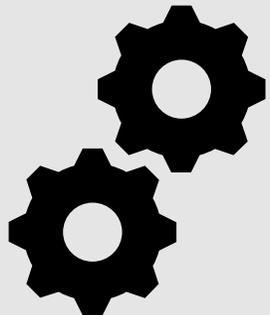
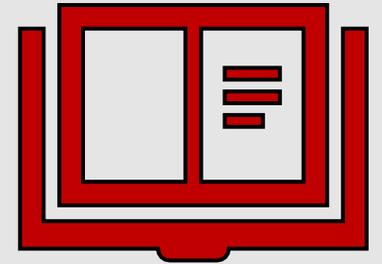


# Designing an Epidemiological Study

BERDC Special Topics Talk 5



**DaCCoTA**

DAKOTA CANCER COLLABORATIVE  
ON TRANSLATIONAL ACTIVITY

Dr. Mark Williamson

Biostatistics, Epidemiology,  
and Research Design Core

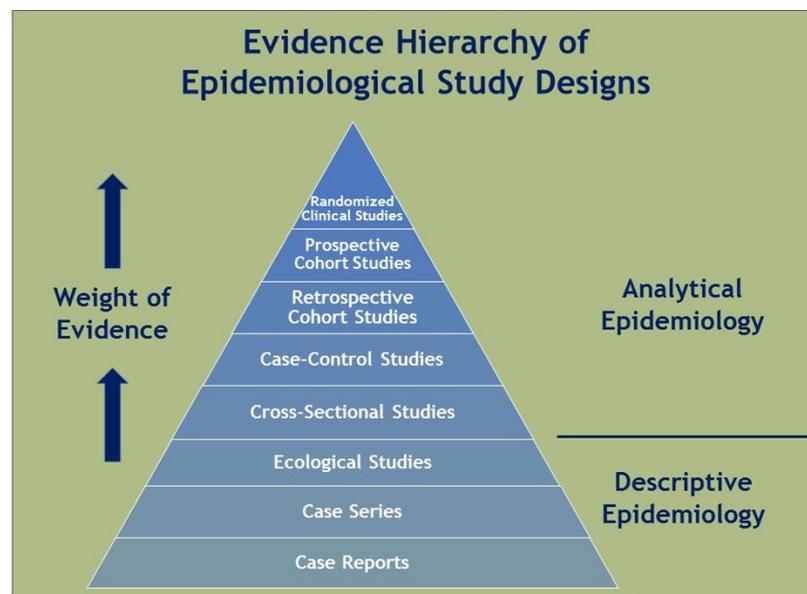
# Introduction

**Goal:** Explore the basics of epidemiological study designs

- Different designs have different pros and cons
- Study design proceeds after identifying a research target
- Take a moment to try out the pre-test:

[https://und.qualtrics.com/jfe/form/SV\\_0jEq7kXYxhXizKm](https://und.qualtrics.com/jfe/form/SV_0jEq7kXYxhXizKm)

*‘Epidemiology is the study of how disease is distributed in populations and the factors that influence or determine this distribution’*



# Studies covered

## Experimental

- Randomized: Clinical Trial
  - Parallel
  - Crossover
- Non-randomized:
  - Field Trial
  - Community Trial

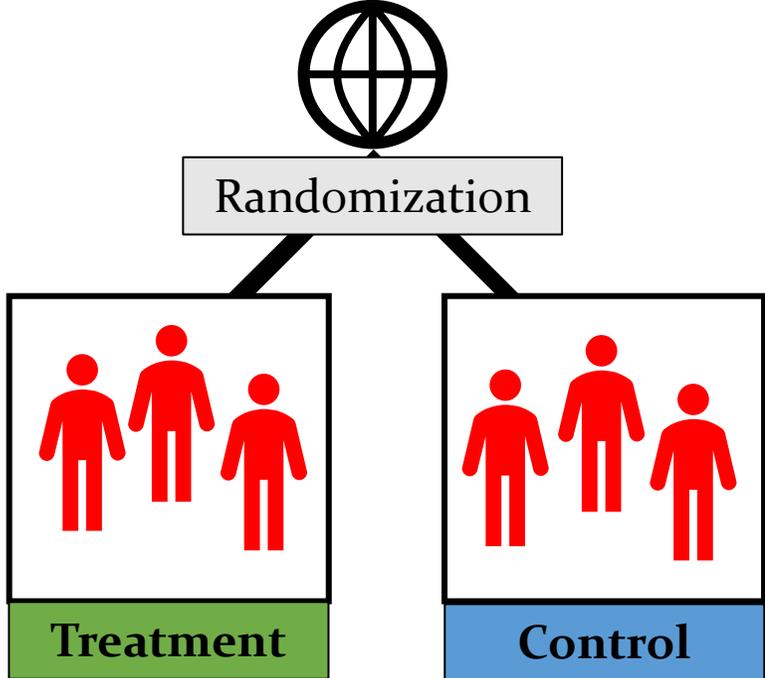
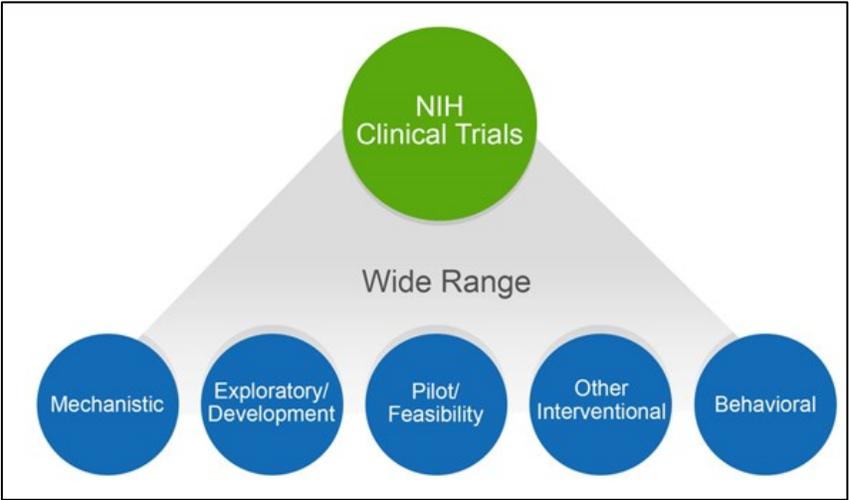
## Observational

- Population:
  - Descriptive: Health Survey
  - Analytic: Ecological Study
- Individual:
  - Descriptive:
    - Case report
    - Case series
  - Analytic:
    - Cross-sectional
    - Case-control
    - Case-crossover
    - Cohort (Prospective/Retrospective)

# Clinical Trial

*'A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes'*

Pros	Cons
<ul style="list-style-type: none"> <li>• Causation</li> <li>• Translation</li> </ul>	<ul style="list-style-type: none"> <li>• Feasibility</li> </ul>



- Examples:**
1. Patulin for common cold
  2. COVID-19 vaccine effectiveness
  3. Radon risk via smartphone app

# Clinical Trial cont.

## Experimental and Random

### Number of Arms

- One, Two, Three+

### Levels of Blindness

- Single, Double, Triple

### Phases

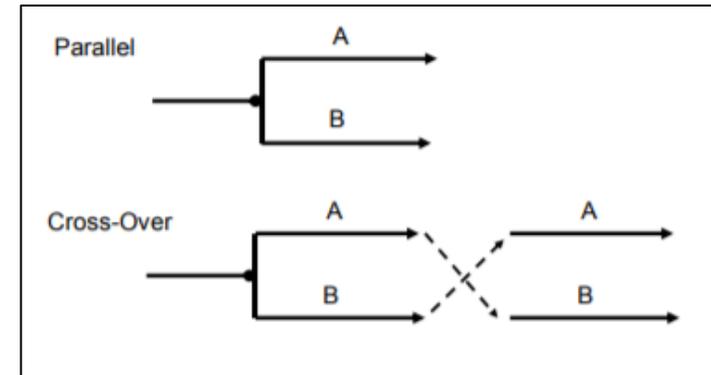
- I, II, III, IV

### Parallel vs. Cross-Over

- Parallel: each patient receives one 'treatment'
  - Short term, more patients
- Cross-Over; each patient receives both 'treatments'
  - Wash-out period
  - Long term, less patients

### Factorial Design

- Randomized to two or more 'treatments'



		Treatment A	
		+	-
Treatment B	+	Both A and B (cell a)	B only (cell b)
	-	A only (cell c)	Neither A nor B (cell d)

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# Field/Community Trial

Experimental and quasi-random/non-random

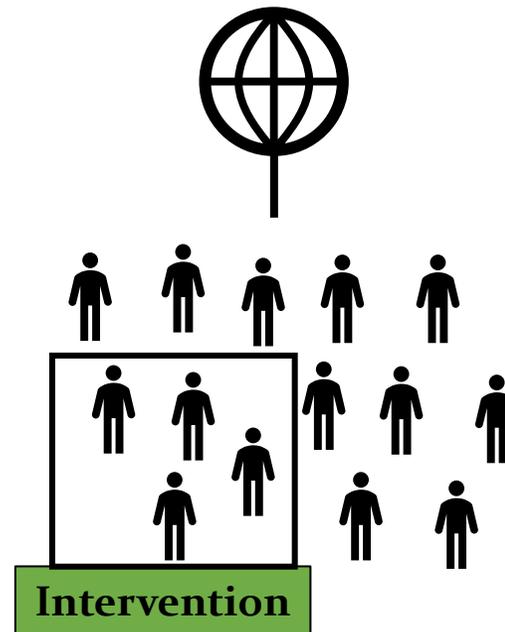
Field:

- 'On the ground'
- General population
- Generally healthy
- 'Intervention' to see if risk of disease is reduced
- Preventative in nature

Community:

- Extension of field trial
- Totality of the community is unit of assignment

Pros	Cons
<ul style="list-style-type: none"><li>• Early Assessment</li></ul>	<ul style="list-style-type: none"><li>• Scale</li><li>• Causality</li></ul>



## Examples:

4. Gambia Hepatitis Intervention Study
5. Minnesota Heart Health Program

# Health Survey

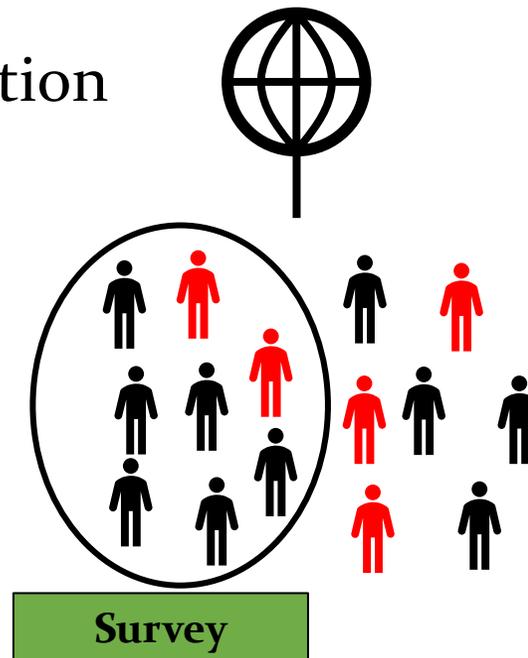
Observational, Descriptive, Population-level

- De-identified individuals
- Often summarized by geography or demographics
  - Ex. state/county or sex/age/ethnicity
- Large sample size

Can consist of different types of information

- Questionnaires
- Physical examinations
- Clinical investigations

Pros	Cons
<ul style="list-style-type: none"><li>• Scope</li><li>• Recruitment</li></ul>	<ul style="list-style-type: none"><li>• Resolution</li></ul>



## Examples:

6. BRFSS
7. NHANES

# Ecological Study

Observational, Analytic, Population-level

Look for associations between occurrence of disease and exposure to possible causes

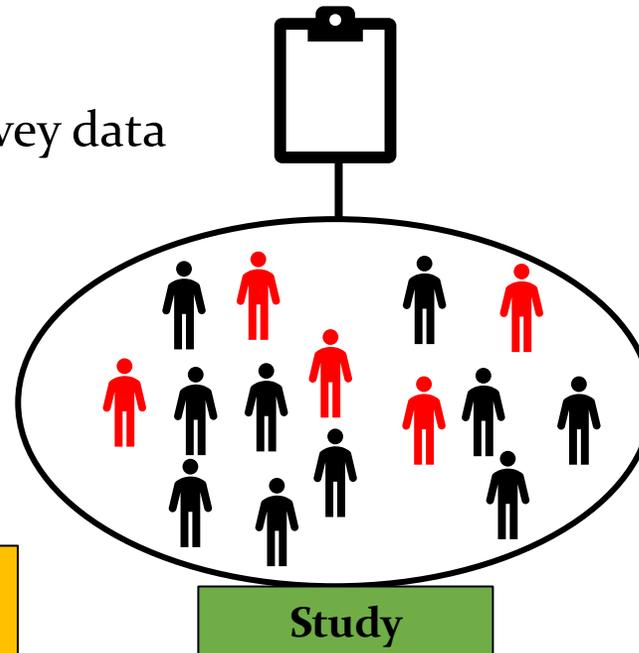
Structurally the same as a Health Survey

- Aggregated, large samples, etc.
- Usually testing a hypothesis based on survey data

Common considerations

- Geography
- Time
- Demographics
- Socioeconomics

Pros	Cons
<ul style="list-style-type: none"><li>• Scope</li><li>• Data access</li></ul>	<ul style="list-style-type: none"><li>• Resolution</li><li>• Causation</li></ul>



## Examples:

8. Lymphocytic leukemia and radon by state
9. Vitamin D and cancer

# Case Report/Series

Observational, Descriptive, Individual-level

## Case Report:

- Details of diagnosis, treatment, response to treatment, and follow-up of individual patient
- Useful for illustrating new or unusual features
- Can be used to help determine the cause of a disease outbreak
- Usually include demographic information

## Case Series:

- Extension of the case report
- Three or more patients

Pros	Cons
<ul style="list-style-type: none"><li>• Resolution</li></ul>	<ul style="list-style-type: none"><li>• Scope</li></ul>



- Examples:**
10. Gastroenteritis at a University in Texas
  11. Discovery of HIV in US

# Cross-Sectional Study

Observational, Analytic, Individual-level

One point in time (snapshot)

- no follow-up
- exposure status and outcome collected at same time

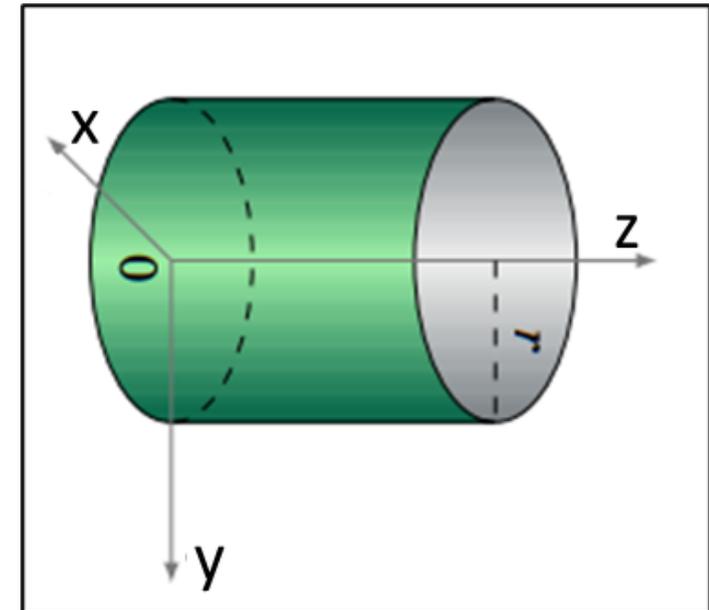
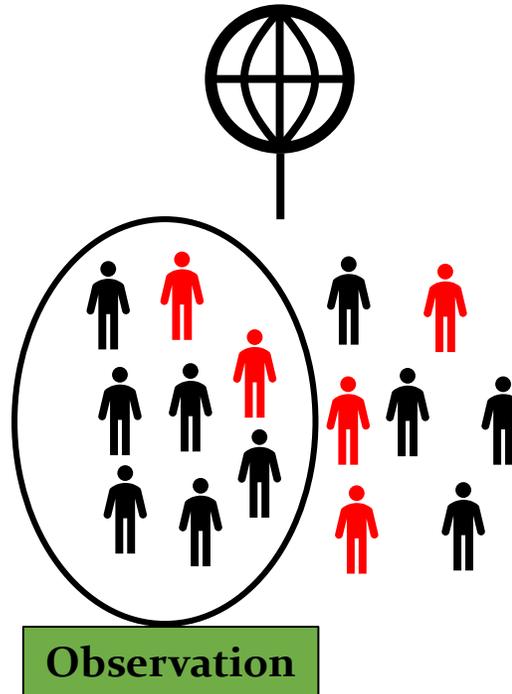
Weakest of the observational, analytic designs

Best for prevalence

## Examples:

12. Bone mineral density and menopause
13. Lung function and dust exposure in Uranium mine workers

Pros	Cons
<ul style="list-style-type: none"><li>• Easy Setup</li><li>• Prevalence</li></ul>	<ul style="list-style-type: none"><li>• Correlation</li><li>• Time trends</li></ul>



# Case-Control Study

Observational, Analytic, Individual-level

Used to determine association between risk factors (exposure) and outcomes

Two groups of patients (cases and controls)

Retrospective look in past for possible exposure

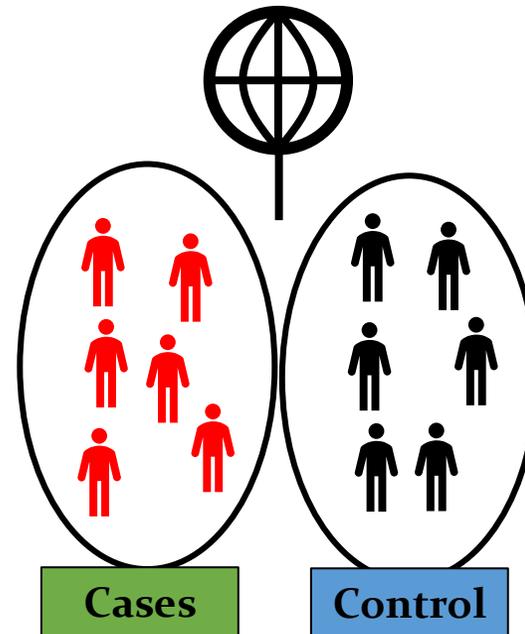
Subject to recall bias

Good for rare diseases and long latency

## Examples:

14. Melanoma and UV radiation
15. Long Island Glaucoma study

Pros	Cons
<ul style="list-style-type: none"><li>• Easy Setup</li><li>• Chronic disease</li></ul>	<ul style="list-style-type: none"><li>• Correlation</li></ul>



# Case-Crossover Study

Observational, Analytic, Individual-level

Similar to Case-Control

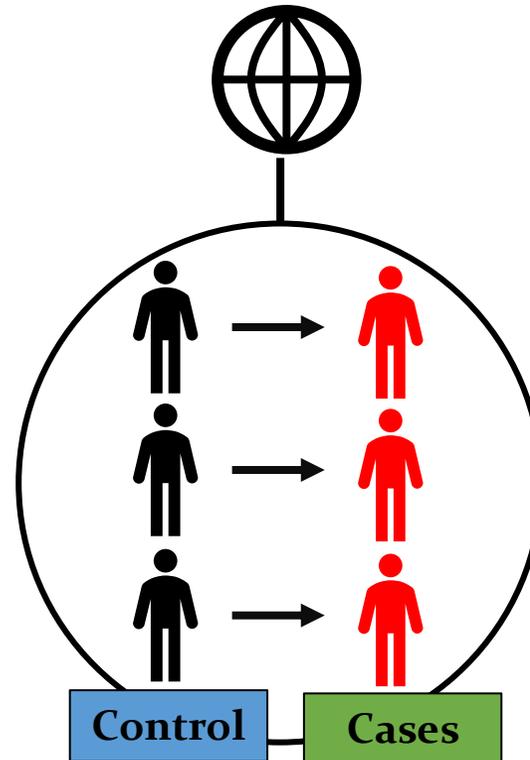
Examines 'triggers' within an individual

One individual is both case and control

Period of case and period of control  
needs to be set up carefully

## Examples:

16. Elder mortality and temperature
17. Fatigue and traffic accidents



Pros	Cons
<ul style="list-style-type: none"><li>• Case-control match</li><li>• Chronic disease</li></ul>	<ul style="list-style-type: none"><li>• Correlation</li><li>• Design</li></ul>

# Prospective Cohort Study

Observational, Analytic, Individual-level

Sometimes called 'longitudinal study or follow-up study'

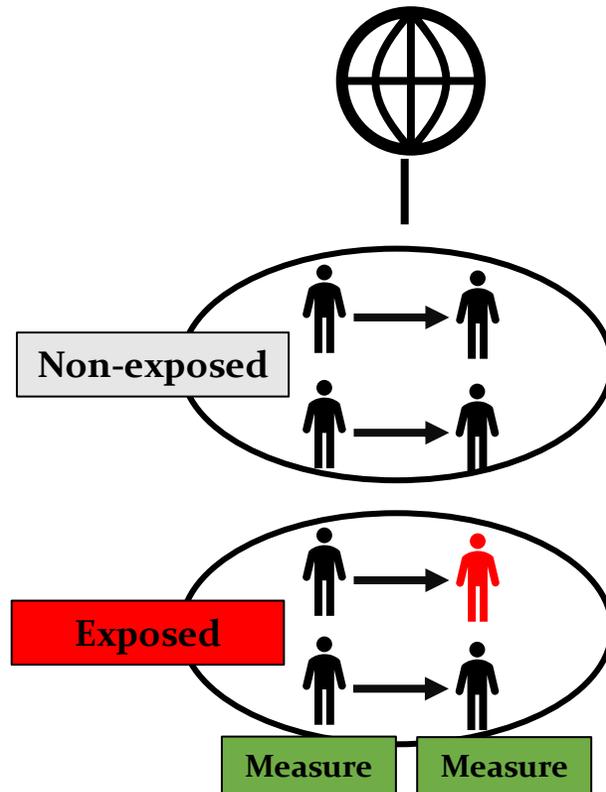
Harder but more powerful than retrospective

Group are identified by exposure status

Cohorts are followed over time to see who develop a disease (across exposed and non-exposed groups)

Prone to selection bias

- Examples:**
- 18. Framingham heart study
  - 19. Nurses Health Study

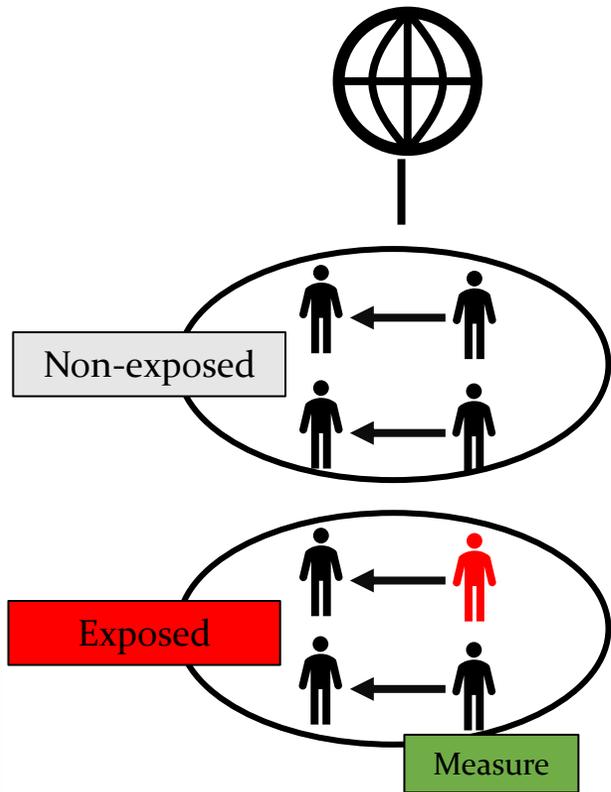


Pros	Cons
<ul style="list-style-type: none"><li>• Correlation</li><li>• Control</li></ul>	<ul style="list-style-type: none"><li>• Set up</li><li>• Expense</li></ul>

# Retrospective Cohort Study

Observational, Analytic, Individual-level  
 Easier but less powerful than prospective  
 Exposure and outcome has already occurred  
 Cohorts are assessed for disease status (across exposed and non-exposed groups)  
 Relative risk is a common output  
 Prone to selection bias and recall bias

- Examples:**
- 20. Lane-Claypon's breast cancer risk factors
  - 21. Cyclosporiasis in PA residential facility



Pros	Cons
<ul style="list-style-type: none"> <li>• Set up</li> <li>• Expense</li> </ul>	<ul style="list-style-type: none"> <li>• Correlation</li> <li>• Control</li> </ul>

# Wrap-up

The type of study depends on:

- Research question
- Data availability
- Time and resources

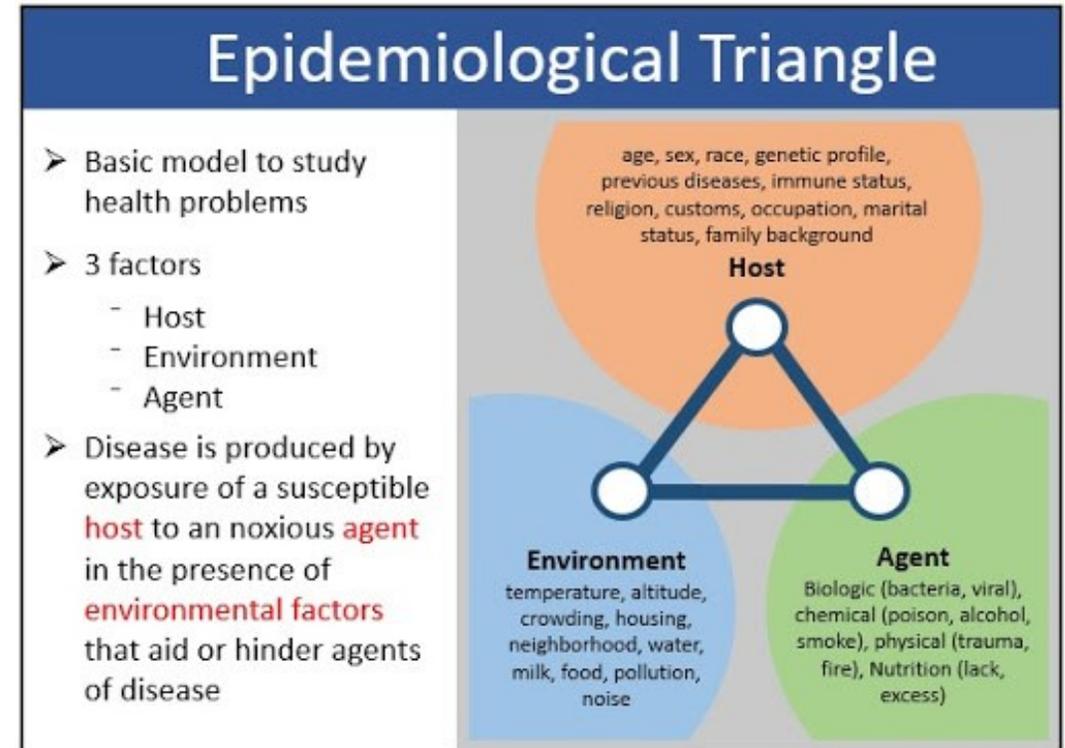
The aim is not perfection but rather competence

What matters is if the epidemiology problem can be solved

Please take the post-test and survey:

Post-test: [https://und.qualtrics.com/jfe/form/SV\\_6lKnyb5ZKSQxkpM](https://und.qualtrics.com/jfe/form/SV_6lKnyb5ZKSQxkpM)

Survey: [https://und.qualtrics.com/jfe/form/SV\\_cGYtxw2H9UxtdVs](https://und.qualtrics.com/jfe/form/SV_cGYtxw2H9UxtdVs)



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## Examples:

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