

UM-CIRHT Webinar Series

Developing a Research Protocol

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UM-CIRHT Framework: Research Life Cycle



Beza et al , 2018. The UM-CIRHT Framework



Figure 6. Research Milestones to Build a Cadre of Independent Investigators at Partner Schools

Research Process



Critical Message of Last Webinar

- The way your research question is framed drives the design of your study
- **Well defined research question is crucial before developing detailed study plan/protocol**
- Research question drives design. Sample size determination determines feasibility (recruitment ability, adequate funding, and timeline). Then you write the research protocol.



“The question being asked determines the appropriate research architecture, strategy, and tactics to be used-not tradition, authority, experts, paradigms, or schools of thought”

Dave Sackett. BMJ 1999



Overview of Common Study Designs



Clinical Research Designs

Table 1.1 Types of epidemiological studies

Type of study	Alternative name	Unit of study
<i>Observational</i>		
Ecological study	Correlational study	Populations
Cross-sectional study	Prevalence study; survey	Individuals
Case-control study	Case-referent study	Individuals
Cohort study	Follow-up study	Individuals
<i>Experimental</i>		
<i>Intervention studies</i>		
Community trial	Community intervention study	Communities
Field trial	–	Healthy individuals
Randomized controlled trial	RCT	Individuals
Clinical trial	Therapeutic study ^a	Individual patients

^aClinical trials are included here since conceptually they are linked to epidemiology, although they are often not considered as epidemiological studies. Clinical trials have developed into a vast field of its own because of methodological reasons and their economic importance.

Ahrens, W. and Pigeot, I. eds., 2014. *Handbook of epidemiology*. New York, NY: Springer.

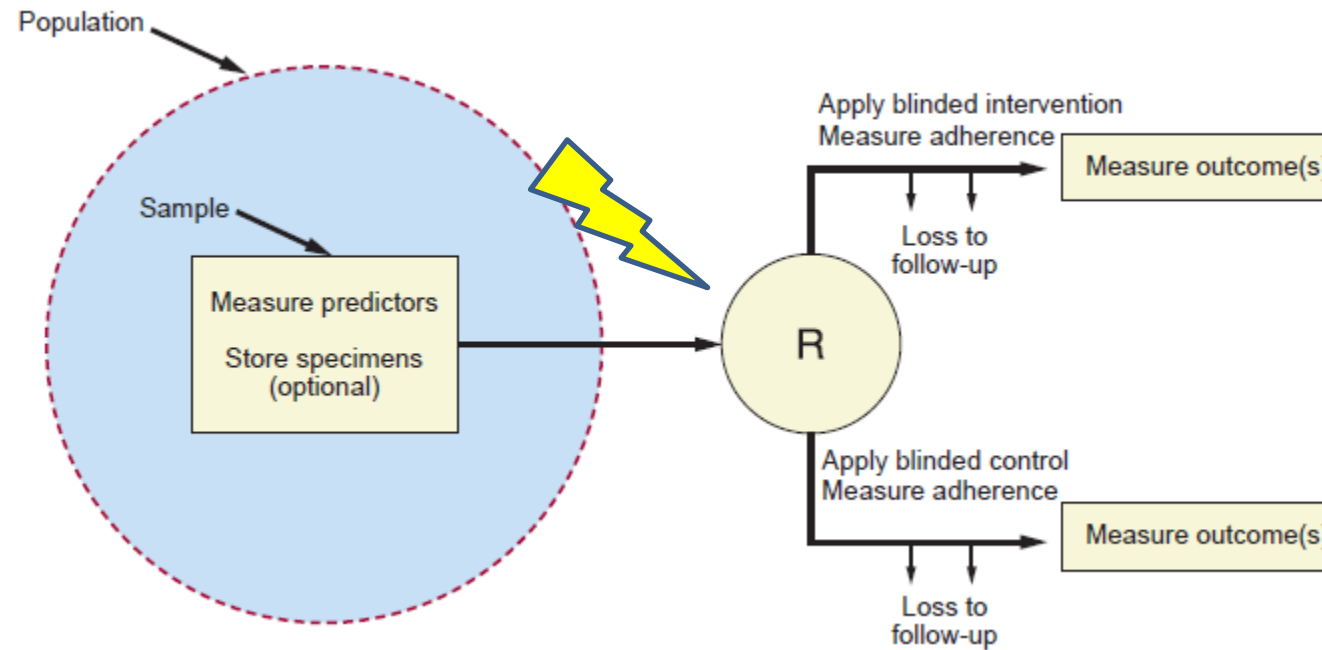


Qualitative Study Designs

- Purpose: to gain deeper understanding that is not feasible in surveys
- To help develop future tools for larger surveys
 - Example: decision making
- In-depth interviews
- Focus group discussions
- Can be used alone or along with quantitative methods in mixed-method designs



Experimental Study Designs



Hulley SB, *Designing clinical research*. LWW; 2013.



Randomized Controlled Trials –Examples

- In family planning, does an interactive computerized educational module for women in the waiting room improve LARC uptake compared to standard brochures in the waiting room?
- In abortion care, does a pre-procedure paracervical block result in lower reported pain score compared to pre-procedure acetaminophen?

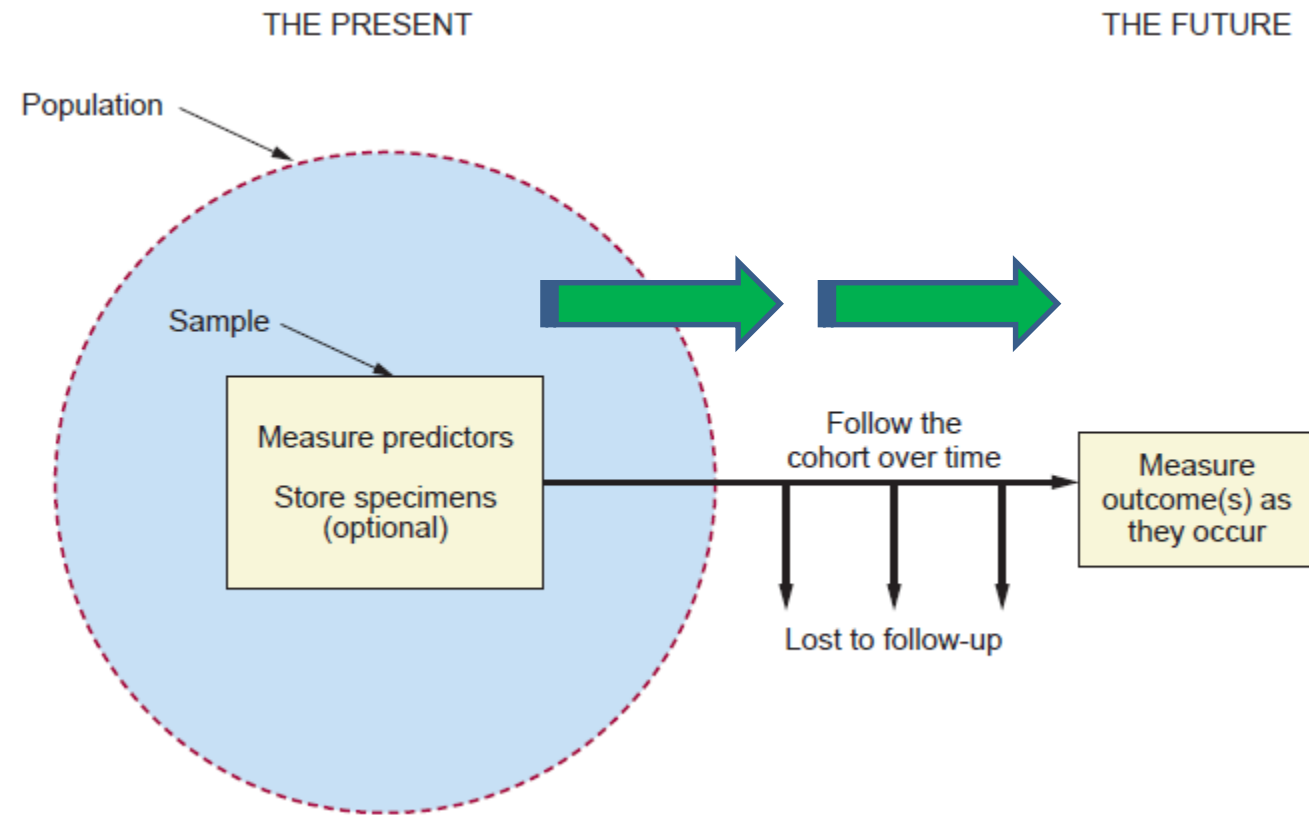


Common Observational Study Designs

- Cohort studies
- Case-control
- Cross-sectional



Cohort Studies-Prospective



Hulley SB, *Designing clinical research*. LWW; 2013.

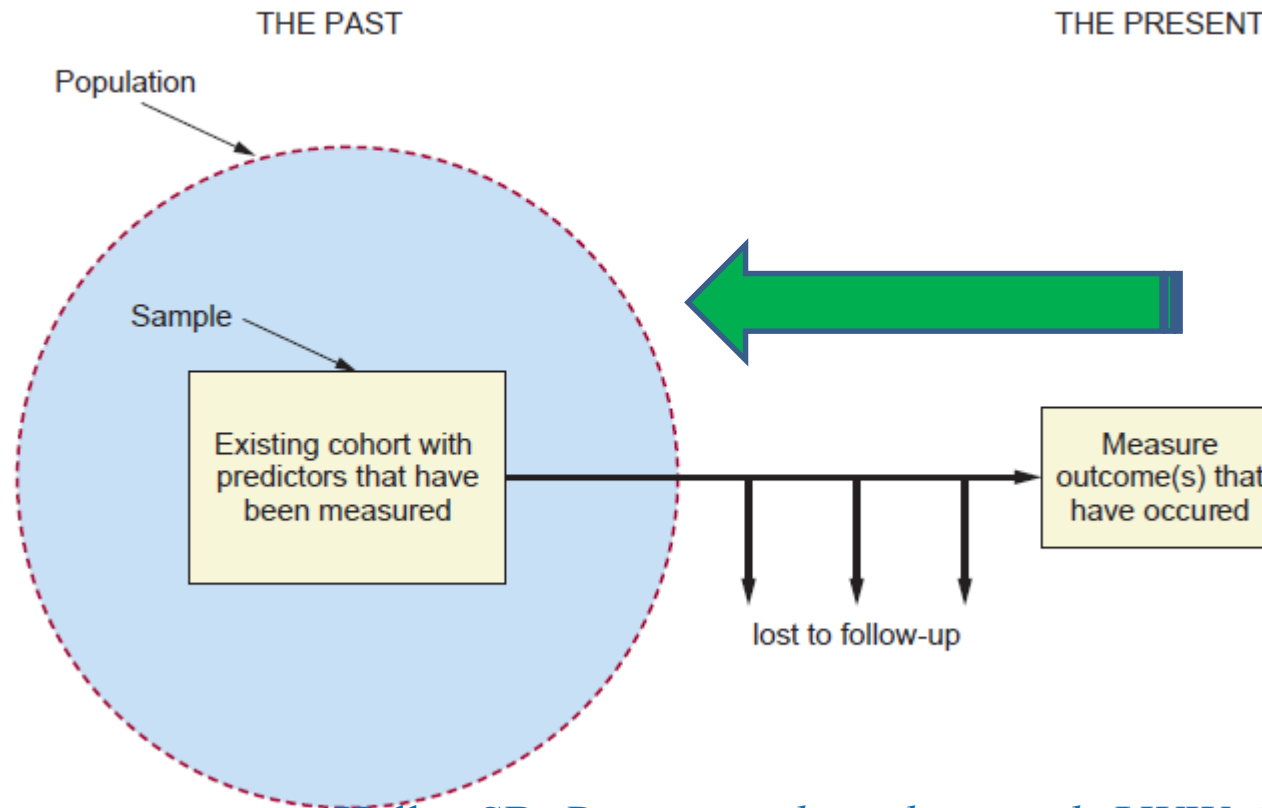


Cohort Studies-Prospective Cohort Example

- What factors in the family planning counseling visit predict which women are still on the same contraceptive method six months later?
- A prospective cohort design will help evaluate the factors



Cohort Studies-Retrospective



Hulley SB, *Designing clinical research*. LWW; 2013.

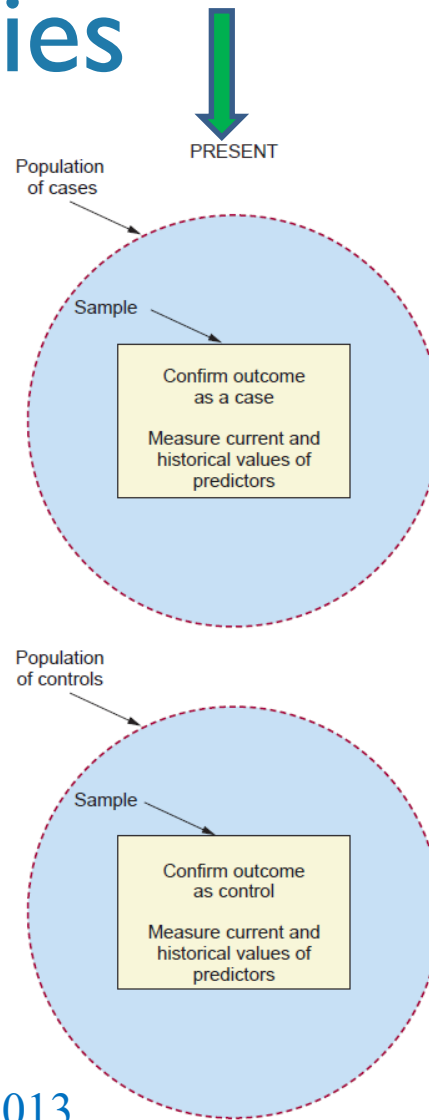


Cohort Studies-Retrospective Cohort Example

- What is the two year LARC (IUD/Implant) continuation rate among a cohort of women in Rwanda?
- A retrospective cohort design (using a national insurance database, with clearly defined inclusion/exclusion criteria) can help investigate the rate
- Example: doi: 10.1080/13625187.2018.1535653.



Case-Control Studies



Hulley SB, *Designing clinical research*. LWW; 2013.

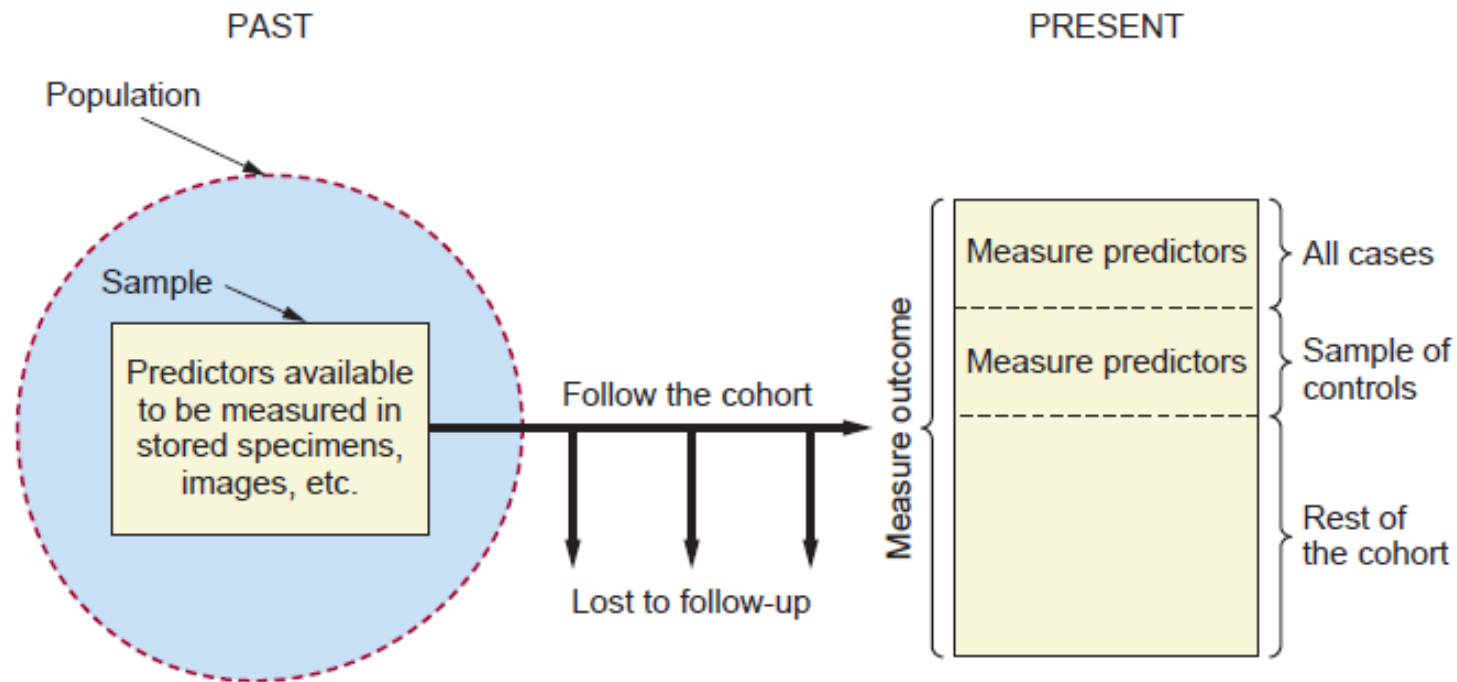


Case-control Studies-Example

- Does a history of exposure to family planning counseling in the prenatal period differ between women in the immediate postpartum period who choose a LARC method of contraception versus those who do not?



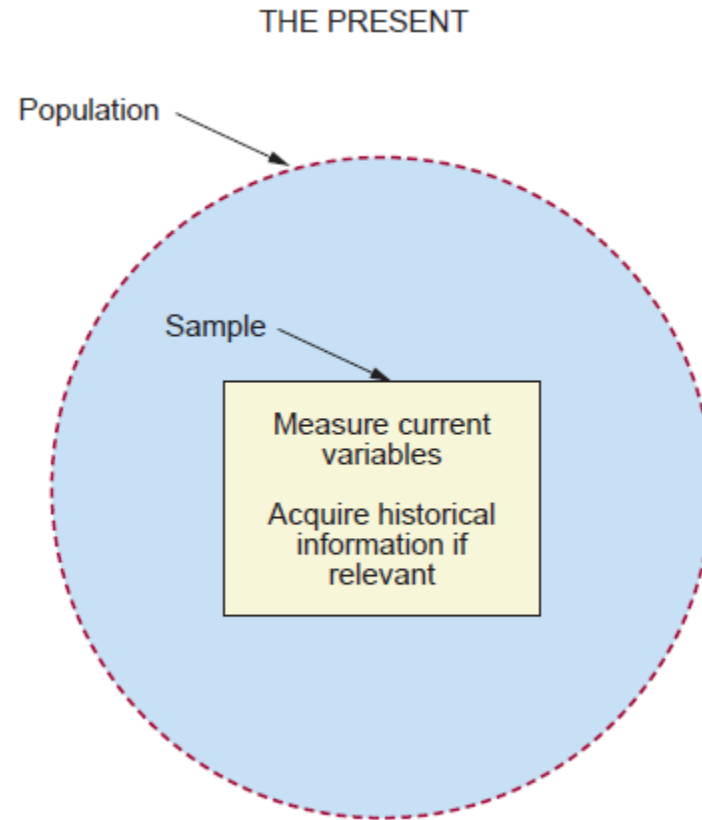
Special Case: Nested Case-Control Studies



Hulley SB, *Designing clinical research*. LWW; 2013.



Cross-Sectional Studies



Hulley SB, *Designing clinical research*. LWW; 2013.



Cross-Sectional Studies-Examples

- Do women attending a health center from urban and rural areas have different uptake of LARC?
- Does fidelity to a standardized counseling method increases LARC uptake? Monitors with a checklist
- What is the patients' perception of providers' professionalism/empathy?



Study Design Strengths

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	Randomized Trials	Cohort Studies	Case-Control Studies	Cross-sectional Studies	Ecological Studies
Estimates:	Incidence	Incidence		Prevalence	
Can assess:	Multiple outcomes	Multiple outcomes	Multiple exposures		Group level exposures
Good for:	Modifiable exposures	Rare exposures	Rare outcomes		Aggregate information
	Preventing against bias- especially confounding (known and unknown)	Exposure precedes disease	Delayed outcomes		Exposures that vary at group level

Weiss review lectures. UW-SPH

Study Design Limitations

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	Randomized Trials	Cohort Studies	Case-Control Studies	Cross-sectional Studies	Ecological Studies
Inefficient for:	Rare outcomes	Rare outcomes	Rare exposures		
Vulnerable to:		Confounding	Confounding Recall bias Selection bias	Confounding Reverse causality	Confounding Ecological fallacy
Difficulties:	Expensive May not be ethical Need modifiable exposure	Expensive May need long follow-up	Finding suitable controls Can't estimate incidence or prevalence	Exposure NOT known to precede outcome	No individual level data

Weiss review lectures. UW-SPH

Components of a Research Protocol

TABLE 1.1 ANATOMY OF RESEARCH: THE STUDY PLAN

DESIGN COMPONENTS	PURPOSE
Research questions	What questions will the study address?
Background and significance	Why are these questions important?
Design	How is the study structured?
Time frame	
Epidemiologic design	
Subjects	Who are the subjects and how will they be selected?
Selection criteria	
Sampling design	
Variables	What measurements will be made?
Predictor variables	
Confounding variables	
Outcome variables	
Statistical issues	How large is the study and how will it be analyzed?
Hypotheses	
Sample size	
Analytic approach	

Hulley SB, *Designing clinical research*. LWW; 2013.



Pay Attention!

- Read sponsor instructions!
 - Page numbers, word limit, margins, font, etc.
 - Sections



Abstract of a Research Protocol

- This is the first page of the protocol but written last
- Summary of the protocol
- One paragraph
 - Background – 2 sentences on the importance and gap you are addressing
 - Objectives/Aims
 - Design



Research Question

- Often in the form of specific aims and hypotheses
 - Often a paragraph first to state rationale
 - State one overall goal
 - Not more than three specific aims for a large study for 1-2 a pilot study
 - Some also call these “objectives”
 - Any hypotheses should be placed under the corresponding aim/objective



Background and Significance

- This section should be written after you have done all your background work and finessed your research question
 - One or two pages
- No separate literature review needed



Background and Significance

- Focused to the research question
- Build the story of why it is important, what is known, and where the gap in knowledge is, and how your study is addressing it
- Demonstrate how your study will advance the area/field (impact)



Research Design

- This is part of the approach section in NIH-type grants
- A schematic diagram is always helpful
- Include brief justification for the selected study needed
- Subject information



Research Design

- Visit numbers, how often measurements are collected
- Details of each measurement (outcome, exposure, and associated factors)
- Details of surveys/questionnaires, focus group discussions



Research Design - Study Subjects

- Recruitment
- Feasibility
- Inclusion Criteria
- Exclusion Criteria
- Screening, (if there is any intervention)
- Randomization (for RCTs)

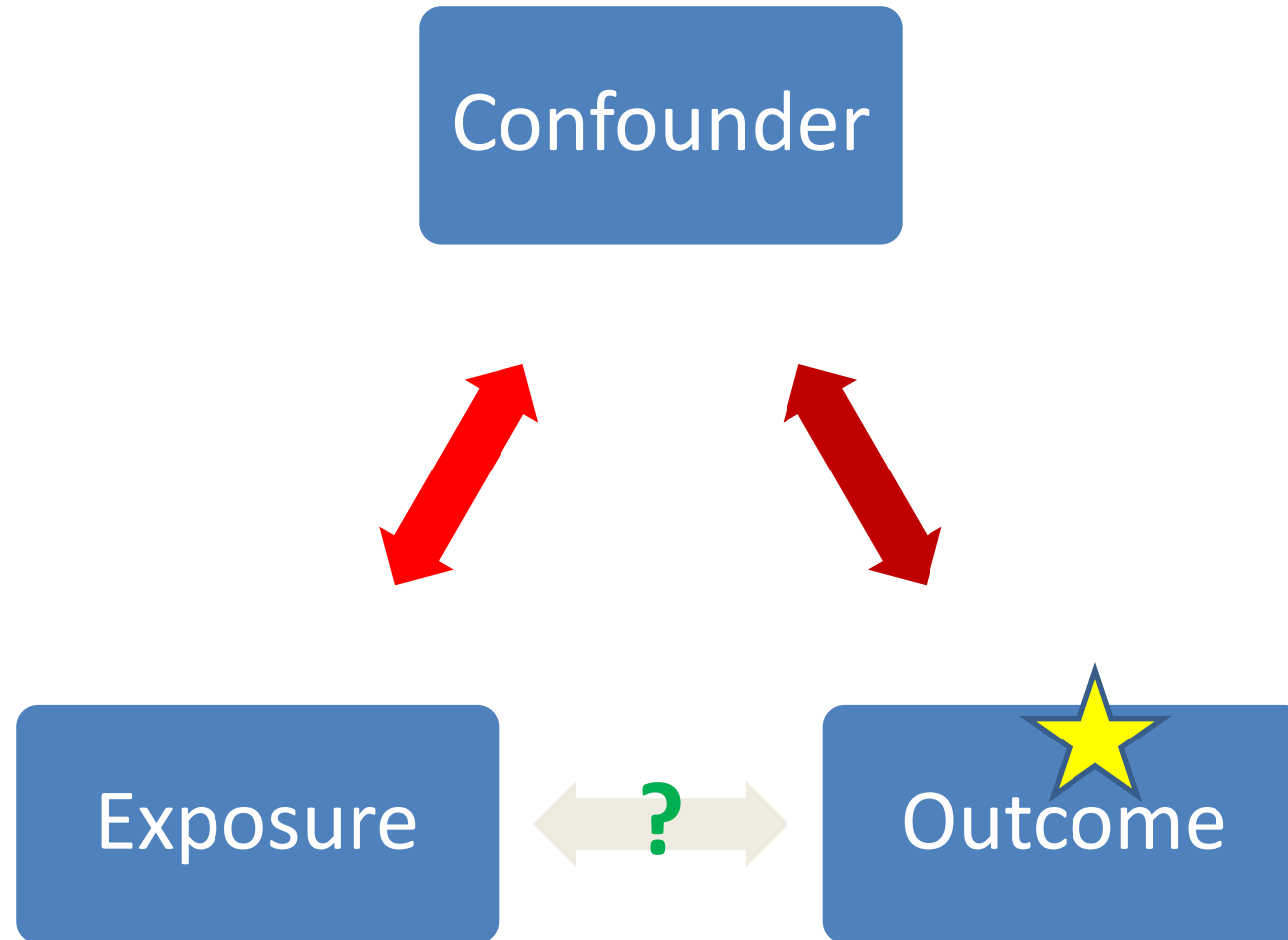


Research Design - Measurement

- ~Variables
- Which variables to measure?
 - An important decision in study design consideration
- For most analytic design types, broadly classified into:
 - Outcome variable(s)
 - Predictor variable(s)
 - Confounding variable(s)



Measurements



Research Design - Measurement

- Outcome variables*
 - Drives the kind of statistical analysis
 - Part of PICO(T)
- Predictor/independent variables
- Confounders



Statistical Analysis

- Best statistical analyses sections are stated for each specific hypothesis
- Do not make this a general section that can be applied to any research question of similar design
 - Tailor it to your specific aims
- Includes sample size/power determination



Additional Items in Research Protocol

- Timeline
- Limitations and alternative plans
- References



Concluding Remarks

- Keep everything focused on your well developed research question
- Convince the reader of the importance of filling the gap in knowledge that you are addressing – not just the importance of the topic in general
- The design and analysis should closely align with your stated question



Thank You
Questions?