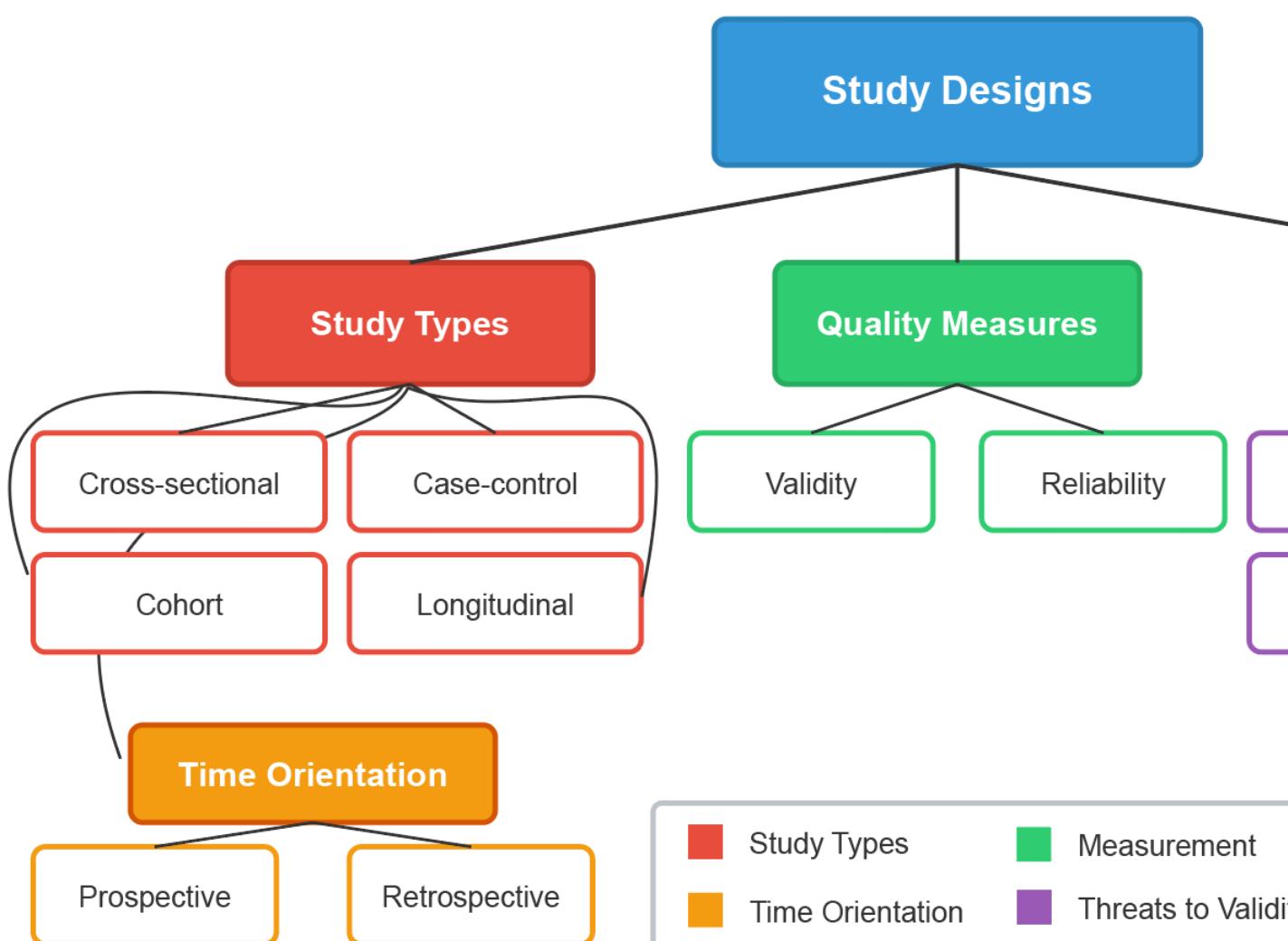


# Designing Popular Health Studies

March 31 and April 2 2022  
Eric Delmelle



# Chapter Overview

- Research design fundamentals in epidemiology and public health
- Measurement validity and reliability
- Error and bias in population health research
- Study design approaches:
  - Cross-sectional
  - Case-control
  - Cohort
  - Experimental
- Qualitative methods and their integration with quantitative methods
- Ethical considerations in population health research

# 1

# A Matter of Measurement

## Primary vs. Secondary Data

### Primary data:

- Data collected specifically for the purpose

### Secondary data:

- Data collected for other purposes but reorganized and reanalyzed.

### Examples:

- Health insurance claims data
- Employment records
- National health surveys

# 2

# Primary vs. Secondary

- Primary data

- Collected specifically for a new study
- Controlled by the researcher
- Tailored to answer specific research questions

- Secondary data

- Pre-existing data collected for another purpose
- Often large-scale and readily available
- May require cleaning or transformation

While primary data offers control and precision, secondary data can save time and resources.



# 3

# Levels of Measurement

Level	Description	Example
Nominal	Categories with no ranking	Blood type, Sex
Ordinal	Ordered categories	Health self-rating: excellent, good, fair, poor
Interval	Equal units, no true zero	Temperature in °C
Ratio	Equal units with true zero	Weight, Blood pressure

Understanding measurement levels is crucial for selecting appropriate analyses. A variable can always be reduced to a lower level of measurement (continuous to categorical), but not elevated (categorical to continuous).

# 4

# Ecological Studies and

- **Unit of analysis:** Group (e.g., city-level data)
- **Examples:**
  - Community fluoride levels and dental caries
  - Countries' smoking rates and lung cancer rates
- **Ecological fallacy:** Attributing group-level associations to individuals
- **Example:**
  - Classrooms with more women had higher average grades
  - But individual-level analysis showed men had higher grades in each classroom

Classroom A

F 70

F 70

F 70

F 75

F 70

F 80

F 80

F 80

M 95

M 100

Class Mean

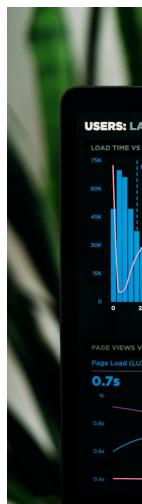
F 74, M 98, FM

79

# 5 Variables and Levels of Measurement

- **Categorical variables:**
  - *Dichotomous* (e.g., male/female)
  - *Polytomous* (e.g., blood type)
  - *Nominal* (no implied order)
  - *Ordinal* (ranked, e.g., “good” > “fair”)
- **Continuous variables:**
  - *Interval scale* (e.g., temperature in Celsius)
  - *Ratio scale* (e.g., body weight, height)

Note: Continuous variables can be converted to categorical, but not vice versa.



# 6

# Types of Research Desi

**Key concepts to distinguish studies:**

- **Purpose:** Descriptive vs. analytical
- **Investigator control:** Observational vs. intervention
- **Directionality:** Forward vs. backward
- **Sample selection:** Based on exposure, disease, or both
- **Timing:** Prospective vs. retrospective

**Study Types:** - Cross-sectional - Case-control  
- cohort - Prospective cohort - Randomized c

# 7 Basic Terminology: Exposure and Disease

- **E** = “Exposure”
  - Risk factor (e.g., smoking, occupational hazard)
  - Intervention (e.g., drug, prevention program)
- **D** = “Disease” or outcome
  - Disease, injury, death
  - Any health-related outcome
- $E_0$  and  $D_0$  = Absence of exposure/disease
- $E_1$  and  $D_1$  = Presence of exposure/disease



# 8

# Study Designs Summary

Study Type	Purpose	Control	Directionality	Strengths
Cross-sectional	Descriptive/ Analytical	Observational	Concurrent	Reliable Snapshot
Case-control	Analytical	Observational	Backward	Blind Comparative
Retrospective cohort	Analytical	Observational	Forward	Blind easier
Prospective cohort	Analytical	Observational	Forward	Blind easier
Randomized control trial	Analytical	Interventional	Forward	Blind exact

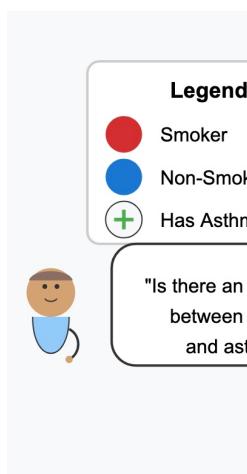
# 9

# Cross-Sectional Studies

- Also called **prevalence studies**
- Exposure and outcome assessed **simultaneously**
- Can be descriptive or analytical
- Provides a “snapshot” of a population
- Relatively quick and inexpensive

## Limitations:

- Cannot establish temporal sequence
- Only includes survivors of disease
- Not suitable for rare diseases



A snapshot of exposure and outcome measures

10

## In-class exercise

11

# Case-Control Analysis

- Cannot directly compute relative risk
- Use **odds ratio (OR)** as an estimate:

$$OR = \frac{ad}{bc}$$

- In a 2×2 table:



What

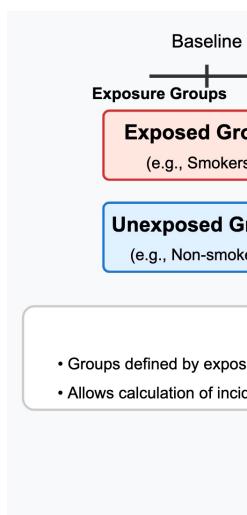
	$D_1$	$D_0$
$E_1$	$a$	$b$
$E_0$	$c$	$d$

- When disease is rare,  $OR \approx RR$

12

# Cohort Studies

- Start with **exposure status** ( $E_1$  and  $E_0$ )
- Follow forward to observe outcome
- Two types:
  - **Prospective:** Start now, follow into future
  - **Retrospective:** Look back at historical exposure
- Can study multiple outcomes
- Directly computes incidence and relative risk



13

# Cohort Analysis

- Relative Risk (RR) quantifies association between exposure and outcome:
  - Allo...
  - D...
  - A...
  - U...
- In a 2x2 table:

$$RR = \frac{a/(a+b)}{c/(c+d)}$$

	$D_1$	$D_0$
$E_1$	$a$	$b$
$E_0$	$c$	$d$

- Time...
- Poten...
- Not...
- Diagn...
- May...

## Chall...

14

# Randomized Controlled Trials (RCTs)

- Gold standard for assessing causal relationships
- Participants randomly allocated to intervention ( $E_1$ ) or control ( $E_0$ )
- Minimizes confounding and bias through:
  - Randomization
  - Blinding (single, double)
- Can be conducted at individual or group level

Phases of RCTs

- Phase I: (recruit sample)
- Phase II: (assess effects)
- Phase III: (monitor)
- Phase IV: (disseminate)

Randomized controlled trials known as RCTs

15

# Validity and Reliability

## Measurement Validity

- **Face validity:** Appears reasonable on the surface
- **Content validity:** Covers full scope of concept
- **Construct validity:** Reflects theoretical concept
- **Criterion validity:** Correlates with external standard
- **Concurrent validity:** Correlates with present condition
- **Predictive validity:** Forecasts future outcome

## Study Validity

- **Internal validity:** Consistency within sample
- **External validity:** Generalizability to other populations

## Reliability

- **Test-retest:** Stability over time
- **Inter-observer:** Consistency between observers
- **Intra-observer:** Consistency over time

16

# Reliability vs. Validity

- **Reliability** = consistency of measurement
- **Validity** = accuracy of what is intended to be measured
- A tool can be reliable but not valid
- A tool cannot be valid if it is not reliable



Unreliable



Reliable

Target  
reliability

17

# Types of Error

## Random Error

- Caused by chance or sampling variation
- Affects **precision**
- Can be reduced by increasing sample size
- Produces unpredictable fluctuations

## Systematic Error

- Consistent, due to flaws in design
- Affects **validity**
- Not reduced by increasing sample size
- Must be addressed

18

# Major Types of Bias

Selection Bias

Information Bias

Confounding

- Systematic differences between those selected and those not selected
- Examples:
  - Low response rate
- Healthy worker effect
- Volunteer bias
- Berkson's bias (hospital sampling)
  - Loss to follow-up
  - Survivor bias

19

# Controlling for Confounding

## At Design Stage

### 1. Randomization

- Evenly distributes confounders across groups

### 2. Restriction

- Limit study to specific subgroup

### 3. Matching

- Pair participants with similar characteristics

## At Analysis Stage

### 4. Stratification

- Analyze strata

- Mantel-Haenszel estimate

### 5. Multivariable

- Include covariates
- Logistic regression

20

# Effect Modification (Int)

- Occurs when the effect of exposure differs across levels of a third variable
- Not the same as confounding
- Can be additive or multiplicative
- Additive Model:

$$RREM = RRE + RRM - 1$$

- Multiplicative Model:

$$RREM = RRE \times RRM$$

- Interpretation:

- If  $RREM >$  expected  $\rightarrow$  synergism
- If  $RREM <$  expected  $\rightarrow$  antagonism

Exam  
smo  
risk

Example

No

Lung  
No L

21

# Qualitative Methods

- Originates from the social sciences
- Explores perceptions, beliefs, experiences
- Often used to:
  - Understand lived experiences
  - Explore context and meaning
  - Inform survey and tool development
- Common techniques:
  - In-depth interviews
  - Focus groups
  - Participant observation
  - Document analysis



Mixed n  
qualita  
quantit

22

# Types of Qualitative Methods

Observation

Interviews

Document Analysis

- **Participant observation:** Researcher immersed in setting to observe behavior
- Captures real behavior and interactions
- Varies in degree of participation

23

# Integrating Qualitative Quantitative Methods

Ways to integrate qualitative methods:

1. **Pre-study:** To develop hypotheses or instruments
2. **During study:** To explain unexpected results
3. **Post-study:** To interpret and validate findings
4. **Standalone:** As an alternative or complement to quantitative

Example: Regional Health Needs Assessment

- **Quantitative:** Epidemiologic data, service access
- **Qualitative:** Focus groups with residents, interviews with key informants



Com  
give

24

# Ethical Considerations

## Four Ethical Principles:

1. **Autonomy** – Respect for individuals
2. **Beneficence** – Maximize benefits
3. **Non-maleficence** – Do no harm
4. **Justice** – Fair treatment and burden distribution

## Research Issues

- Informed consent
- Confidentiality
- Data security
- Vulnerable populations
- Institutional review boards
- Research integrity and transparency

# 25 Key Takeaways

- Choose the study design that best answers your research question
- Recognize and control for bias and confounding
- Understand the role of validity and reliability
- Combine methods when appropriate
- Always prioritize ethics and participant rights



“No  
sup  
the  
Kue