Chapter Three
Research Methodology

Research Methods is a systematic and principled way of obtaining evidence (data, information) for solving health care problems.

Research Methodology

METHODS AND KNOWLEDGE

Other methods of known used in the health science:

- Authority
- Rationalism
- Intuition.

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Basis of scientific method:

- **Scepticism (open to doubt and analysis)**
- **Determinism (events in the world occur according to regular laws and causes)**
- **Empiricism (enquiry ought to be conducted through observation and experiments).**

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Hypotheses are propositions about relationships between variables or differences between groups that are to be tested.

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Theories are sets of logically related or linked ideas (abstractions) about how the world or some process works.

The fundamental building blocks of theory are concepts. In other words theories consist of a series of statements (propositions) about a relationships between concepts.

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A variable is simply a property that may vary from case to case. Example, a room temperature.

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- Design (*experimental* or observational)
- Sampling (*selecting a group of cases from a population)*
- Measures (*Measurement refers to the procedure of attributing qualities or quantities to specific characteristics of objects, persons or events*)
- Intervention (if applicable)
- Analysis.

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Design Elements

***Experimenta*l or Observational**

EXPERMENTAL RESEARCH

In experimental studies the intervention is under the control of the researcher.

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EXPERMENTAL RESEARCH

Independent Variables: in an experiment an Independent Variable is the variable or condition manipulated or controlled by the researcher.

Dependent Variables: the outcome variables are termed Dependent Variables.

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EXPERMENTAL RESEARCH

The aim or goal is to determine how changes in the Independent variable affect some outcome the dependent variable.

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EXPERMENTAL RESEARCH

By controlling the timing or amount of the intervention or which subjects get it and which ones do not, the chances are minimized that other factors outside of the researcher's control could have affected the results.

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Observational Studies

By contrast the researcher does not control the intervention in observational studies but rather observes the effects of an experiment in nature.

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DATA GATHERING

- Prospective studies that involve gathering data after the study have begun.
- Retrospective studies the data have already been collected for other reasons at sometime in the past.

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THE NEED FOR CONTROL OR COMPERISON GROUP

A control group consist of subjects that undergo exactly the same conditions as the group receiving the treatment, the casual effect of which being investigated. In field research in applied clinical setting we include control groups in the design to ensure internal validity.

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Internal Validity

In a study internal validity is the ability of the researcher to attribute differences in the groups or participants to the independent variable.

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SAMPLING

- Definition of the population – researchers defines the population to which they wish to generalize the results.
- A population is an entire set of persons, objects or events which the researcher intends to study.

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SAMPLING

- A sample is a group of cases to be selected from a population.
- A Cohort is a group of people who share some attribute.
- Selection of the sample – using an appropriate sampling method, the sample is selected from the population.

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SAMPLING

- A representative sample is a sample that accurately reflects the characteristics of the population from which it is drawn. Sometimes called “unbiased” sample.

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SAMPLING

- **A Biased sample is one that is not representative. It does not reflect the composition of the population to which the researcher is attempting to generalize.**

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SAMPLING

- **Random sampling is one in which all members of the population have an equal chance of selection.**

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SAMPLING

Random sampling The procedures for drawing a random sample involves two steps:

- Construction of a list of all members of the population.
- Using a method such as dice, coins or random number tables to select randomly from the list the number of members required for the sample.

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SAMPLING

Quota sampling involves a preset number of cases in each subcategory of a given population.

Stratified random sampling same as quota sampling except that each quota is filled by randomly sampling from each subgroup.

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SAMPLING

Area sampling is a sample taking on the basis of location of cases.

Systematic sampling is working through a list of the population and choosing, say, every 10^{th} or 20^{th} case for inclusion in the sample.

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SAMPLING

Incidental sampling, or Haphazard sampling, or convenience sampling is the cheapest and easiest sampling method to use. However, it not necessarily biased.

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SAMPLING

Optimal number of cases - Sampling error is reflected in the discrepancy between the true population parameter and the sample statistic.

The greater the sample size the smaller the probability of sampling error.

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Subject Allocation

Assignment of subjects into groups

Assignment procedures – using an assignment procedure, the participants are allocated to groups.

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Subject Allocation

Random Assignment to independent groups, all subjects have the same probability of being assigned to the experimental group or the control group.

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Assignment of subjects into groups

Matched groups

Matched subjects are formed, that a pair of experimental and control subjects are chosen to be similar as possible in terms of certain key variables, such as age, sex, race, socioeconomic status, number of hospital admissions, or diagnosis.

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Assignment of subjects into groups

Matched groups

Then one member of the pair is randomly assigned to one group and the other member to the other group. This ensures that the two groups have similar characteristics.

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Assignment of subjects into groups

Under matched groups

If they differ on some variable that is related to the outcome of the study.

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EXTERNAL VALIDITY OF EXPERMENTS

External validity refers to the extent to which the results of an investigation can be generalized to other samples or situations.

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THREATS TO VALIDITY

The purpose of any study is to tell us what is “really” happening in the world. Does streptokinase reduce cardiac mortality? What causes sudden infant death syndrome?

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THREATS TO INTERNAL VALIDITY

1. History
2. Maturation
3. Testing
4. Instrumentation
5. Regression to the mean
6. Selection or assignment errors
7. Mortality

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THREATS TO INTERNAL VALIDITY

History

This refer to events that intervene between the pre-test and post–test that do not form part of the treatment being investigated by the researcher

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THREATS TO INTERNAL VALIDITY

Maturation

In a study overtime, the patients may naturally mature. This is a particular problem with pediatric and geriatric populations.

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THREATS TO INTERNAL VALIDITY

Testing

The patient as a result of familiarity with the testing procedures, appear to improve spontaneously.

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THREATS TO INTERNAL VALIDITY

Instrumentation

During the time between measurements, the measuring instrument might change

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THREATS TO INTERNAL VALIDITY

Regression to the mean

Refers to the phenomenon whereby groups of subjects that are chosen because of extreme scores on any variable will have scores that are less extreme and closer to the mean value when they are retested.

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THREATS TO INTERNAL VALIDITY

Selection or Assignment Errors

The groups being compared may be different at the outset because of inadequate assignment or selection procedures, rather than as a result of any treatment effects.

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THREATS TO INTERNAL VALIDITY

Mortality

Mortality in a study refers to when a participant withdraws from the study before its completion.

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THREATS TO VALIDITY

We hope that the result of our sample can be generalized to the population at large so the our findings also hold true for similar people. Consequently it is disturbing, at the least, to find different studies coming to opposite conclusions.

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THREATS TO VALIDITY

Subject Selection Biases

Subject selection biases involves many factors that may result in the subjects in the sample being unrepresentative of the population.

Healthy workers Bias, Incident-Prevalence

Volunteer Bias

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THREATS TO VALIDITY

Hawthorne Effect:

An effect which results in the improvement of subjects performances through being observed and/or social contact. It is the same as the Placebo effect.

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THREATS TO VALIDITY

The Rosenthal effect:

The expectancy effects, the phenomenon where the expectation of the researchers in a study influence the outcome. It is the same as the Placebo effect.

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THREATS TO VALIDITY

Blind: The purpose of blinding is to prevent various biases from affecting the results.

A person is considered blind if he or she is unaware of the group to which a subject belongs.

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THREATS TO VALIDITY

Single Blinding: If only the subject is unaware but the experimenter knows, the study is called single blind.

Double Blinding: If both the subject and the researcher do not know the study is called double blind.

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EPIDEMIOLOGIC RESEARCH STRATEGIES

DESCIPTIVE OR ANALYTICAL DESIGNS

These are most appropriate when for one reason or another, experimental control over the independent variable is not feasible.

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EPIDEMIOLOGIC RESEARCH STRATEGIES

DESCIPTIVE OR ANALYTICAL DESIGNS

SURVEYS

Surveys are investigations aimed at describing accurately the characteristics of populations for specific variables.

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EPIDEMIOLOGIC RESEARCH STRATEGIES

DESCIPTIVE OR ANALYTICAL DESIGNS

When surveys are used in health care research

1. **To establish the attitudes, opinions, or beliefs**
2. **To study characteristics of population on health related variables.**
3. **To collect information on the demographic characteristics (age, sex, income, etc.).**

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EPIDEMIOLOGIC RESEARCH STRATEGIES

DESCIPTIVE OR ANALYTICAL DESIGNS

Naturalistic comparison study: a type of study in which naturally occurring groups are compared with one another.

There are extraneous variables which can be controlled in this type of investigation, such as ages, and educational background.

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EPIDEMIOLOGIC RESEARCH STRATEGIES

DESCIPTIVE OR ANALYTICAL DESIGNS

Correlational studies: Studies that are concerned with investigating the associations between variables.

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EPIDEMIOLOGIC RESEARCH STRATEGIES

QUASI-EXPERIMENTAL DESIGNS

Time-series designs: A series of measurements taken repeatedly from the same person or group of people, over time.

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EPIDEMIOLOGIC RESEARCH STRATEGIES

QUASI-EXPERIMENTAL DESIGNS

Multiple-group time-series designs: A type of research design where two groups or cases are repeatedly measured over time to produce a series of measurements. One group or case receives an intervention and the other does not. The effects of intervention may then be studied by comparing the two series.

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EPIDEMIOLOGIC RESEARCH STRATEGIES

EXPERIMENTAL DESIGNS

1. Randomized Control Trial
2. Cross-Over Design similar to quasi-experimental design

These are called experimental design because the intervention is under the control of the investigator.