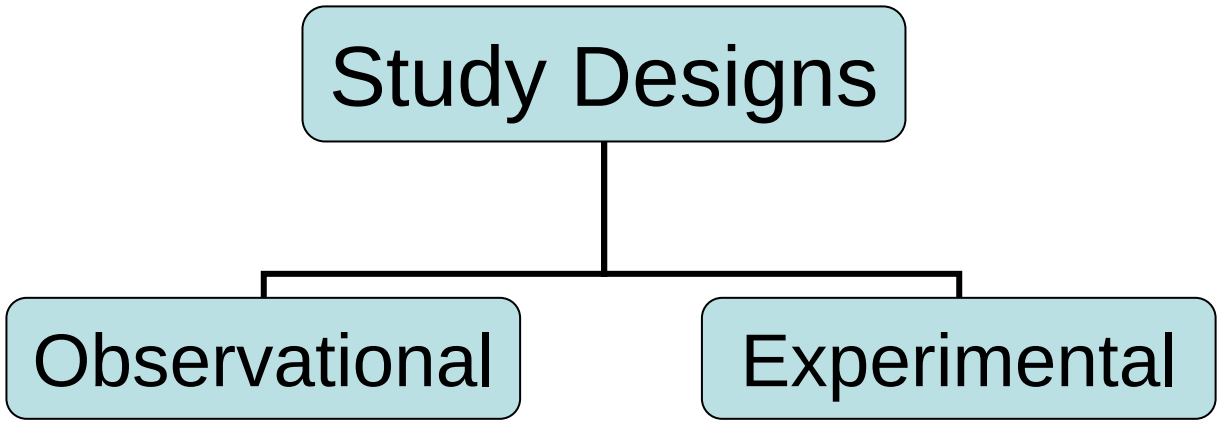
1. There are multiple constructed realities
2. Investigator & subject are **interdependent**
3. **Not generalizable**
4. **Cause and effect** relationship can **not** be determined
5. **Value bound** (inability to separate values from inquiry)

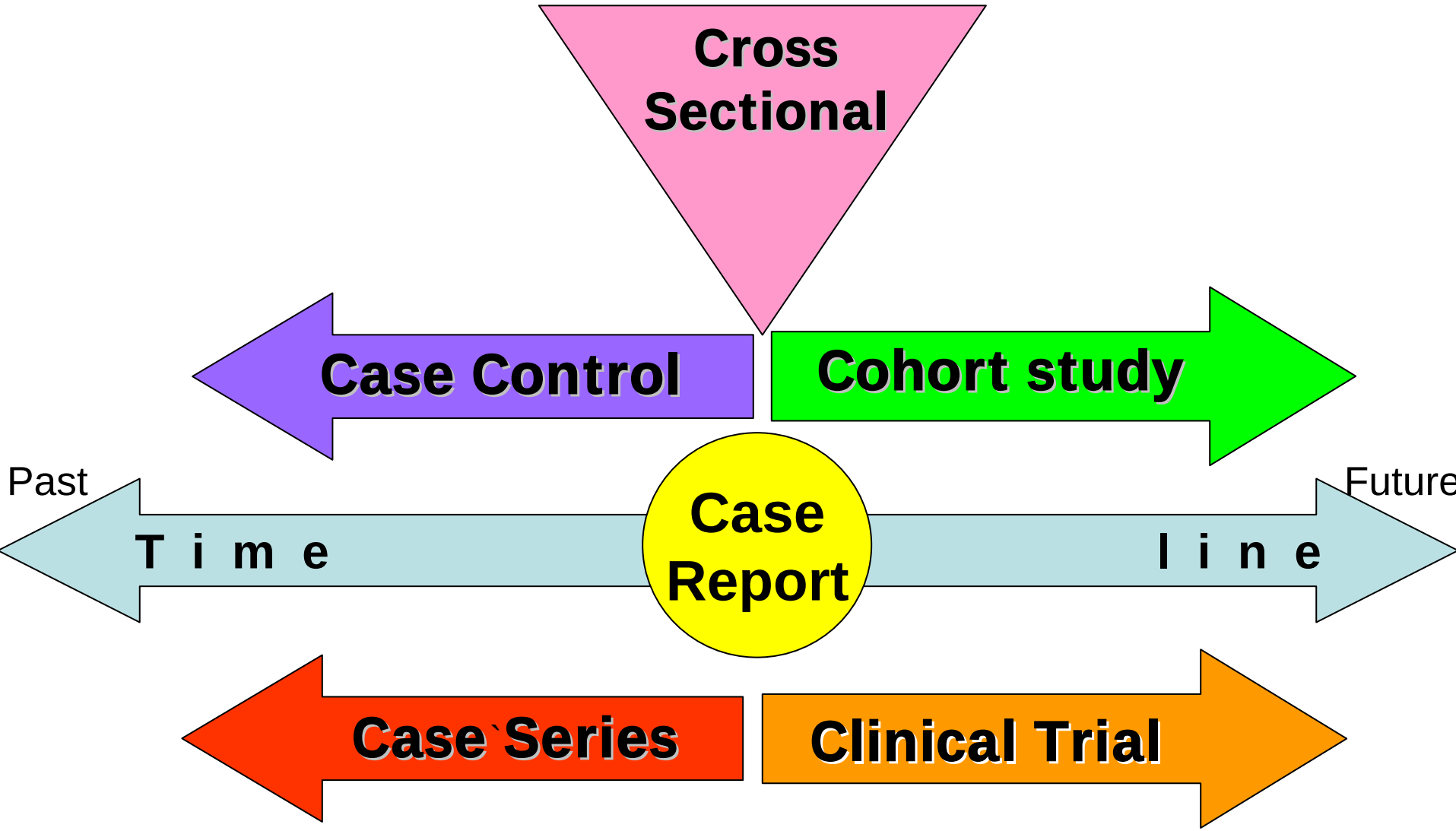
Single-system paradigm assumptions

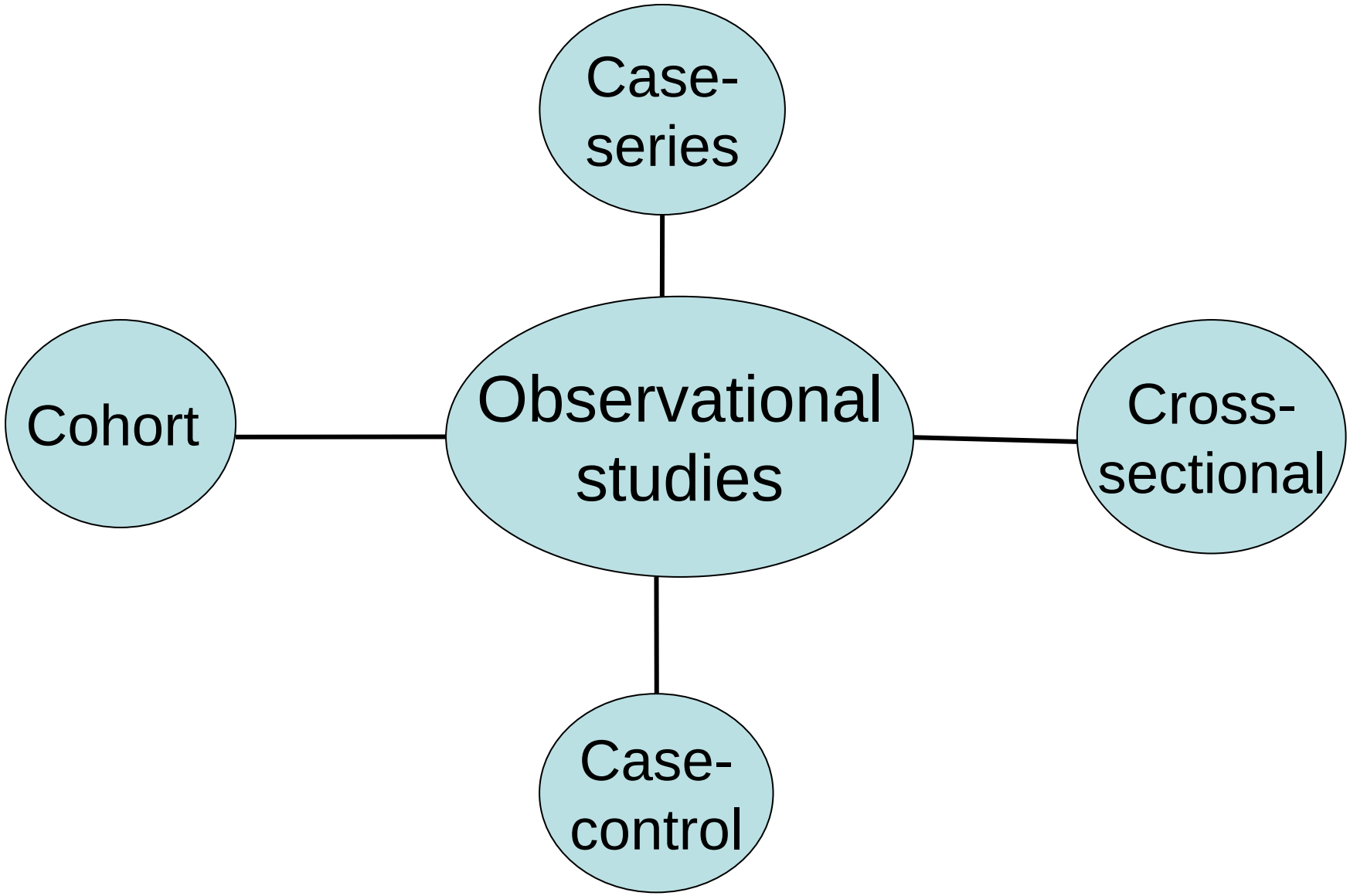
The general assumptions behind the quantitative paradigm apply here with minor differences:

- The effectiveness of treatment is subject and setting dependent (not generalizable)
- Focus on individuals rather than groups

Not synonymous with “case-report” or “case-study”


Study Designs
Observational
Experimental


Cross Sectional
Case Control
Cohort study
Past
Future
T i m e
l i n e
Case Report
Case`Series
Clinical Trial


Case-series
Cohort
Observational studies
Cross-sectional
Case-control

Case-series studies

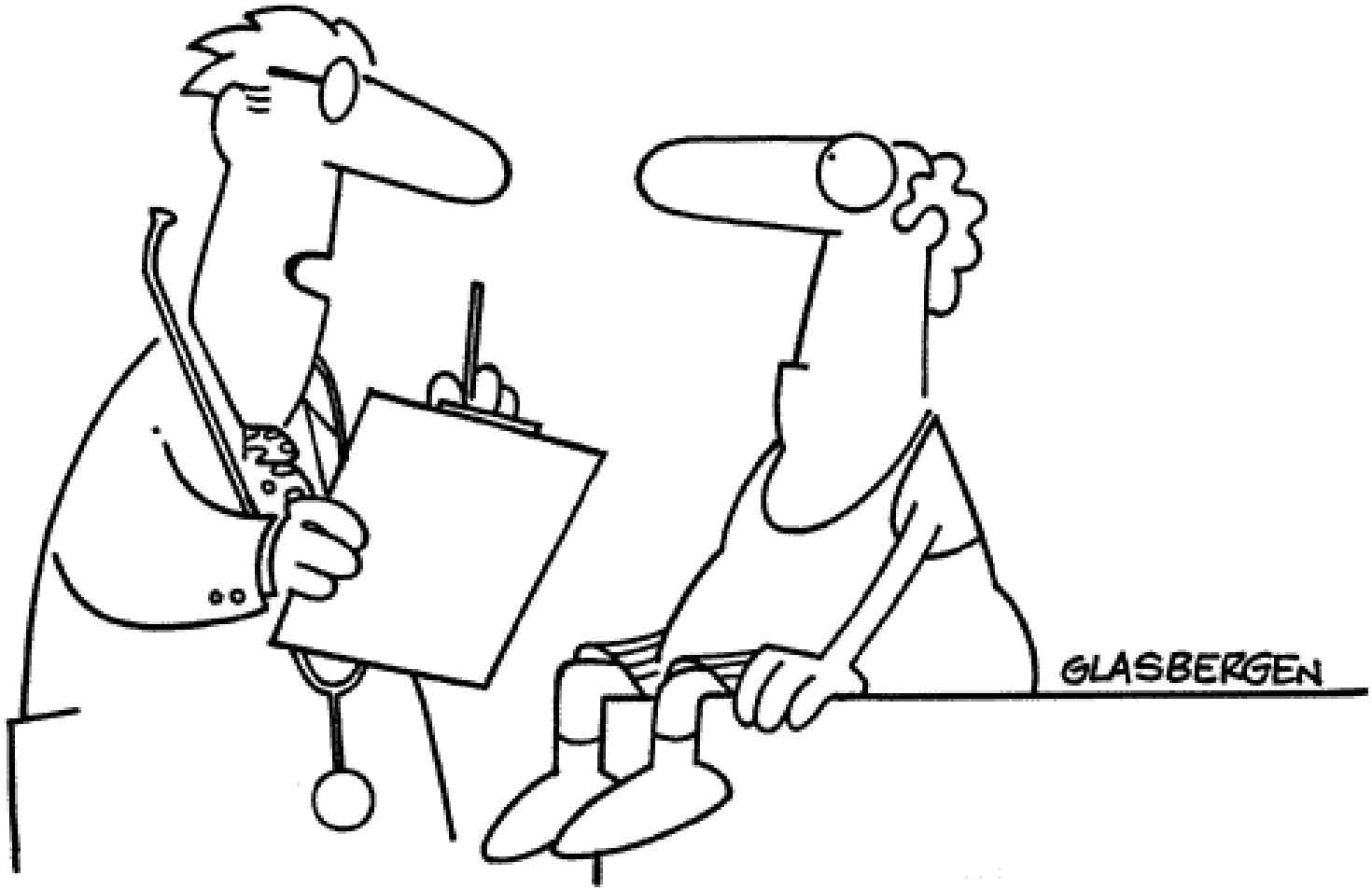
- Simple description of interesting observations in a small number of subjects
- Generally not planned before
- Do not involve hypothesis
- Do not include control subjects

Case-series studies
Example

Wong et al. (2003). Clinical presentation and outcome of severe acute respiratory syndrome in dialysis patients. **Am J Kidney Dis** ;42:1075-1081.

Case-series studies

- Advantage:
  - easy to write
  - useful in new observations or disease
- Disadvantage:
  - subject to **bias** related to subject selection



"We can't find anything wrong with you, so we're going to treat you for Symptom Deficit Disorder."

Case-control studies

- Start with the presence or absence of an outcome, and look back into the past to detect possible causes or risk factors

Cases= individuals with disease or outcome

Controls= individuals without disease or outcome

Case-control studies
Example

Mutsch et al. (2004). Use of the inactivated intranasal influenza vaccine and the risk of Bell's palsy in Switzerland. **N Engl J Med**; 350:896-903.

Cases= 250 individuals with Bell's palsy

27% vaccinated

Controls= 722 individuals without Bell's palsy

1% vaccinated

Case-control studies

- Advantages:
  - can be easily performed (cheap & quick)
  - useful for rare diseases
  - allow the investigation of multiple risk factors

- Disadvantages:
  - recall bias
  - can not establish cause-effect relationship

Cross-sectional studies

- Observational studies in which all the measurements are performed on a single occasion (no follow-up period)

- Prevalence: the proportion of the population who has the disease at one period of time

Cross-sectional studies
Example

Al-Eisa E, Egan D, & Wassersug R (2004). Fluctuating asymmetry and low back pain.

Evolution and Human Behavior; 25: 31-37.

Cross-sectional studies

- Advantages:
  - ➢ can be easily performed (cheap & quick)
  - ➢ no follow-up loss

- Disadvantages:
  - ➢ not useful for rare disease
  - ➢ can not establish cause-effect relationship

Cohort studies

- Cohort = group of subjects that have something in common and are followed over time

- Prospective vs. Retrospective

Prospective cohort studies

- The researcher defines a **sample** of subjects and identifies certain **risk factors** (e.g., hypertension, diabetes) that may predict the subsequent **outcome**

Prospective cohort studies Example

- Purpose:

  to examine factors associated with the development of cardiovascular disease

Prospective cohort studies Example

1. Assemble the cohort: 6000 subjects from Framingham, Massachusetts in 1948

2. Measure potential risk factors: diabetes, hypertension, smoking, hypercholestremia

3. Follow-up and measure outcomes: the subjects were followed for 20 years to determine the occurrence of coronary artery disease

Prospective cohort studies

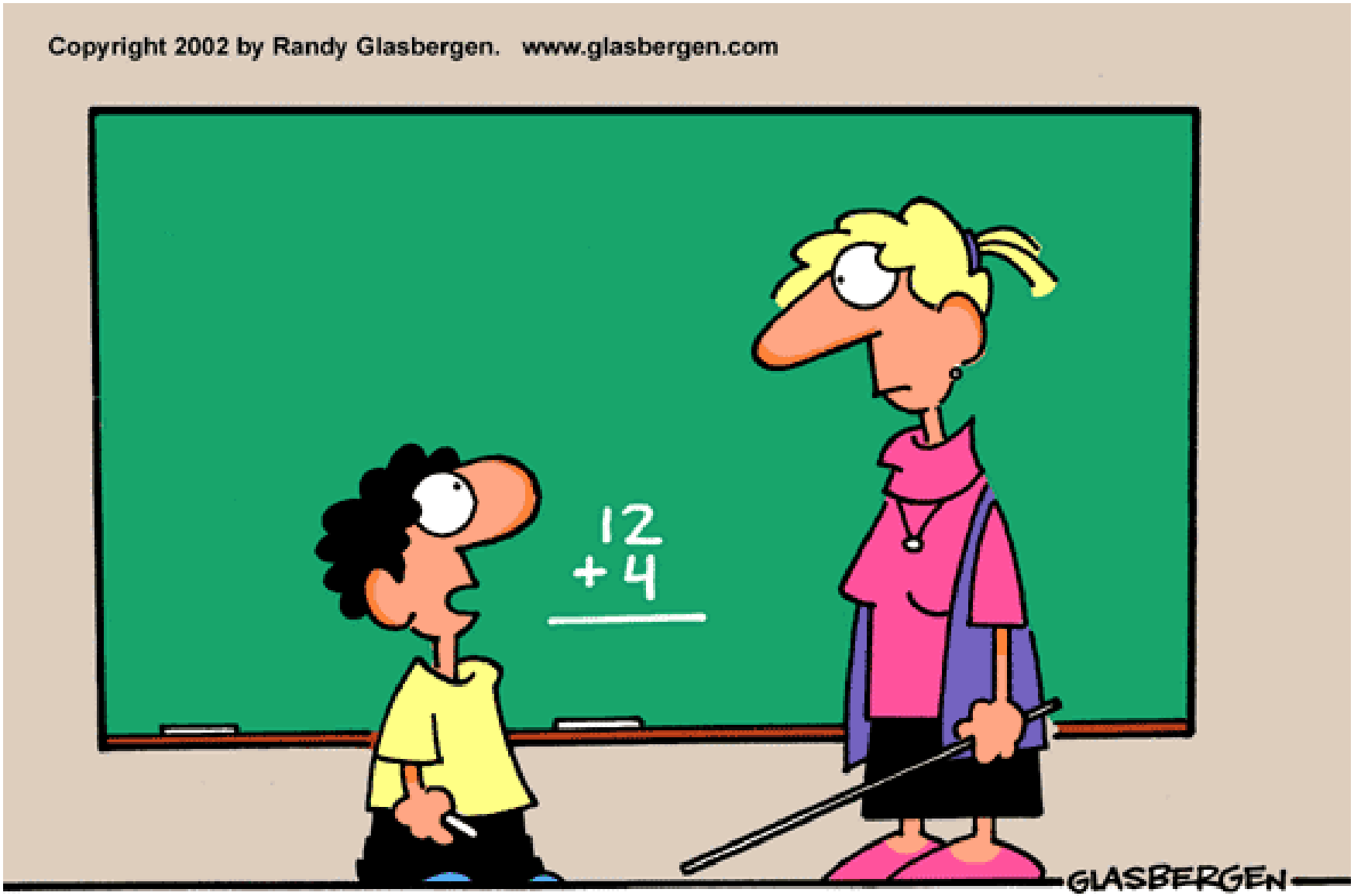
- Advantages:
  - useful when experimental study cannot be conducted for ethical or practical reasons
  - information on incidence
  - variables are measured accurately

- Disadvantages:
  - expensive and time consuming
  - impractical for rare diseases

Retrospective cohort studies

- Starts with identifying a cohort, then collect data about predictor variables (which occurred in the past), then follow the subjects to determine the occurrence of the outcome

- Direction of inquiry is still forward in time



"Do I get partial credit for simply having the courage to get out of bed and face the world again today?"