University of Gondar
College of Medicine & Health Sciences
School of Nursing
Community Health Nursing Unit

Nursing Research methodology for Nurses

Chilot Desta (BSc, MPH)
Lecturer of Epidemiology and Bio-statistics
E-mail: chilotdesta@gmail.com
Gondar, Ethiopia

Course syllabus

- **Module Name:** Health system research
- **Course title:** Nursing Research
- **Credit hour:** 2 Cr(32 hrs.)
- **Module Code**: Nurs2103
- **Pre-requisite course:** Epidemiology and Bio-statistics
- **Course delivered to** -undergraduate BSc Nursing students
- **Course instructor** -Chilot Desta(BScN, MPH in EPI/BIO

Course description

- This course is considered as a pre-requisite course for research project.
- It is based on principles, concepts and theory of nursing research as well as methodology to solve community problems.
- Contents will include selecting a research project, statement of the problem, literature review, objectives, methodology, analysis, discussion and conclusion..

- This course will be accompanied by preparing a research proposal and describing findings fully for the partial fulfillment for graduation.
- **Course General Objective**:- At the end of the course the student nurse be able to prepare a complete research proposal and evaluate the quality of research proposal.

Specific Objectives:

At the end of the course the student is able to:

- Choose an appropriate research project after considering important criteria for selection
- Prepare a background statement concerning the problem selected for the study
- Prepare a review of the literature related to the topic
- Develop the research
- Develop a project work plan adapted to the local conditions

cont...

- Prepare a plan for identification and use of a project staff
- Prepare a budget for the project
- plan for dissemination of study findings
- Develop thesis or paper writing approach

Course Content:

Unit 1: Introduction to the course

- ✓ Importance of Nursing Research
- ✓ Historical evolution of Nursing research
- ✓ Future direction of nursing research

Unit 2: Over review of the research process

Basic research terminology

Major steps in the research process

Organizations of a research project

Unit 3- Selecting and identifying a nursing research problem

- Sources of problem
- Developing and refining a research topic
- Criteria for evaluating research problem
- Statement of the research problem
- Research example

Unit 4- Locating and summarizing existing information on a problem

- Purpose of a literature review
- Scope of literature review
- Sources of literature review
- Writing of literature review
- Example of literature review
- Summary

Unit 5. Formulating Hypothesis

- ✓ Purpose The research hypothesis
- ✓ Characteristics of workable hypothesis
- ✓ The derivation of workable hypothesis
- ✓ Wording hypothesis
- ✓ Testing hypothesis

Unit 6 - Types of Nursing Research Approach and research design considerations

- Experimental
- Non experimental
- Some additional types of research
- Nursing models approaches

Unit 7 - Research design considerations

- The concept of research control
- Internal and external validity
- Characteristics of good design
- The time dimensions

Unit 8- Data collection methods

Physiological /.biophysical measure

- Observational methods
- Selection for phenomena for observations
- The observer-observed relationships
- Observational methods unstructured observations
- Observational methods –structured
- Evaluations of observational methods
- Interview and questionnaire
- The constructions of questionnaire
- Types of closed questions

- Individual case report can be expanded to a case
- Steps in schedule constructions
- The administrations of the instruments
- Comparisons of interview and questionnaire

Unit 9 - Measurements and sampling

- Measurements principle
- Levels of measurement
- Advantages of measurements
- Research example

Unit 10. Reliability

- Errors of measurements
- Reliability
- Validity

Unit 11. Sampling

- Basic sampling concepts
- Non probability sampling
- Probability sampling
- Sample size
- Steps in sampling
- Research example

Unit 12 Communication in the research process

- Interpretation of results
- The research reports
- The styles of a research reports

Unit 13. Evaluating research reports

- Evaluating the introduction
- Evaluating the research methods
- Evaluation of the analysis and results
- Evaluation the discussion
- Evaluating other aspects of the report

Teaching methods

- Lecture, Individual and group home take assignments
- Discussion and presentations
- **Assessments**

- Quiz ……5%
- Individual critics of the published and the unpublished research reports ……15%
- Mid exam……20%
- Individual proposal development……20%

50%

- Final exam…… 50%
- Total ……100%
- Active participation has its own value!!!

Attendance criteria

- Attendance of the lectures, group work, topic and proposal defense sessions is a must
- - Will not set for final exam or
- - Will be incomplete

Reference materials

1) The Nursing Research principles and method Denis Polit and etal 2nd edition

2) Degu G, Yigzaw T. Research Methodology Lecture Notes for Healt Science Students. University of Gondar: 2006.

Degu G, Tessema F. Biostatistics for Health Science Students: lecture note series. The Carter Center 9EPHTI), Addis Ababa; January 2005.

4) Corlien M. Varkevisser, Indra Pathmanathan, and Ann Brownlee. Designing and conducting health systems research projects: Volume Proposal development and fieldwork. KIT/IDRC. 2003

5) Zegeye A, Worku A, Tefera D, Getu M, Sileshi Y. Introduction to Research Methods: Graduate Studies and Research Office , Addis Ababa University. 2009

6) Essentials of epidemiology (2nd Edition)

Unit I: Introduction to Nursing research

- Objectives:-
  - Define Nursing research
  - Definition of Evidence based practice
  - Appreciate history of Nursing Research

Brain storming questions

- What is Nursing research?
- What is the purpose of research?

- Nursing research: provides the foundation for Evidence based Nursing practice
- **Research utilization**
- Through Research Utilization, efforts and knowledge obtained from research is

✓ transformed into clinical practice,

✓ culminating in nursing practice that is evidence-based, to help understand the importance of evidence-based practice

✓ **Evidence based practice**: The process of systematically finding, appraising, and using research findings as the basis for clinical practice

Theory

- Research links theory, educations and practice.
- Theoretical formulations supported by research findings may become the foundations of theory-based practice in nursing

BEGINNING OF NURSING RESEARCH

- Research in nursing began with Florence Nightingale with her landmark publication . "**Notes on Nursing" (1859)**
  - It described her views in environmental factors that promote physical and emotional well-being.
  - Her most widely known research contribution involved an analysis of factors affecting soldier mortality and morbidity during the Crimean War.


rence Nightingale in the Crimean W

EARLY Research

- Most studies in the early 1900s concerned nurses' education.

Example:

- In 1923, a group called Committee for the Study of Nursing Education, studied the educational preparation of nurse teachers and administrators and the clinical experiences of nursing students.

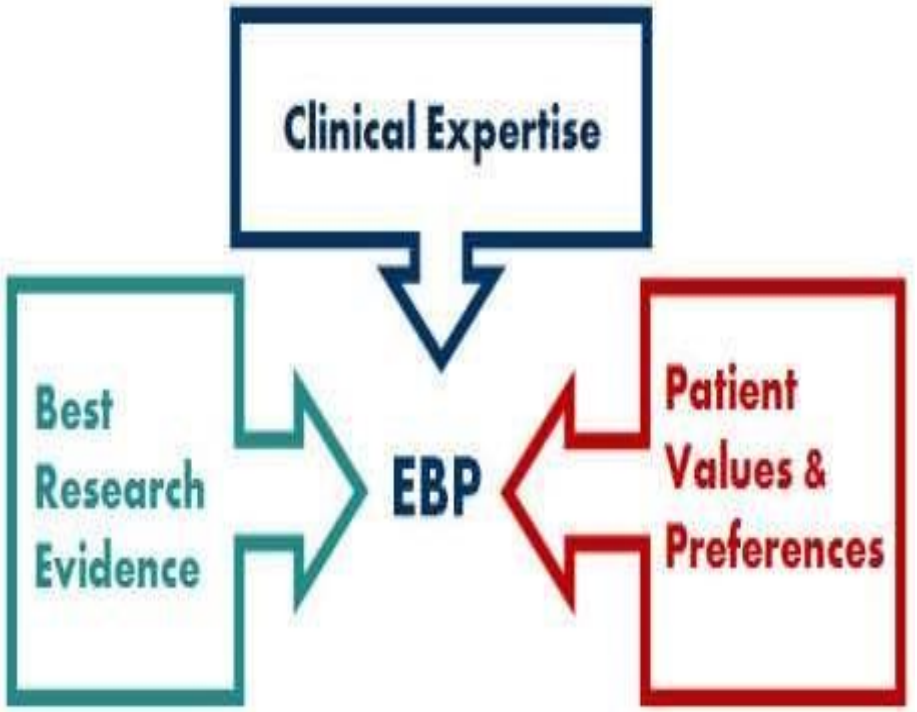
Cont..

- Nursing research continues to develop at a rapid pace and will undoubtedly flourish in the future.
- And the priority for nursing research in the future will be the promotion of excellence in nursing practices.

TRENDS TOWARDS THE FUTURE

- The future of nursing research will be to promote excellence in nursing science and practice.
- Future nurses will intensify their research skills and use those skills to address emerging issues of importance to the profession and the patients.

MORE FOCUS ON EVIDENCE BASED RESEARCH



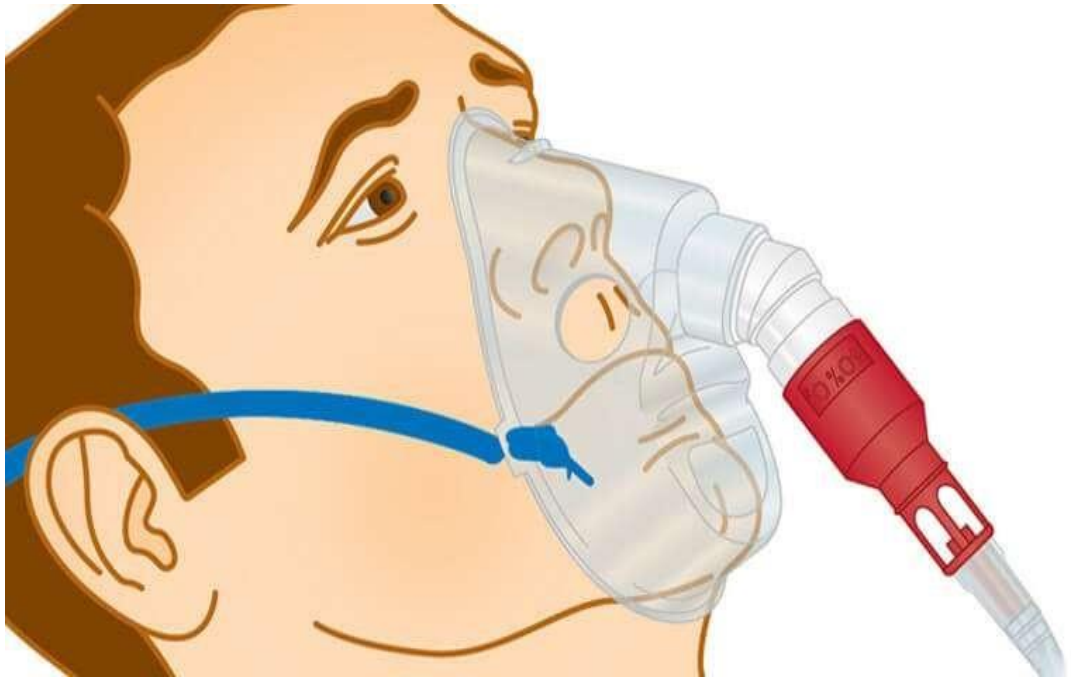
Evidence-based research involves collecting, evaluating and implementing evidence to improve patient care and outcomes.


Evaluating Evidence Use
Evidence-based Practice
Applying Evidence to Practice
Appraising Evidence
Searching for Evidences
Formulating Your Clinical Question

Example

Well implemented EVIDENCE-BASED INFECTION- CONTROL POLICIES have helped to reduce hospital acquired infections to a great extent.

TRENDS TOWARDS THE FUTURE



Oxygen use in patients with COPD

Nurses follow evidence-based practice in nursing when it comes to giving oxygen to patients with COPD.

Example

- Intravenous Catheter size and blood administration

EVP indicates that nurses should use a smaller-gauge catheter, which increases patient comfort.

DEFINITION OF NURSING RESEARCH

- Research is a process of systematic inquiry or study to build knowledge in a discipline.
- The purpose of research is to validate and refine existing knowledge and develop new knowledge.
- The results of research process:
- provide a foundation on which practice decisions and behaviors are laid
- create a strong scientific base for nursing practice and application of results demonstrates professional accountability to insurers and health care consumers.

- Nursing research is a systematic approach used to examine phenomena important to nursing and nurses, that clinical practice be based on scientific knowledge.
- Evidence generated by nursing research provides support for the quality and cost-effectiveness of nursing interventions.

❑ The introduction of evidence-based change into the direct provision of nursing care may occur at the individual level of a particular nurse or at varied organizational or social levels.

- Nursing research aimed at impacting the direct provision of nursing and health care to recipients of nursing care,
- Nursing research also is needed to generate knowledge in areas that affect nursing care processes indirectly.
- This helps to begin nursing research adventure by developing an appreciation of the significance of research in nursing and the research roles of nurses through a historical and futuristic approach.

Nurse Researcher Roles

- Two nursing roles are specifically focused on research: the clinical nurse specialist (CNS) and the clinical nurse researcher (CNR).
- Research findings are being used increasingly as the basis for clinical decisions.
- Evidence-based practice can be defined as the process of systematically finding, appraising, and using research findings as a basis for making decisions about patient care.

Research is a process that takes place in a series of steps:

1) Formulating the research question or problem
2) Defining the purpose of the study
3) Reviewing related literature
4) Formulating hypotheses and defining variables
5) Selecting the research design
6) Selecting the population, sample, and setting
7) Conducting a pilot study
8) Collecting the data
9) Analyzing the data
10) Communicating conclusions

- The most common designs used in health care research are case study, survey, needs assessment, experimental, quasi-experimental, methodologic, meta-analysis, and secondary analysis.

Nursing research

- Links education, theory, nursing practice) provides the basic for expanding the unique body of scientific knowledge that forms the foundation of nursing practice.

- Nurses become knowledgeable consumers of research through educational processes and practical experience,
- Must have a basic understanding of the research process and
- Have Critical appraisal skills
- that provide a standard for evaluating the strengths and weaknesses of research studies before applying them in clinical practice.

- Nurses at all levels of educational preparation have responsibility to participate in the research process.
- The role of the graduate is to be a knowledgeable consumer of research.
- Research studies will emphasize clinical issues, problems, and outcomes.
- Priority will be given to research studies that focus on promoting health and developing cost-effective health care systems.

. Thank you very much for your attention!!!

Unit 2: Over review of the research process

Objectives

- Define research and its purpose
- Identify type of research
- Identify Characteristics of Research
- Define health research
- Identify main components of any research work

Research

- It is gathering information needed to answer a question, and thereby help in solving a problem.
- The search for truth
- A systematic process of collecting and analyzing information (data) for some purpose.

1. The Purpose of Doing Research

- The purposes of research may be organized into three groups

✓ explore a new topic,

✓ describe a social phenomenon, or

✓ explain why something occurs.

- Studies may have multiple purposes (e.g. both to explore and to describe) but one purpose usually dominates.

Descriptive Research

- It presents a picture of the specific details of a situation, social setting, or relationship.
- It seeks to determine the answers to
- who, what, when, where, and how questions.

Goals of Descriptive Research

- Describe the situation in terms of its characteristics i.e. provide an accurate profile of a group;
- Give a verbal or numerical picture (%) of the situation;
- Present background information;
- Create a set of categories or classify the information;
- sequence, set of stages; and
- Focus on 'who,' 'what,' 'when,' 'where,' and 'how' but not why?

Explanatory Research

- The desire to know "why," to explain, is the purpose of explanatory research.
- It builds on exploratory and descriptive research and goes on to identify the reasons for something that occurs
- Explanatory research looks for causes and reasons.

✓ For example, a descriptive research may

Descriptive research

E.g., 10% of the parents abuse their children,

Explanatory research

E.g., less educated parents are more likely to abuse their children

Goals of Explanatory Research

- Explain things not just reporting. Why?
- Determine which of several explanations is best.
- Determine the accuracy of the theory; test a theory's predictions or principle.
- Advance knowledge about underlying process.
- Build and elaborate a theory; elaborate and enrich a theory's predictions or principle.
- Extend a theory or principle to new areas, new issues, new topics
- Provide evidence to support or refute an explanation or prediction.

2. The Uses of Research

- To advance general knowledge,
- To solve specific problems.

❖ Based on the uses research can be

- **Basic Research** (also called academic research or pure research or fundamental research) or
- **Applied Research**

A. Basic research

- Basic research advances fundamental knowledge about the human world.
- It focuses on refuting or supporting theories that explain how this world operates such as
  - ✓ What makes things happen?
  - ✓ Why social relations are a certain way? and
  - ✓ Why society changes?
- Basic research is the source of most new scientific ideas and ways of thinking about the world.

Cont..

- A new idea or fundamental knowledge is not generated only by basic research.
- Applied research, too, can build new knowledge.
- Nonetheless, basic research is essential for nourishing the expansion of knowledge.
- Researchers at the center of the scientific community conduct most of the basic research.

B. Applied Research

- Tries to solve specific policy problems or help practitioners accomplish tasks.
- Theory is less central to applied research.
- Seeking a solution on a specific problem for a limited setting.
- It is descriptive research,; its main strength is its immediate practical use.
- Conducted when decision must be made about a specific real-life problem.

Research must be:

Purposeful: what do you want to be able to contribute?

Targeted: Who are the audiences?

Credible: consider sources of information, method of data collection, personnel involved…

Timely: Is the information needed?

❖**Research is done to find solutions to health problems.**

Nature of Research

- **Systematic** – plan, identify, design, collect data, evaluate
- **Logical** – examine procedures to evaluate conclusions
- **Empirical** – decisions are based on data (observation)
- **Reductive** – general relationships are established from data
- **Replicable** – actions are recorded

3.The Research (Data Collection) Techniques Used

	Qualitative Research	Quantitative Research
Objective	▪ To gain a qualitative understanding of the underlying reasons	▪ To quantify the data and generalize the results from the sample to the population of interest
Sample	▪ Small number of non-representative cases	▪ Large number of representative cases
Data Collection	▪ Unstructured	▪ Structured
Data Analysis	▪ Non-statistical	▪ Statistical
Outcome	▪ Develop an initial understanding ▪ answers to questions why? How?	▪ Recommend a final course of action ▪ questions about how much? How many? How often?

Types of research

Biomedical Research (Basic biological processes, structure and function of the human body, pathological mechanisms)	**Clinical Research** (Efficacy of preventive, diagnostic, and therapeutic procedures, natural history of diseases)
Epidemiologic Research (Frequency, distribution, and determinants of health)	**Health Systems research** (Effectiveness, quality, and costs of services: development and distribution of resources for care)

Types of research cont….

Epidemiological Research

- Example: Prevalence and risk factors of surgical site infection among admitted patients in UOGCSH

Clinical Research

Example: studying the effectiveness of coartem in treating malaria

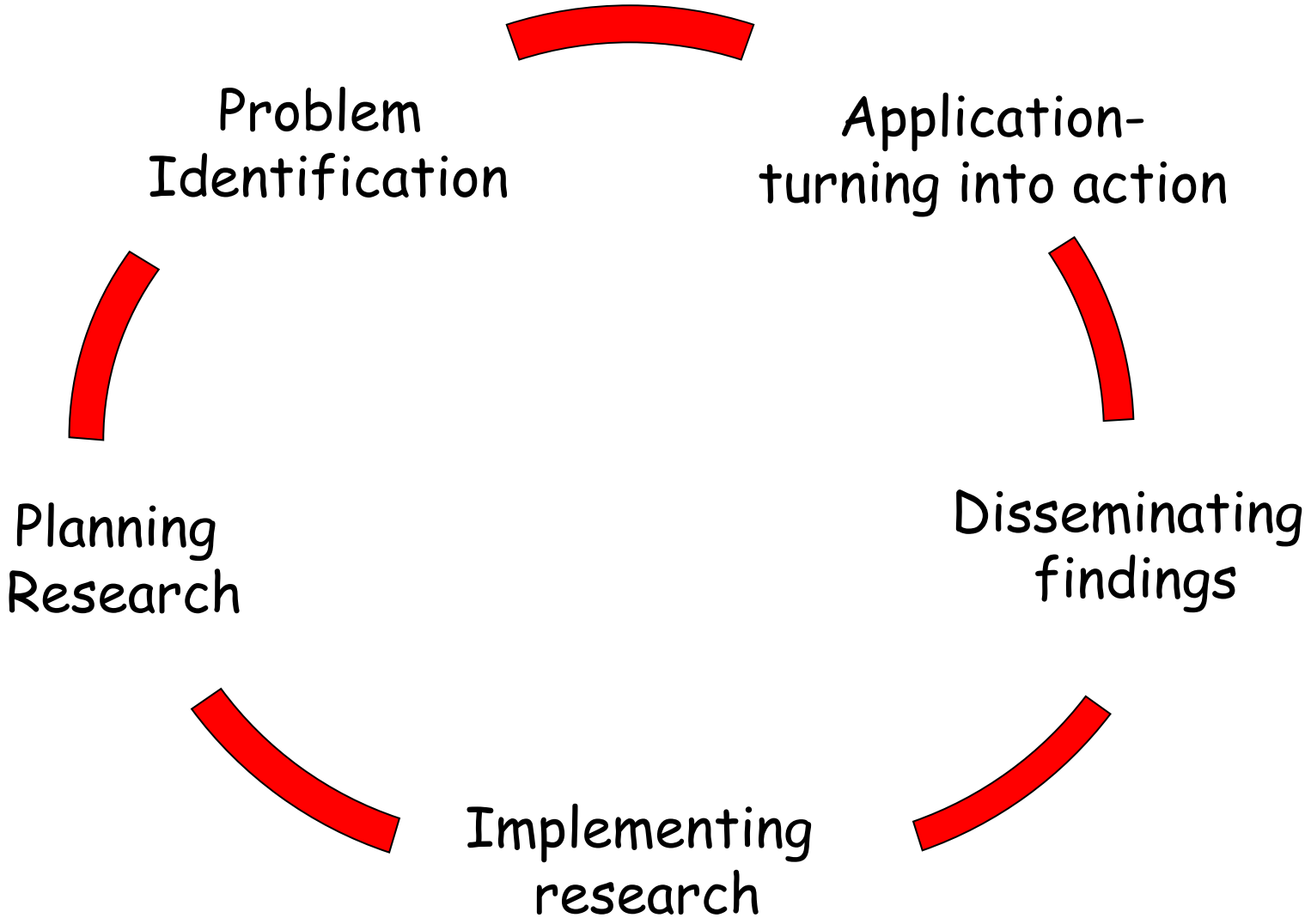
Health system research

- It is the application of principles of research on health.
- It is the generation of **new knowledge** using scientific method to identify and deal with health problems.
- To generate knowledge essential to effectively promote the health of the population
- Example: Study of the underlying reasons for emergency hospital admission of patients with diabetes.

Characteristics of Research

- It demands a clear statement of the *problem.*
- It *requires a plan.* It is not aimlessly looking for something.
- It builds on *existing data*, using both positive and negative findings.
- *New data* should be collected as required and be organized in such a way that they answer the original research question/s.
- Research project follow *a logical sequence*.
- It is a *circular* process.

Research Cycle



Main components of any research work

1. Preparing a research proposal
2. Field work (i.e. data collections)
3. Analyzing data and preparing a research report

Planning Research (Developing Proposal)

- The development of a health project goes through a number of stages.
- Formulation of the research proposal is the major task in the process of developing a research project.
- A written proposal is important:
  - To clearly define the problem under study
  - To avoid reinventing the wheel
  - To clearly depict the methodology to be used
  - To be cost and time conscious
  - To be clear about what to expect in the end

❑Components/outline of Research Proposal

1. Research topic
2. Summary(1 page)
3. Statement of the Problem (1 page)
4. Literature review (2-4 page)
5. Justification of the study (1/2 page)
6. Objectives(1/2 page)
7. Methodology (3 page)
8. Ethical Considerations(1/2 page)
9. Dissemination and Utilization of Results(1/2 page)
10. Work plan(1 page)
11. Cost of the Project(Max 2 page)
12. References(Use Vancouver Style)
13. Annex
14. Assurance of Investigator

Selecting and identifying a nursing research problem

Objective: at the end of this lesson you are able to:

- Identify research problems
- List criteria for prioritizing research problems
- write a research topic?
- Analyze the problem
- Formulate the problem statement
- Write Justification

Problem identification

- Research is done with a certain purpose
- The purpose of research may be; to solve a problem, to improve a program or to get new knowledge
- The first task of a researcher is identifying a research problems

Research Problem

What is a problem?

- . . . any situation where a gap exists between the actual and the desired state.
- A problem does not necessarily mean that something is seriously wrong.
- It could simply indicate an interest in improving an existing situation.
- Thus, problem definitions can include both existing problems in the current situation as well as the quest for idealistic states in the future.

Where can we get a research problems?

- Sometimes students faced difficulties …to get research problems though they are standing on a lot of problems
- it is not due to the absence of research problems; rather due to the difficulty of identifying research problems
- We can get research problems in different ways from deferent source:-

✓ From carful environmental observation and from our day to day activities

✓ From reading

✓ From discussion

✓ From the social, political and economical changes

✓ From personal interest

✓ From scarcity of information

Cont.

When you can answer the following questions, you are ready to conduct research that leads to a paper

1. What problem do you want to solve?
2. Who cares about this problem and why?
3. What have others done to solve this problem and why is that inadequate?
4. What is your proposed solution to this problem?
5. What is new about your approach?
6. Who will care if you succeed?
7. How long will it take?
8. How can you demonstrate that this is a good solution?

Individual work

Identify three research problems

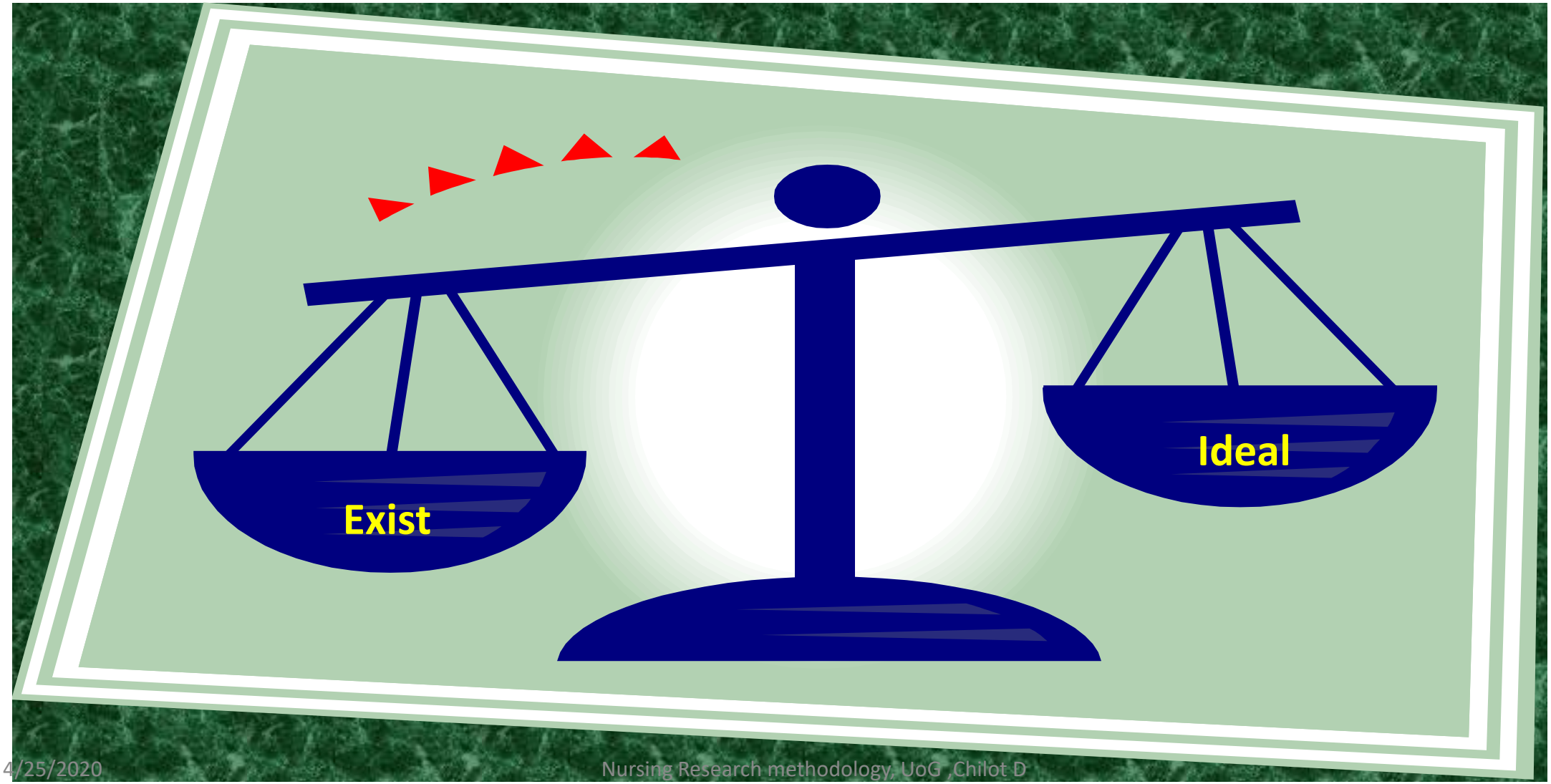
Research Problem/Question Formulation

What is a problem?

- A discrepancy between what you believe to be and what it is in reality?
- A potential research problem should qualify the following three conditions:
  - ❑ *A perceived gap between what is what should be*
  - ❑ *A question (reason) exists about why there is a discrepancy*
  - ❑ *At least two or more possible and plausible solutions exist*

What is A Problem?

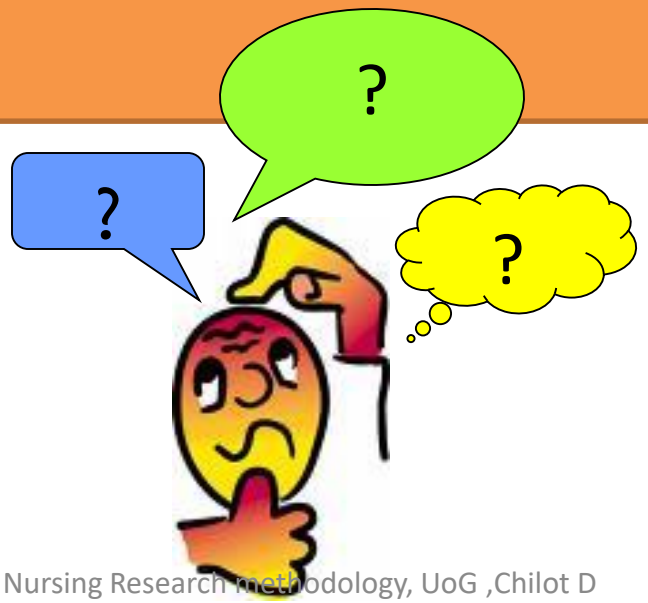
What is ≠ What should be



Whether a problem requires research or not

The reasons for this difference is unclear

More than one possible answer to the question or solution to the problem



Example 1

- **Problem situation:** In district " **Y** " a report showed that in the first month there were 500 children under one year old who started immunization, but at the end of the year it was found out that there were only 25 children who completed their vaccination.
- **Discrepancy:** All the 500 children at district " **Y** " should have completed their vaccination but only 5% out of those who started vaccination have completed.
- **Problem (research) question:** Why only 5% of the children completed their vaccination?

Definite answer: Out of the 1 hospital, 2 health centers and 10 health stations found in district "**Y**" only 2 health stations were functioning, the rest were closed due to **insecurity** in the area.

Does it needs research?

In the above example, assuming that all the given information is true, there is no need of undertaking a research, since definite answer is obtained to the problem situation.

Example 2

- Problem situation: In district "Z" (population 100,000) there are 2 health centers, 1 hospital and 15 health stations and all of them function smoothly. However, at the end of the year it was found that the EPI coverage was only 25%.

- *Discrepancy:* Although district "Z " had 100% availability of health services and at least 80% of the children should have had full vaccinations the EPI coverage was only 25% as seen above.

- *Problem question:* What factors influence the low EPI coverage in district "Z"?

Possible answers:

- Mothers might have problems for not attending in the EPI sessions.
- The MCH, EPI, OPD, etc… programmes might not have been integrated; hence children might have missed opportunities in getting immunization.
- The follow up of defaulting children might not be effective and other reasons.

Thus, the above problem situation is researchable.

Individual class work

- **Whether a problem you identified requires research or not?**
- **Select the three most researchable problem**

Criteria for prioritizing problems for research

- Each problem that is proposed for research has to be judged according to certain guidelines or criteria. There may be several ideas to choose from.

  ♣ Before deciding on a research topic, each proposed topic must be compared with all other options.

- *7 Criteria for selection of a research problem*

1. **Relevance:** **The topic you choose should be a priority problem:**

   - ***How large or widespread is the problem?***
   - ***Who is affected?***
   - ***How severe is the problem?***

2. **Avoidance of duplication:** Find out whether the suggested topic has been investigated before

   - either within the proposed study area or in
   - another area with similar conditions

3. **Feasibility:** Consider the complexity of the problem and the resources you will require to carry out the study.
   - Think about the resources required to conduct the study
   - manpower, time, equipment and money that are locally available
   - possibility of obtaining technical and financial assistance from external sources
4. **Political acceptability**: It is advisable to research a topic that has the interest and support of the authorities. This will facilitate the smooth conduct of the research and increases the chance that the results of the study will be implemented.

5. Applicability of possible results and recommendations:

- Is it likely that the recommendations from the study will be applied?
- This will depend not only on the blessing of the authorities but also on the availability of resources for implementing the recommendations.

6. Urgency of data needed

- How urgently are the results needed for making a decision?
- consider which research should be done first and which can be done late?

7. Ethical acceptability

We should always consider the possibility that we may inflict harm on others while carrying out research. Therefore, it will be useful to review the proposed study.

b) Scales for rating research topics

Relevance

1 = Not relevant
2 = Relevant
3 = very relevant

Avoidance of duplication

1 = Sufficient information already available
2 = Some information available but major issues not covered
3 = No sound information available on which to base problem-solving

Feasibility

1 = Study not feasible considering available resources
2 = Study feasible considering available resources
3 = Study very feasible considering available resources

Political acceptability

1 = Topic not acceptable
2 = Topic somewhat acceptable
3 = Topic fully acceptable

Scales for rating research topics

Applicability

1 = No chance of recommendations being implemented
2 = Some chance of recommendations being implemented
3 = Good chance of recommendations being implemented

Urgency

1 = Information not urgently needed
2 = Information could be used but a delay of some months would be acceptable
3 = Data very urgently needed for decision-making

Ethical acceptability

1 = Major ethical problems
2 = Minor ethical problems
3 = No ethical problems

The above rating should be based on the **existing data** and **not on mere assumptions.**

Scales for rating research topics

Proposed topic	1. Relevance	2. Avoidance of duplication	3. Urgency	4. Political acceptability	5. Feasibility	6. Applicability	7. Ethical acceptability	Total no. of points

Rating scale: 1=low, 2=medium, 3=high

Topic/title writing

- The research topic or title should be specific and clear.
- The topic should indicate the WHAT, WHO, WHERE and WHEN clearly.

- The title clearly identifies the study and may contain a brief description of the study design and objectives.

Title- Should be in line with your general objective

  - Should tell readers what your study is about and where it will be done

Titles Formulation Tips

Titles should:

- Describe contents clearly and precisely, so that readers can decide whether to read the report

Titles should NOT:

- Include wasted words such as "studies on," "an investigation of" "assessment of"
- Use abbreviations and jargon

Good Titles

- Prevalence of stunting among under five children in UOGCSH, northwest ethiopia,2020

Poor Titles

- An Investigation of Hormone Secretion and Weight in Rats
- Assessment of prevalence and associated factors of virological failure

Examples:

1. Prevalence and associated factors of virological failure among children HIV patients at Deberetabor hospital, North west Ethiopia 2020

2. Prevalence and associated factors of neonatal sepsis among neonates at Amhara regional referral hospitals, North west Ethiopia ,2014.

Assignment

1. **list 3 research problems and prioritize by using a rating scale (1=low, 2=medium; 3= high) applied to seven criteria.**

2. **Select ONE Research Problem which has highest score**

3. **Write** a 'clear research topic/title ' for the selected research problems

- **Defend your first choice in the class.**

Research Problem Statement: Definition

- WHAT is it about and WHY should it be studied?

- Clear and concise description of the main (priority) focus of the research problem or theme identified for the investigation or research.

- Helps to justify the importance of a research question

PROBLEM STATEMENT: PROCESS

- Helps to critically analyze the problem
- Facilitates decisions on the focus and scope of the research agenda
- Enables the concerned parties to pool knowledge around the problem.
- Clarifies the problem and the possible factors.

- Enables to systematically point out why the proposed research on the problem should be undertaken and what is hoped to get achieved.

- Helps to derive/generate the research objectives and questions in details

Statement of the problem

Includes:

- **Magnitude**, frequency and distribution: Affected geographical areas & population groups affected by the problem
- ***Causes*** of the problem: What is the current knowledge of the problem and its causes? Is there consensus? controversy? conclusive evidence?
- **Possible solutions**: In what ways have solutions to the problem been attempted? What has been proposed? What are the results?
- ***Unanswered questions:*** What remains to be answered? What areas have not been possible to understand, determine, verify, or test?
  - If necessary a short list of definitions of crucial concepts

Justification

- It is also called significant of the study, purpose of the study and rational of the study
- Why your research is needed?
- E.g.
  - Others not large enough
  - Different populations
  - Different intervention
  - No study done before

- A statement indicating the size of the problem (and effect on the health service) and *why the study is appropriate*

- Explain what the potential benefits are – to patients and the health service

- Explain what your study will add to the body of evidence already available.

Assignment two

For the selected topic:-

- write statement of the problem and
- justification

Chapter 3 : Locating and summarizing existing information on a problem

Objective:

- What is Literature review
- Why it is necessary
- Resources(Source of information)
- How to write a literature review
- Conceptual framework
- Referencing

What is literature review

- Literature: Printed information about something

- Review: Consider carefully
  - Starting point to refine statement of the problem
  - Part of the introduction of a research

- Review of the literature
  - classification and evaluation of what have written, organized according to guiding concept

literature review...

1) This section must be based on peer reviewed journal or other published materials that are accessible in public domain (use non-published materials in the Statement of the problem/introduction if necessary but not in the literature review section).

2) Group findings from several studies (literature) according to common theme rather than discussing individual paper: themes could be qualitative versus quantitative approaches, magnitude of the problem, risk factors, effectiveness of interventions etc.

3) Provide strong "umbrella" sentences at the beginnings of paragraphs, "signposts" throughout, and brief "so what" summary sentences at intermediate points in the review.

Why/use of LR

- Prevent duplicating
- It increase your knowledge and helps to refining statement of the problem
- Become more familiar with the various types of methods
- It provides a framework for establishing the importance of the study
- It serves as a benchmark for comparing the results with other findings

➢ Describe the characteristics of previous study (where, when, who conduct, findings, conclusion…)

➢ Comment on strengths and limitation of studies and findings

➢ Identify the GAP in knowledge

Resources

Libraries

- Published information (books, journals..)

Internet/ web sites

- PUBMED / MEDLINE: – http://www.ncbi.nlm.nih.gov/PubMed/
- WHO website: - http://www. who.int
- Free Medical Journals :-http://www.freemedicaljournals.com
- HINARI:- http://www. Healthinternetwork.net
- Medspace:- http://www. medscape.com

How to write a review of literature?

- Take research problem
- Find a focus
- Organize
- Decide the order of issue to discuss
- Write coherent discussion in your own words
- Be critical to avoid possible bias
- Well quoted
- Write study design & area and sample size(sometime)

Conceptual framework

- It is a set of broad ideas and principles used to structure a subsequent presentation.
- Every research activity is conceptualized and will be carried out within some contextual framework.
- Conceptual frame- works represent ways of thinking about a problem or a study, or ways of representing how complex things work.

Referencing

- Referencing is a standardised method of **acknowledging sources** of information and ideas that you have used in your assignment in a way that uniquely identifies their source.

- Avoid **Plagiarism:-** The use of another person's work without acknowledgement

- ***A reference list*** is a list of sources that you have quoted from or cited in your text

Referencing systems

- A number of referencing systems are in common use today including:
  - **Vancouver** (number) .
  - **Harvard** - (author, date).
  - **APA** (American Psychological Association)
  - **MLA** (Modern Linguistics Association)

A. Vancouver system

For an article the following information should be noted:

- Author(s)' Surname followed by initials. Title of article. *Name of Journal*. Year, Volume(number): page numbers of article.
  - **Example:** *Sengayi M, Dwane N, Marinda E, Sipambo N, Fairlie L, Moultrie H. Predictors of loss to follow-up among children in the first and second years of antiretroviral treatment in Johannesburg, South Africa. Global health action. 2013;6(1):19248.*

Vancouver cont…

- **For a book the following information should be noted:**
- Author(s)' Surname followed by initials. *Title of book. Place: Publisher,* Year, Edition
- **Example:** Abramson J. *Survey methods in community medicine. Edinburgh:* Churchill Livingstone, 1990, 4th ed.

Vancouver cont..

- **For a chapter in a book, the reference can include:**
- Author(s) of chapter (Surname(s) followed by initials). Chapter title. In: Editor(s) of book, (Surname(s) followed by initials) (eds). *Title of book.* Place: Publisher, Year: Page numbers of chapter.

- **Example:** Todd J and Barongo L. Epidemiological methods. In: Ng'weshemi J, Boerma T, Bennett J and Schapink D (eds). *HIV prevention and AIDS care in Africa; A district level approach. Amsterdam: KIT Press, 1997: 51-68.*

Vancouver cont..

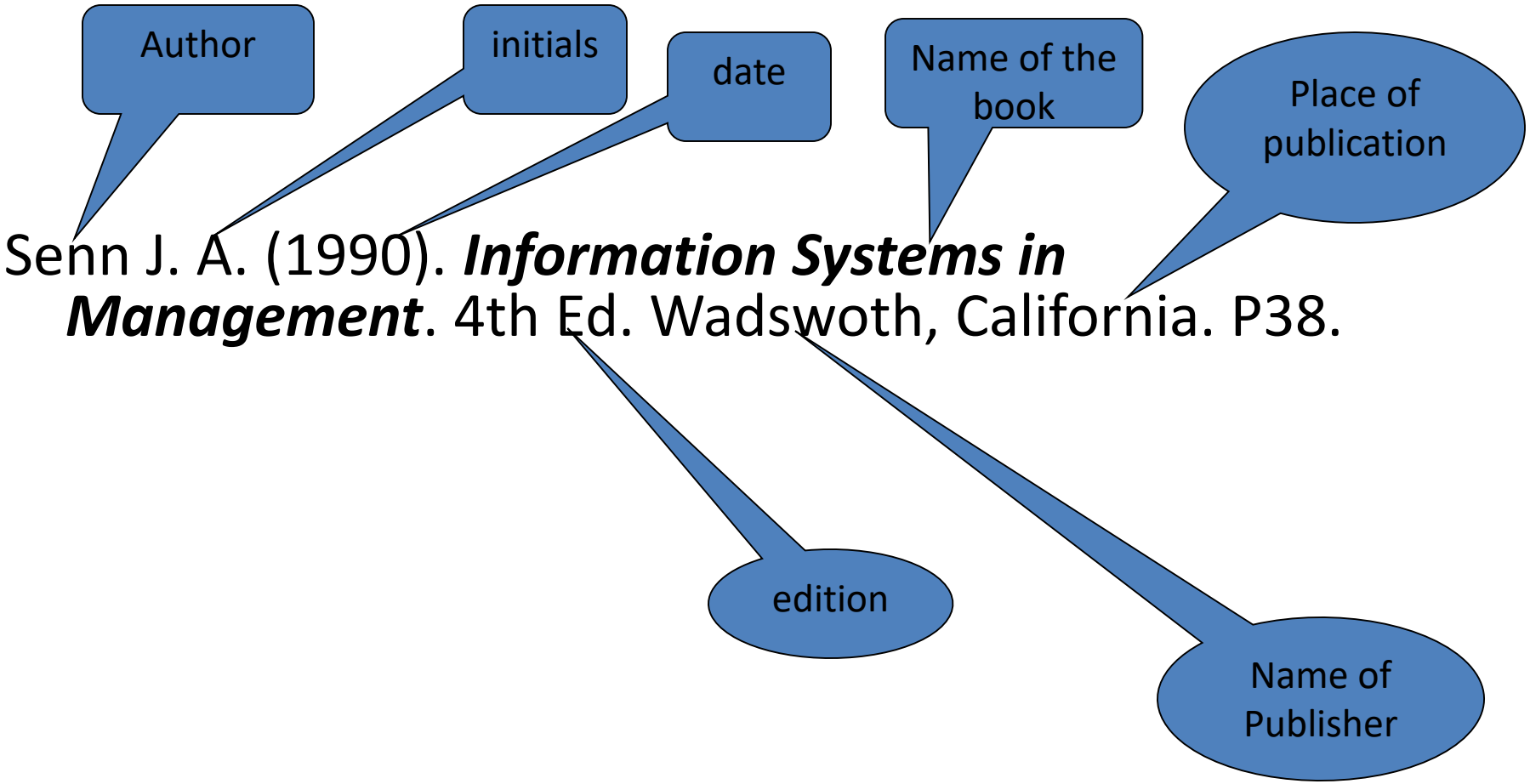
- When you use the Vancouver system, you will use consecutive numbers in the text to indicate your references

- At the end you will then list your references in that order, using the format described above

B. The Harvard System

- Using the Harvard system, reference to sources is made at an appropriate place in the text by stating:
  - **surname**(of author(s);
  - **year of publication**;
  - **page number**(s), (optional)

Example of Harvard system



From journal

- Vogal L. C., Swinkels W. *et al.*(1976). Operational Study of the Outpatient Department at the Government Hospital ,Kimbu Kenya , East African medical Journal, 53(3).
- Surname , initials ,Date of publication, title of article, name of journal , volume and issue number , page.

From WWW

- Backer, L.A. (2002). Strategies for better patient flow and cycle time. Downloaded from Family practice management at http://www.aafp.org/fpm/20020600/contents.html(accessed on 14/3/2006)

Surname,Initials.Date.Title of article.name of journal. Available at www. .accessed on.

Sample End references

- ABEBE N, ALEMU K, ASFAW T & A, A. 2014. Predictors of mortality among HIV positive adults on antiretroviral therapy in Deberemarkos Referral Hospital, Northwest Ethiopia. . Journal of AIDS and HIV.
- AMIR SHROUFI, HILARY GUNGUWO, MARK DIXON, MARY NYATHI, WEDU NDEBELE, JEAN-FRANÇOIS SAINT-SAUVEUR, FABIAN TAZIWA, CECILIA FERREYRA, MARI-CARMEN VIÑOLES, A. & FERRAND, R. A. 2013 Jul 17. . HIV-infected adolescents in southern Africa can achieve good treatment outcomes: results from a retrospective cohort study. PMC, 27.
- ARRIVÉ E, DICKO F, AMGHAR H, AKA AE, D. H. & BOUAH B, E. A. 2012. HIV status disclosure and retention in care in HIV-infected adolescents on antiretroviral therapy (ART) in West Africa. PLoS One. , 7:e33690. .
- AULD, A. F., TUHO, M. Z., EKRA, K. A., SHIRAISHI, R. W., MOHAMED, F., KOUAKOU, J. S., ETTIÈGNE-TRAORÉ, V., SABATIER, J., ESSOMBO, J. & RIVADENEIRA, E. D. 2014. Temporal trends in mortality and loss to follow-up among children enrolled in Cote d'Ivoire's national antiretroviral therapy program. The Pediatric infectious disease journal, 33, 1134-1140.
- BAMIDELE-ABEGUNDE, D. December 7th, 2015. EXPLORING PREDICTORS OF LOSS-TO-CARE AMONG PEOPLE LIVING WITH HIV,University of Lagos, Nigeria, .

References cont…

- In Harvard System, put the surname of the author, year of publication and number(s) of page(s) referred to between brackets, (E.g. Shiva 1998:15-17)

- If this system of citation is used, the references at the end of the proposal, should be listed in Alphabetical order.

EndNote

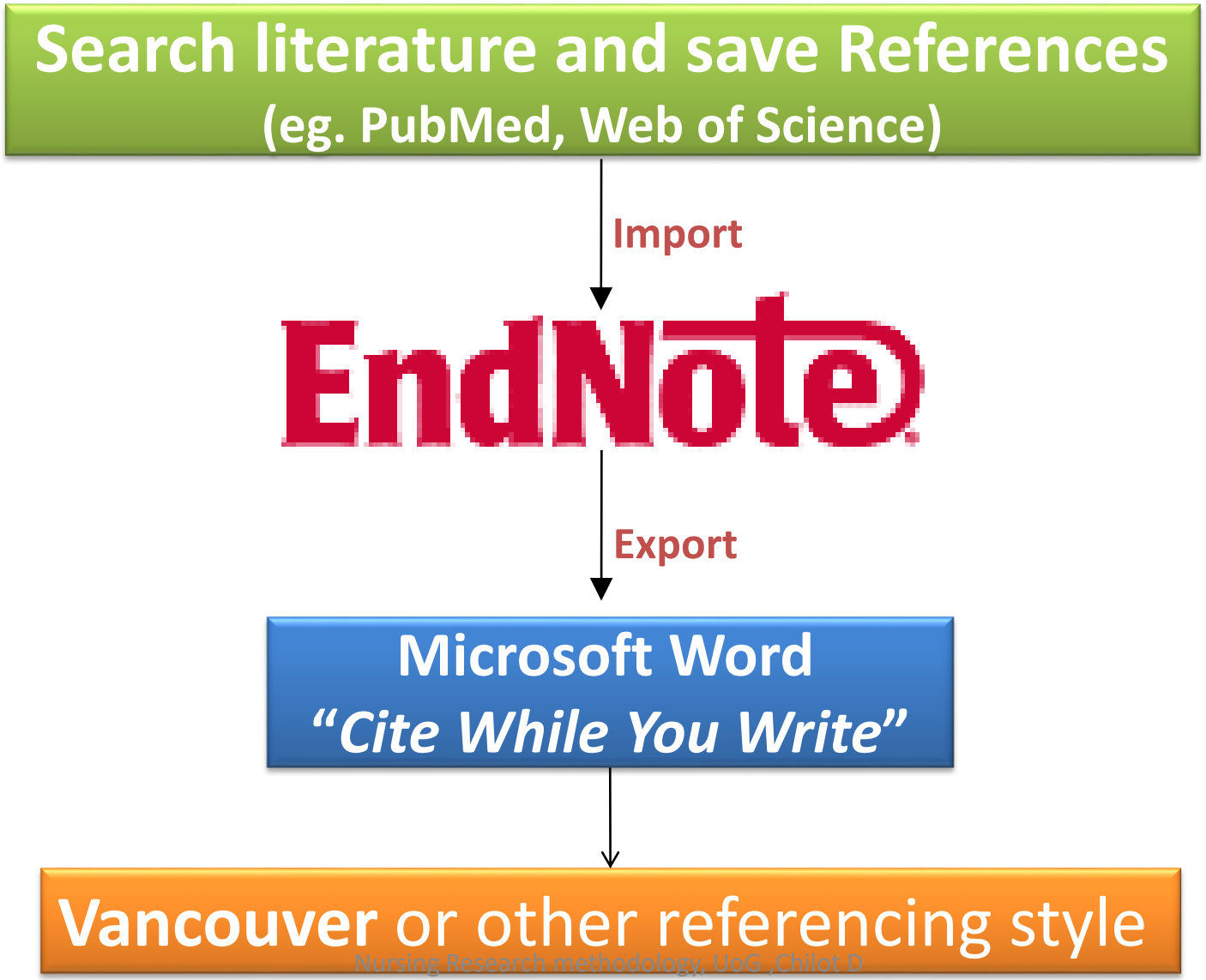
A software for Referencing

EndNote

- A software that:

1. **searches literatures** from web libraries
2. **stores** and **organizes references** from different sources
3. **Inserts** citations into a Word document
4. automatically **format your references** according to a predefined citation style

Flow Process in EndNote



5 Steps to Import Citations into your research paper

1. **Install** EndNote on your PC/Laptop
2. **Create** an EndNote Library
3. **Collect** References and **Import** into EndNote
4. **Insert (Cite)** the References in MS word
5. Change **Reference (Citation) Style**

Step 1: Install EndNote on PC/Laptop

1. Open the folder Endnote 7

2. Double click the setup.exe

3. Copy the serial number from the text file Endnote PDF Serial Number.txt and paste

4. And run the software

Step 2 : Create an EndNote Library

a) Open EndNote.

b) Click on **File → New...** to create a new EndNote Library.

c) Enter a filename.

d) Click **Save**.

Step 3 : Collect References/Citations

a) Method 1: Search in databases and export citations (PubMed)

b)Method 2: Search PubMed directly in EndNote

c) Method 3 : Manually enter a Reference

Step 3 : Collect References/Citations
Method 1
Search in databases and export citations

a)Perform search in PubMed

b)Mark references to be saved

c)From the **Display** drop-down menu, select **MEDLINE**.

d)From the **Send to** drop-down menu, select **File**.

e)Save the file as a **.txt** file

Method 1 Con'd: Import into EndNote

a) Open an EndNote library previously created.

b) To import references, click on  A dialogue box "Import" appears:

   i. **Import data file:** Browse for the saved file from PubMed

   ii. **Import option :** Click **Other filters.** Look for the database name **PubMed (NLM).** Click **Choose.**

c) Click **Import.** The references will appear in your active EndNote Library.

Step 3 : Collect References/Citations
Method 2:
Search PubMed directly in EndNote

- Valid only for Freely Available Databases
- This Method good for **Known** Citations

a) In an EndNote Library, under **Online Search** on the left, click on **PubMed (NLM).**

b) Enter keyword in search box

c) ***Retrieved records from 1 through XX***. Enter the desired number for XX.

d) **All** records (relevant?) will be saved into EndNote

Step 3 : Collect References/Citations
Method 3:
Manually Create a Reference in EndNote

- Useful for working papers / manuscripts which are not found in databases

a) In an EndNote Library, at the top, click on **References→New Reference**

b) Under **Reference Type:**, click on the drop-down menu and select accordingly (eg. Web Page)

c) Enter information such as *author, year, title*

d) Simply click on X (close the window) and the reference will be saved

Other Features

a) Remove Duplicates

   i. In an EndNote Library, click **References** on the menu bar→ **Find Duplicates**

b) Organise References into Groups (or folders)

   i. Highlight a reference in EndNote Library

   ii. Right – Click→ **Add References To** → **Create Custom Group…**

   iii. Type a group name. Enter.

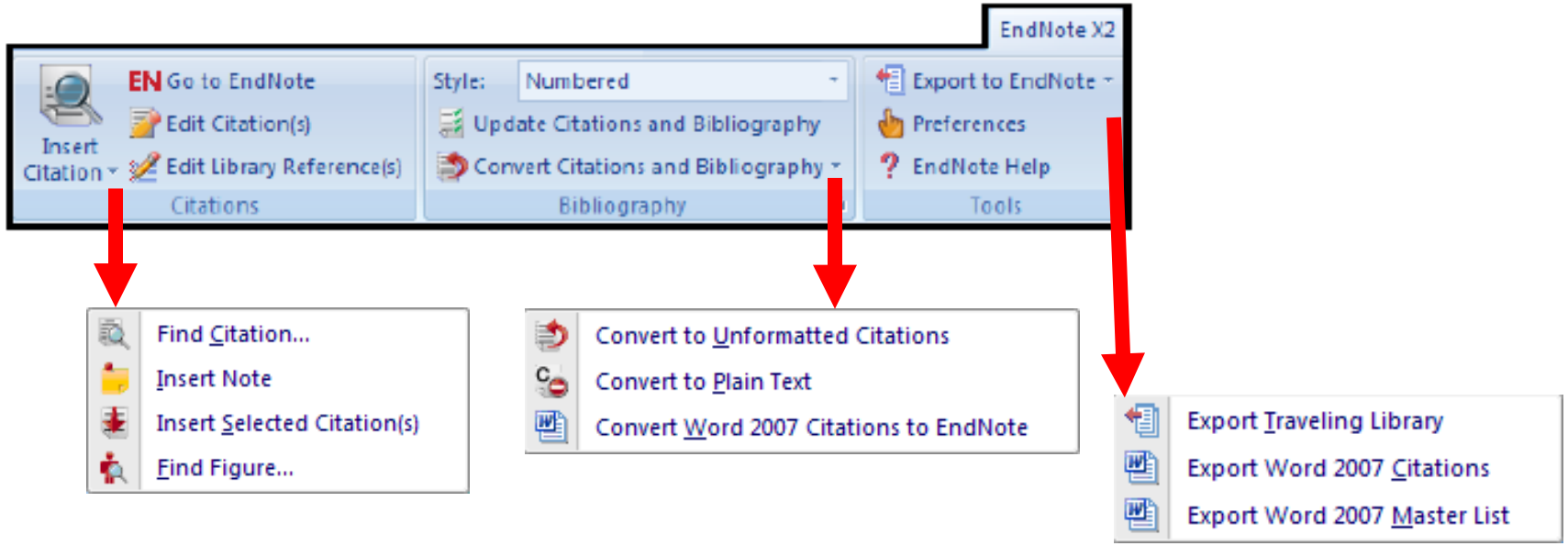
c) Auto-Filtering with Smart Groups

d) Compress a Library and Email to Colleague

e) Direct Links to Web of Science via Library Proxy

CWYW Toolbar in Microsoft Word

Microsoft Word 2007



Step 4: Insert References in Word (Cite While You Write)

a) In an EndNote library, highlight a reference.

b) In Microsoft Word, place cursor at insertion point.

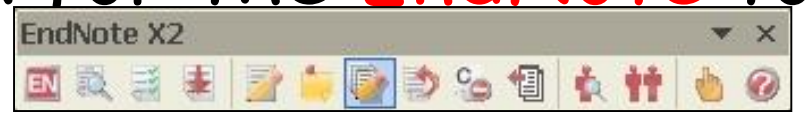
c) Look for the EndNote toolbar:

   i. For Word 2007, click on the button **Insert Citation**. Click **Insert Selected Citation(s)**.

d) The reference is inserted.

Step 5: Change Reference Style

a) In Microsoft Word, look for the EndNote toolbar:



   i. **Ie: → Select another style**

b) Under **With output style,** click **Browse...**

c) Select the desired journal style. Eg. JAMA

d) The references are now re-formatted.

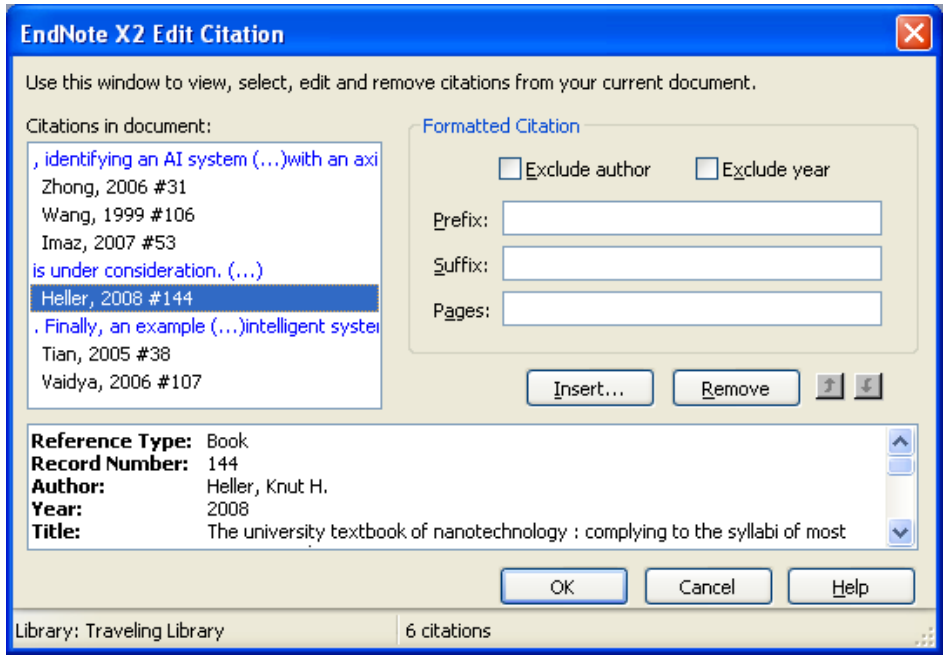
Other CWYW Features

- Edit Citation(s)

  Use this command to make any changes inside a citation, such as adding page numbers or removing author names from author-date citations.

- Edit Library Reference(s)

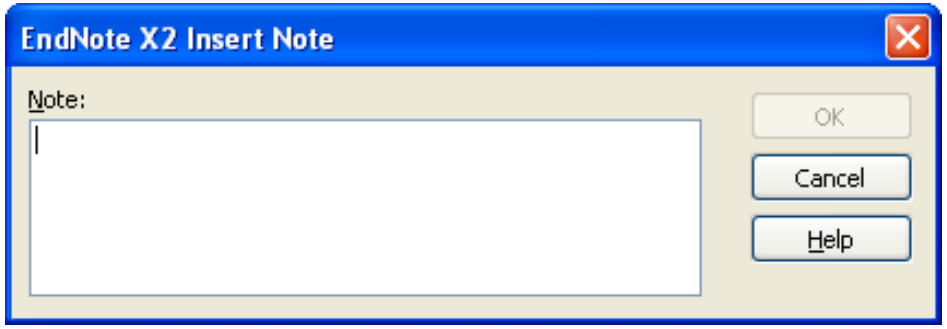
  This command allows you to quickly access the specific record for any selected citation.



Other CWYW Features

- Insert Note

  Use this command to insert explanatory notes to be numbered as though they were bibliography entries, and then placed in the bibliography.



Other CWYW Features

- Unformat Citation(s) 

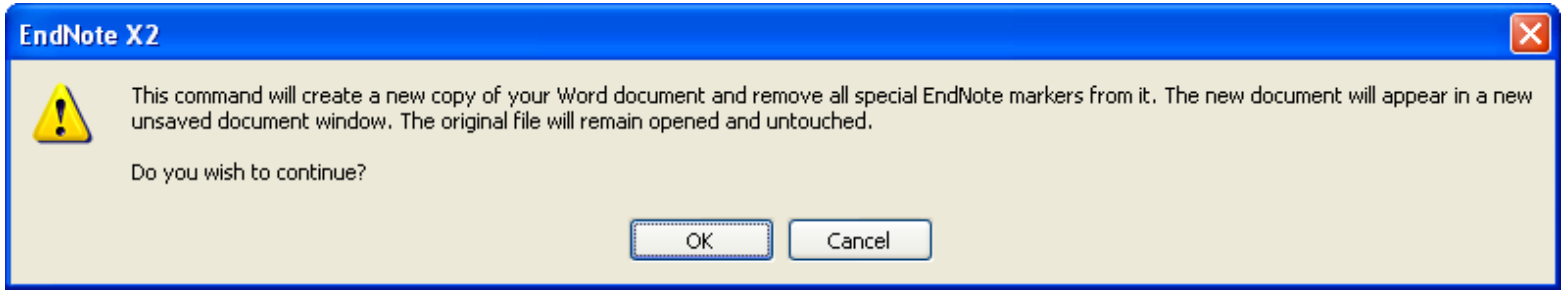
  This command will remove the formatted bibliography and citations and replace all citations with plain-text placeholders that EndNote can match to library records to create formatted citations. This command is commonly used when moving documents between word-processing programs.

(Heller, 2008) → {Heller, 2008 #144}

Other CWYW Features

- Remove Field Codes

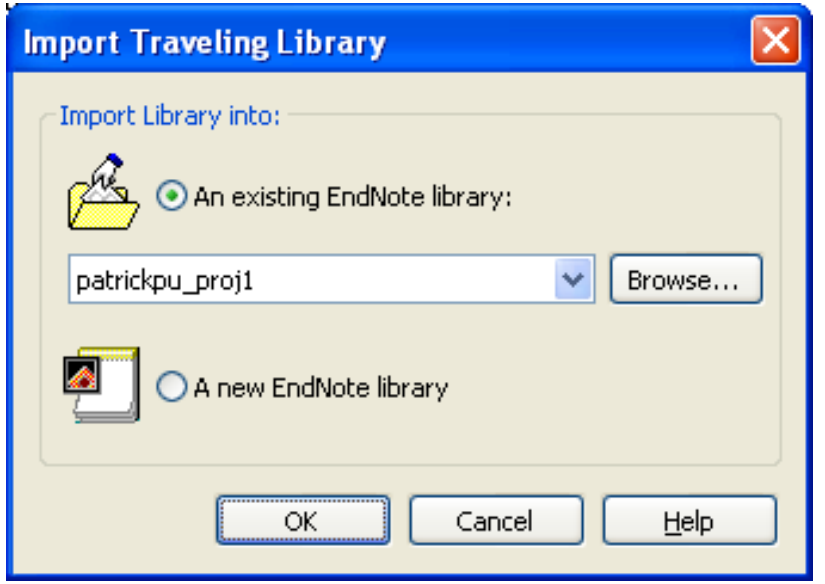
  This command will create a second copy of the document with all EndNote field coding removed (you can generally recognize field codes such as formatted EndNote citations by their turning grey when you select them in Word). It is used when sending documents to a publisher because the field coding used for EndNote citations can sometimes cause problems for publishers' page layout programs.



Other CWYW Features

- Export Traveling Library

  EndNote creates a hidden "traveling" library containing only the references used in each paper. This traveling library is part of the coded information contained in each citation. Use this command to export the references (exclude Notes, Abstract, Figure & Caption) in this traveling library to a regular EndNote library.



Best Wishes in Your

Literature Searching and Referencing!!

Assignment three

- Write literatures for your research proposal using van cover style of referencing

- Chapter 4: Research hypothesis
- Hypothesis is considered as an intelligent guess or prediction, that gives directional to the researcher to answer the research question.
- Hypothesis or Hypotheses are defined as the formal statement of the tentative or expected prediction or explanation of the relationship between two or more variables in a specified population.

- Hypothesis is derived from the research problems, literature review and conceptual framework.

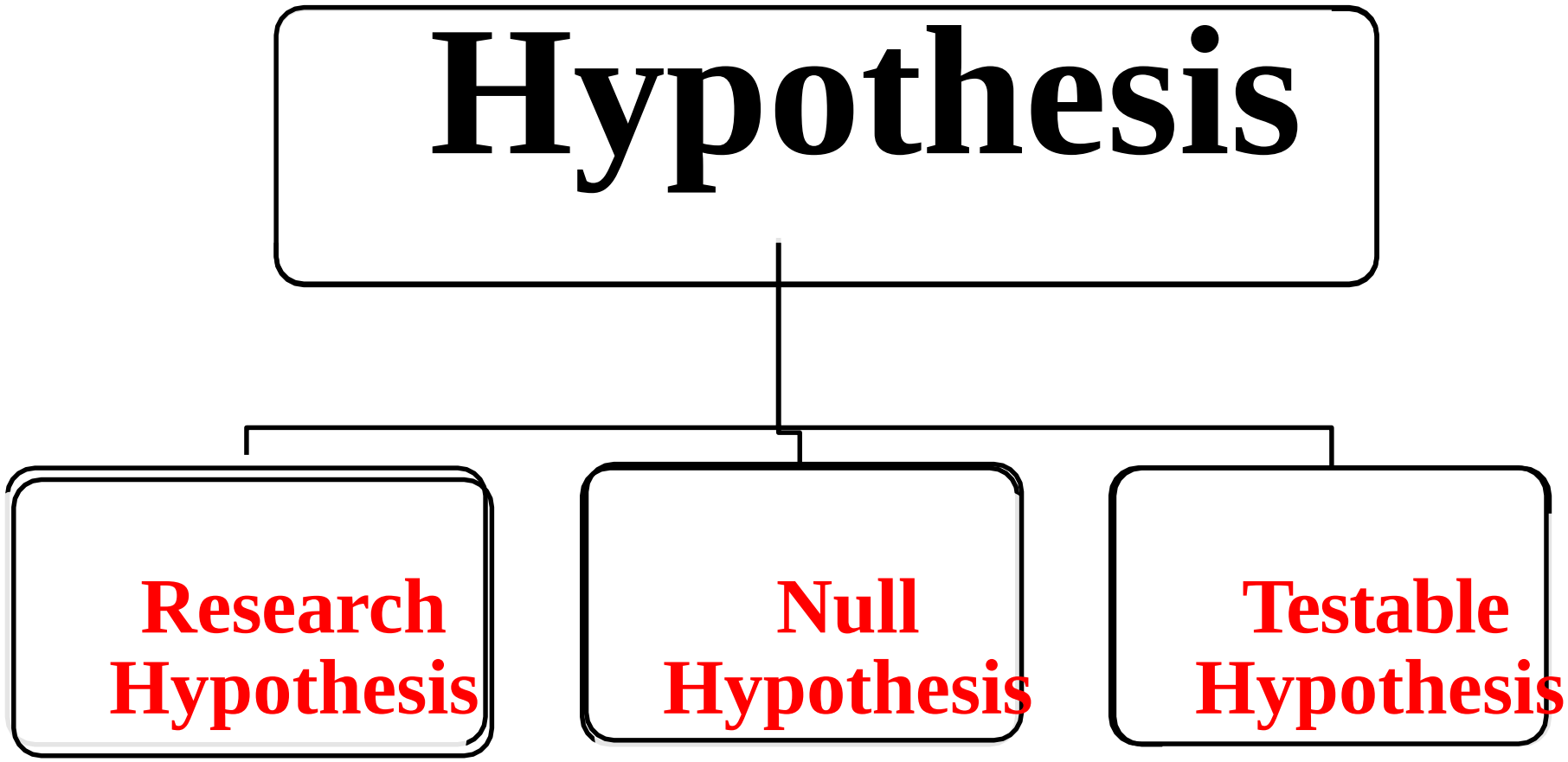
- Hypothesis in a research project logically follow literature review and conceptual framework.

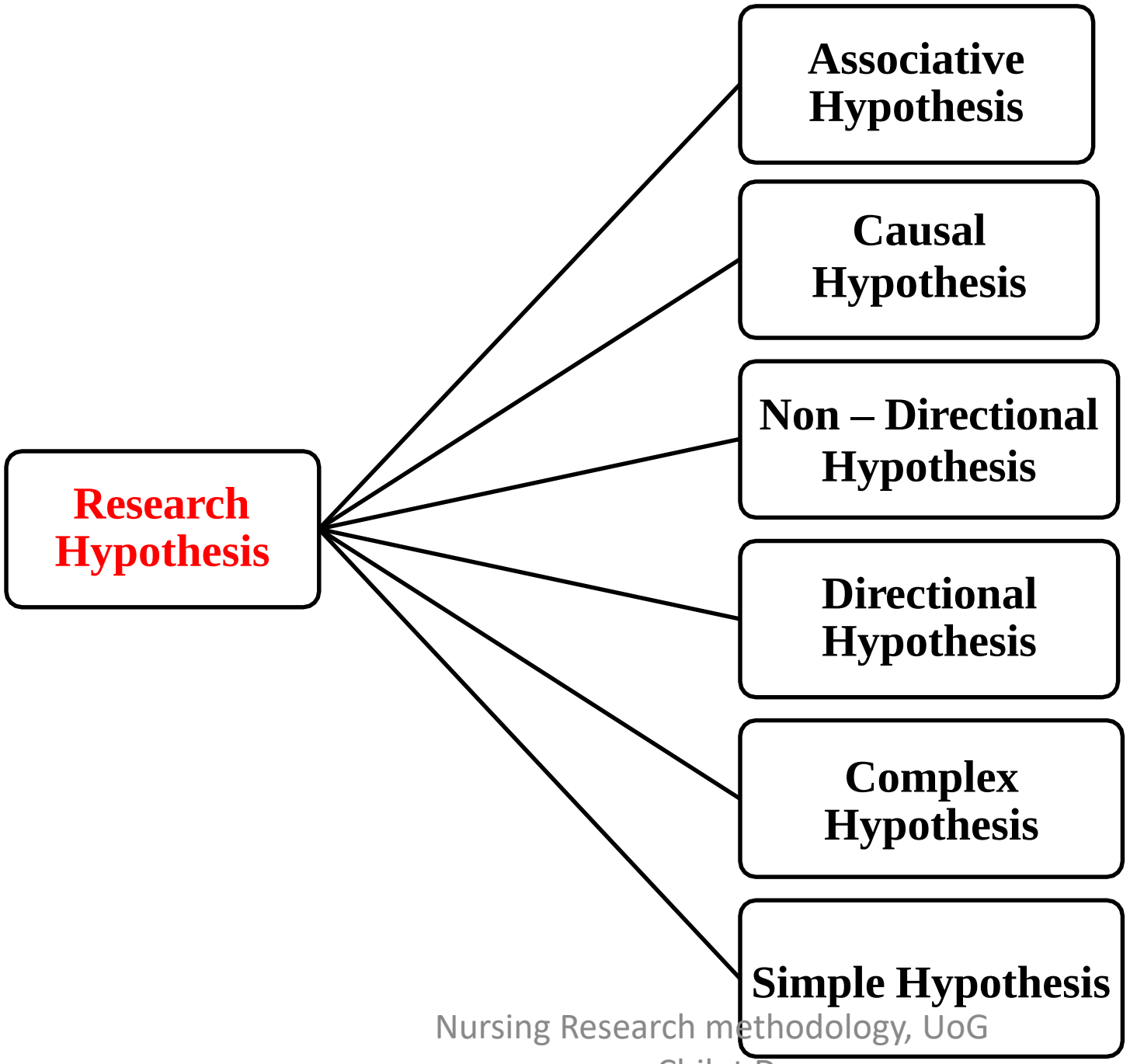
Hypothesis

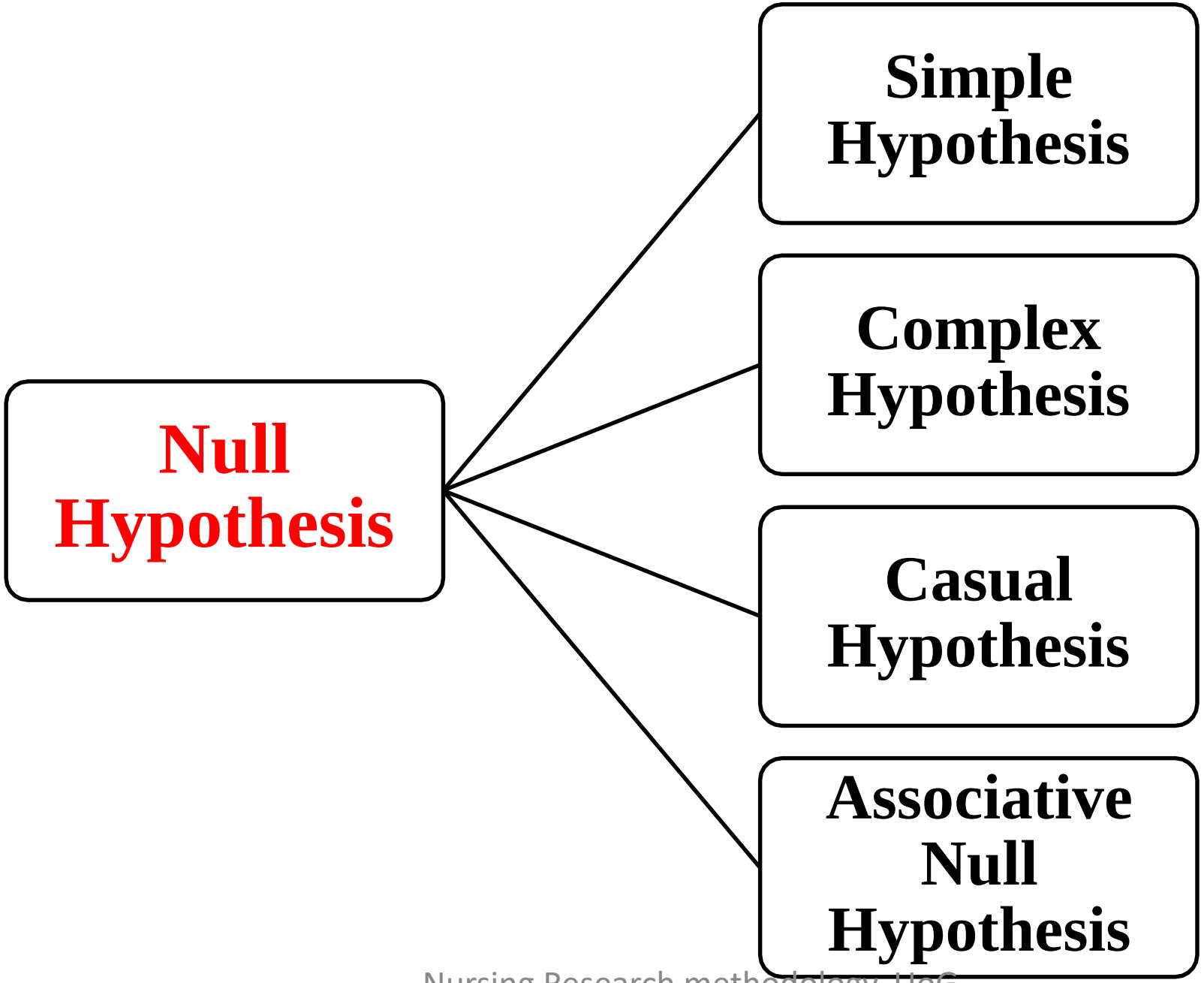
- It provides clarity to the research problem and research objectives
- It describes, explains or predicts the expected results or outcome of the research.
- It indicates the type of research design.
- It directs the research study process.

- It identifies the population of the research study that is to be investigated or examined.

- It facilitates data collection, data analysis and data interpretation


Hypothesis
Research Hypothesis
Null Hypothesis
Testable Hypothesis


Research Hypothesis
Associative Hypothesis
Causal Hypothesis
Non – Directional Hypothesis
Directional Hypothesis
Complex Hypothesis
Simple Hypothesis


Null Hypothesis
Simple Hypothesis
Complex Hypothesis
Casual Hypothesis
Associative Null Hypothesis

Research Hypothesis

Simple Hypothesis

- simple hypothesis predicts that, there exist a relationship between the independent variable and dependent variable.

- **Example**- two hourly positions- changing of a fully bedridden patient will prevent bedsore.
  - In the **above example** 2 hourly position changing is independent variable and bedsore prevention is dependent variable.
  - The statement shows that there exists a relationship between 2 hourly positioning and bedsore prevention.

Complex Hypothesis

- complex hypothesis predicts that there exists relationship between two or more independent and dependent variable.

- **Example** – for a fully bed ridden patent 2 hourly position changing, 2 hourly back care and a high protein diet will build up body resistance, will promote blood circulation and will prevent bedsore.
  - In the above example, **three independent variable** are:- A) 2 hourly position changing, B) 2 hourly back care, C) high protein diet.
  - And **three dependent variable** are:- a) promotion of blood circulation, B) building up of body resistance,
    C) prevention of bed sore.

Directional Hypothesis

- Directional Hypothesis predicts the direction of the relationship between the independent and dependent variable.

- **Example**- High quality of nursing education will lead to high quality of nursing practice skills.

Non directional Hypothesis

- **Non -directional Hypothesis** predicts the relationship between the independent variable and the dependent variable but does not specific the **directional of the relationship**.
- **Example**- teacher student relationship influence student's learning.

Causal Hypothesis

- Causal Hypothesis predicts a **cause** and **effects** relationship or interaction between the independent variable and dependent variable. This hypothesis predicts the effect of the independent variable on the dependent variable.

- In this the independent variable is the experimental or treatment variable. The dependent variable is the outcome variable

- Example – early postoperative ambulation will lead to prompt recovery.

Associative hypothesis

- Associative Hypothesis predicts an associative relationship between the independent variable and the dependent variable.
- When there is a change in any one of the variables, changes also occurs in the other variable.
- The associative relationship between the independent and dependent variables may have either.
  - Positive association
  - Negative association

Null Hypothesis

- is also called **statistical hypothesis** because this type of hypothesis is used for statistical testing and statically interpretation.
- The null hypothesis predicts that, there is no relationship between the independent variable and dependent variable.
- Example- Nasogastric tube feeding does not alter body temperature

Simple null hypothesis

- **Example** – bed rest will not relives sever asthmatic dyspnea. In the above example, the independent variable that is, bed rest does not have any causal relationship with the dependent variable that is, severe asthmatic dyspnea.

Complex null Hypothesis

- Example- smoking, drug abuse, alcoholism, tobacco use etc. have no relationship in the occurrence of malaria, mumps or chicken pox

Causal null Hypothesis

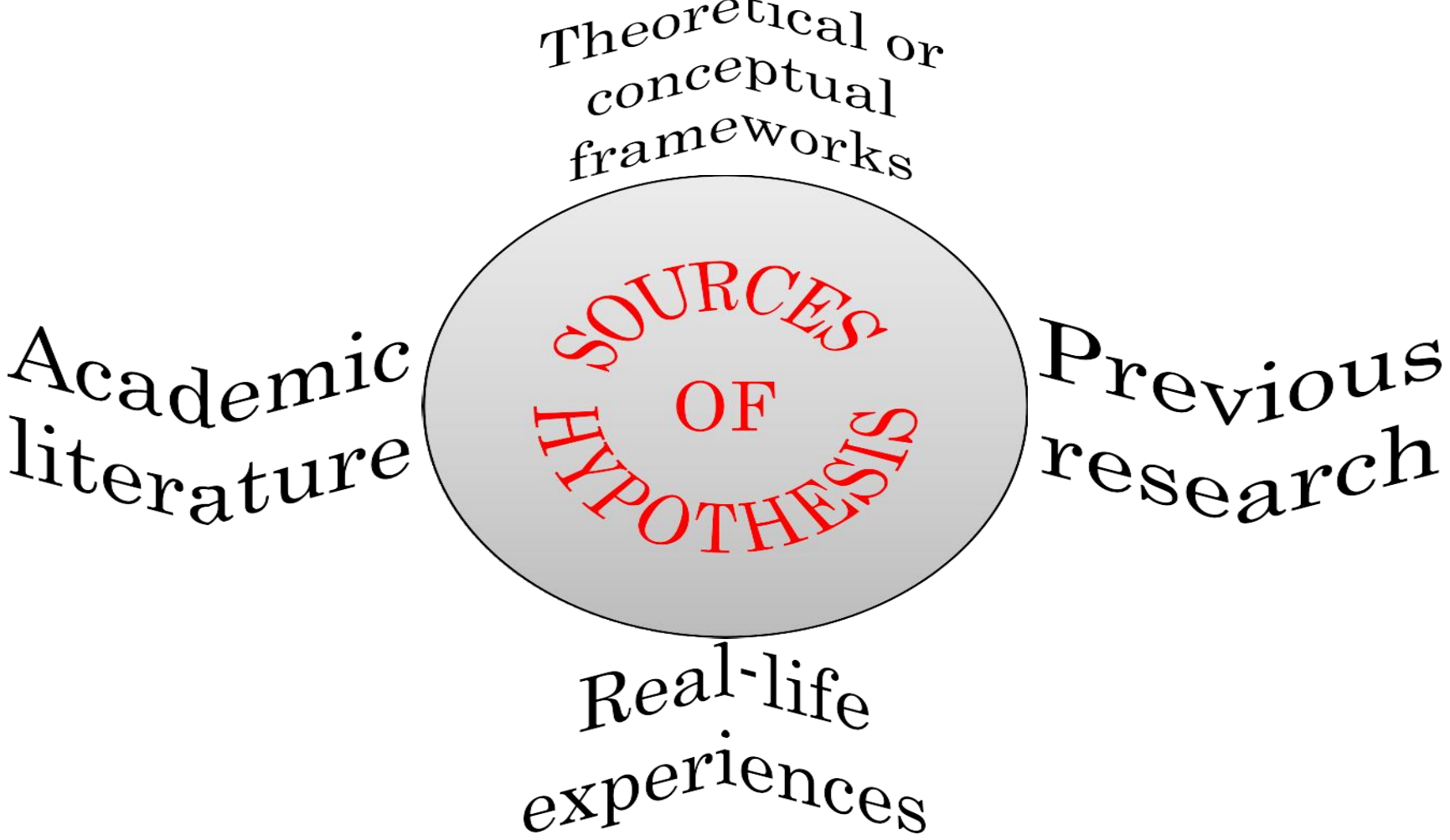
- **Example**- high intake of fluid does not cause tissue oedema.
- In the above example, the independent variable, that is, high fluid intake does not have any causal relationship with the dependent variable such as, tissue oedema.

Associative null Hypothesis

- Example- Increased does in antibiotics will not reduce body temperature

Testable Hypothesis

- The testable hypothesis predicts relationship between the independent variable and the dependent variable and theses variable are testable or measurable.
- **Example** – Increase in patient's body temperature causes increase in patient's pulse rate.


Theoretical or conceptual frameworks
Academic literature
SOURCES OF HYPOTHESIS
Previous research
Real-life experiences

Theoretical or conceptual frameworks:

- The most important sources of hypotheses are theoretical or conceptual frameworks developed for the study.
- Through a deductive approach these hypotheses are drawn from theoretical or conceptual frameworks for testing them.
- For example, Roy's adaptation Model is used in a research study, where a hypothesis can be drawn from a concept of the theoretical mode that 'patient's adaptation to a chronic illness depends on availability of social support for them.'

Previous research:

- Findings of the previous studies may be used for framing the hypotheses for another study.
- For example, in a small sample descriptive study, a researcher found that a number of patients admitted with coronary artery disease had increased body mass index.
- In another research study, a researcher may use this finding to formulate a hypothesis as 'Obese patients have increased risk for development of coronary artery disease'.

Academic literature

- Academic literature is based on formal theories, empirical evidences, experiences, observation, & conceptualizations of academicians.
- These literatures may serve as good sources for formulating hypotheses for research studies.

Research Objectives

- **What is research objectives?**

It summarizes what is to be achieved by the research / study

WHERE ARE YOU GOING?

“If you are not certain of where you are going, you may well end up somewhere else (and not even know it!).”

Set objective

Evaluate performance

Importance of developing objectives

- Focus the study
- Avoid the collection of unnecessary data
- facilitate the development of research methodology and help to orient the
  - collection,
  - analysis,
  - interpretation and
  - utilization of data
- Helps for evaluating the research project

Type of Objective

- **General Objective**
  - What is expected to be achieved by the study *in general terms*
  - should be clearly related to the statement of the problem.
- **Specific Objectives**
  - Breaking down the general objective into smaller, logically connected parts

How to write the General objectives?

Objective should be **closely related to problem statement**

- **Example problem:**
  - Low utilization of FP clinic
- **General Objective:**
  - To identify the reasons for low utilization of FP clinic in Gondar

How to write the specific objectives?

- **Focused**, each S. objective cover a single point/idea
- **Ordered** in a logical sequence, e.g. We don't put associated factors before prevalence
- **Realistic** and feasible to answer
- **Operational**, using *action verbs* such as:
  - determine - verify -identify
  - describe - assess - compare
  - calculate - establish -explore
- Avoid use of non-action verbs(to appreciate, study, understand, Believe , Know)
- **Measurable** outcomes at the end of the research

Objectives should be:-

- Specific
- Measurable
- Achievable
- Realistic
- Time bound

Example- 1

- **Problem=** un known magnitude of diabetes in Gondar town.
- **Title=**
  - Prevalence and Associated Factors of diabetes among Adults of Gondar Town, North West Ethiopia
- **General Objective=**
  - To assess the prevalence and associated factors of diabetes among adults of Gondar town, North West Ethiopia, April 2012
- **Specific objectives**
  - To determine the prevalence of diabetes among adult of Gondar town, North West Ethiopia, April 2012
  - To identify factors associated with diabetes among adult of Gondar town , North West Ethiopia, April 2012

Example-2

- Title= time to adjuvant chemotherapy and its determinates among breast cancer patients at University of Gondar Referral Hospital, Northwest Ethiopia 2020
- General Objective:
  - To assess time to adjuvant chemotherapy and its determinates among breast cancer patients at University of Gondar Referral Hospital, Northwest Ethiopia 2020
- Specific Objective=
  - To determine median time of adjuvant chemotherapy among breast cancer patients at University of Gondar Referral Hospital, Northwest Ethiopia 2020
  - To identify the predictors of time to adjuvant chemotherapy among breast cancer patient at University of Gondar Referral Hospital,2020

Example- 3

- **General Objective:** knowledge, attitude and practices of hand hygiene among health sciences students at UOGCSH
- **Specific Objectives**
  - To determine the knowledge of health sciences students about hand hygiene at UOGCSH
  - To determine the attitude of health sciences students about hand hygiene at UOGCSH
  - To determine the practices of health sciences students about hand hygiene at UOGCSH

Assignment four

- **Write general and specific objectives for your research proposal?**

Learning objectives

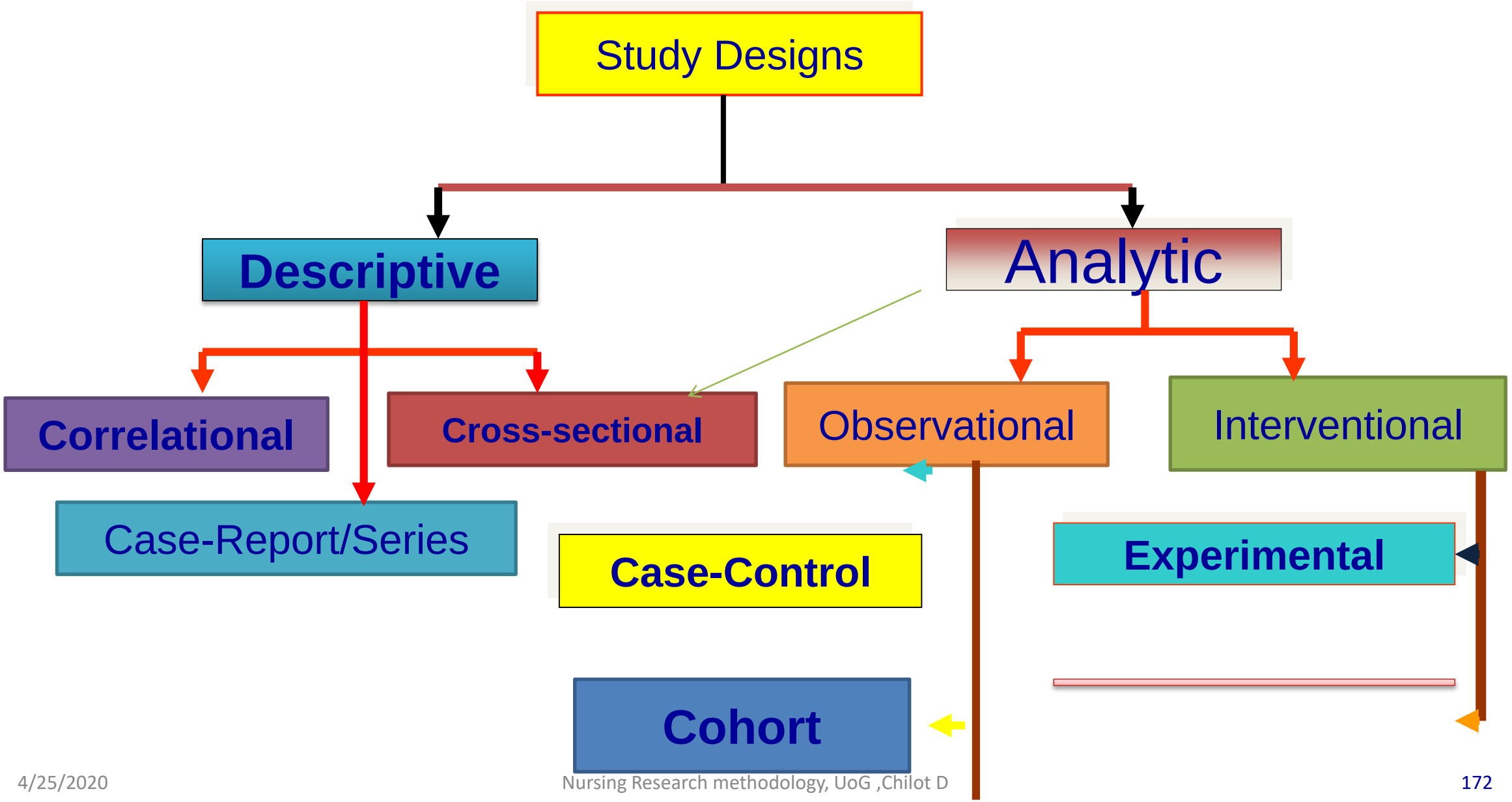
After the end of this session, students will be expected to:

- Describe different Epidemiological study designs
- Discuss the difference between descriptive and analytical studies
- Describe the purpose of descriptive studies and analytical studies
- State strength and limitation of studies designs
- Identify appropriate study design for a research problem

Study design

- A study design is a specific plan or protocol for conducting the study, which allows the investigator to translate the conceptual hypothesis into an operational one
- Arrangement of conditions for the collection & analysis of data
- It is overall structure of the study

Types of study designs



Quick assignment

Why Cross Sectional study is grouped under both descriptive and analytic study designs? – individual work

DESCRIPTIVE STUDY DESIGNS

- Descriptive studies focus on the frequency and distribution of disease
- Analytic studies focus in elucidating the determinants of disease
- Descriptive study is one of the basic types of epidemiology describing the frequency and distribution of diseases by time, place and person

Application of descriptive studies

- Useful for health managers to allocate resource and to plan effective prevention programs
- To generate hypothesis, an important first step in the search for disease determinants or risk factors of disease
- It is less expensive and less time-consuming

analytic studies

Application:

- To search for cause-effect relationship and mechanism
  - Why?
  - How?
- It focuses on determinants of disease by testing hypothesis regarding exposure and outcome of interest
- To quantify the association between exposure and outcome of interest

Analytic studies...

Basic features:

- Key feature of analytic epidemiology is comparison group
- Appropriate comparison group needed:
  - Exposed versus non-exposed
  - Case versus control
  - Experimental versus non-experimental
- It is the use of comparison group that allows testing of epidemiologic hypotheses

Descriptive epidemiological study designs

Case report

- It is the study of health profile of a single individual using a careful and detail report by one or more clinicians
- Report is usually documented if there is **unusual medical occurrence**, thus it may be first clue for identification of a new disease occurrences
- It is useful in constructing a natural history of individual disease

Case series

- Case series describe the experience of a group of patients with a given disease or similar diagnosis
- E.g. The first five AIDS cases in USA. In 1980 and 1981, five
- cases of PCP were reported among young homosexual men
- in Los Angeles hospitals.

❖ Both case report and case series are:

- Documentation of new or unusual medical occurrences.
- Gives the first clues in the identification of new disease

and adverse effects of exposures

Advantages of case reports and series

- Useful for the recognition of new disease
- Useful for constructing of the natural history of a disease
- Enable to know manifestation of new disease
- Use to formulate hypothesis and to detect an epidemic occurrence of a disease
- Simple, quick, inexpensive

Disadvantages of case reports and series

- Unable to test for statistical association between exposure and outcome variables
- It is difficult to test for hypothesis
- Presence of a risk factor that is simply chance
- Rates can not be calculated since the population corresponding to the source of cases can not be well defined
- Studies are prone to atomistic fallacy (cannot be inferred to the population)

Ecological studies

- Uses data from entire population to compare disease frequencies - between different groups during the same period of time, or in the same population at different points in time
- The main difference between ecological studies and the other types of study, ecological studies are carried out at the population level
- They use aggregate data and do not measure outcomes and risk factors at individual level

- **e.g. Hypertension rates and average per capita salt consumption compared between two communities.**
- **Fluoride content of water and dental caries**
  - Proportion of people with dental caries in a village

    Vs
  - Fluoride content of water supply in the village

- Measures of association in ecological study is correlation coefficient (r)
- Correlation coefficient quantifies the extent to which there is a linear correlation of exposure and outcome variables

  $(-1 \leq r \leq 1)$

❑ Advantages

- ❖ It is useful for the formulation of hypotheses
- ❖ Quick and inexpensive
- ❖ Often use already available information

Disadvantages

- Based on averages and may miss actual contributing factors
- Unable to link exposure with disease at individual level
- Lack of ability to control for potential confounders
- Presence or absence of correlation does not imply valid statistical association

Cross-sectional studies

- It is also called prevalence study (survey study)
- It is the major type of descriptive study designs
- Survey is conducted in a population, to find prevalence of a disease and exposure at a point in time
- Exposure and disease status are assessed simultaneously among individuals at a point in time
- Point in time indicates the speed of data collection i.e. be days, weeks, months, years but the measurement is takes place only once

Cross-sectional studies...

- It helps administrators in assessing the health status and health care needs of a population
- Used to assess prevalence of acute and chronic diseases, disabilities and utilization of health care resources
- The purpose is for effective health care planning, priority setting, resource allocation and administration

Advantages

- Quick and inexpensive
- Multiple factors and outcomes assessed at a time
- Provide early clues for hypothesis generation
- Can be used to compare population with different characteristics as in comparative cross sectional studies
- Provide estimates of prevalence of all factors measured.
- Used for planning
- Greater generalizability.

Limitation of cross-sectional studies

- The prominent limitation is "Egg or chicken dilemma"

Since exposure and disease status is assessed at a single point in time, temporal relationship between exposure and disease can not be clearly determined

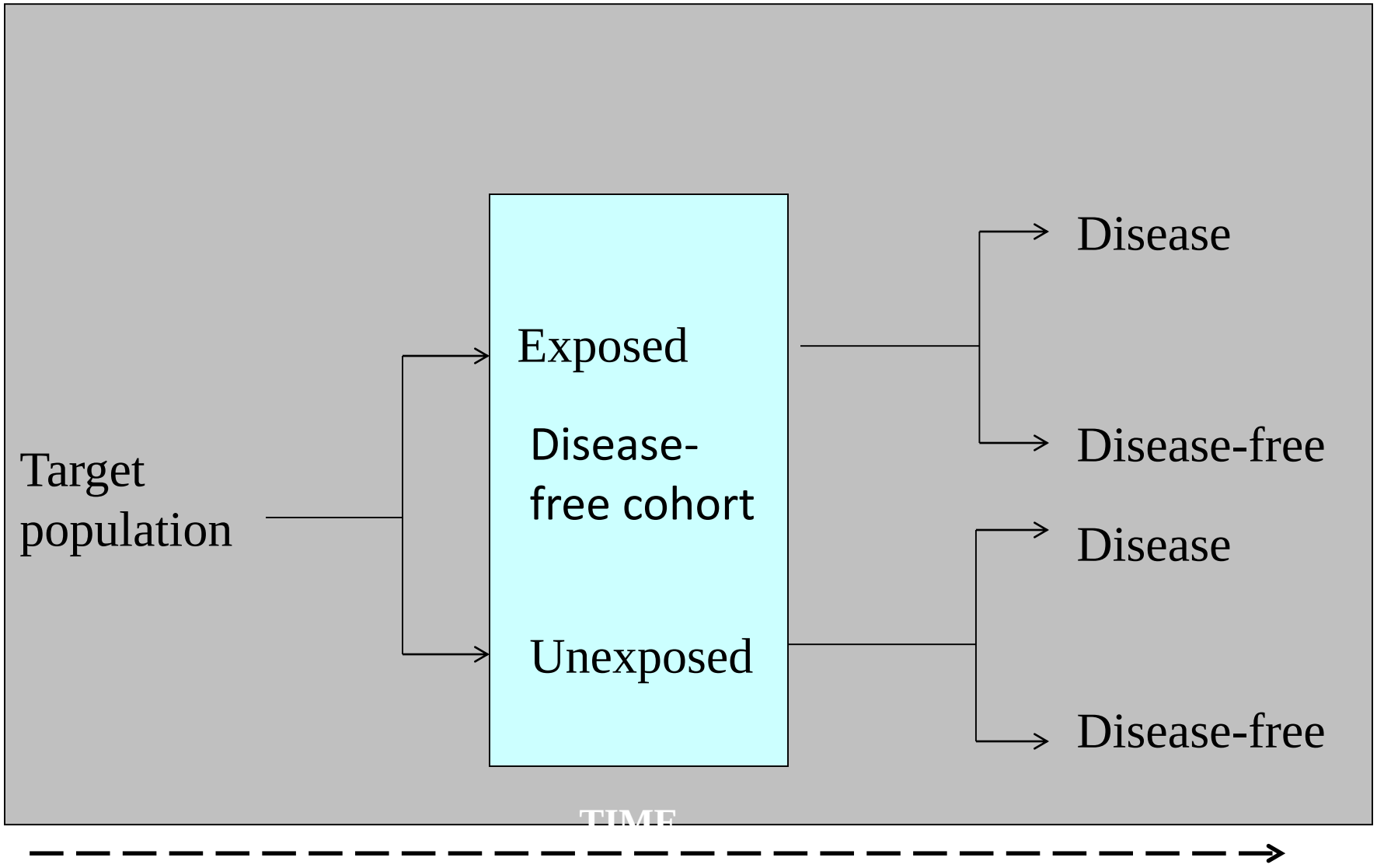
- Not good for rare diseases or rare exposures
- No hypothesis testing (for pure descriptive one)

Analytic Study Designs

cohort study

- A cohort study is an observational research design which begins when a cohort initially free of disease (outcome of interest) are classified according to a given exposure and then followed (traced) over time
- The investigator compares whether the sub-sequent development of a new cases of disease (other outcome of interest) differs between the exposed and non-exposed cohorts

Cohort study



Basic elements of cohort studies

- "Disease free" or "without outcome" population at entry
- Selected by exposure status
- Follow up is needed to determine the incidence of the outcome
- Compares incidence rates among exposed against non-exposed groups

Data to be collected in cohort studies

- Data on the exposure of interest to the study hypotheses
- Data on the outcome of interest to the study hypotheses
- Characteristics of the cohort that might confound the association under study

What is exposure and outcome of interest?

Example: Is smoking a cause of lung cancer?

- Cohort design: Identify smokers as exposed and non smokers as non exposed then follow both groups over time (e.g. 10 years) and check for development of lung cancer in both groups.
- If smoking is a cause of lung cancer, large proportion of smokers will develop lung cancer compared to the nonsmokers

Sources of exposure and outcome information

- Pre-existing records
- Information supplied by the study subjects
- Direct physical examination or screening tests
- what are the possible outcomes in cohort studies?

Types of population in cohort studies

- **Open population**
- Closed population

Follow up time in cohort studies

- The outcome has not occurred at the beginning of the study
- Length of follow-up time required is dependent on:
  - the incidence rate of the outcome
  - the size of the population at risk
  - the latency period of the outcome

Types of cohort studies

- Cohort studies can be classified depending on the temporal relationship between the initiation of the study and the occurrence of the outcome of interest
  - *Prospective cohort studies*
  - *Retrospective cohort studies*

Cohort study design

Classical (prospective)

1. measure exposure

2. measure outcome

Historical (retrospective)

1. Record of exposure

2. measure outcome

Prospective cohort studies

- Study participants are grouped on the basis of past or current exposure status
- Both groups are followed into the future in order to observe the outcome of interest
- At the beginning of the study the outcome has not yet occurred
- Regarded as more reliable than the retrospective, if the sample size is large and follow-up is complete

Steps in prospective cohort studies

1. Define the population at risk
2. Determine exposure status to a factor of interest
3. Make sure that study subjects are free of the disease of interest at time of enrolment
4. Follow exposed and non-exposed forward in time to ascertain whether they develop the outcome of interest
5. Compare the outcomes in the exposed and non-exposed groups
6. Conclude whether the exposure to risk factor contributes for the outcome of interest

Retrospective cohort studies

- Both exposure and outcome status have occurred at the beginning of the study
- Studies only prior outcomes and not future ones
- A historical cohort study depends upon the availability of data or records that allow reconstruction of the exposure of cohorts to a suspected risk factor and follow-up of their mortality or morbidity over time

Advantages and disadvantages of retrospective cohort studies

- All of the relevant variables may not be available in the original records
- It may be difficult to ascertain that the study population was free from the condition at the start of the exposure to primary risk factor
- Attrition problems may be serious due to loss of records, incomplete records, or difficulties in tracing or locating all of the original population for further study

When a cohort study is warranted?

- Study of incidence, risk factors, natural history or prognosis
- Have a hypothesis about exposure and outcome of interest
- Interval between exposure and outcome should not be too long (long latency period causes loss to follow up)
- Need to measure outcomes prospectively
- Need to study multiple outcomes for single exposure factor

Strength of cohort studies:

- Particularly efficient when exposure is rare
- Can examine multiple effects of a single exposure
- Minimize bias in outcome measurement if prospective
- Allows direct measurement of incidence (risk) and prognosis (natural history)
- Can elucidate temporal relationship between exposure and outcome of interest (if prospective)

Limitation of cohort studies:

- Costly and time consuming if disease is rare and/or long latency period (if prospective)
- Validity of the results can be seriously affected by loss to follow up (if prospective)
- Relatively statistically inefficient unless disease is common (need large sample size)
- If retrospective, requires availability of adequate records
- In-efficient for evaluation of rare diseases, unless attributable-risk is high
- Exposure status may change during the course of study

Case-Control Studies

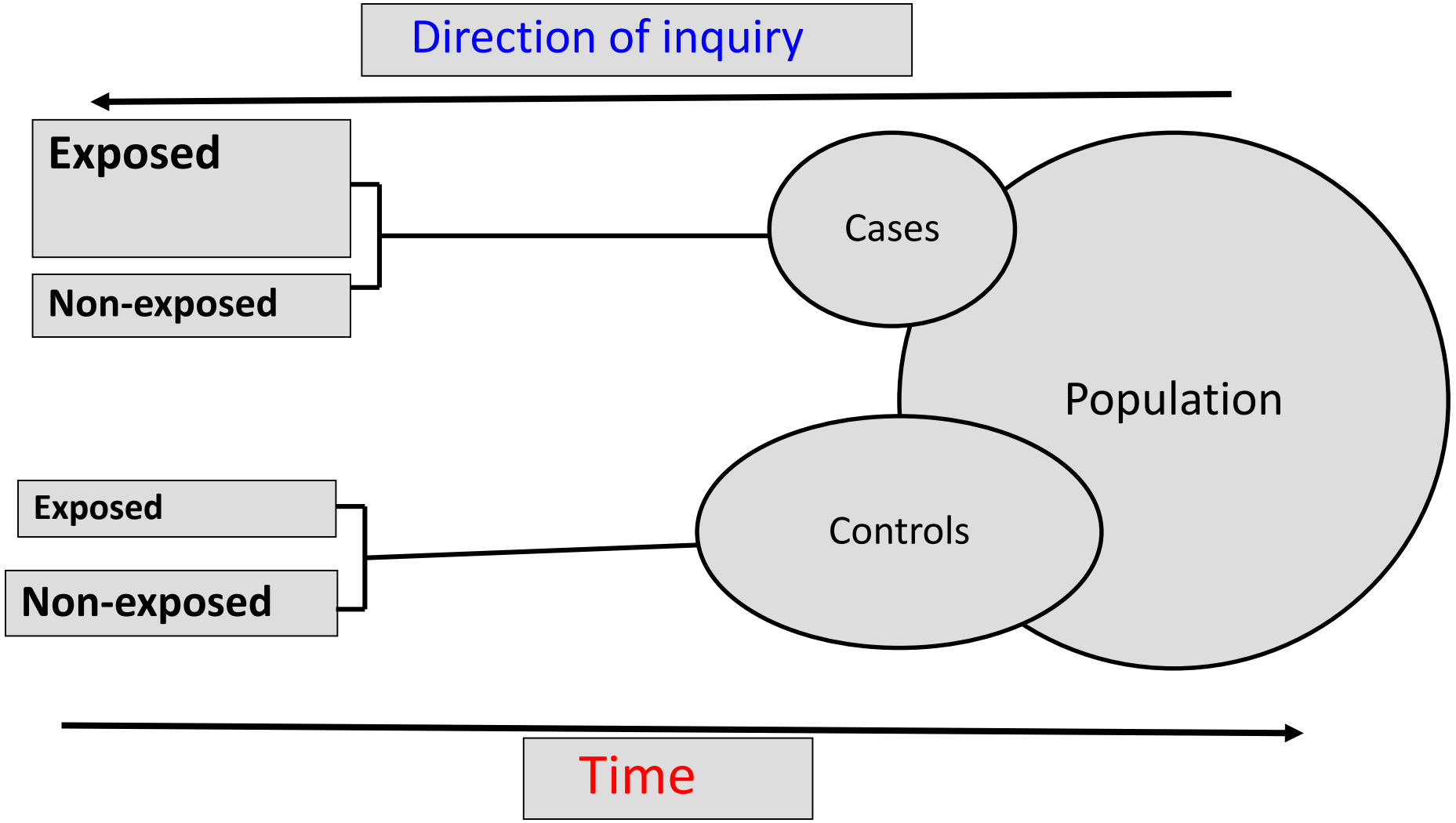
Definition of case-control studies

- A case control study is one in which persons with a condition ("cases") and suitable comparison subjects ("controls") are identified, and then the two groups are compared with respect to prior exposure to risk factors
  - Subjects are sampled by their **outcome status**

case-control studies…

- Case-control study examines the association between disease and potential risk factors by taking:
  - Case group or series of patients who have a disease of interest
  - Control (comparison) group of individuals without the disease are selected for investigation and then proportions with the exposure of interest in each group are compared

Case-control studies



Steps of case-control studies

1. Define cases and controls
2. Identify group of cases
3. Identify group of controls
4. Ask (review) both groups for previous history of exposure to risk factors under study
5. Measure frequency of exposure to risk factors occurrence in both groups
6. Compare frequency of exposure to risk factors between cases and controls
7. Conclude that previous history of exposure to risk factors contributed for the cases more than controls or not

What is case…

- It is the outcome of interest under study
- It can be:
  - A disease

    E.g. HIV status, malaria case
  - A behavior

    E.g. Alcohol drinking habit, cigarette smoking
  - Occurrence of an event

    E.g. migration

Selection of case …

- Define ‘disease’ and how it will be measured
- Selecting the source population of cases (homogeneous cases)
- Sources of cases are commonly:
  - All persons with the disease in a population during a specific time of period
  - All persons with the disease seen at a particular facility (e.g. a hospital) in a specific time period

Sources of cases

Hospital-based:

- easy and in-expensive to conduct
- it is prone for selection bias

Population-based:

- avoids selection bias
- allows the description of a disease in the entire population and the direct computation of rates of disease in exposed and non-exposed groups

What is control?

- It is the comparison group (referent)
- It should be free of the disease (outcome of interest under study)
- It should be as similar as the cases in all aspects except for the disease of interest under study
- Controls must have the same opportunity of getting exposure to risk factors as cases and should be subjected to the same inclusion and exclusion criteria

Sources of controls

1. Population-based controls
2. Hospital-based (health institution) controls
3. Specials controls: neighbourhood, friends, spouses or relatives (siblings)
   - Potential bias regarding ethnic backgrounds, socioeconomic status and environmental exposures

   E.g. If diet and smoking as exposure factor will underestimate the effect of exposure to the occurrence of disease

Population-based controls

Advantages:

- Generalizability will be improved (representativeness)
- If all cases in the general population known
- Direct calculation of risk rate is possible

Disadvantages:

- Costly and time-consuming
- Sampling frame is not available
- Less cooperative (increases selection bias i.e. non-response bias)
- Re-call bias increases (because they are healthy)

Hospital-based controls

Advantages:

- Minimize re-call bias
- Convenient
- Cooperative non-case patients (minimize non-response bias)

Disadvantages:

- Control disease may be linked to exposure of interest
- Hospitalized controls differ from general population

Ratio of controls to cases

- A single control group is optimal in most of the times
- However, ratio of controls to cases may vary from 1:1 to 4:1
- Trade-off: cost *versus* power of the study
- Decision based on power calculation
- More than one control groups may be recommended when the single control is not appropriate or has a specific deficiency

Strengths of case-control studies

- To investigate rare disease (less than 10%)
- Suitable for the evaluation of diseases with long latency period
- Quick with time and in-expensive
- Relatively efficient with small sample size comparing with cohort studies
- Little problem with attrition of study subjects
- Can examine multiple etiologic exposures for single outcome

Limitation of case-control studies

- In-efficient for rare exposures
- No calculation of rates and risks possible
- In some situations, the temporal relationship between exposure and disease may be difficult to establish
  - Temporal exposure–disease uncertainty
- Prone to selection and information bias
- Selection of controls difficult some times

Interventional Studies

Definition of interventional studies

- ”An epidemiological experiment in which subjects in a population are randomly allocated into groups, usually called *study* and *control* groups to receive and not receive an experimental preventive or therapetuic procedure, maneuver, or interventition” (John M.Last, 2001)

- Investigators must formulate a hypothesis before launching an experimental study

Interventional studies

- This is an epidemiological design that closely resembles the controlled experiment in basic science researches
- The main distinction from other types of analytic studies is that individuals are allocated into experiment or control group by the investigators
- The active manipulation of the agent by the investigator is the hallmark that distinguishes experimental studies from observational analytic studies

Study groups in interventional studies…

- It is very important that the two groups gain equal of attention in the study
- Unequal attention leads to differences attributed to the amount of attention each group receives, not to the intervention- known as Hawthorne effect
- Ideally, the intervention and the control populations are at the same stage of the natural history of the disease and are similar in the characteristics that affect disease outcomes, differing only in the exposure of interest to the intervention study

When an experimental studies warranted ?

- The research questions cannot be answered by observational studies
- Existing knowledge is not sufficient to determine clinical or public health practices and policies

Steps of interventional studies

1. Selection of study population
2. Allocation of treatment regimen
3. Maintenance and assessment of compliance
4. Ascertainment of outcomes
5. Analysis & conclusion of experimental studies

1. Selection of study population

- The first step in any experimental design will be to identify the appropriate reference population
- It is the general group to whom the result of a study is applicable
- Reference population can be:
  - All human beings
  - Geographically restricted population
  - Either sex
  - Restricted by age group, etc…

Experimental population

- These are listed prior to the beginning of the experiment as inclusion/exclusion criteria
- It is the actual group in which the trial is planned to be conducted
- Consideration of selection of experimental population:
  - Sample size of study subjects should be high
  - It should be a sample that should be voluntary to stay till time of outcome ascertainment
  - The sample should obtain complete and accurate follow up

Study population

- Once experimental population are defined, the next step is to select 'study participants'
- Thus, the experimental population are then screened for eligibility
- Eligible members of the experimental population are invited to participate after they are fully informed about:
  - Application of the trial
  - Study procedure
  - Possible risks and benefits etc…

- Those who are willing to participate and who are eligible are the actual 'study subjects'

- Selection of study population on their willingness has its own disadvantage (losing external validity)

  - ✓ These willing/ voluntary may be different from those non-voluntary groups

- Knowledge of difference or similarity in baseline variables between participants and non-participants is necessary to assess for generalizability

2. Allocation of treatment regimen

- Individuals are assigned to receive one of the two or more treatment groups
- Effects of new treatment, procedure or program are compared with one or more comparison groups:
  - Continuation of standard medical practice
  - Another dosage of the new treatment
  - Another therapy or program
  - Placebo
  - No treatment

Randomization of study subjects

- There is a need of assignment of study population into the two or more groups by randomization
- To help assure that groups are similar, subjects are randomly assigned to experimental or control groups
- Randomization is performed to increase the likelihood that groups would be similar in baseline characteristics
- Randomization is supposed to have the effect of distributing confounders (both known and unknown equally) between the intervention and control groups

3. Maintenance and assessment of compliance

- An intervention study requires the active participation and cooperation of the study subjects
- Study subjects may be able to deviate from the study for many reasons:
  - Side effects
  - Desire to seek other therapies
  - Forgetting to take their medication
  - Simple withdrawal of their consent
  - disease progression and death etc…
- Monitoring compliance is important because non-compliance will decrease the statistical power of the study
- A very serious threat to the clinical trial is the attrition of patients if it is more than 10-15 %

4. Ascertainment of outcomes

- One should specify explicitly what outcomes are expected, and what criteria are to be applied to determine occurrence of outcomes
- The outcomes may include prevention of a condition, cure of a condition, improvement in the condition, alleviation of pain, improved physical or mental health, etc…
- It should be aimed at ensuring the results not to be biased by complete and accurate measurement of the outcome

Ascertainment of outcomes…

- Presence of knowledge of allocation of study subjects could result in a bias called "observation bias"
- Even after randomization, it is possible that experimental subjects may be treated differently than controls
- To avoid this observation bias, blinding the study /masking may be necessary

Levels of blinding

Non-blinded/open - All know which intervention a patient is receiving (common in community trials)

Single blinded - The observer is aware but the study subjects is not aware of treatment assignment

Double blinded - Neither the observer nor the study subjects is aware of treatment assignment

Triple blinded - The observer, study subjects and data analyst are not aware of treatment assignment

Placebo use

- The purpose of placebo is to match as closely as possible the experience of the comparison group with that of the treatment group
- A placebo is a biologically inactive substance given to the control group so that they think they are being treated equally as treatment group
- The placebo should be similar to the drug being tested in respect to appearance (size, texture, odor, color and taste)

Is placebo use ethical?

- When there is no known successful therapy, a placebo is ethical
  - However, withholding a known treatment to be effective is not ethical

- Using a placebo instead of the experimental drug is ethical:

  – Because the experimental drug is not known to be beneficial and could actually be harmful

Decision of terminating a trial

- There is a need of a guideline for deciding when to terminate a study trial

- In experimental study, there is a need of an independent group that monitors and keeps the welfare of study subjects
- Data safety and monitoring board

5. Analysis of experimental studies

- The classic analytic approach for an experimental study is known as an intent- to-treat or treatment assignment analysis (effectiveness)
- An analysis in which data would be analyzed according to randomized group assignment, regardless of whether participants shift their treatment
- The alternative to an intent-to-treat analysis is known as an efficacy analysis when participants take the full treatment per prescription

Features of quality interventional studies

- Random allocation of intervention/exposure
- Blinding of study participants
- Placebo use

Strengths of interventional studies:

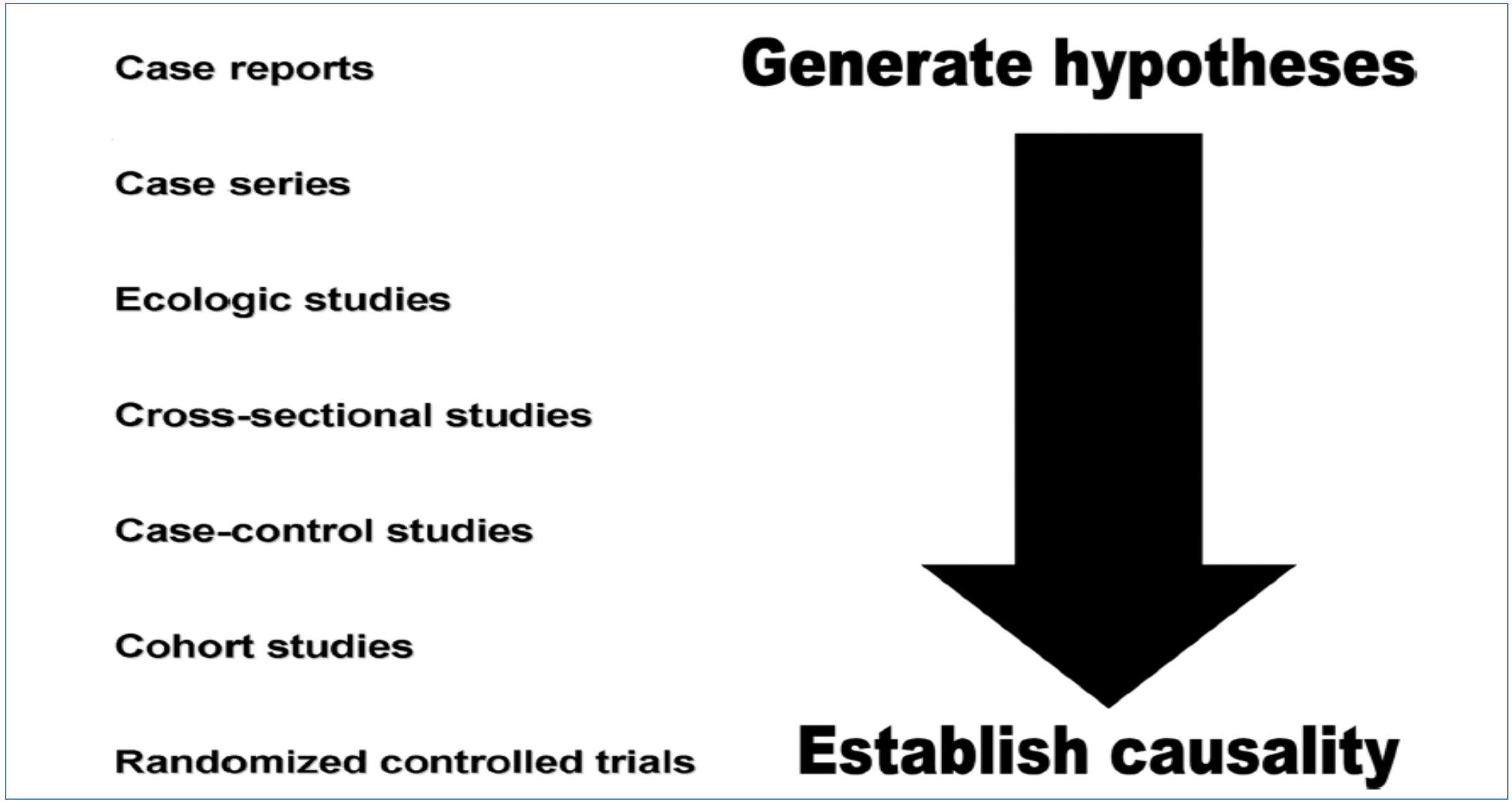
- Randomization minimizes selection bias and confounding factors
- Blinding minimizes observer bias
- Placebo could blind patients

❑ The best type (gold standard)

Limitations of interventional studies:

- Ethical issues in question
- Feasibility issues
- Cost implications
- Loss to follow up and drop outs issue

Hierarchy of Epidemiologic Study Design



Choice of Study Design

The choice of study design is mainly determined by:

- Objective of the study
- Available resources/ Funds
- Time
- Researcher Skills

Objective and study design

Objective	Study Design
To quantify the magnitude and distribution of a health state/event	Descriptive
To compare groups to elicit the causes/risk factors	Analytical
To assess the efficacy of drugs, treatments, interventions	Experimental

Study area/setting

- Where will the research take place?
- The setting where the study will be conducted
- Mentioned:
  - The location of the area/setting
  - Size of the population
  - Availability of Health service
  - Other issue related with your research

Research Methods

Topic :-**Incidence and predictors of virological failure among adult HIV patients on first line anti-retroviral therapy at University of Gondar Comprehensive specialized Hospital, Northwest Ethiopia**

- The stud will be conducted at University of Gondar Compressive Specialized Hospital is a teaching Hospital, which serves around five million people. The hospital started ART service in 2005. More than 9010 adults and 810 pediatrics patients were enrolled in the HIV care from 2005 to now. Currently around 5,524 patients actively following their ART in this Hospital. The ART clinic has four tropical infectious disease and HIV medicine professionals, 10 nurses, one physician and one Health officer.

Study period

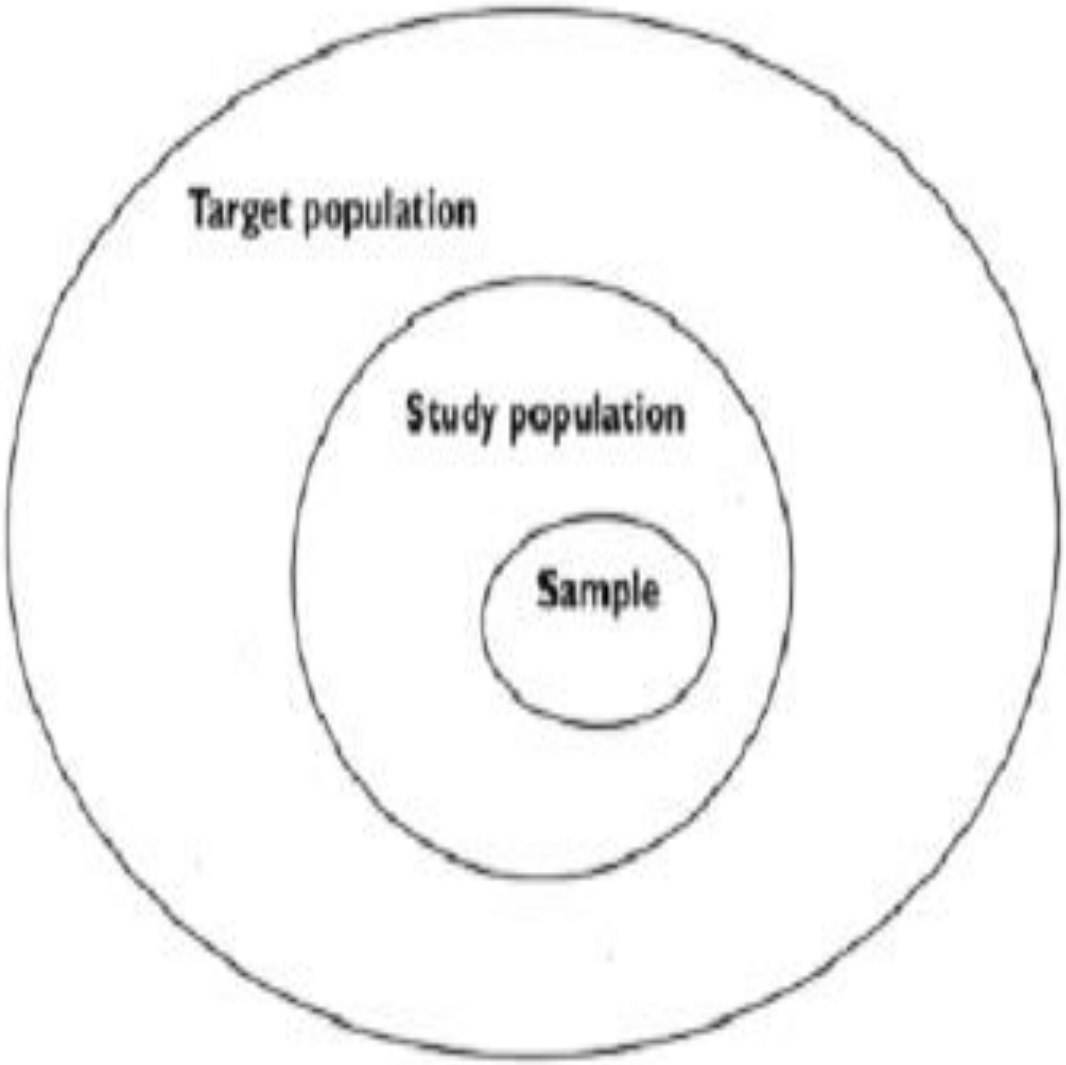
- The period where the data will be collected.
  - **Example:** the study will be conducted from January to March, 2020.

Source and Study population

- ***Target/source/theoretical population***
  - Source population refers to the entire group of individuals or objects to which researchers are interested in generalizing the conclusions.
  - A collection of items that have something in common for which we wish to draw conclusions at a particular time.
  - The target population usually has varying characteristics and it is also known as the theoretical or target population.

Study population

- But, because of practicalities, entire target population often cannot be studied.
- The specific population from which data are collected



Eg., In a study of the prevalence of Corona virus among orphan children in Ethiopia, a random sample of orphan children in lideta kifleketema were included

Target population: All orphan children in Ethiopia

Study population: All orphan children in Addis Ababa

Sample population: orphan children in lideta kifle ketema

Inclusion and Exclusion Criteria

- **Inclusion Criteria:** the set of criteria which is important to include the study participant in to the research
- **Exclusion criteria:** which help us to exclude those individuals which will not be part of our study.
  - They should be part of the inclusion criteria

•VALIDITY AND RELIABILITY

VALIDITY

- Validity Refers to the degree which the tool measures, what it is intended to measure,
- It refers to whether the instrument or scale is quantifying what it claims to.
- Does it measure what you think it measures.

- e.g. 'Weight' scale measures body weight and it is valid;

TYPES OF VALIDITY

1) Face validity
2) Content validity
3) Construct validity
4) Predictive validity
5) Concurrent validity
6) Criterion related validity

Face Validity

- Just on its face the instrument appears to be a good measure of the concept.
- Face validity refers to whether the instrument looks as though it is measuring the appropriate construct. Although face validity should not be considered strong evidence for an instrument's validity
  - e.g. Concept=pain level
  - Measure=verbal rating scale "rate your pain from 1 to 10".

Face validity is sometimes considered a subtype of content validity.

Content Validity

- Content validity concerns the degree to which an instrument has an appropriate sample of items for the construct being measured and adequately covers the construct domain.
- Content validity is relevant for both affective measures (i.e., measures relating to feelings, emotions, and psychological traits) and cognitive measures.
- For example, a depression measure should cover the checklist of depression symptoms.

Construct Validity

- In construct validity, the investigator is concerned with the questions the concept under investigation being adequately measured? Is there a valid basis for inferring the scores?
- This begins when the investigator formulates hypotheses, based on theory.
- Evidence of construct validity is not established within a single study. Variables like anxiety.

Predictive Validity

- Predictive validity refers to the adequacy of an instrument in predicting performance or behavior of individuals on some future criteria, e. g. How well does the admission test predict the future performance of the student?
- The ability of one measure to predict another future measure of the same concept.

Concurrent Validity

- Concurrent validity refers to an instrument's ability to differentiate individuals who change on a present criterion.
- It involves concurrent (i.e. simultaneous) measurement of the scale being validated.
- E.g.- a psychological test to differentiate between those patients in a mental institution who can and cannot be released could be correlated with current behavioral ratings of health care personnel.

Criteria-Related Validity

- Check the performance of operationalization against some criterion.
- In criterion-related validity, a prediction is made about how the operationalization will *perform* based on our theory of the construct.
- For example, the instrument measuring anxiety state is said to be valid if the anxiety scores correlate with some criterion, such as, person who are known to be anxious (e. g. Student prior to a difficult examination) would be expected to have high scores on the anxiety scale.

RELIABILITY

- Means "repeatability" or "consistency".

- It is an ability of an instrument to consistently measure, what is suppose to measure.
- A measure is considered reliable if it would give us the same result over and over again (assuming that what we are measuring isn't changing!).

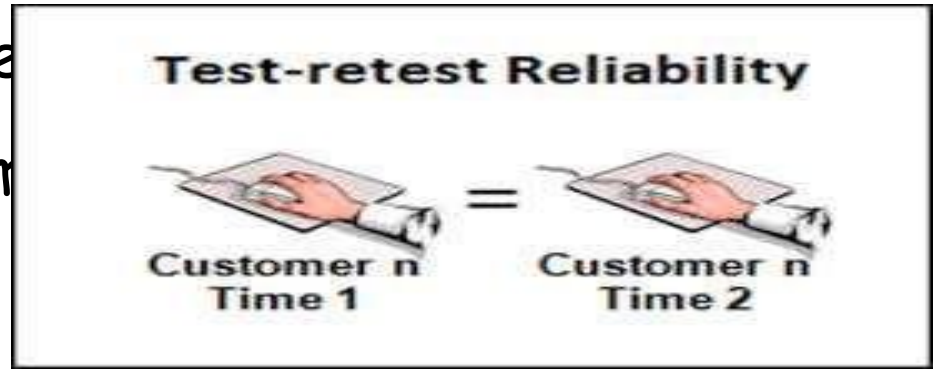
Types of Reliability

1) Stability
2) Equivalence
3) Internal consistency

1) Stability

- **Stability measure by a method called as Test-Retest method.**

- Used to assess the consistency of a measure from one time to another.
- The administration of the same subjects two or m conditions

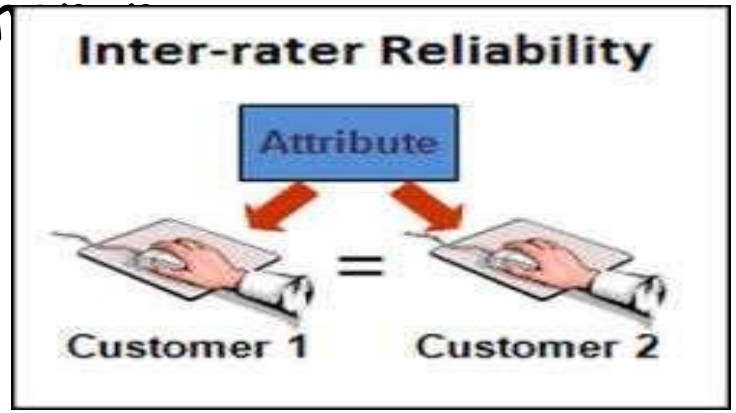


2) Equivalence

- equivalence checked by 2 method

1) Inter-Rater or Inter-Observer Reliability

- Used to assess the degree to which different raters/observers give consistent estimates of the same phenom



2) **Parallel method** (contd.)

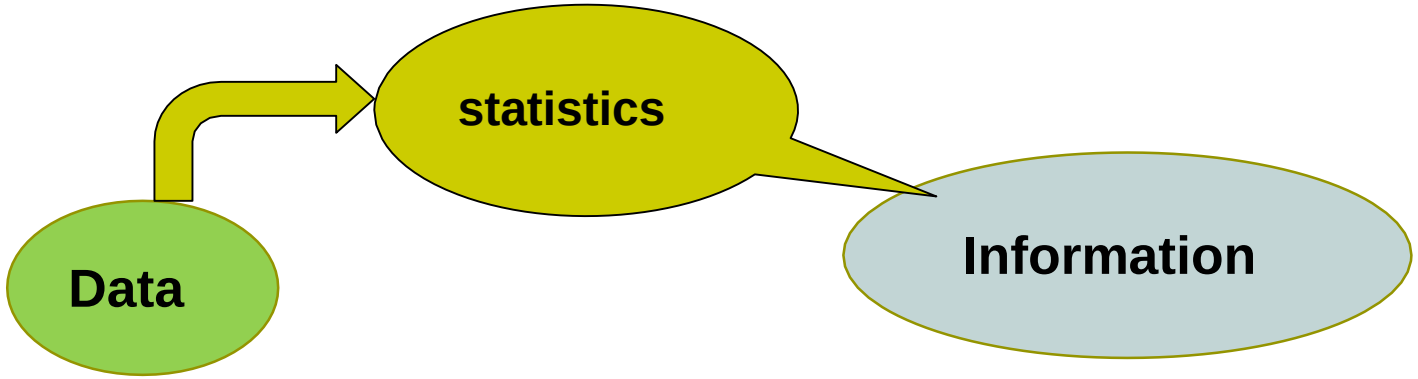
- Used to assess the consistency of the results of two tests constructed in the same way from the same content domain.
- Create a large set of questions that address the same construct and then randomly divide the questions into two sets and administer both instruments to the same sample of people.
- The correlation between the two parallel forms is the estimate of reliability.
- One major problem with this approach is that you have to be able to generate lots of items that reflect the same construct.

3) Internal Consistency Reliability

- Used to assess the consistency of results across items within a test.
- It is an ability of an instrument to measure all its sub parts.
- Split halves technique used with cronbach's alpha formula.
- We are looking at how consistent the results are for different items for the same construct within the measure.

Data and information

- What is data?
  - (Types of data)
- what is information?
- Where does ***data*** come from?
- **Statistics** is a tool for converting ***data*** into ***information***



Sample

- is a group of people, objects, or items that are taken from a larger population for measurement.
- group of items from which observation will be actually made

- The sample should be **representative** of the population to ensure that we can generalize the findings from the research sample to the population as a whole.

Basic Terms

- **A population:** is a group of individuals persons, objects, or items from which samples are taken for measurement
- **Census:** Obtained by collecting information about each member of a population
- **Sample:** Obtained by collecting information only about some members of a "population"
- **Sampling Frame;** is the list of people from which the sample is taken.
- **Probability samples:** each population element has a known (non-zero) chance of being chosen for the sample.
- **Non-probability samples:** we do not know the probability that each population element will be chosen, and/or we cannot be sure that each population element has a non-zero chance of being chosen

Advantage of sampling

Samples offer many benefits:

- **Save costs:** *Less expensive to study the sample than the population.*
- **Save time:** *Less time needed to study the sample than the population*
- **Accuracy:** *Since sampling is done with care and studies are conducted by skilled and qualified interviewers, the results are expected to be accurate.*
- **Destructive nature of elements:** *For some elements, sampling is the way to test, since tests destroy the element itself.*

Limitations of Sampling

- **There is always error**

- **Sampling error** is any type of bias that is attributable to mistakes in either drawing a sample or determining the sample size

- **Non-sampling** error is any error which will be committed during data collection, coding, entry, and so on

Sample Size Determination

- How many completed questionnaires do we need to have a representative sample?
- Generally the larger the better, but that takes more time and money.
- Answer depends on:
  - How different or dispersed the population is.
  - Desired level of confidence.
  - Desired degree of accuracy.
  - Desired margin of error

Sample Size …

- Sample size may be determined by using:
  - Subjective methods (*less sophisticated methods*)
    - The rule of thumb approach: eg. 5% of population
    - Conventional approach: eg. Average of sample sizes of similar other studies;
    - Cost basis approach: The number that can be studied with the available funds;
    - Depending on the number of independent variables
  - Statistical formulae (*more sophisticated methods*)
    - Confidence interval approach.

Sample size determination using statistical formulae:

The confidence interval approach

- **To determine sample sizes using statistical formulae, researchers use the confidence interval approach based on the following factors:**
  - ***Desired level of data precision or accuracy;***
  - ***Amount of variability in the population (homogeneity);***
  - ***Level of confidence required in the estimates of population values.***
- **Availability of resources such as money, manpower and time may prompt the researcher to modify the computed sample size.**

Statistical Formula

- Sample size formula, in general, depends on the number of study population:
  - Single population
  - Two population

1. Sample size for single population proportion

- If the study aims to be conducted on single population, then we need the following
  - What is the **probability of the event** occurring?
  - How much **error** is tolerable (confidence interval)? How much **precision** do we need?
  - How **confident** do we need to be that the true population value falls w $n = \frac{z^2_{\alpha/2} p(1-p)}{w^2}$ e interval?

- Then the formula for the sample size of single population proportion is defined as:

$$n = \frac{z^2_{\alpha/2} p(1-p)}{w^2}$$

- Where
  - α = The level of significance which can be obtain as 1-confidence level.
  - p = best estimate of population proportion
  - w = Maximum acceptable diffrence
  - $z_{\alpha/2}$ = The value under standard normal table for the given value of confidence level

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Some Considerations

- The final sample size will be corrected for:
  - Nonresponse, lost to follow up, lack of complince and so on.
  - Connsider the total size of the population (N): if $N < 10000$ then we need correction formul which is defined by:

$$n_f = \frac{n_0}{1 + \frac{n_0}{N}}$$

Where n_f=final sample size, n_0=sample size from the above formula and N=total population.

  - take the design effect in to account if needed

Design effects

- The loss of effectiveness by the use of cluster sampling instead of simple random sampling is design effect.

- Working definition of design effect is that factor by how much sample variance for the sample plan exceeds simple random sample of same size.

- How much worse your sample is from a simple random sample
  - For cluster sampling, design effect is 2
  - For multistage sampling design effect is equal to the number of stages

Example

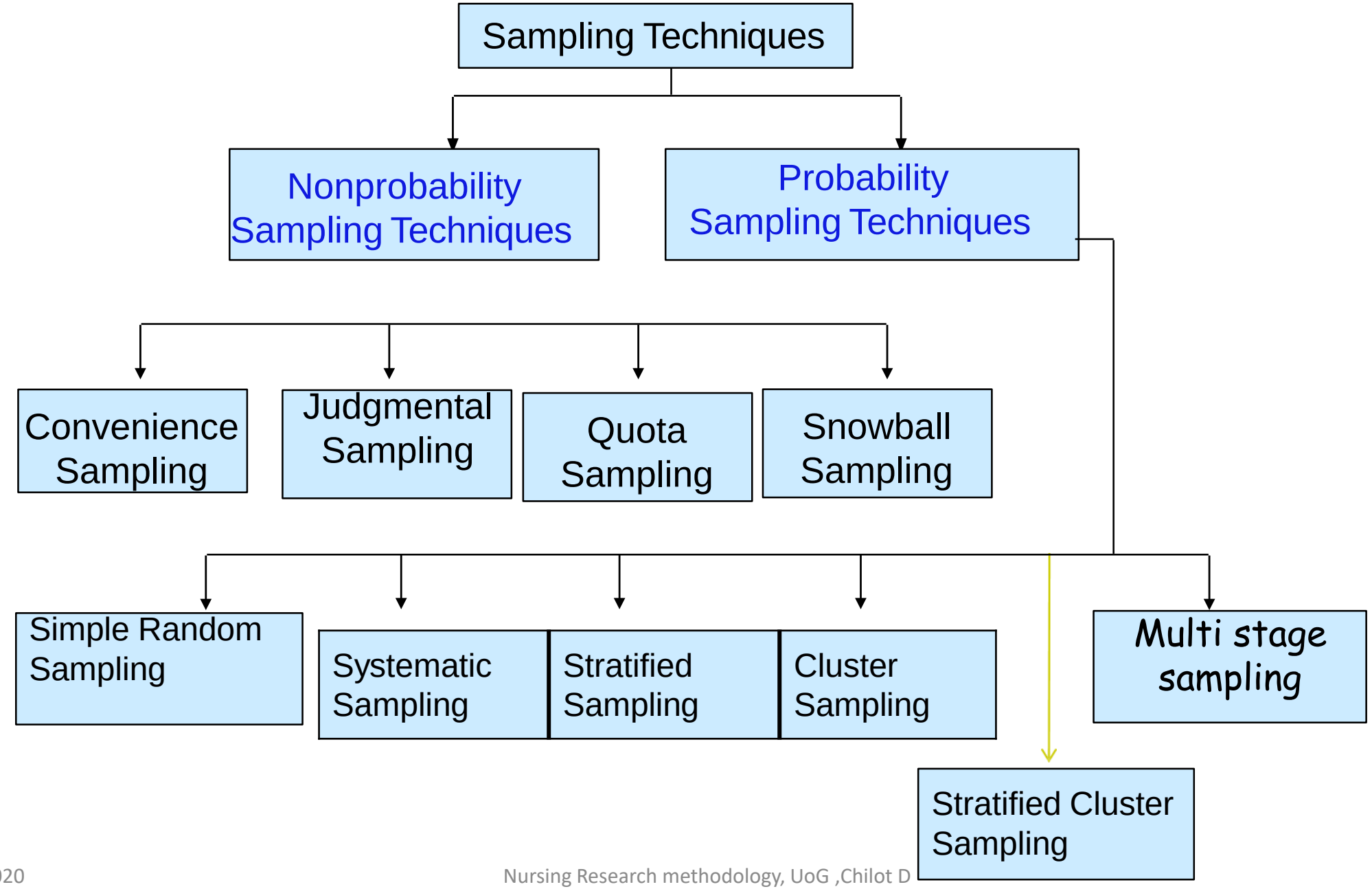
- One of MSc Nursing student want to conduct a research on the prevalence of surgical site infection. Given that the prevalence from the previous study found to be 35% , what will be the sample size he should take to address his objective?

- **Solution**
  - Margin of error d= 5%
  - A confidence level of 95% will give the value of as Za/2=1.96.
  - Then using the formula of:
  - n=350

$$n = \frac{z^2_{\alpha/2} p(1-p)}{w^2}$$

Sampling Technique

Sampling is the process of selecting a small number of elements from a larger defined target group of elements such that the information gathered from the small group will allow judgment to be made about the larger groups


Sampling Techniques
Nonprobability Sampling Techniques
Probability Sampling Techniques
Convenience Sampling
Judgmental Sampling
Quota Sampling
Snowball Sampling
Simple Random Sampling
Systematic Sampling
Stratified Sampling
Cluster Sampling
Multi stage sampling
Stratified Cluster Sampling

Probability/Random sampling

- If the characteristic we are going to study is uniformly distributed throughout the larger population, we can use:
  - Simple random sampling (SRS), or
  - cluster sampling provided that there is a means to cluster the population
- If there is another variable by which the distribution of the characteristic could importantly vary, we can stratify the population by that variable (stratified sampling)
- Stratification could be integrated with SRS, systematic random sampling, cluster sampling, or multistage sampling

Cont…

- ✓ Sometimes the population that we want to study could be distributed in a very large geographic area or large population.
- ✓ In that case, covering the whole study area will be costy.
  - ➢ Multistage sampling could be more appropriate

Example

- To study the prevalence of use of family planning in Dabat district, we may assume that the distribution is uniform in all the kebeles of the district. Therefore, we can select 6 kebeles randomly from which only some of the households and then at least one of the women will be sampled.

Questions: In this example, identify the number and name of stages?

How can we decided?

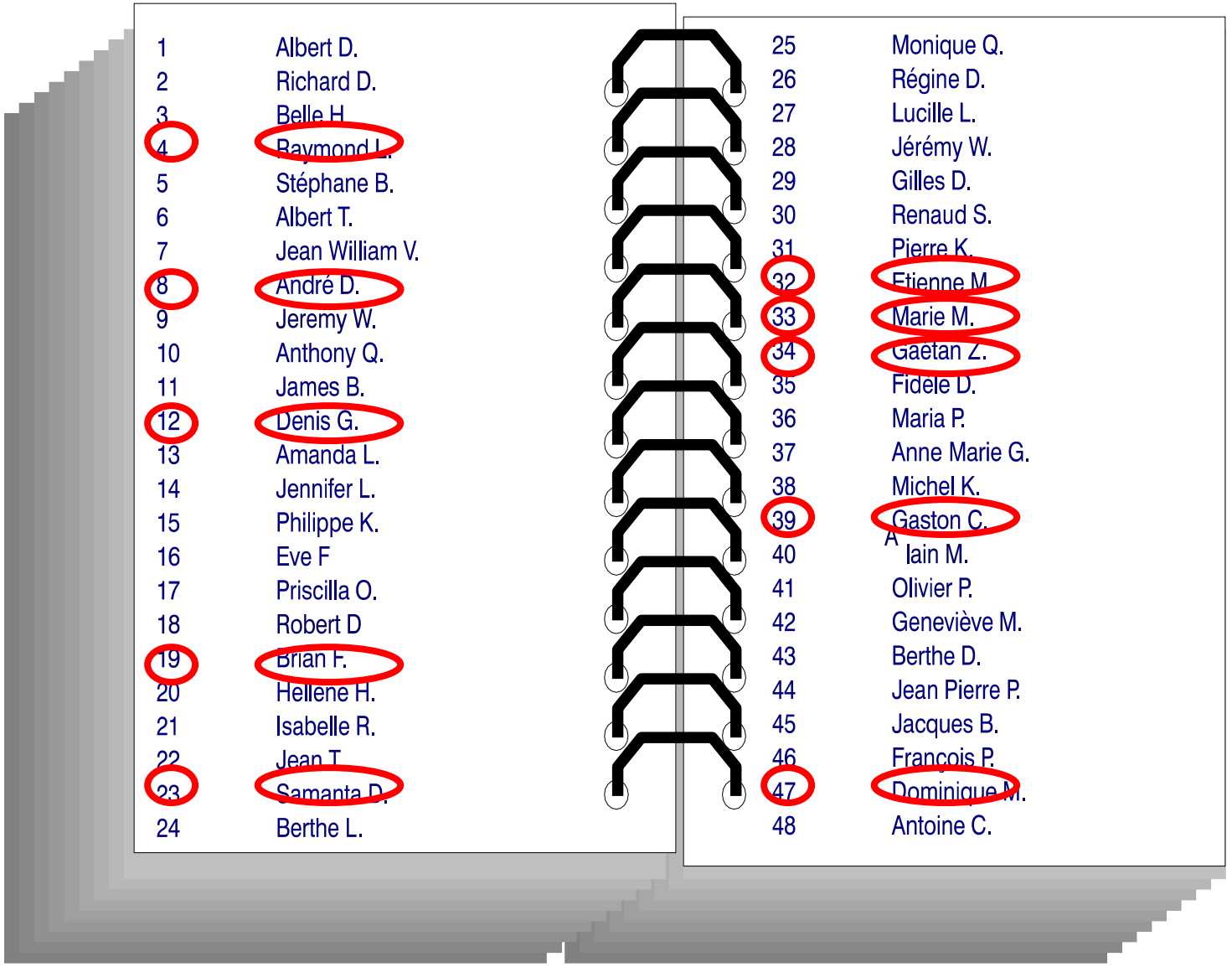
- To decided type of sampling technique use in our study, we have to considered:
  - Homogeneity with respect to the variable of interest
  - Availability of frame
  - Geographical area

1. Simple Random Sampling

- Simple random sampling is the most straightforward of the random sampling strategies.
- All possible samples of n subjects are equally likely to occur

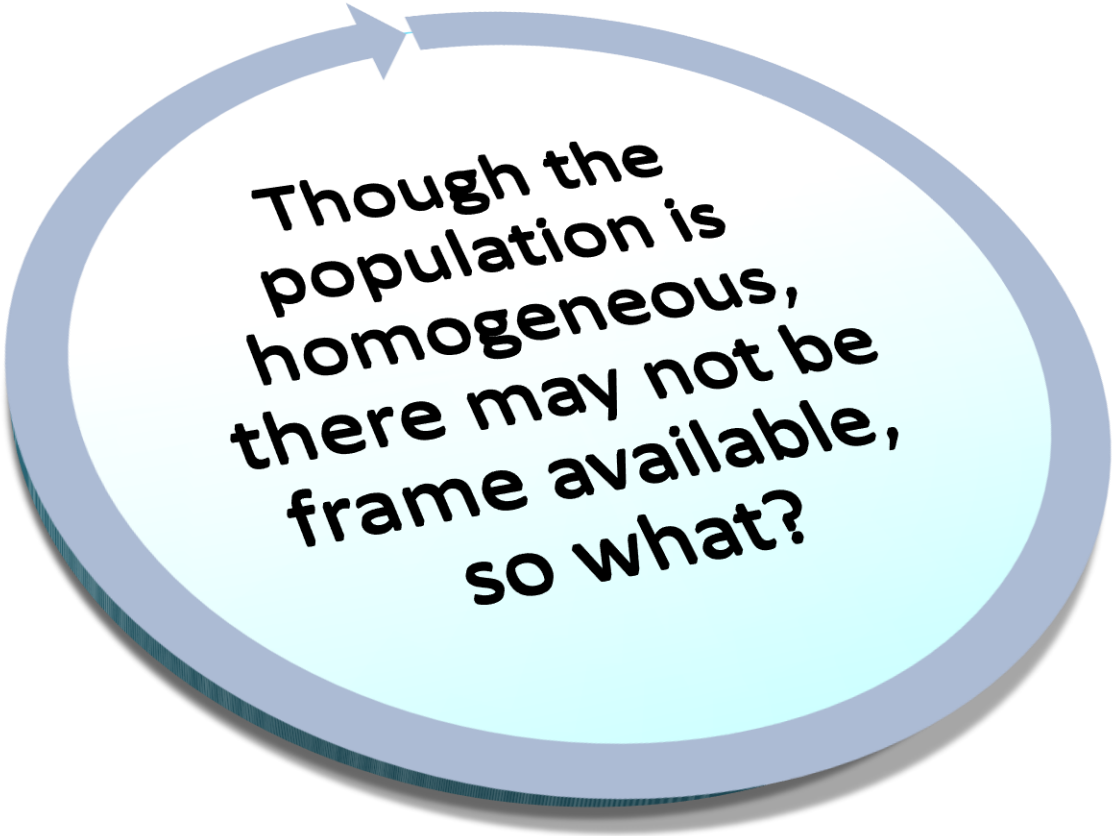
- How do we actually take a random sample?
- Depending on the complexity of the population, we can use different tools to select n samples from the frame.
  - These are lottery method,
  - table of random number
  - computer generated random number.
- Lottery method is appropriate if the total population is not too large, otherwise if the population is too large then it will be very difficult to use lottery method.
- Thus, table of random number or computer generated random number is the feasible method to be used.

Simple random sampling



Assumption of the population

- Homogeneity with respect to the variable of interest
- Availability of frame


Though the population is homogeneous, there may not be frame available, so what?

2. Systematic random sampling

- The population is assumed to homogeneous, but no frame is available

- Selection of individuals from the sampling frame **systematically**
- Individuals are taken at **regular intervals** down the list
- *The starting point is chosen **at random***

Important if the reference population is arranged in some order:

- Order of registration of patients
- Numerical number of house numbers
- Student's registration book

Steps in Drawing a Systematic Random Sample

1: Obtain a list of units that contains an acceptable frame of the target population

2: Determine the number of units in the list and the desired sample size

3: Compute the skip interval

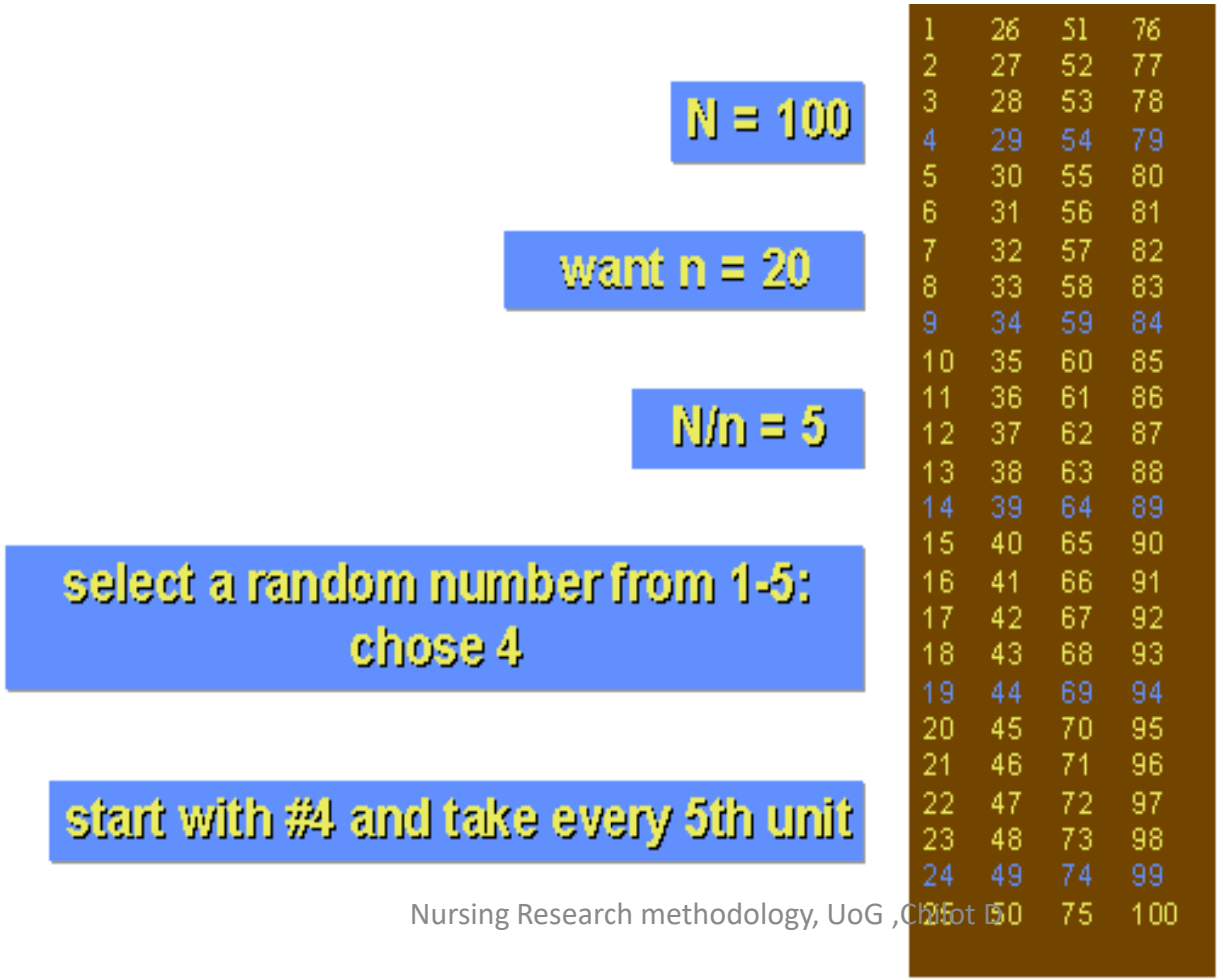
- The population is listed in a particular order, then every k^{th} unit is selected
  - Start at a random point between 1 and *k*
  - Here k is chosen so that $N \approx kn$

4: Determine a random start point

5: Beginning at the start point, select the units by choosing each unit that corresponds to the skip interval

Systematic random sampling

- Example: the researcher wants to know the prevalence of malnutrition among under 5 children in woreda x



E.g. Systematic sampling

- N = 1200, and n = 60
  - ⇒ sampling fraction = 1200/60 = 20
- List persons from 1 to 1200
- Randomly select a number between 1 and 20 (ex : 8)
  - ⇒ 1st person selected = the 8th on the list
  - ⇒ 2nd person = 8 + 20 = the 28th
  - etc .....

05:28


Even though
there is frame,
the population
may be
heterogeneous,
so what?

3. Stratified Random Sampling

Stratified random sampling is a method of probability sampling in which the population is divided into different subgroups and samples are selected from each subgroup

Stratified sampling

A three-stage process:

- **Step 1-** Divide the target population into homogeneous subgroups or strata
- **Step** 2- Decided which type of stratified sampling to use
- **Step 3-** Draw random samples fro each stratum
- **Step 4-** Combine the samples from each stratum into a single sample of the target population

Stratified samples can be:

- **Proportionate:** involving the selection of sample elements from each stratum, such that the ratio of sample elements from each stratum to the sample size equals that of the population elements within each stratum to the total number of population elements.
- **Disproportionate:** the sample is disproportionate when the above mentioned ratio is unequal.

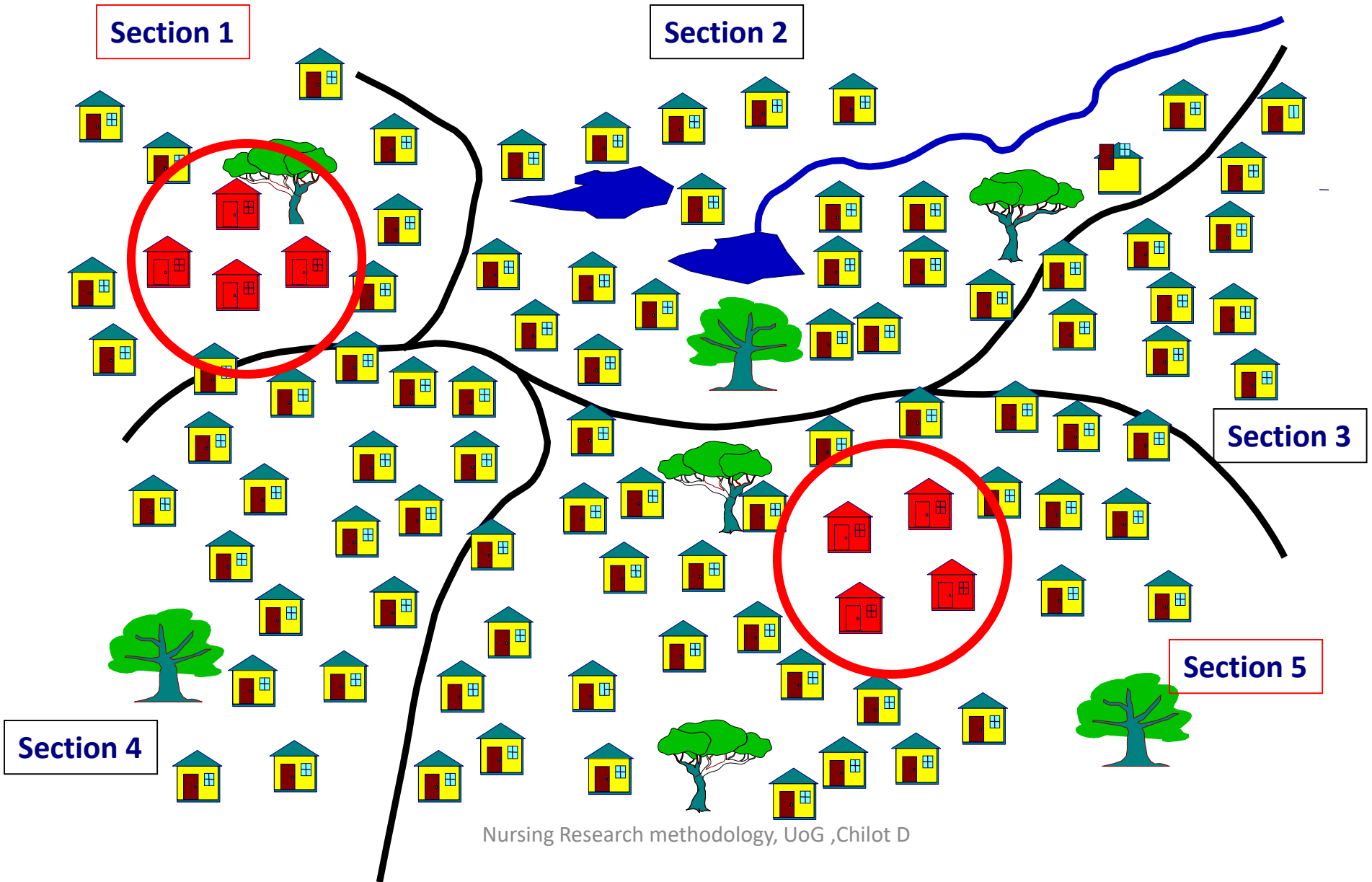
Cluster sampling

- If the study covers wide geographical area, using the other methods will be too costly.
- The idea is, divided the total population in to different clusters and then the unit of selection will be cluster.
- Therefore, total population in the selected cluster will be taken as the sample.

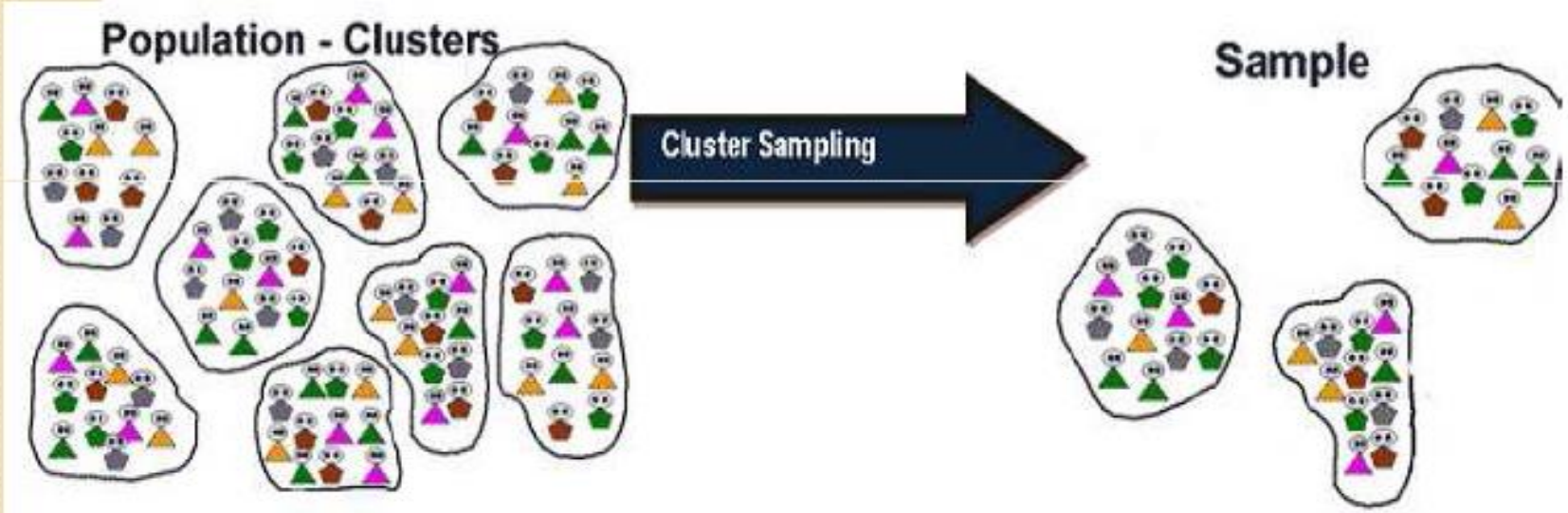
Cluster sampling

- Steps in cluster sampling are:
  - Define the population
  - Determine the desired sample size
  - Identify and define a logical cluster (can be kebele, Got, residence, and so on)
  - Make a list of all clusters in the population
  - Estimate the average number of population number per cluster
  - Determine the number of clusters needed by dividing the sample size by the estimated size of the cluster
  - Randomly select the required number of clusters (using table of random number as the total number of clusters is manageable)
  - Include in the sample all population in the selected cluster.

Example: Cluster sampling



- Consider the following graphical display:



45

Cluster sampling

- **Advantages**
  - Simple as complete list of sampling units within population not required
  - Less travel/resources required
- **Disadvantages**
  - Potential problem is that cluster members are more likely to be alike, than those in another cluster (homogenous)….
  - This “dependence” needs to be taken into account in the sample size….and the analysis (“design effect”)

Multi-stage Sample Designs

- Many surveys use complex sample designs that combine several of the above elements in a multi-stage sampling framework
- Sometimes the population is too large and scattered for it to be practical to make a list of the entire population from which to draw a SRS.
- Suppose that each unit in the population can be divided into a number of smaller units, or subunits

Multistage …

- The prime stimulus for multi-stage sampling is administrative convenience

- As with cluster sampling, we select c of C clusters, but now instead of sampling all units in each cluster, we take a random sample. Most large surveys carried out this way

Selecting a sampling method

- Population to be studied
  - Size/geographical distribution
  - Heterogeneity with respect to variable
- Availability of list of sampling units
- Level of precision required
- Resources available

Non-probability sampling

- Every element in the universe [sampling frame] does not have equal probability of being chosen in the sample.
- Operationally convenient and simple in theory.
- Results may not be generalized.
- When using non-probability sampling, sample size is unrelated to accuracy, so cost benefit consideration must be used.

Non-probability samples…

- **Convenience sampling**
  - *Drawn at the convenience of the researcher. Common in exploratory research. Does not lead to any conclusion.*
- **Judgmental sampling**
  - *Sampling based on some judgment, gut-feelings or experience of the researcher. If inference drawing is not necessary, these samples are quite useful.*
- **Quota sampling**
  - It is the non-probability equivalent of stratified sampling.
  - This differs from stratified sampling, where the stratums are filled by random sampling.
- .

5. Snowball sampling

- It is a special non-probability method used when the desired sample characteristic is rare.
- Snowball sampling relies on referrals from initial subjects to generate additional subjects.
- What we need to do in case of snowball sampling is that first identify someone who meets the criteria and then let him/her bring the other he/she knew.
- While this technique can dramatically lower search costs, it comes at the expense of introducing bias because the technique itself reduces the likelihood that the sample will represent a good cross section from the population.

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Conclusions

- Probability samples are the best
- Ensure
  - Representativeness
  - Precision
- …..within available constraints

Variables

- variable…
  - any observation that can take on different values
- attribute…
  - a specific value on a variable

Examples

Variable	Attribute
age	

Examples

Variable	**Attribute**
age	18, 19, 20, etc...

Examples

Variable	Attribute
Gender or sex	

Examples

Variable	Attribute
Gender or sex	Male, female

Examples

Variable	Attribute
satisfaction	

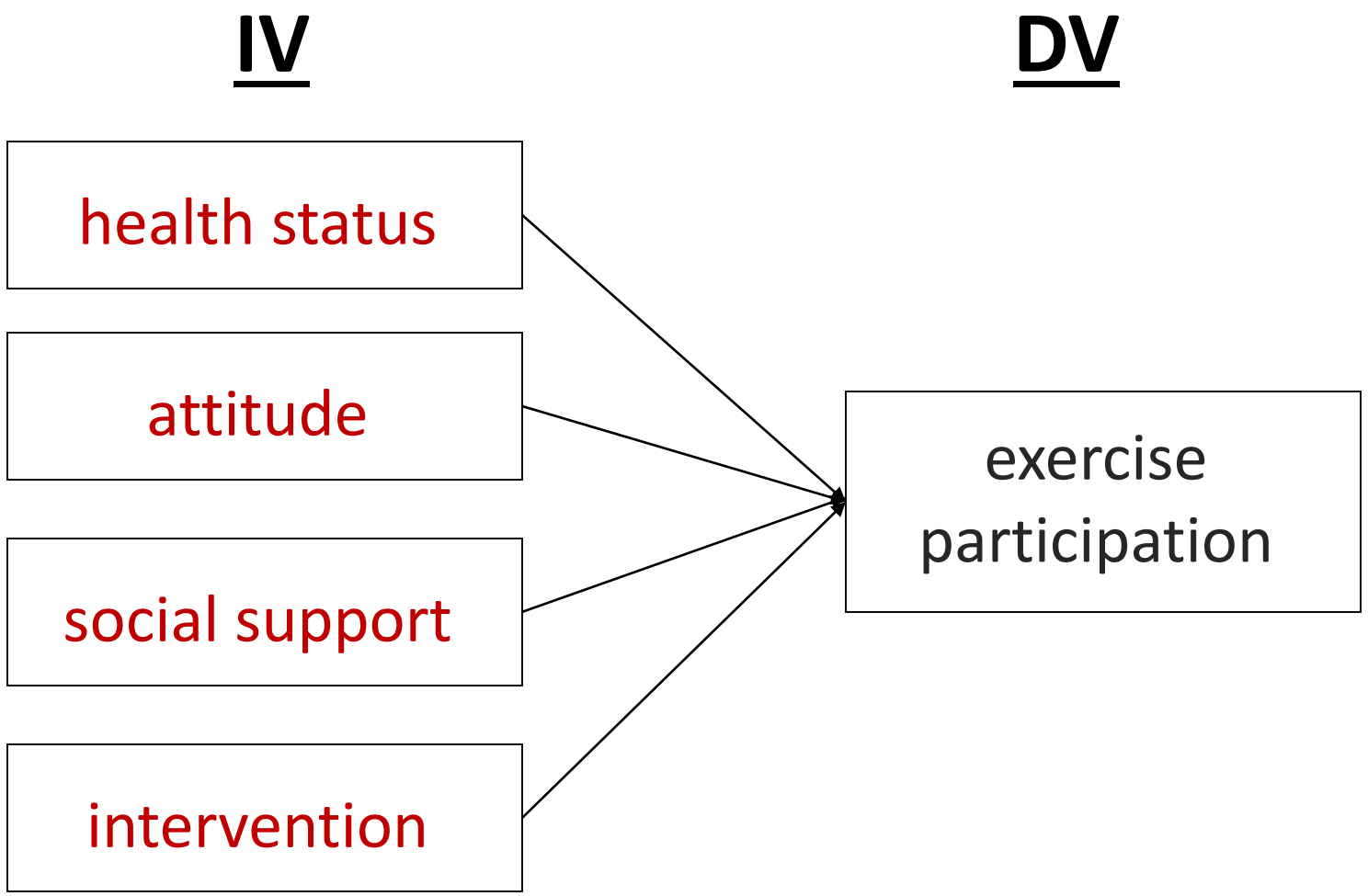
Examples

Variable	Attribute
satisfaction	1 = very satisfied
	2 = satisfied
	3= somewhat satisfied
	4 = not satisfied
	5 = not satisfied at all

Types of Variables

- independent variable (IV)…
  - what you (or nature) manipulates in some way
- dependent variable (DV)…
  - what you presume to be influenced by the IV

Examples


IV
DV
health status
attitude
social support
intervention
exercise participation

Example

- In a study to determine whether surgery or chemotherapy results in higher survival rates for a certain type of cancer, whether or not the patient survived is one variable, and whether they received surgery or chemotherapy is the other.
  - Which is the explanatory variable and which is the response variable?

Dependent Vs Independent

- Determined by the statement of the problem and objectives of the study
  - Relationship between smoking and lung cancer
    - Independent variable: smoking
    - Dependent variable: Lung cancer
  - Study on reasons for smoking
    - Independent variable: peer pressure, to release stress, etc
    - Dependent variable: smoking

Example

- In a study to determine whether surgery or chemotherapy results in higher survival rates for a certain type of cancer, whether or not the patient survived is one variable, and whether they received surgery or chemotherapy is the other.
- Which is the explanatory variable and which is the response variable?

Operationalizing variables

- Some variables are measureable as such, but some need indicators
- Conceptual definition

  Characteristic we would like to measure

  e.g- knowledge level
- Operational definition

  Characteristic we would actually measure

  In a set of 10 questions:
  - 0-3 correct answers → poor
  - 4-6 correct answers → reasonable
  - 7-10 correct answers → good

Data Collection Methods

- Sources of data
- Types of data collection methods
- Factors considered in choice of method
- Data collection tool

Primary data

New data which are originally collected for a specific purpose

Examples: Survey

Secondary data

An existing data to investigate research questions other than those for which the data were originally gathered (routinely available information).

Examples: Hospital statistics

Types of data collection methods

- **Quantitative data collection methods (in numbers)**
  - Using available information (secondary data)
  - Interviewing
  - Administering questionnaire

- **Qualitative data collection methods (in words)**
  - Focus group discussion (FGD)
  - In-depth interview (IDI)
  - Observation

Using available information

- Census data
- Unpublished reports
- Hospital records
- Information routinely collected by others

Using available information cont…

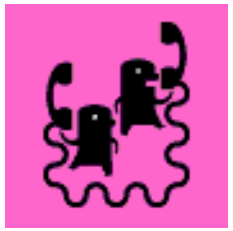
- Advantage of available data – collection is inexpensive

- Disadvantage of existing data:
  - It is some times difficult to gain access to records or reports
  - Data may not always be complete and precise enough, or too disorganized

Interviewing

- A technique that involves oral questioning of respondents (questionnaire)

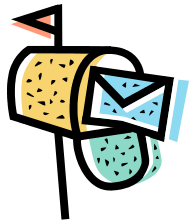
- Face to face interview
- Telephone interview



Administering written questionnaire

- Also called self-administered questionnaire
- Questions are presented that are to be answered by the respondents in written form

- Gather the respondents & give instruction
- Mailing
- Online



Administering written questionnaires cont…

Advantages:

- less expensive
- permits anonymity & may result in more honest responses
- does not require research assistants
- eliminates bias due to phrasing questions differently with different respondents

Administering written questionnaires cont…

Disadvantages:

- Cannot be used with illiterates
- there is often a low rate of response
- questions may be misunderstood

Types of questions

- **Closed questions**
- **Open-ended questions**
- **Semi-opened questions**

Closed questions

- A list of possible answers or options
- Commonly used for background variables
- Should be exhaustive & mutually exclusive

What is your marital status?

1. Single
2. Married
3. Divorced
4. Separated
5. Widowed

Open-ended questions

- Free to answer with fewer limits imposed by the researcher
- Useful for exploring new areas

What is your opinion on the services provided in the antenatal (AN) care?

_____

_____

Semi-opened questions

What is your occupation?

(1) Dependent

(2) Manual labourer

(3) Government employee

(4) Private employee

(5) Owned business

(6) Others (please specify) _____

Steps in designing a questionnaire

Step 1: Think for the **objectives and variables**

Step 2: Decide on the main section

Step 3: Write out the questions

Step 4: Sequencing the questions

Step 5: Compose a draft

Step 6: Take out any questions that are not essential

Step 7: Validate

Step 8: Pretest

Points to consider

- Use simple language
- Avoid conjunctive items
- Avoid questions that have ambiguous words or phrases
- Avoid questions about behavior that are not bounded by time
- Start with the easy questions
- Ask all respondents each question in exactly the same way
- Do not overload your interview schedule

Focus group discussion

- Group discussion of 6-12 persons
- Guided by a facilitator

- Group members talk freely and spontaneously on a certain topic

In-depth interview and key informant interview

- Group interviews are not appropriate for asking sensitive issues

- Interview guide
  - IDI guide
  - KII guide

Observation

A technique which involves systematically selecting, watching and recording behavior and characteristics of living beings, objects or phenomena

- **Participant observation**

  The observer **takes part** in the situation he or she observes

- **Non-participant observation**

  The observer watches the situation, openly or concealed, but **does not participate**

Factors to be considered in choice of method

- Review your study objective
- What type of information do you require
- Independent and dependent variables
- Characteristics of the study population (age, literacy)
- Accessibility to sample (time, infrastructure)
- Which type of data collection technique will be used to gather the information you need

View different methods of data collection

Prevalence of hypertension may be obtained by

- Measuring blood pressure

  (clinical measurement)
- Asking a person if he/she has hypertension

  (interview)
- Record study

  (document review)

Differences between data collection techniques and data collection tools

Data collection techniques	Data collection tools
Using available information	Checklist; data compilation forms
Observation	Eyes and other senses, pen/paper, watch, scales, microscope, etc..
Interviewing	Interview guide, checklist, questionnaire, tape recorder
Administering written questionnaire	Questionnaire

Conclusion on Data collection

- Data collection techniques and tools
  - Data collection method
  - Data collection tool
  - Who will collect the data?
  - Who will supervise the data collection?
  - How long will take the data collection? etc

Data Quality Control Issues

Describe/provide:

- Operational definitions of crucial concepts
- training of data collectors/supervisor
- Field testing the research methods and tools
- Supervision data collection process

Pretesting and Pilot study

- 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

Data processing

Refers to:

- data checks and correction, and
- data entry into a computer

- No matter how carefully the data have been entered some errors are inevitable.
- The aim of this process is to produce a relatively 'clean' data set ready for analysis

Data analysis

- Data analysis: coding, entering, cleaning, storing, recoding, choice of statistical methods
- A plan for data analysis should include the following information:
  - Identification of the analysis tasks to be completed
  - Identification of the statistical software to be used for the analysis
  - A schedule or work plan for the analysis of the data
  - A plan for quality control of the data analysis, including regular checks which involve review and assessment of the quality of a sample of the analysis already performed

Ethical Considerations

- Professional obligation to safeguard the safety of study participants
- Refer to national and international guidelines
- Describe potential ethical concerns and mechanisms to minimize harm and maximize benefits
  - *Every research can potentially cause ethical concerns!!*

- Description of ethical issues related to the study. For example consider:
  - Approvals from relevant groups (e.g. UoG)
  - Informed consent (subject information and informed consent form appended)
  - Benefit of the research
  - Confidentiality

Dissemination and Utilization 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

Work plan

- Work plan summarizes (in a table, chart, graph) the various components of a research project and how they fit together.
- Includes:
  - Tasks to be performed
  - When the task will be performed
  - Who will perform the task (identify human resource needed for each task)
  - Number of staff needed to perform the task

Work plan cont..

A work plan can serve as:

- a tool in planning the details of the project activities and later the project funds.
- a visual outline or illustration of the sequence of the project operations.
- a management tool for the principal investigator and/or members of his/her team, showing what tasks and activities are planned, their timing, and when various members will be involved in the tasks;
- a tool for monitoring and evaluation, when the current status of the project is compared to what was foreseen in the work plan.

Work plan….

- Ways of presenting a work plan
  - Work schedule
  - GANNT chart
  - PERT chart.

Work plan cont..

The Work Schedule

- Is a table
- Summarizes:
  - tasks to be performed
  - duration of each activity, and
  - staff responsible.
- *The work schedule does not show how various tasks are related, nor give a visual picture of the time schedule*.

Work plan cont..

The GANTT Chart

- Is a planning tool which depicts graphically the order in which various tasks must be completed and their duration of activity.

A typical Gantt chart includes the following information:

- The tasks to be performed
- Who is responsible for each task; and
- The time each task is expected to take.
- The length of each task is shown by a bar that extends over the number of days, weeks or months the task is expected to take.

The Gantt chart *doesn't show how various tasks are related.*

GANNT CHART

S.N	Activity	Responsible Agent	Feb	Mar	April	May	June
1	Development of the research proposal	Investigators					
2	Securing ethical clearance						
3	Securing budget	Funding agency					
4	Ethical clearance from respective authorities	Investigator					
5	Recruitment and training of data collectors and supervisor	Investigator					
6	Pre-testing questionnaire	Investigator, supervisor and data collector					
7	Data collection	Investigator, supervisor and data collector					
8	Data coding, entry and cleaning	Investigator					
9	Data analysis	Investigator					
10	Thesis write up & submission of first draft	Investigator					
11	Second draft submission	Investigator					
12	Defense	Investigator					
13	Final report submission						

Work plan cont..

The PERT Chart

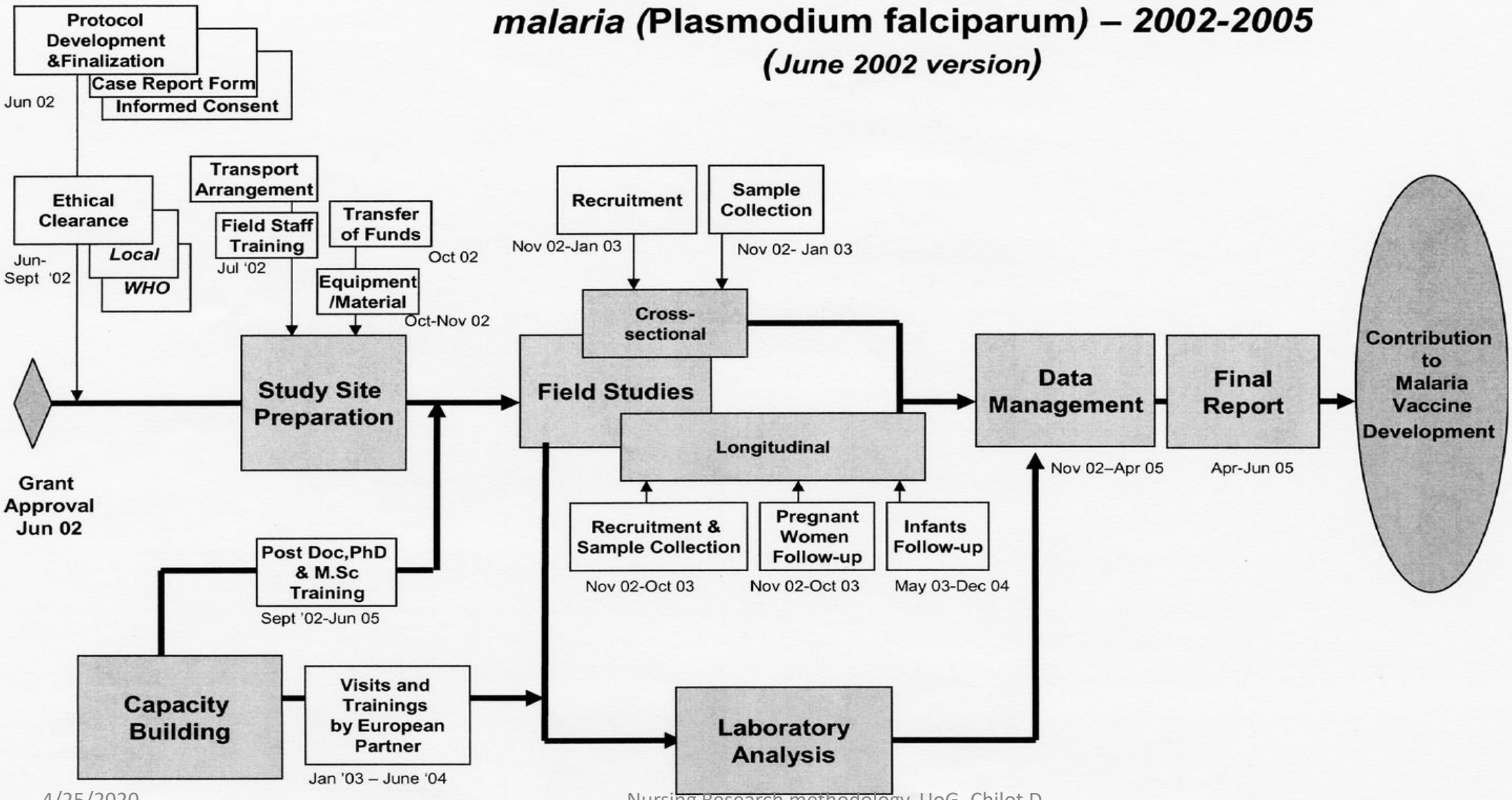
- PERT - Program Evaluation Review Technique
- PERT chart involves identifying the various "steps" necessary for implementing a project and then planning the optimal feasible schedules for completing a study.
- **PERT chart** shows the steps or events in the project that must be completed as well as illustrating graphically how the steps are interrelated.
- It has the added advantage of helping the investigator determine the best timing for particular tasks and how to complete the project in the least possible time.

- *It doesn't indicate who will complete the work*
- *It is somewhat more complicated to use than the other techniques.*

Example - PERT chart

KEP antibodies levels in humans naturally exposed to malaria (Plasmodium falciparum) – 2002-2005

(June 2002 version)



Budget

- How should a budget be prepared?
  - It is necessary to use the work plan as a starting point.
  - Specify, for each activity in the work plan, what resources are required.
  - Determine for each resource needed the unit cost and the total cost.
  - The budget for the fieldwork component of the work plan will include funds for personnel, transport and supplies.
  - Include a 5%-10% contingency fund

Annex

- Include in the appendices of your proposal any additional information you think might be helpful to a proposal reviewer.
- For example, include:
  - Biographical data on the principal investigator
  - The study questionnaire if you have it.
  - The consent form.
  - A copy of the approval from the Institutional Review Board.

Your Proposal

- Simple and clear
- Good statement of the problem: why do you want to study?
- Pertinent literature review
- Few objectives
- Clear and detailed methodological description
- Good work plan
- Reasonable budget

Results and Discussion

- At the end of this chapter you will be able to write a research results and discussion

Results

- Purpose → to describe the results of data analysis that are relevant to the study

- This component is the core section of the scientific report and which is presented by tables, figures, chartes, *etc.*

- The results should be presented in an orderly sequence using an outline

- The sequence of the results should follow the sequence of the objectives and Methods section

Results cont...

- Use past tense
- Do not interpret results
- Avoid extra words
- Determine whether the data are best presented in the form of
  - text,
  - figures, or
  - tables.

Text

- Describe what you found, not what you did
- Present results in a logical sequence
- Consider sub-sections
- Do not repeat all of the data from the tables and figures in the text;
- Make sure all numbers in text are consistent with tables/figures

Use of tables & figures

- Tables are referred to as "tables", and all other items (graphs, photographs, drawings, diagrams, maps, etc.) are referred to as "figures"

- Tables & figures need numbers & clear title

Discussion

Purpose → to interpret your results & justify your interpretation

- The discussion is considered the heart of the paper and usually requires several writing attempts.

- Discussion should be kept as short as possible while clearly and fully stating, supporting, explaining, and defending your answers and discussing other important and directly relevant issues.

Discussion cont...

- Do not present any new data that were not shown in the result section
- Organize the Discussion from the specific to the general: your findings to the literature, to theory, to practice.
- Address all the results relating to the questions, regardless of whether or not the findings were statistically significant
- Discuss any unexpected findings.
- Write the limitation and strength of your study

Conclusion and Recommendation

- A conclusion is where you summarize the paper's findings and generalize their importance,

Conclusion cont…

- Conclusions should be short, as they have been elaborately discussed in the discussion section
- Strive for accuracy and originality in your conclusion.
- By the time you reach the end of your conclusion, there should be no question in the reader's mind as to the validity of your claims.

Recommendations

- Recommendations are usually placed in roughly the same sequence as the conclusion

- Recommendations may at the same time be summarized according to the groups towards which they are directed

Example

  - Policy makers
  - Managers at district or lower level
  - Staff who could implement the activities
  - The community at large
  - Researchers

Thank you !!!