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# Global health

👤 slide # : **medical research**

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# Medical Research Methodology

## Introduction

Health research is not only about the development of new tools and advancing our understanding about health and disease. It is important to inform policy and decision-making in health systems.

### Why?

- Health research may be pursued as a career in a public or private research organization.
- Research may be done in pursuit of prestige or under the pressure of the threat of “publish or perish” when climbing the ladder of a successful academic career.
- A strong argument can, however, be made that all health professionals should do some research, or at least get enough knowledge about the research process, even if they wish to spend the rest of their lives dealing with patients or health administration.

### Importance for medical personnel

1. To get PhDs, Masters and Bachelors??
2. To provide solutions to complex problems
3. To investigate laws of nature
4. To make new discoveries
5. To develop new products
6. To save costs
7. To improve our life
8. Human desires

### Definition

- Research can be defined as the *systematic collection, description, analysis and interpretation of data to answer a certain question or solve a problem*. It can be used to improve the health of individuals or groups.
- The research process changes “information” into “knowledge”, through critical assessment and relating it to other existing human knowledge. As they go through this research exercise, health managers and policy-makers need to understand more about the process of research.
- In a sense, most of us may be conducting some research in our daily life. When we, for example, want to buy a car in a proper way, we collect information about models and dealers, analyze it, then try to reach a “scientific” conclusion on which car to buy.
- The use of complex instrumentation is not a necessary requirement for good research.

- Key attributes of good research are proper planning, accuracy in data collection and proper unbiased interpretation.
- There is only one type of research: *good research*.
- Bad research does not deserve the name of research. Badly done research is not only a waste of time, money and effort. It can be considered unethical if it exposes research subjects to the inherent risks of experimentation with no reward to them, to others or to their communities.

### **So research is**

Hunting for facts or truth about a subject, organized scientific investigation to solve problems, test hypotheses, develop or invent new products

Research is systematic, because it follows certain steps that are logical in order. These steps are:

1. Understanding the nature of problem to be studied and identifying the related area of knowledge.
2. Reviewing literature to understand how others have approached or dealt with the problem.
3. Collecting data in an organized and controlled manner so as to arrive at valid decisions.
4. Analyzing data appropriate to the problem.
5. Drawing conclusions and making generalizations.

#### ***High quality research:***

- It is based on the work of others.
- It can be replicated (duplicated).
- It is generalizable to other settings.
- It is based on some logical rationale and tied to theory.
- It is doable (achievable)!
- It generates new questions or is cyclical in nature.
- It is incremental.
- It is a political activity that should be undertaken for the betterment of society.

#### ***Bad quality research:***

- The opposites of what have been discussed.
- Looking for something when it simply is not to be found.
- Plagiarizing other people's work.
- Falsifying data to prove a point.
- Misrepresenting information and misleading

Bad research does not deserve the name of research. Badly done research is not only a waste of time, money and effort. It can be considered unethical if it exposes research subjects to the inherent risks of experimentation with no reward to them, to others or to their communities.

## **Characteristics of research**

1. It requires clear objectives and a plan (it is not aimlessly looking for something in the hopes that you will come across a solution).
2. It builds on existing data, using both positive and negative findings.
3. New data should be *systematically* collected and analyzed to answer the original research objectives.

### **Research types:**

#### **I. According to the purpose of research:**

- 1- Basic
- 2- Applied

#### **II. According to the method of research:**

- 1- Descriptive
- 2- Historical
- 3- Correlation
- 4- Experimental, etc...

The research process begins with selecting a field and topic for research, then planning the research, writing up the plan as a research protocol, and, where appropriate, submitting it as a research proposal for funding. Implementation of the research project is followed by describing and analyzing the research results. The research results then need to be carefully and objectively interpreted. Research is not complete until it is communicated to those who may benefit from it. This commonly involves writing and publishing a scientific paper, and/or making a scientific presentation. The research process not only involves doing the research, but also assessing and evaluating research done by others. Throughout the research process, and particularly where the research involves human subjects, rules of ethical conduct must be carefully observed.

## **Steps in conducting research**

- 1- Prioritizing and selecting a research topic
- 2- Literature review
- 3- Development of a research proposal
- 4- Getting formal institutional approval
- 5- Data collection (field work)
- 6- Data processing and analysis
- 7- Report writing
- 8- Recommendations for implementation of the research findings

### **Contents of Protocol:**

1. Title
2. Researchers with their positions (authors)
3. Introduction

4. Aim
5. Subjects/Material and methods
6. References

*N.B. You must include questionnaire, format or check list within.*

**Contents of Scientific paper:**

1. Title
2. Researchers with their positions (Authors)
3. Abstract
4. Introduction
5. Aim
6. Subjects and methods
7. Results
8. Discussion
9. References
10. Annex/ Appendix

**Proposal:**

1. It forces the investigators to clarify their thoughts and to think about all aspects of the study;
2. It is a necessary guide if a team (not a single investigator) is working on the research;
3. It is essential if the study involves research on human subjects or is on experimental animals, in order to get the institution's ethical approval;
4. It is an essential component of a research proposal submitted for funding.

During the process of the development of the proposal, investigators can and should try to benefit from the advice of colleagues and experts in refining their plans. But once a proposal for the study has been developed and approved, and the study has started and progressed, it should be adhered to strictly and should not be changed.

The research proposal is generally written according to the following format:

1. Project title
2. Project summary

3. Project description:
4. Rationale
5. Objectives
6. Methodology
7. Data management and analysis
8. Ethical considerations
9. References

### **Types of research papers**

- **Essay paper (Review article):**
  - A review article.
  - Explore a health problem (magnitude, causes, treatment, etc.).
  - Report and discuss the review of literature of the problem under the research.
- **Research thesis paper (Original article):**
  - Deal with study population (individuals, events, objects).
  - Include sections about methodology and results.
  - May be a descriptive, analytical, or experimental study (see later).
- **Case report and case series study:**
  - Report and discuss unusual event (s)

### **Research Area**

Areas of research are very broad and overlapping. Selection of research actually **based on:**

1. The researcher's specialty, interest, scientific background and experience.
2. Actual need for research in this area.
3. Available resources (interest of funding body).

### **Research topic**

After choosing a research area, which is quite broad, the researcher has to narrow his queries to more specific subjects or research topics.

*The priority of a topic for research will depend on:*

1. Characteristic of a topic: impact on health, magnitude, prevention, treatment...
2. Characteristics of the proposed study: feasibility, cost-effectiveness, applicability of the results.

### **Criteria for prioritizing and selecting a research topic**

- 1- Relevance: How large or widespread is the problem? Who is affected? How severe is the problem?
- 2- Avoidance of duplication: No sound information available
- 3- Urgency of data needed (timeliness): Data urgently needed for decision-making or developing interventions at various levels (from community to policy) Political acceptability of study: Topic is acceptable to high level policymakers, or has the interest and support of the local/national authorities.
- 4- Feasibility of study: Study is feasible, considering available resources.
- 5- Applicability of results: Good chance of recommendations being implemented.
- 6- Ethical acceptability: No ethical problems.

### **Title of the research**

A good title should be short, accurate, and concise. It should make the central objectives of the study clear to the reader. It is important to specify what population will be investigated, and where it will be conducted. It is preferable to write the research setting in the title. **Example:** « Life style Factors and the Risk of Adult Leukemia in Canada »

Some authors prefer to include hint about the study results in the title, and some prefer to write it in the form of question. **Example:** “Active smoking increases the risk of adult leukemia in Canada” or “Could active smoking increase the risk of adult leukemia in Canada

**Some examples for title:**

- Controlled Study with ranitidine for the prevention of recurrent duodenal ulcer.
- A study of hepatitis C prevalence in health care workers in the West of Scotland.

- Slower metabolism and reduced intake of nicotine from cigarette smoking in Chinese-Americans.

## Review of literature

A literature review is an account of what has been published on a topic by accredited scholars and researchers.

Besides enlarging your knowledge about the topic, writing a literature review lets you gain and demonstrate skills in two areas:

- **Information seeking:** the ability to scan the literature efficiently, using manual or computerized methods, to identify a set of useful articles and books
- **Critical appraisal:** the ability to apply principles of analysis to identify unbiased and valid studies.

### *A literature review must do these things*

- be organized around and related directly to the thesis or research question you are developing
- synthesize results into a summary of what is and is not known
- identify areas of controversy in the literature
- formulate questions that need further research

### *There are five stages to your literature review:*

1. Find models
2. Problem formulation
3. Literature search
4. Evaluation of findings
5. Analysis and interpretation of literature

### *Where could you make literature review?*

*The sources of information may include the following:*

- Text-books in libraries.
- Index Medicus, which identify journal articles by subject, author and title.
- Computer-based literature searches such as MEDLINE.
- Bibliographies, such as those found at the end of books, articles and theses, or prepared as separate documents.
- Statistics collected at national, provincial and/or departmental levels.
- Opinions and beliefs of key informants (e.g. health managers and community leaders).



Finally, literature review prevents the duplication of work that has been done before. It helps the researchers to find out what others have found and reported on the problem. It helps the researcher to become more familiar with the various types of methodology that could be used in the study. It should provide convincing arguments why this particular research project is needed (i.e., rationale of the study).

### **Definition of health problem**

On defining the health problem you must mention the following (within your introduction section):

- **Importance of the problem under the study**

1. Is the problem acute or chronic?
2. Magnitude of the problem in the population
3. Who's affected?
4. What its impact?
5. Feasibility of its solving?

- **Rationale of the study** (Why you conduct the study (causes ))

- **Objectives of the study: examples**

- to decrease magnitude of the problem, or
- to search for its causes, etc

### **Research Questions**

**The research questions should be:**

1. Specific
2. Precise
3. Clear
4. Simple in language
5. To the target of the study problem and objective

**Example:** in lung cancer study

In cross sectional study:

1. What is the prevalence of lung cancer in the community?
2. What are the socio-demographic characteristics of lung cancer cases in comparison with non cases?

In Case control study:

1. Is there association between lung cancer and smoking?
2. Is there association between asbestos exposure and lung cancer?

In prospective study:

1. What are the incidence rates of lung cancer in smoker and non smoker?
2. Is there association between lung cancer and smoking habit?

### **Hypothesis**

A hypothesis can be defined as “a tentative prediction or explanation of the relationship between two or more variables. A hypothesis, in other words, translates the problem statement into a precise, unambiguous predication of expected outcomes.”

Study hypotheses serve to direct and guide the research. They indicate the major independent and dependant variables of interest.

They suggest the type of data that must be collected and the type of analysis that must be conducted in order to measure the relationship among the variables.

A hypothesis can be simple in form, predicating the relationship between one independent and one dependant variable.

Eg. “Health education involving active participation by mothers will produce more positive changes in child feeding than health education based on lectures.”

**Independent variable:** Type of health education

**Dependant variable:** Changes in child feeding

A hypothesis can be stated in the “null” format, which simply states, for example, that ‘**there is no significant relationship between or among the variables of interest**’. On the other hand, a hypothesis can be stated in a “**directional**” or “**alternative**” format.

### **Research objectives**

**Why should research objectives be developed?**

The formulation of objectives will help you to:

1. Focus the study (narrowing it down to essentials)
2. Avoid the collection of data which are not strictly necessary for understanding and solving the problem you have identified; and
3. Organize the study in clearly defined parts or phases.

Properly formulated, specific objectives will facilitate the development of your research methodology and will help to orient the collection, analysis, interpretation and utilization of data.

**How should you state your objectives?**



- ⇒ Specific
- ⇒ Measurable
- ⇒ Attainable
- ⇒ Relevant
- ⇒ Time-bound

**Formulation of General and specific research objectives**

The general objective of a study states what researchers expect to achieve by the study in general terms.

It is advisable to break down a general objective into smaller, logically connected parts. These are normally referred to as specific objectives. Specific objectives should systematically address the various aspects of the problem, and the key factors that are assumed to influence or cause the problem. They should specify what you will do in your study, where and for what purpose.

**N.B.:** *Goals are* Long term objectives. They help with other similar studies to improve some studied health problems Ex.: the study aims “to decrease ARI among infants

**Objective’s verbs (Bloom’s Taxonomy)**

Type of study	Objective’s verbs
Cross sectional	To explore, know, identify, determine,

Case-control	To examine, investigate, test, analyze, assess
Prospective	As in case control study
RCT	To compare, investigate, estimate, assess

## Methodology

This section summarizes the most important points of the research design including:

- **Variables:** It is necessary to identify the variables that will be involved in the research project being designed. Four types of variable are important in research: Independent (predisposing/risk factors), Dependent (outcome/condition/disease), Confounding, and Background variables. It is also necessary to specify whether these variables are Numerical (continuous/discrete), or Categorical (ordinal/nominal). Operational definition of different study variables should be clearly phrased (how they'll be measured precisely).
- **Study design:** Descriptive (e.g. cross-sectional surveys), Analytic (e.g. cohort and case-control), Experimental strategies (e.g. clinical and preventive trials).
- **Study population, Selection Criteria, Sample Selection and Size, Sampling method.**
- **Study Setting.**
- **Data Collection Procedures, data collection tools** (e.g. questionnaire or interview schedule, clinical examination, laboratory tests, screening procedures, records, etc.).
- **Plan of Data Processing and Analysis:** This should include the plan for processing and coding data, either by manual sorting, machine sorting, or computer programme, and choice of statistical methods to be applied to each hypothesis.
  - a) **Ethical Considerations:** e.g. Ethical approval, Informed consent form.
  - b) **Pilot Study (Pretesting the methodology):** is the carrying out a preliminary study, going through the entire research procedure with a small sample.

It may be possible to pre-test:

- The reactions of respondents to the research procedures and to questions related to sensitive issues.
- The appropriateness of study type and research tools selected for the purpose of the study.
- The appropriateness of format and wording of questionnaires and interview schedules and the accuracy of the translations.
- The time needed to carry out interviews, observations or measurements.
- The feasibility of the designed sampling procedures.

- The feasibility of the designed procedures for data processing and analysis.

### Work plan

- A work plan is a schedule that summarizes, in a clear fashion, various components of a research project and how they fit together.
- It should include:
  1. The various tasks to be performed
  2. When the tasks will be performed
  3. Who will perform the tasks

### Plan for utilization and dissemination of research results

- The proposal should indicate what reports or other means of disseminating research findings are planned.
- Any or all of the following are appropriate for disseminating the results of the study:
  - ⇒ Progress reports
  - ⇒ Final report
  - ⇒ Publications
  - ⇒ Seminars, workshops, and conferences
  - ⇒ Discussion with policymakers and program managers

### References

The references in your text can be numbered in the sequence in which they appear in the report and then listed in this order in the list of references (Vancouver system).

<b>How to format various reference sources?</b>
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<b>■ Journals</b>
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Harrison KL, Forster TH. Instruction to authors. <i>Aust J Med Sci</i> 1996; 17: 45-47.
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<b>■ Author(s) of a book</b>
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Murray-Smith S. Right Words: A guide to English usage in Australia. 2nd ed. Melbourne: Penguin Books; 1990.
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<b>■ Author(s) of a chapter in a book</b>
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Bogduk N. Spinal pain: backache and neck pain. In: Gandevia SC, Burke D, Anthony M, editors. Science and practice in clinical neurology. Melbourne: Cambridge University Press; 1993; 39-57.
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<b>■ Internet referencing:</b>
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<b>1. Document/Individual Work</b>
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Tyner R. Sink or Swim: Internet search tools and techniques (version 3) [WWW document]. Okanagan University College, 7 July 1998. <http://oksw01.okanagan.bc.ca/libr/connect96/search.htm> [accessed 19 July 1998].

## **2. Journals**

Zorn P, Emanoil M, Marshall L, Panek M. Advanced searching: Tricks of the trade. *Online* [WWW]. 1996 May; 9 pages. <http://www.onlineinc.com/onlinemag/MayOL/zorn5.html> [accessed 19 July 1998].

## **Annexes**

These may include:

- Interview schedule/ questionnaires (and/or other data collection tools).
- Informed consent form
- Institutional/Ethical approval for the study

## **Ethical Considerations**

In designing research, especially research that involves human subjects, it is important to consider the underlying ethical principles. Proposal for such research must be reviewed by the relevant Ethical Committee. To this end all ethical issues must be dealt with at inception. Such action takes care of possible conflicts between competing sets of values. The general ethical principles governing research on human subjects, especially in medico-sociological research, have been described in the 'Declaration of Helsinki', 1975.

### **The main principles include:**

- a) Scientific merit: any research should be merited, and the method must be appropriate to the aims of the investigation.
- b) Equitable selection of subjects.
- c) Informed consent: individuals must understand the nature of the study and possible implications.
- d) Confidentiality
- e) Coercion: the rights of individuals must be protected. Coercion and deception must be avoided at all costs.
- f) Field trial (reconnaissance) must observe and obtain consent.

g) Enhance the benefits and eliminate harms. The overall problems of the community should always be paramount.

h) Provision of incentives; no hard rule should exist. Care must be exercised in each situation under specified circumstances.

i) Feedback of the Results; the community must know the findings, so as to relate to these findings. This should reinforce future interest in community-based research.

j) Anonymity of communities; i.e. a community's right to confidentiality is important.

**Stages of research at which a researcher should be sensitive to ethical issues:**

- 1- Selection of the project and statement of the problem
- 2- Review of literature
- 3- Research design
- 4- Personnel and administration
- 5- Analysis, reporting and dissemination of results