

CHAPTER-6

METHODOLOGY

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Adama, Ethiopia

Objectives

After completing this chapter, the student should be able to:

1. Identify the pertinent questions to consider when developing the methodology of a proposal
2. Describe and understand various components of the methods section in a proposal
3. Explain the cyclical nature of the different steps in designing the methodology.
4. Analyze circumstances for appropriate use of the different study designs
5. Use appropriate study designs which properly answer the research question/

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Subsections

- the study design
- Setting
- Source/study population
- variables
- sample size and sampling techniques
- Data collection
- Data quality control
- Data management: coding, entering, cleaning, storing, recoding (software to be used)
- Data analysis: choice of statistical methods
- Ethical Concerns

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Design options

Broadly:

- ◆ Quantitative
- ◆ Qualitative/exploratory
- ◆ Mixed/both

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Criteria for selecting a research design

- 1) the research problem
- 2) personal experience
- 3) Audience/users
- 4) Resources available for the study

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1) the research problem

Research problems call for specific approaches

Eg. If the problems calls for:

- a) the identification of factors that influence an outcome
- b)) the evaluation of an intervention

Then a quantitative approach is best

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If a concept or phenomenon needs to be understood because little research has been done on it before,

qualitative approach is preferred

Qualitative research is exploratory and is useful when the researcher does not know the important variables to examine

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A mixed methods/ design is useful when either the quantitative or qualitative approach by itself is inadequate to best understand a research problem

The strength of both quantitative and qualitative research can provide the best understanding in this case

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2) personal experience

- Researcher's personal training and experience influence the choice of the approach/the design
- An individual trained in technical, scientific writing, statistics, and computer statistical programs and familiar with quantitative journals would most likely choose the quantitative design

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- Individuals who enjoy writing in a literary way or conducting personal interviews, or making up-close observations may prefer qualitative approach
- The mixed methods researcher is an individual familiar with both quantitative and qualitative research

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3) Audience

- Researchers write for audiences that will accept their research
- These audiences may be journal editors, journal readers, conference attendees, or colleagues in the field

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- Diff. types of study design are not considered equal in the strength of evidence they provide
- Hierarchy:
 - Randomized controlled trial (High strength)
 - Cohort, case control study
 - Observational, descriptive studies

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- Investigators may not be able to select the design that gives a high level of evidence
- The design that gives a high level of evidence may not be:
 - feasible to do or
 - ethical to do

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- Mixed methods are becoming popular
- The problems addressed by social & health science researchers are complex, and the use of either quantitative or qualitative approaches by themselves is inadequate to address this complexity
- Mixed methods utilize the strengths of both qualitative & quantitative research

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Quantitative designs include

- ❖ Cross sectional – the commonest of all
- ❖ Cohort / prospective or retrospective/
- ❖ Case control
- ❖ Experimental

Qualitative designs include

- ❖ Focus Group discussion
- ❖ In-depth interview
- ❖ Observation

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Cross sectional study design:

- A cross-sectional study is a study in which disease and exposure statuses are measured simultaneously in a given population.
- Cross-sectional studies can be thought of as providing a "**snapshot**" of the frequency and characteristics of a disease in a population at a particular point in time.
- it provides a prevalence rate at a particular point in time (**point prevalence**) or over a period of time (**period prevalence**).

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Strength

- relatively quick and inexpensive
- Shows relative distribution of conditions
- Often provides early clues for hypothesis generation.

Limitation :

- Weakness for establishing causation since uncertainty on whether exposure presided disease.
- Not effective if disease is rare

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Cohort:

definition of “cohort”

- Group of people who have something in common when they are assembled.
- A group of individuals that are all **similar in some trait and move forward together** as a unit
- Designated group of people who are followed or traced for a particular period of time

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- Cohort study is **the observation of a cohort / cohorts, over time, to measure outcome's**
 - Also called longitudinal, follow-up studies
- Groups are defined on the basis of exposure to risk factors.
- At the beginning free from the disease

Defined
Population

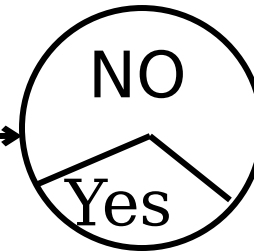
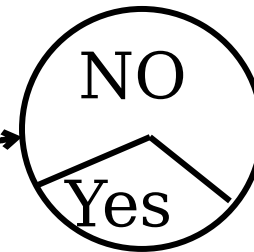
Study Sample

Representative Sample?

Target Pop:
**Population
at Risk**

Exposed

Not Exposed



Time

Disease/Outcome
Present?

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❖ Case control:

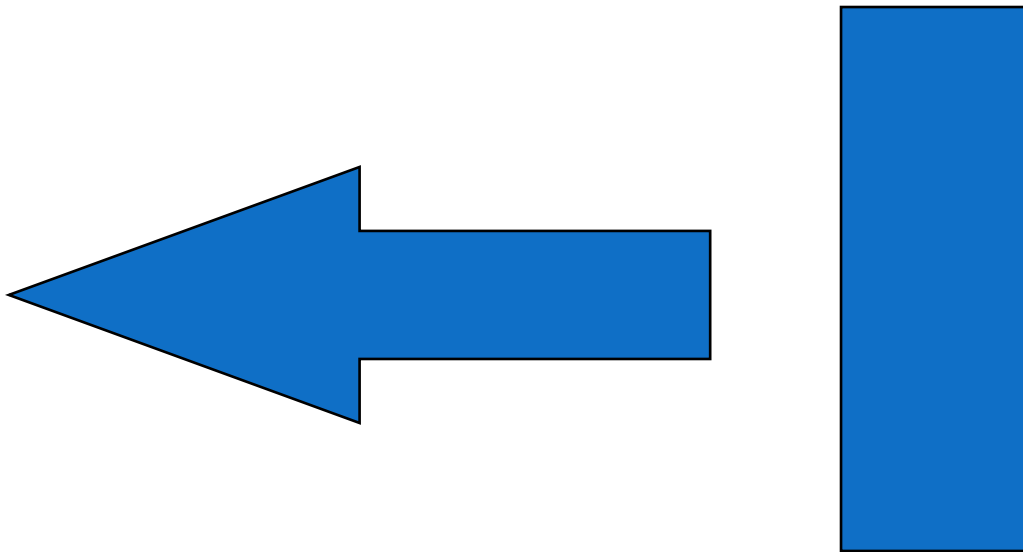
- It is usually **retrospective/ backward in direction**
- Identify one group of subjects with disease (cases) and one group without disease (controls), then look back historically to identify differences in predictor variables [exposure (s)].

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- Mostly cannot provide estimates of prevalence or incidence
 - (diseased are sampled)
- Rather, provide estimate of association between presence or absence of disease and predictor variables

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Cases: Disease
Controls: No disease



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Experimental

- A method where: -
 - Investigator can “control” the exposure
- Similar to laboratory experiments except living populations are the subjects
- Generally involves random assignment to groups

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- **Clinical trials** are the most well known experimental design
- The ultimate step is testing causal hypotheses
- In an experiment, we are interested in the consequences of some treatment on some outcome.
- The subjects in the study who actually receive the treatment of interest are called the **treatment group**.
- The subjects in the study who receive no treatment or a different treatment are called

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Source population: target population from which we draw sample population

- Also called target population (reference population)

Study Population: sample population included in the study

- The population of individual units (whether persons, households, etc.) to be investigated.

E.g.

- source population, all food handlers working in AU.

- Study population representative of food

handlers selected by sampling technique

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Sample size & Sampling technique

- Sample size determination depends on
 - objective of the study;
 - design of the study;
 - plan for statistical analysis;
 - accuracy of the measurements to be made;
 - degree of precision required for generalization;
 - degree of confidence with which to conclude.

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- the minimum sample size required, for a very large population ($N \geq 10,000$) is calculated as:

$$n = Z_{\frac{\alpha}{2}}^2 \frac{\sigma^2}{d^2}$$

- n – the required sample size
- z – the standard normal distribution usually taken as 1.96
- d – the **proportion** of the problem to be studied taken from previous similar studies.
- If no previous similar studies, take maximum value i.e. 50%
- d – width or margin of error, usually 5%.

To estimate a single population proportion

$$n = Z_{\frac{\alpha}{2}}^2 \frac{P(1 - P)}{d^2}$$

Sample size calculations

- **Example:** Suppose you want to estimate the proportion of people in a population who support a certain policy, with a 95% confidence level and a margin of error of 3%. Based on prior knowledge or a pilot study, you estimate that the proportion is around 0.6.

Solutions

To estimate a single population proportion

$$n = Z_{\frac{\alpha}{2}}^2 \frac{P(1 - P)}{d^2}$$

Con'ted-----

$$n = (1.96)^2 \cdot 0.6(1-0.6) /$$

$$(0.03)^2 = 3.8416 \times 0.6(0.4) / 0.0009$$

- $n = 3.8416 / 0.0009 = 4268.44$

- **$n = 4269$ rounded.**

Example-2

- Suppose we want to estimate the proportion of people in a city who support a particular political candidate with a margin of error of 5% and a confidence level of 95%. We know that the population size is 100,000 and we expect the proportion to be around 50%. What is the required sample

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Variables

A **VARIABLE** - a characteristic of a person, object or phenomenon which can take on different values.

-it may be in the form of numbers (e.g., age) or non-numerical characteristics (e.g., sex).

- it is important to make a distinction between **dependent** and **independent variables**.
- The variable that is used to describe or measure the problem under study is called the *DEPENDENT* variable.

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- The variables that are used to describe or measure the factors that are assumed to cause or at least to influence the problem are called the *INDEPENDENT* variables.
- **Background variables**, such as age, sex, educational level, socio-economic status, marital status and religion, should be considered.
- Also called **socio demographic variables**.
- These background variables are often related to a number of **independent variables**

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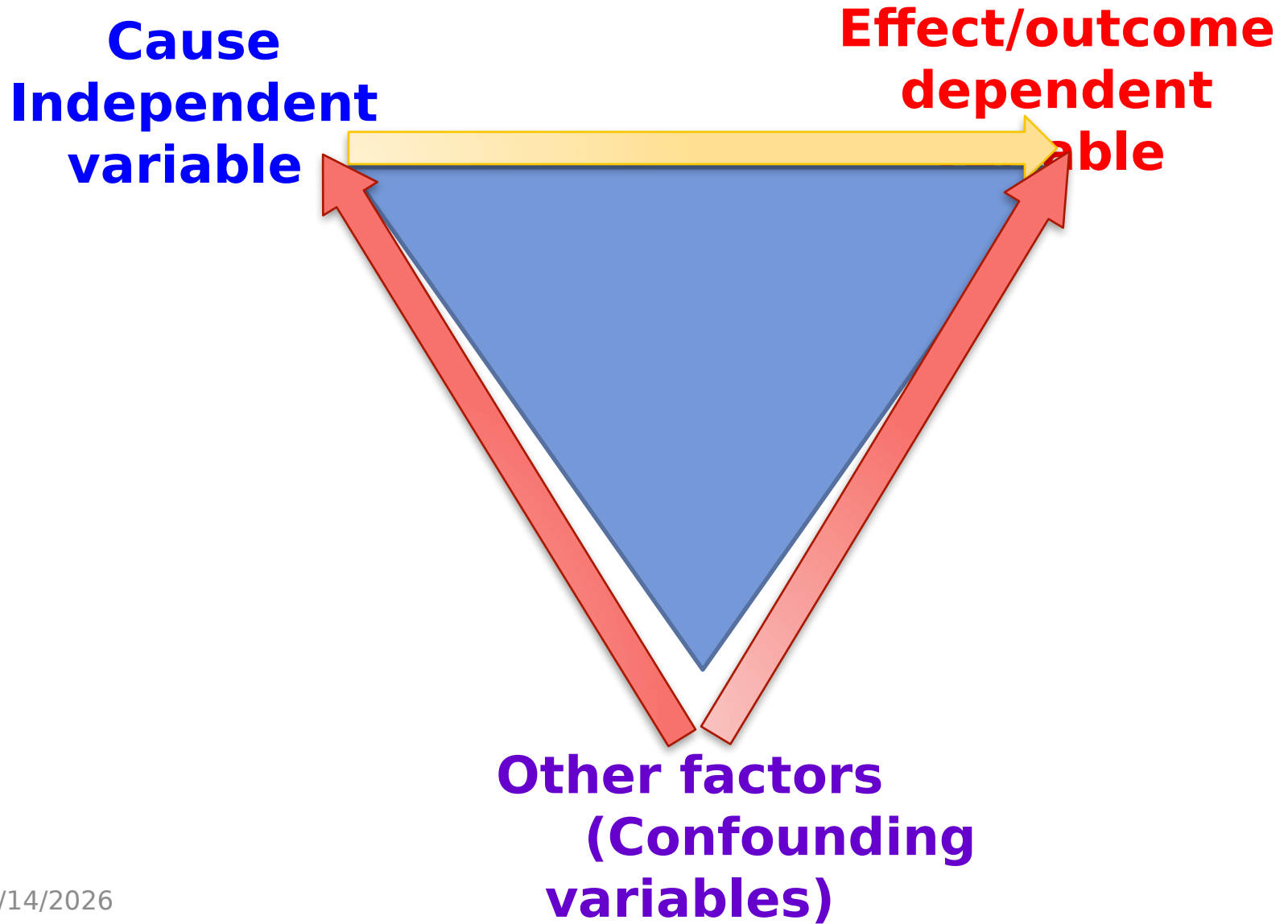
VARIABLES ...

- **For example**, in a study of relationship between **smoking and lung cancer**,
 - "***suffering from lung cancer***" (with the values yes, no) would be the **dependent** variable and
 - "**smoking**" (with the values no, less than a packet/day, 1 to 2 packets/day, more than 2 packets/day) would be the **independent** variable.

CONFOUNDING VARIABLE

- A variable that is associated with the problem and with a possible cause of the problem is a potential confounding variable.
- This type of variable may either ***strengthen or weaken*** the apparent **relationship** between the ***problem and a possible cause***.

Con'ted



Example

- A relationship is shown between the low level of the mother's education and malnutrition in under 5s. However, **family income** may be related to the mother's education as well as to malnutrition
 - **Independent variable** □ level of the mother's education
 - **Dependent variable** □ malnutrition
 - **Confounding variable** □ family income

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Operationalizing variables (operational definitions)

- Many variables can easily be measured
- For some variables it is some times not possible to find **meaningful categories** unless the variables are made operational with one or more indicators
- Operationalizing variables means that you make them measureable

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Ex1- determining level of knowledge

- There is a need to develop a series of questions to assess knowledge
- The **answer** to these questions form an indicator of someone's knowledge on the issue, which can then be categorized

E.g. if 10 questions were asked, you might decide that the knowledge of those with:

- 0 to 3 correct answers is poor
- 4 to 6 correct answers is reasonable, and
- 7 to 10 correct answers is good

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Data collection technique and tools

Different data collection techniques like:

- Observation
- Telephone
- Postal
- Self administered questionnaire
- Face to face interview

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Tools can be

- Questionnaire
- Checklist
- Recorded logbooks
- Microscope etc

E.g. A structured questioner was prepared by principal investigator for a face to face interview.

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Data Quality Control Issues

Describe/provide:

- Operational definitions of crucial concepts
- Selection and training of field workers/research staff
- Field testing the research methods and tools
- Supervision and quality control

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Pretesting

- **Pretest** – usually refers to a small-scale trial of particular research components
- **Pilot study** – is the process of carrying out a preliminary study, going through the entire research procedure with a small sample

Why pretest or pilot study?

- It serves as a trial run that allows to identify potential problems in the proposed study as a result:-
 - Time, effort and money can be saved in the long run

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What aspects can be evaluated during pretesting?

- 1) reaction of the respondents to the research procedure.
- Availability of the study population
- Acceptability of the methods
- Acceptability of the questions asked
- Willingness of respondents to answer the questions and collaborate with the study

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2) the data collection tools

- Whether the tools allow you to collect the information you need and whether these tools are reliable
- How much time is needed
- Whether there is **any need to revise** the format or presentation of interview guide/questionnaires, including whether:
 - The sequence of questions is logical
 - The wording of questions is clear

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3) Sampling procedures

- Whether the instructions concerning **how to select** the sample are followed in the same way by all staff involved
- **How much time is needed** to locate individuals to be included in the study

Ethical Considerations

- Professional obligation to safeguard the safety of study subjects
- Refer to national and international guidelines
- Describe potential ethical concerns and mechanisms to minimize harm and maximize benefits

Consent must be obtained from the relevant authorities, individuals and the community.

Every research can potentially cause ethical concerns!!

Dissemination of Results

- Briefly describe the dissemination plan
 - Feedback to the community
 - Feedback to local authorities
 - Identify relevant agencies that need to be informed
 - Scientific publication
 - Presentation in meetings/conferences
- Briefly describe how the study results can be best translated into application

***THANK YOU,
ALL!***