

Chapter 02

Basic Research Methodology

A faint, stylized illustration of two hands shaking is visible in the background, centered behind the main title. The hands are rendered in a light teal color, matching the background, and are positioned as if in a firm handshake.



Definition

RESEARCH

Research is a quest for knowledge through diligent search or investigation or experimentation aimed at the discovery and interpretation of new knowledge. (WHO)

Research is an art of scientific investigation.



Definition

RESEARCH

A systematized effort to gain new knowledge (Redman).

A careful investigation or inquiry specially through search for new facts in any branch of knowledge (Advanced learners' Dictionary)



Scientific Research Steps

1. Formulation of problems
2. Setting research objectives
3. Designing the study
4. Methods of data collection
5. Statistical analysis
6. Interpretation and dissemination of the results



Empirical

Theoretical / Conceptual



Philosophical



Categories of Research

Basic and applied

Other categories



EMPIRICAL RESEARCH

- **Health research mainly follows the empirical approach.**
- **It is based on observation and experience more than upon theory and abstraction.**
- **It can be qualitative & quantitative.**
- **Health Science Research deals with information of a quantitative nature.**

Empirical Research involves:

- ① The identification of the population of interest.
- ② The characteristics (variables) of the individuals (units) in the population.
- ③ The study of variability of these characteristics among the individuals in the population.

Quantification in Empirical Research:

- ① Measurement of variables.
 - ② Estimation of population parameters.
 - ③ Statistical testing of hypothesis.
- Empirical research relies on experience or observation without due regard to system or theory.



THEORETICAL / CONCEPTUAL RESEARCH

✳ It is related to some abstract idea(s), theory.

E.g. • In abstraction with mathematical models.

- Advances in understanding of disease occurrence and causation cannot be made without a comparison of the theoretical constructs with that which we actually observe in populations.

✳ Empirical & theoretical research complements each other in developing an understanding of the phenomena, in predicting future events.

Basic / fundamental / pure



Applied

BASIC / FUNDAMENTAL / PURE

- ✿ It means formation of theory or generalization.
- ✿ Basic research is usually considered to involve a research for knowledge without a defined goal of utility or specific purpose.



APPLIED / ACTION

- Solution for immediate problems.
- Applied research is problem oriented.

OTHER CATEGORIES OF RESEARCH

- ① Longitudinal / one time.
- ② Field setting / laboratory / simulation.
- ③ Clinical / diagnostic.
- ④ Historical.
- ⑤ Conclusion oriented / decision oriented.

**Bio-medical
(Cellular Research)**



**Health
Research
Triangle**

Behavioral

**(Beliefs / attitudes / practices
in the society by man)**

Health Research

(Environmental)



SCIENTIFIC FOUNDATIONS OF RESEARCH ORDER

- ✿ Scientific method is not common sense.
- ✿ In arriving at conclusion “common sense” can’t be employed **e.g. – Fever is a symptom of the**
- ✿ To arrive at conclusion an organized observation of entities or events which are classified or ordered on the basis of common properties and behaviors are required.

- ✿ It is this commonality of properties and behaviors that allows predictions which carried to the ultimate, become laws e.g. A number of Allergic Rhinitis cases are studied and it is found a number cases are having a group of common causes from which prediction is made and there after etiology become conclusive as from 'Allergens'.



SCIENTIFIC FOUNDATIONS OF RESEARCH

INFERENCE AND CHANCE

- Reasoning or inference is the force of advances in research.
- In terms of logic, It means that a statement / or a conclusion ought to be accepted because one or more other statements / premises (evidence) are true.
- Inferential suppositions, presumptions or theories may be so developed, through careful constructions, as to pose testable hypothesis.



SCIENTIFIC FOUNDATIONS OF RESEARCH

INFERENCE AND CHANCE

- The testing of hypothesis is the basic method of advancing knowledge in science.
- Two distinct approaches or arguments have evolved in the development of inferences. They are such as: **deductive and inductive.**



SCIENTIFIC FOUNDATIONS OF RESEARCH

INFERENCE AND CHANCE

- In deduction, the conclusion necessarily follows from premises (evidence) / statements, as in syllogism e.g. [All 'A' is 'B', all 'B' is 'C' therefore all 'A' is 'C'] or in algebraic equations.
- Deduction can be distinguished by the fact that it moves from the general to the specific.

- **It does not allow for the elements of chance or uncertainty.**
- **Deductive inference, therefore, is suitable to theoretical research.**

INDUCTION

Inductive reasoning is distinguished by the fact that it moves from the specific to the general (from sample to population). It builds:-

- Health research being primarily empirical depends entirely upon inductive reasoning.
- The conclusion does not necessarily follow from the premises or evidence (facts). We can say only that the conclusion is more likely to be valid if the premises are true, i.e. there is a possibility that the premises may be true but the conclusion is false.

Scientific Foundations of Research

Evaluation of probability

- It is a critical requirement in research design.
- Evaluation of probability ensures validity.
- The most salient elements of design, which are meant to ensure the integrity of probability and prevention of bias, are:
 - a) Representative sampling.
 - b) Randomization in the selection of study group.
 - c) Control group for comparison.
 - d) Blinding of experiment.
 - e) Use of probability (statistical) method in analysis & interpretation.

Probability is a measure of uncertainty or variability of the characteristic among individuals in the population.

HYPOTHESIS (A guess or imaginary idea)

- Hypothesis are carefully constructed statements about a phenomenon in the population.
- It may be generated by deductive or inductive reasoning from prior observations.

SOURCE OF HYPOTHESIS

- a) General culture**
- b) Scientific theory**
- c) Analogies**
- d) Personal experience**

Method of difference

**Method of
Analogy**

**Mill's Canons of
Inductive Reasoning**

**Method of
agreement**

**Method of
concomitant variation**



QUALITIES OF WORKABLE HYPOTHESIS

- a) **Specific**
- b) **Conceptually clear**
- c) **Related to available technique**
- d) **Capable of empirical test**
- e) **Simple**

UTILITY IN RESEARCH

- a) Hypothesis gives point to inquiry.
- b) Hypothesis helps in deciding in which to proceed.
- c) Hypothesis helps in selecting pertinent facts.
- d) Hypothesis helps in drawing specific conclusion.

STUDY DESIGN

**Observational type
of research**



A sample of population is observed for various characteristics.

**Experimental type
of research**



Testing of hypothesis is best done by experiments.

Factors other than those under consideration can be controlled.

Not often possible in human diseases due to ethical and practical considerations.

Research Designing and Methodology

Definition of problem

e.g. Occurrence of lower respiratory tract infection in children after vaccination.

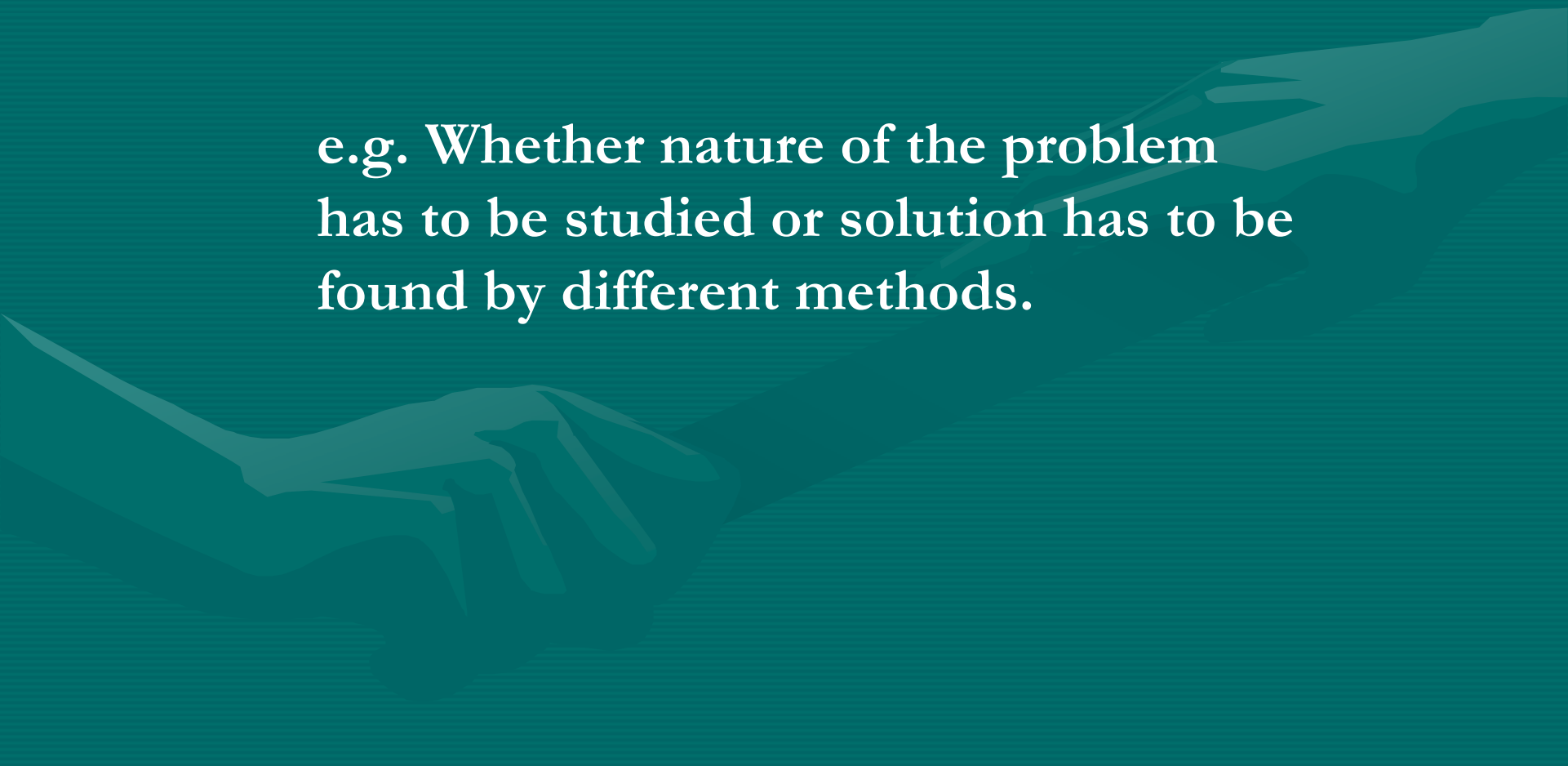
Selection of research topic should be based on

- Magnitude of the problem and its impact
- Urgency of the need for a solution.
- Relevance to the aim of the funding agency.
- Amenability of the problem to investigation.
- Feasibility of the approach.
- Chances of success, etc.

Aim and Objectives



e.g. Whether nature of the problem has to be studied or solution has to be found by different methods.



Review of Literature

Critically review the literature on the problem under study:

- Any such work done by other in the past.
- State whether you want to confirm the findings.
- Challenge the conclusion.
- Extend the work further.
- Bridge some gaps in the existing knowledge.

Hypothesis



An assumption, positive or negative.

e.g. Crataegus Q is not more effective than Crataegus in potency.

Constitutional medicines act better than mother tinctures for hypertension, etc.

A) Definition of the population under study

- I. It may be country / state / districts / town / village / families / specific groups.
- II. Age group
- III. Income group
- IV. Occupation
- V. Sexes
- VI. Define clearly who are to be included and who are not to be included, i.e. (Inclusion and exclusion criteria)

B) Selection of the sample

- **It should be unbiased.**
- **Sufficiently large in size to represent population under study.**

Sample size

For Qualitative Data

$$N = 4pq/L^2$$

Where 'p' is the positive character, $q = 1-p$
L= allowable error, 10% or 20% of 'p'

For Quantitative Data

$$L = 2\sigma/\sqrt{n} \text{ or } \sqrt{n} = 2\sigma/L \text{ or}$$

$$n = 4\sigma^2/L^2$$

Sample size for analytical studies:

a. Testing equality of two proportions: $\pi_1 = \pi_2$

$$n = [\{Z_{1-\alpha} \sqrt{2 \bar{\pi} (1 - \bar{\pi})} - Z_{\beta} \sqrt{\pi_1 (1 - \pi_1) + \pi_2 (1 - \pi_2)}\} / \delta]^2$$

Where $\bar{\pi} = (\pi_1 + \pi_2) / 2$

b. Sample size for a case - control study

c. Comparison of two population Means.

$$n = [(Z_{1-\alpha} - Z_{\beta}) \sigma / \delta]^2$$

d. Comparison of more than two groups and methods.

Sampling methods

i) Simple random sampling

- Choose random number from the table.

ii) Stratified sampling

- (Selecting 50% male & 50% female)

iii) Systemic sampling

- Systematically it is chosen.

iv) Cluster sampling

- Cluster may be identified (households) and random samples of cluster.

v) Multistage sampling

- In several stages.

Specifying the nature of study

Epidemiological studies:

These are field and not hospital based.

Studies are more likely to be unbiased.

e.g. Infant mortality is higher in rural than in urban areas.

Nature of Study

a) Longitudinal

Observations are repeated in the same population over a prolonged period of time by means of follow up examinations.

- **Prospective study:** Longitudinal follow up of population over a period of time.
- **Retrospective study:** Longitudinal study in profile of a sample or population. E.g. Mortality of women over 45 years.

Nature of Study

b) Cohort studies:

Longitudinal studies in which the sample is a cohort. A cohort is a group of persons exposed to same sort of environment. E.g. women between 15 to 45 yrs. exposed to radiation.

Nature of Study

c) Interventional studies:

It involves three phases:

- **Diagnosis or identification phase**
- **Intervention by treatment or service for a specific**
- **Assessment phase for result.**

Nature of Study

d) Experimental studies: Trials are made such as a drug or medical service and the result is watched.

e) Cross-sectional studies: (Non-experimental):

Onetime or at a point of time study of all persons in a representative sample of a specific population. E.g. Examination of all children in age group 5 to 14 yrs. detection of cancer cases and study of the factors that lead to cancer.

Nature of Study

f) Control studies:

- Control group should be identical to the experimental group in all respects except for the factor under study.
- Sometimes not possible so ignored. E.g. Withdrawing antibiotic in pneumonia.
- Sometimes not required. E.g. Prevalence of cancer in smokers (sufferers) is compared with prevalence of cancer in non-smokers (controls).

Ruling out subjective bias in subjects under study

a) Single blind trial

b) Double blind trial

Errors in the inference

Two common sources of errors
that needs to be controlled result from
problem with **'reliability'** and
'validity'.

Reliability

If the observations are repeated under similar conditions the inference should to be similar.

- Reliability of the sample is achieved by selecting a large sample.
- Reliability is measured by using ‘random error’

Validity

- The inference should be reflection of the true nature of the relationship.
- Validity is achieved by insuring the sample selection is unbiased.
- Validity is measured by using ‘bias’.

Statistical Tools or Tests of Significance

Z – test

$$Z = \bar{X} - \mu / SE (\bar{X})$$

(between sample means)

Where \bar{X} = Sample mean

μ = Population mean

SE = Standard error

Z = Observed difference between two sample means / Standard error of difference between two sample means (between two sample means)

Requirements to Apply Z – Test:

- 1. The sample or samples must be randomly selected.**
- 2. The data must be quantitative.**
- 3. The variable is assumed to follow normal distribution in the population.**
- 4. The sample size must be larger than 30.**

t – test

Requirements to Apply t – Test:

1. The sample or samples must be randomly selected.
2. The data must be quantitative.
3. The variable is assumed to follow normal distribution in the population.
4. The sample size must be less than 30.

$$t = \frac{\bar{X} - \mu}{SE(\bar{X})}$$

Where \bar{X} = Sample mean

μ = Population mean

SE = Standard error

Chi – square Test (χ^2 test)

It has got the following three very important applications in medical statistics as tests of:

- **Proportion – To find significance in same type of data.**
- **Association between two events.**
- **Goodness of fit – To test fitness of an observed frequency distribution of qualitative data to a theoretical distribution.**

To apply χ^2 test

Three Essential Requirements:

- A random sample
- Qualitative data
- Lowest expected frequency (value) not less than 5

$$\chi^2 = \sum \frac{(O - E)^2}{E}$$

Where O = Observed value

E = Expected value

Variance Ratio Test: (F – test)

This means comparison of sample variance. It is applied to test the homogeneity of variances.

$$F = S_1^2 / S_2^2$$

$S_1^2 =$ Variance of first sample $(S_1^2 > S_2^2)$

$S_2^2 =$ Variance of second sample

ANOVA Test (Analysis of Variance Test)

This test is not confined to comparing two sample means but more than two samples drawn from corresponding normal population.

Presentation in brief

1. Title of the Article

2. Abstracts

- A brief summary of the work done.
- Major observations and results.

3. Introduction

- Name of the problem
- Clear reasons for understanding the particular research.
- Put forward the hypothesis.
- Enumerate aim and objectives of the study.

4. Review of Literature

5. Materials and Methods

- **Definition of population under study**
- **Selection of sample**
- **Nature of study**
- **Ruling out the observational and instrumental errors.**

6. Results

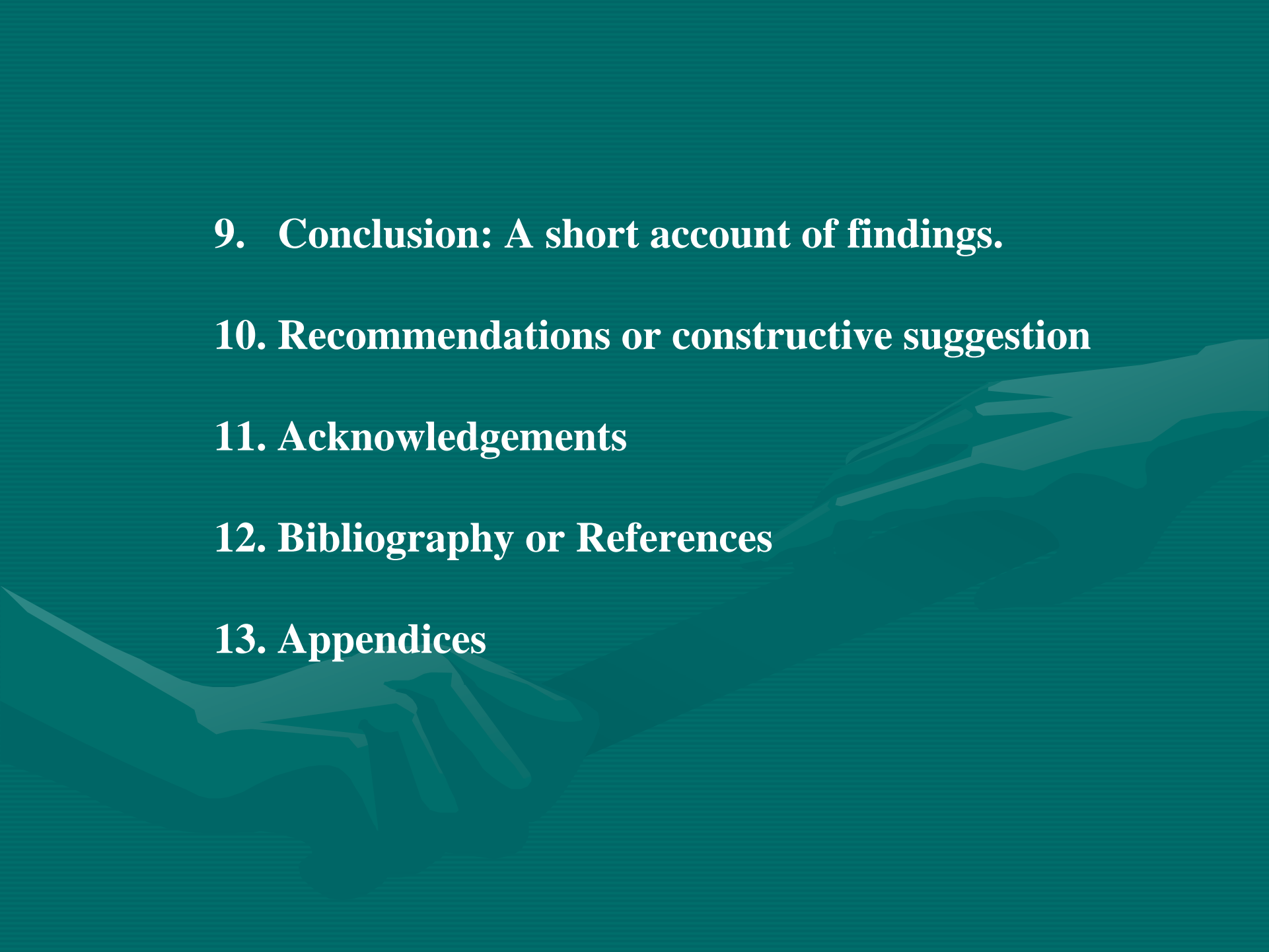
- **Presentation of data.**

7. Analysis of the results

- **Unbiased statistical analysis**

8. Discussions

- **Compare the results obtained in your work with those in the literature.**
- **Discuss the reasons for differences and similarities**
- **Mention pitfalls in your study.**

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- 9. Conclusion: A short account of findings.**
 - 10. Recommendations or constructive suggestion**
 - 11. Acknowledgements**
 - 12. Bibliography or References**
 - 13. Appendices**

Thank You

The image features a dark teal background. In the center, the words "Thank You" are written in a large, bold, sans-serif font. The text is filled with a vibrant rainbow gradient, transitioning from pink on the left to purple on the right. The letters have a slight 3D effect with a thin white outline. Below the floating text, a computer keyboard is visible, with the words "Thank You" faintly embossed on the keys. In the lower-left foreground, there is a faint, stylized illustration of a hand reaching out, rendered in a lighter shade of teal.