General Study Design

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Objectives

1. Understand the advantages and disadvantages of various observational and experimental designs.
2. Describe the advantages of randomized experiments

Quiz

For Each of the following situations, which would be the best study to perform?

A. Enumerative

B. Cross-Sectional

C. Case-control

D. Retrospective Cohort

E. Prospective Cohort

F. Randomized Controlled Trial

G. Quasi-experimental

Question 1

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Question 2

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Question 3

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Question 4

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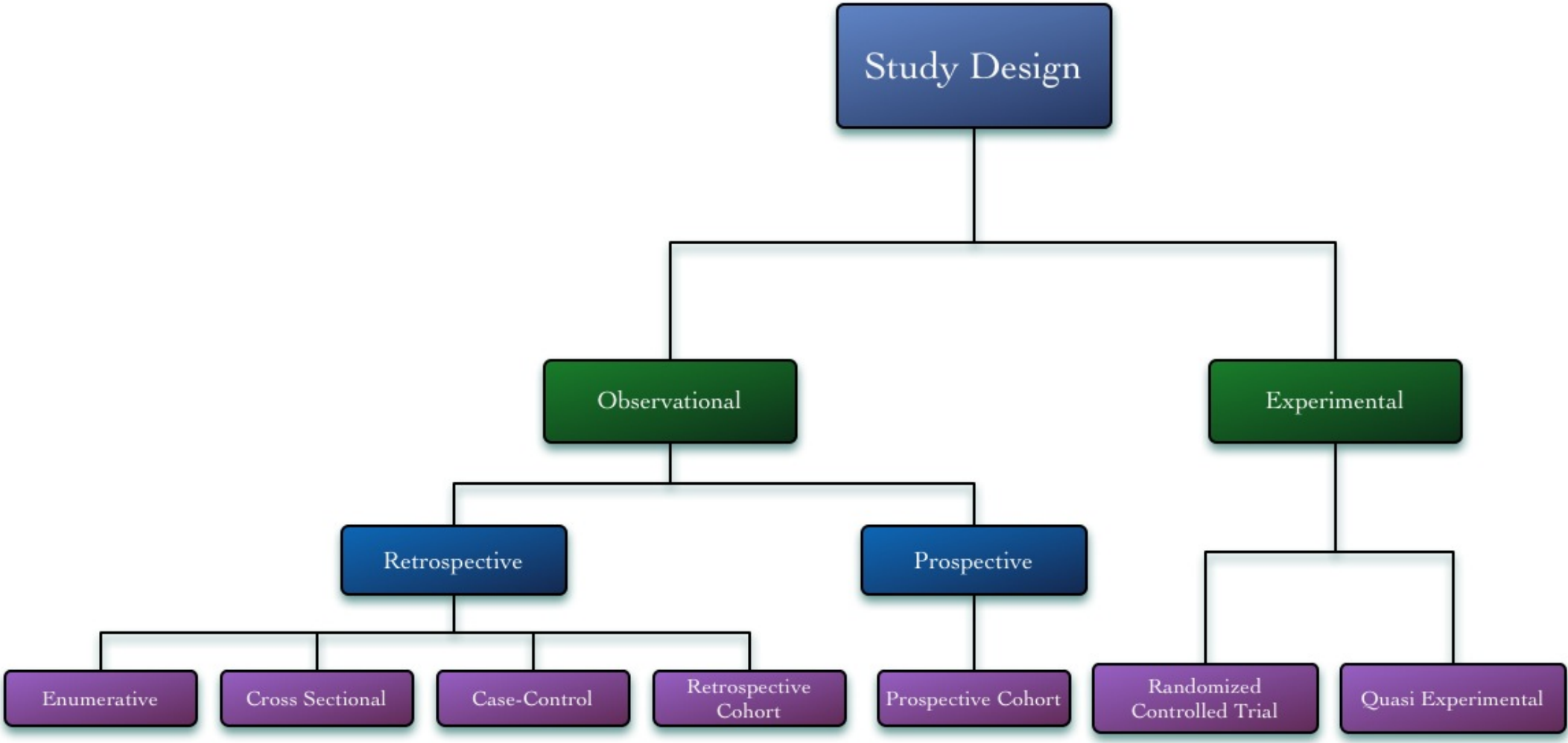
Study Design
Observational
Experimental
Retrospective
Prospective
Enumerative
Cross Sectional
Case-Control
Retrospective Cohort
Prospective Cohort
Randomized Controlled Trial
Quasi Experimental

Observational vs Experimental

What is the basic difference between observational and experimental designs?

Observational Studies

- Researcher observes and collects information
- Does not change the subjects
- There is no intervention
- May be retrospective or prospective

Experimental Studies

- Researcher intervenes to change something about the current process
- Always Prospective

Retrospective

Looks backwards in time

Prospective

Looks foreward in time

Enumerative Studies

- The researcher describes what is seen
- We will take action on what we see

Enumerative Study

Example: A researcher surveys a group of students after a virtual reality educational session in disaster triage

Enumerative Study

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What are the advantages and disadvantages?

Enumerative Studies

Advantages

- Simple to design and perform
- Easy to understand
- Require no complicated statistics
- No Ethical issues

Disadvantages

- Make no inference about large populations
- Make no inference about future events
- No causality can be proven
- Often rely on self report

Cross-Sectional Studies

- Draw a random sample from the population and record information
- We will make assumptions about the entire population based on the sample
- Can be used to describe association but not causality
- Usually population is fixed (if we had time we could take a census of the whole population)

Cross Sectional Studies

Advantages

- Easy to perform
- Sampling plan is usually easy
- Random sample to make inference about larger populations (can cover large population quickly)
- No ethical issues

Disadvantages

- May show association but not causality
- Some statistics required
- Often rely on self-report

Case-Control Studies

- Identify two groups
  - Case
  - Control
- Collect information about both groups and compare
- Cannot calculate incidence or prevalence of the disease
- Cannot use relative risk
  - Odds Ratio

Case-Control Study

Example: A researcher wishes to study the effect of N-95 masks during influenza pandemic. 10 cases of emergency physicians who contracted influenza are compared to 10 cases who did not to analyze their use of the N-95 mask.

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Case-Control Studies

Advantages

- Can be used for rare events
- Can calculate odds ratio

Disadvantages

- May have recall bias
- Cannot calculate true relative risk
- Cannot calculate incidence of the disease

Prospective Cohort Study

- Starts with a group of subjects and follows them forward in time
- Usually we study the effect of one factor on a result
- At the time of study is begun, none of the subjects has the disease in question.

Retrospective Cohort

- These are longitudinal studies
- Start with a group of individuals and follow them foreward in time
- Allows to calculate prevalence and relative risk
- In the case of retrospective cohort study, exposure and results have already happened

Prospective Cohort Study

Example: An investigator is studying the effect of proximity to a terrorist event and risk of Post traumatic stress disorder. A group of victims of a bioterrorism event are questioned about their proximity to the event followed to see who develops PTSC.

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Cohort Studies

Advantages

- Can estimate incidence
- May provide prospective data

Disadvantages

- Time consuming
- Costly
- If disease is rare, then follow many normal subjects
- Loss of patients to follow-up

Randomized Experiment

- In Medicine usually called "Randomized Controlled Trial"
- A sample is randomly allocated to receive some treatment (or lack of treatment)
- Sample is followed to look for some outcome

Randomized Experiment

Example: A researcher wishes to assess the speed of video versus standard laryngeoscopy for prehospital use. EMS providers are randomized to one of the two devices and time to successful intubation is measured.

Randomized Experiments

Advantages

- Controls for all main forms of bias
- Can assess causation

Disadvantages

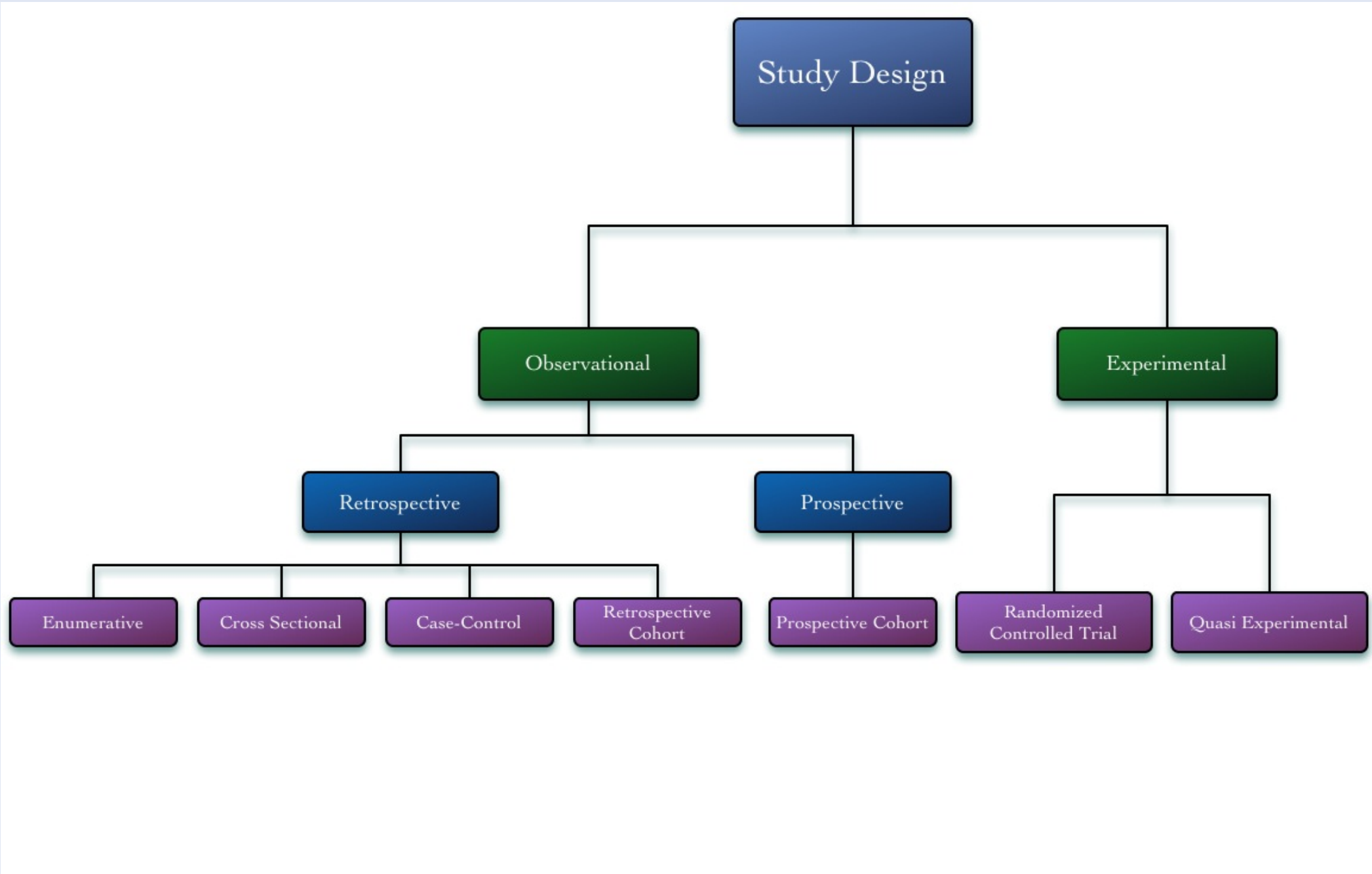
- Ethical concerns
- Costly
- May limit generalizability

Quasi Experimental Designs

- Studies the effects of an intervention
- Similar to randomized experiment but group assignment is usually not random
- Often the intervention is not planned by the researcher

Quasi Experimental Designs

- Several Types
  1. Natural Experiments
  2. Non-Equivalent Groups
  3. Pre-test / Post-test
  4. Interrupted time Series
  5. Regression Discontinuity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General Study Design

Questions?

Randomized Experiments

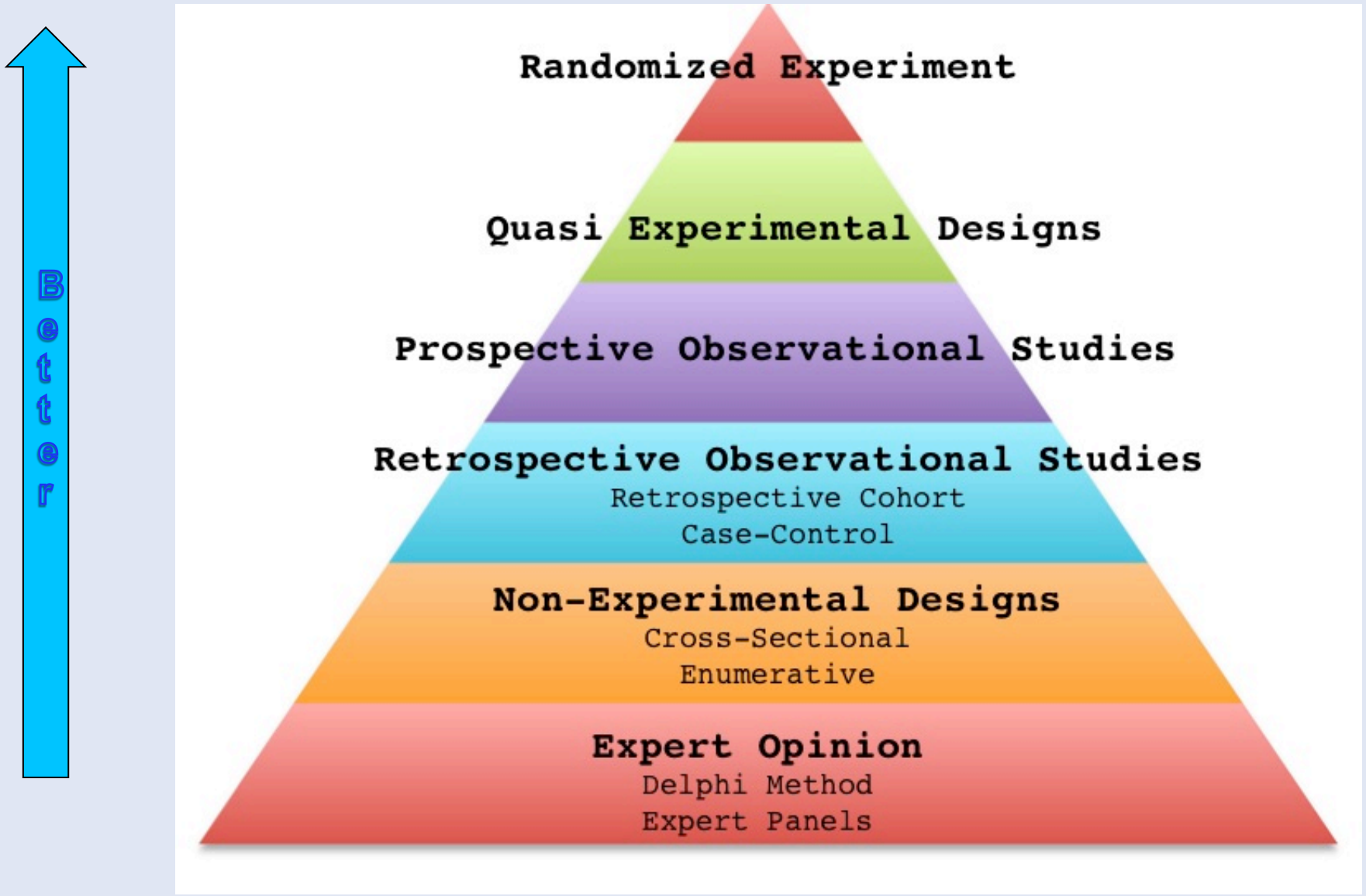
Quiz: Choosing a Car

Which is the best car?

Choosing a Methodology

Which is the best methodology?

Which is the Best Methodology



Choosing Methodology

- Remember that the rest of the literature will judge your work by this pyramid
- START AT THE TOP!!

Randomization

What's so cool about randomization?

Randomization

1. Eliminates selection bias
2. Avoids confounding
3. Balances group with respect to covariates:
   - Known
   - Unknown
4. Allows statistical assessment of causality

Selection Bias

What is selection Bias?

Give an example.

Selection Bias

What is selection Bias?

- The treatment groups are not equal at the onset of the experiment.

- Example:
  - A study shows that patient in the emergency department who were given Intravenous antibiotics are more likely to die than those given oral antibiotics

Confounding

What is confounding?

Give an example.

Confounding

Sometimes the results are complicated by confounding, which are really surrogates for the actual important variable.

Example: A study shows increased number of dental fillings is associated with higher reading ability among students.

Confounding

Sometimes the confounding source is known and can be controlled in the experiment

- Example: Age

Only randomization can control for unknown confounding.

Covariates

What is a covariate?

Give an example

Covariates

What is a covariate?

A secondary variable that influences relationship between the response and a factor

Covariates

Give an example of a study that is compromised by a covariate?

To assess the effect of different modalities of learning, participants could choose from lecture, online classes, or self study module.

Here ‘learning style preference’ is a covariate

Causality

Only a randomized experiment can prove causality

Randomized or not Randomized?

You are conducting a study on the effect of video laryngoscopy on success of intubation. You take 10 volunteers by walking through the ICU and taking the next 10 people you see, and randomly assign them to use standard or video laryngoscopy on their next attempt.

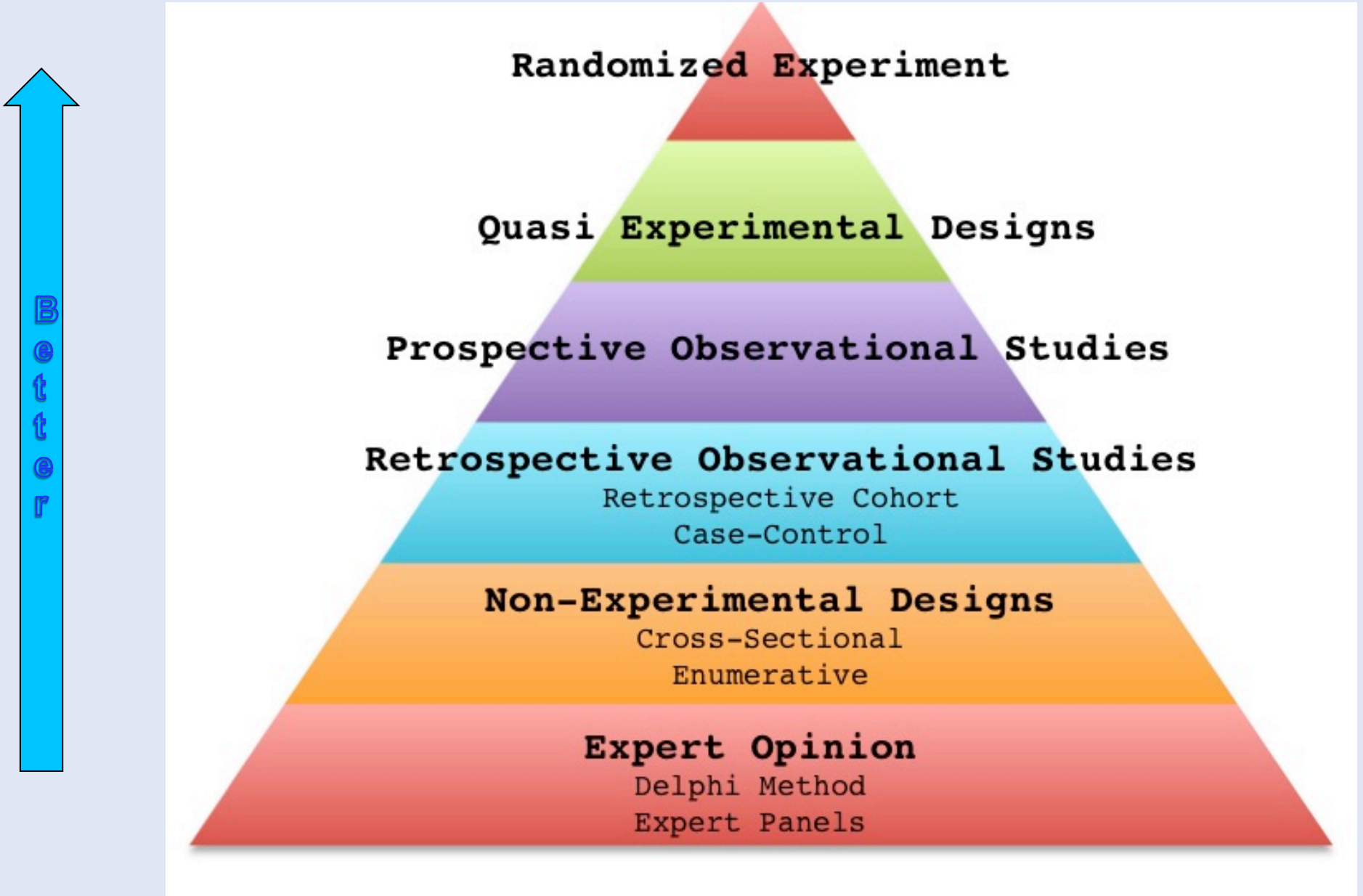
Your co-investigator states "this is not a randomized trial, since the volunteers were not taken randomly from the population of all people working in the ICU."

Is this true?

Randomized

- In an experiment "randomized" applies to the group assignment.
- The subjects are not necessarily a random sample from the population

Which is the Best Methodology?



Maxim

Randomized experiments are considered the highest form of evidence.

Randomized Experiments

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Math Lesson

How do we calculate odds ratio and relative risk?